



Council of the European Union
General Secretariat

Brussels, 25 March 2024

Interinstitutional files:

2023/0453 (COD)

2023/0454 (COD)

2023/0455 (COD)

WK 4643/2024 INIT

LIMITE

ENV

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

CONTRIBUTION

From:	General Secretariat of the Council
To:	Ad hoc Working Party on One Substance One Assessment
N° Cion doc.:	ST 16973/23, 16972/23, 16961/23 + ADD 1
Subject:	OSOA Package: Follow-up to the AHWP OSOA on 8 March 2024 - comments from delegations

Following the call for comments on the above set out with WK 4185/2024, delegations comments from DK, DE, IE, ES, FR, IT, CY, AT, PT, SI, SK and SE.

DENMARK



Proposal for a Regulation establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

We like to thank you for carefully presenting our comments at the meeting on the 8th of March 2024, and for requesting the Commission to comment on key issues. We would like to use this opportunity to come back on some issues.

As mentioned before Denmark has a general parliamentary scrutiny reservation on the proposal.

Question regarding Article 10 Information on regulatory processes on chemicals

DK Q1:

By formalising and expanding the existing ACT/PACT notification system from REACH/CLP where MS has a right of initiative, to all the Union acts listed in Annex III, Denmark would like to ask for a list of which Union acts in Annex III MS have a right of initiative and therefore would be covered by the proposal. Denmark would also like to ask if the MS obligations in the expanded notification system proposed in Article 10 will be broader than where MS has a right of initiative today.

Questions regarding chapter V Monitoring and outlook framework for chemicals

DK Q2:

We welcome an observatory for specific chemicals, which the Commission considers requiring additional scrutiny. We do at the same time believe that a list on specific chemicals that require further scrutiny would benefit from Member State involvement, and propose to include a process to secure this by amending Article 20, para 2:

“2. By [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall adopt and publish a list of the selected chemicals by means of an implementing Decision **and in consultation with Member States**. The Commission shall review the list of selected chemicals regularly adopt any revision thereof by the same means.

DKQ3:

We welcome the opportunity for ECHA to commission scientific studies. As stated in Article 21, para 1, the purpose of the provision is to support the implementation of Union acts on chemicals listed in Annex I and to contribute to the support, evaluation or development of a Union chemicals policy. These are purposes affect Member States and we therefore believe that the process leading to the commission of such studies would benefit from Member State involvement and propose to include a process to secure this. DK proposes to include this in a new para in Article 21:

5a.

The ECHA shall consult Member States prior to commission of scientific studies.

DENMARK

Remarks from Denmark to COM(2023) 783

Dear Presidency,

Thank you for giving us the possibility to submit comments.

As mentioned at the first Ad hoc Working Party (AHWP) on One Substance One Assessment, Denmark has a general parliamentary scrutiny reservation on the proposal.

Denmark has two general comments which applies across the One Substance One Assessment package:

1. The hazard assessment of substances must be harmonized to the greatest extent possible. Hazard is a substance specific inherent property that in principle does not change without justice to scientific development, and therefore it should ideally always be the same no matter who assesses the hazard. Risk assessment and risk management of chemicals on the contrary is still best done within the relevant legislative areas. It is particularly important for the pharmaceutical industry, because any harmful effects of chemicals in medicine must be compared to the disease that the medicine can help against.
2. It appears that the proposal goes beyond the principle of a stable level of employees, cf. the conclusions from the European Council in June 2020 on the multiannual financial framework (MFF) as the Commission will add additional employees to the EU's institutions. How will the Commission live up to the conclusion by the Council?

Furthermore, with reference to the table presented at the meeting we have the following comment:

Row 40 – Article 3 (1)

This article concerns the identification of endocrine disrupting chemicals (EDs), which should be assessed, if they are present in medical devices. As CLP CMR Category 1 and 2 substances should be assessed, we find it hard to understand why CLP ED Category 2 is not part of the proposal. The classification criteria leading to CLP ED Category 2 is considered to be very thorough.

DENMARK

Ad hoc Working Party on One Substance One Assessment

Dear Presidency,

Thank you for giving us the possibility to submit comments on the proposal for amending Directive 2011/65/EU. As mentioned at the first Ad hoc Working Party (AHWP) on One Substance One Assessment, Denmark has a general parliamentary scrutiny reservation on the proposal.

We like to thank you for carefully presenting our comments at the meeting on the 8th of march 2024, and for requesting the Commission to comment on key issues. However, we like to come back on some issues. With reference to the table presented at the meeting we have the following comments:

Row 37 – Article 1(1) point (b), regarding inclusion of article 4a

We do not agree that no guidance is needed on the interpretation of the term “considered appropriate”. This should be specified. We can, however, be flexible with respect to where an explanatory text is provided. It can be in the legal text, in the preambles or in a guidance document developed by ECHA and adopted by the Expert Group Committee with member state participation.

Row 45 – Article 1(1), point (c), paragraph 8

We appreciate if the Commission assisted by ECHA following the adoption of the proposal could publish guidelines to facilitate the harmonised application of Article 5(1)(a), including consultation of experts designated by each MS.

Row 50 – Article 1(3), point (c)

Here we welcome and support the proposal by the Commission add the following: “for those requirements that relate to the criteria set out in Article 6(1)”

Row 62 – Article 1(4), regarding insertion of Article 6a

Like in Row 50 – Article 1(3), point (c), it needs to be specified that requirements in Annex XVI to Regulation (EC) No 1907/2006 that are relevant for the criteria in article 6.1. should be assessed. “for those requirements that are relevant for the requirements in article 6.1”.

Row 64 – article 1(4), regarding insertion of Article 6b, point (1)

We take note that COM would not ask RAC to assess whether the proposal would live up to the objective in the RoHS-directive. However, we still disagree with the reference to the risk reduction as this is not a criterium in the RoHS directive. We therefore suggest the following text:

“Within 12 months from the date of publication referred to in Article 6a(6), the Committee for Risk Assessment shall adopt an opinion as to whether the restriction is appropriate in reducing **the negative impacts described in Article 6 (1) (a) – (c)** ~~the risk to human health or the environment, specifically by reference to the risks set out in Article 6(1), third subparagraph~~, based on its consideration of the relevant parts of the dossier. This opinion shall take account of the restriction dossier prepared by the Agency at the request of the Commission or by the Member State, and the views of interested parties referred to in Article 6a(6), point (a).”

In any case, as suggested by the Commission at the Ad hoc Working Party (AHWP) on One Substance One Assessment on 8. March 2024, we welcome a note from the Commission on their new and broader understanding of the concept of risk.

**Proposal for a Directive on the reattribution of scientific and technical tasks
to the European Chemicals Agency -**

Presidency's steering note (WK 3533/2024 REV 1)

**Follow-up to ad-hoc Working Party on One Substance One Assessment on
8 March 2024**

Written comments by Germany

Germany would like to thank the Presidency for the opportunity to submit written comments and also would like to thank the Commission for assessing the proposals of the member states in the context of the steering note (WK 3533/2024 REV 1) of March 7, 2024.

We would also like to thank the other member states for their comments. We have taken these into account as far as possible when preparing our position paper.

Germany reserves the right to submit further written comments in the further process.

Article 1(1), point (a), paragraph 4c

Germany thanks the Commission for its assessment of the proposals received and welcomes the Presidency's proposal to specify the deadlines. Germany is still assessing the suggested days of 45 and 60 days respectively.

Germany does not agree with the Commissions argument that deadlines should be flexible. This would lead to less legal clarity and a lack of transparency. After all, why should one application be given a longer deadline than another? This would result in a subjective assessment of the deadline extension by ECHA and make ECHA vulnerable.

If the deadlines are specified in the proposed sense, however, the term "appropriate" in Art. 5 (4) (c) should also be deleted.

Germany also asks that it be examined whether applications can be published on the Agency's website subject to reservation as soon as at least the documents listed in Annex V a-e are available. Early publication of applications leads to less bureaucracy and ensures transparency for producers. Other producers may then decide not to submit an additional application.

Article 1(1), point (b), regarding inclusion of article 4a and 4a (a)

Germany thanks the Commission for its explanations and, against this background, supports the initial proposal of the Commission.

Article 1(1), point (b), regarding inclusion of article 4a (c)

In order to avoid misinterpretations and unjustified changes, especially if contradictory comments were made by stakeholders during the consultation, the applicants should be more closely involved.

Germany therefore proposes the following addition:

„may request the applicant or third parties to submit, within a specified period, additional information **and may set up a meeting of applicants and/or interested parties especially if contradictory information is received during the procedural step under paragraph 4, point (f)**“.

Article 1(1), point (b), regarding inclusion of article 4a (d)

Germany thanks the Commission for its explanations and, against this background, supports the initial proposal of the Commission.

Article 1(1), point (b), regarding inclusion of article 4a

Germany thanks the Commission for its explanations and, against this background, supports the initial proposal of the Commission. Swift processing of exemption applications is necessary to ensure planning and investment security for producers, especially in case of new applications.

Article 1(1), point (c), paragraph 8

Germany supports the publication of guidelines on the harmonized application of Article 5(1)(a) and the consultation of national experts in the process of the preparation of the guidelines.

Article 1(3), point (a)

Germany is still assessing the proposed 5-year review period and would like to understand better why this change was introduced since Germany did follow the Commissions initial reasoning..

Article 1(3), point (c)

Germany supports the Presidency's proposal for the addition “or a group of similar substances” to Article 1(3), point (c) paragraph 2, as this serves as a clarification of the wording. Further, Germany supports the additional wording “for those requirements that relate to the criteria set out in Article 6 (1)”.

Article 1(4), regarding insertion of Article 6a, point (3)

Germany thanks the Presidency for the inclusion of the proposed amendment.

Article 1(4), regarding insertion of Article 6a, point (6b)

Germany supports the Commission's proposal to adapt the text on the basis of the wording of Article 86(9)(b) of the Batteries Regulation.

Article 1(4), regarding insertion of Article 6a

Germany supports the proposal of the Commission with regard to harmonization with the deadlines provided for in Article 86 (9) BattVO.

Article 1(4), regarding insertion of Article 6a, point (6b)

Germany supports the proposal suggested by the Presidency.

Article 1(4), regarding insertion of Article 6b, point (1)

Germany thanks the Presidency for its explanations and, against this background, supports the Presidency's proposal.

Article 1(4), regarding insertion of Article 6b, point (6)

Germany supports the Presidency's proposal not to amend the text, but to leave the Commission's original proposal unchanged.

Article 2

Germany refers to its written comments of 16th February 2024 and repeats the question on Article 2: How long will it take to build up the necessary resources and expertise at ECHA, as the planned transition period of 12 months seems very ambitious?

Given the increasing complexity and number of requests for derogations under Art. 5 of Directive 2011/65/EU, DE remains concerned whether the Committee for Socio-economic Analysis and, where appropriate, the Committee for Risk Assessment will be able to cope with the increase in workload. Well-functioning and staffed committees will be essential to ensure a real increase in efficiency in the processing of applications for exemptions and substance restrictions. Otherwise, it is questionable whether all the objectives of the OSOA initiative can be achieved.

Article 5(5)

Germany thanks the Commission for its explanations and, against this background, supports the initial proposal of the Commission.

Article 20

Germany is still assessing the implications of the proposed changes in Art. 20 and therefore has a scrutiny reservation.

Further comments

Article 5(6)

Germany asks the Presidency to examine whether, in view of the long and complex supply chains, it makes sense to extend the transition periods (24 months) in the event that extension applications are rejected.

Article 6

In general, and especially in the case of new substance restrictions, the principle of "repair as produced" must be ensured so that original spare parts are available for long-life products even after subsequent changes to the exemptions and substance restrictions under RoHS.

GERMANY

22nd March 2024

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals

Follow-up to ad-hoc Working Party on One Substance One Assessment on

8 March 2024

Written comments by Germany

Line nr.		Presidency proposal: amendments (~~deletions~~ /additions)	Presidency justification after WP1: follow-up or proposals to work on amendments, or requests for written comments	Delegates comments/proposals after WP2
1		THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 43, 114, 168(4)(c), 192(1) and 207 thereof, Having regard to the proposal from the European Commission, After transmission of the draft legislative act to the national parliaments, Having regard to the opinion of the European Economic and Social Committee, Having regard to the opinion of the Committee of the Regions, Acting in accordance with the ordinary legislative procedure, Whereas:		
2	Recital 1	The European Green Deal¹ sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability² ('the Strategy') is a crucial delivery of the zero-pollution ambition and introduces the 'one substance, one assessment' approach, which aims to improve the efficiency,		

		effectiveness, coherence, and transparency of safety assessments of chemicals across Union legislation. ¹Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal. COM (2019) 640 final. ²Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability Towards a ToxicFree Environment. COM (2020) 667 final		
3	Recital 2	In order to achieve this objective, a part of the scientific and technical work on chemicals performed at Union level in support of Union legislation needs to be consolidated in the relevant Union agencies, while obligations on Union agencies to cooperate for the development of assessment methodologies and exchange of data and information should be introduced. This would simplify the current set-up, improve quality and coherence of safety assessments across Union legislation and ensure more efficient use of existing resources.		

4	Recital 3	The reattribution of certain existing scientific and technical tasks to the European Chemicals Agency, as well as the attribution of new tasks, were	Many concerns were raised during the commenting about: Concerns on ECHA's capacity, budget (including budget for technical and	

		proposed as part of ongoing revisions of Union acts. This horizontal proposal aims to provide for further attribution of tasks in respect of those Union acts which are not in the process of being revised and is necessary in order to ensure that the European Chemicals Agency is involved in tasks pertaining to its expertise and developed capacities on chemicals. This is in line with the ‘one substance, one assessment’ aim to ensure that technical and scientific work is performed by the appropriate Union agency, benefiting from demonstrated experience and established tools in its field. The proposal for a Regulation is accompanied by a proposal for a Directive for the amendment of Directive 2011/65/EU of the European Parliament and of the Council³, aiming to achieve the same objectives. ³Directive 2011/65/EU of the European Parliament and of the Council as regards the reattribution of scientific and technical tasks to the European Chemicals Agency	infrastructure requirements and training), workload, committees, expertise to take on the extra tasks. This relates amongst others to the expertise of committee members (and not only the number of experts), potential establishment of technical expert groups (and how they relate to the Committees’ role), what is to be left for the founding regulation, potential targeted REACH amendments, ECHA and committees expertise in medical devices and in POP-waste. Some specific elements for discussion: One delegation proposed it would be more appropriate to assign the task(s) to prepare opinions to ECHA, and allow ECHA to best determine the most efficient and appropriate way to deliver a robust opinion. For example, ECHA’s technical experts could draft opinions and establish technical expert working groups to consult with in order for scientific opinions to be delivered. In certain cases, the Executive Director can still use their powers under REACH’s Article 77 (3) to issue a request to RAC and SEAC, thus negating the need for all tasks to have a RAC and/or SEAC opinion. This delegation also prefers that the legislative package makes provisions for ECHA to prepare opinions in some circumstances without	

			the explicit need for those opinions to be drafted by RAC and SEAC. In addition, they explained that their concern is with the capacity of the individual members to deliver the expected workload, even if both Committees were at full capacity. Therefore, they see a need for provisions to be included to allow for amending the composition of the current ECHA's committees to cover also any ad-hoc Article 77(3) requests in light of requests from the Executive Director. Finally, the inclusion of remuneration for Committee Rapporteurs for all tasks needs to be provided for. They also recommend the OSOA legislation package amends Article 85 and 87 of REACH to provide for additional experts to cover the additional work and its associated remuneration. PRES: discussion took place during WP2	

5	Recital 4	As part of the coordinated consolidation and attribution of tasks under the ‘one substance, one assessment’ approach, provisions to allocate a mandate to the European Medicines Agency to develop and cooperate on the development of assessment methodologies, standard formats and controlled vocabularies and exchange of data and information on		

		chemicals have been introduced in Article 138(1), subparagraphs (zd) and (ze), as well as new procedures for ensuring the coherence between scientific opinions in Article 139 of the proposal for a Regulation amending Union pharmaceutical legislation. ⁴ ⁴ Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006, COM(2023) 193 final. [OJ:Please insert correct reference once the Regulation is adopted].		

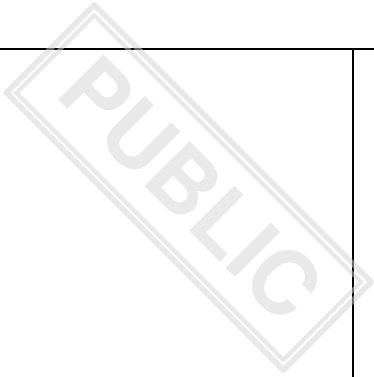
6	Recital 5	To ensure the coherence of methodologies for assessments related to chemicals at Union level, all relevant Union agencies should have an equal mandate to develop such methodologies in the areas falling within their respective missions and should be subject to the same obligations to cooperate amongst each other to develop such methodologies.		
7	Recital 6	To ensure the coherence and efficiency of assessments related to chemicals across Union legislation, it is also important to enable data interoperability		

		and easy exchange of data between the relevant Union agencies, as well as to encourage cooperation on the development of standard formats and controlled vocabularies. Thus, to facilitate data exchange between agencies, any new data formats defined by the European Food Safety Authority or by the European Environmental Agency should be set in cooperation with other relevant Union agencies working on chemicals. To this end, relevant provisions should be introduced in Regulation (EC) No 401/2009 of the European Parliament and of the Council and, in Regulation (EC) No 178/2002 of the European Parliament and of the Council, existing provisions should be strengthened and, where relevant, new ones be introduced. Similar provisions should also be considered to be proposed for a strengthened mandate of the European Chemicals Agency in its founding regulation.		

8	Recital 7	To promote the coherence and efficiency of assessments related to chemicals across Union legislation, steps should be taken by the relevant Union agencies to avoid divergent scientific opinions. Existing cases of divergent opinions have lead to increased uncertainty for operators, as well as to declined public trust in the scientific robustness and coherence of scientific decision making.		

		Proposals to address and strengthen procedures for resolving divergence of scientific opinions concerning the European Medicines Agency with other scientific bodies is proposed as part of the revision of Union pharmaceutical legislation. Similar provisions should also be considered to be proposed for a strengthened mandate of the European Chemicals Agency in its founding regulation, whilst such provisions are not relevant and applicable to the European Environmental Agency, since this agency does not issue scientific opinions on individual chemicals such as to be part in divergent outcomes.		

9	Recital 8	Correspondingly, this Regulation aims to address the eventual divergence between scientific opinions of the European Food Safety Authority and those of other Union agencies. Regulation (EC) No 178/2002 of the European Parliament and Council already contains provisions establishing a procedure to solve divergent scientific opinions. Those resolution procedures should be reinforced, in that the European Food Safety Authority and the other dissenting agency should be bound to make their best effort to resolve the divergence on general scientific issues, and only when they are not able to resolve the divergence, should they refer to risk managers.		

10	Recital 9	In the more specific case of scientific divergence pertaining to the hazard identification of chemical substances, a new procedure enabling the resolution of the divergence should be established. This procedure should enable the Commission to request the European Chemicals Agency, as the Union agency most equipped with expertise and capacity in hazard assessment, as well as long-standing experience with the harmonised classification and labelling process, to develop a proposal for harmonised classification and labelling, in accordance the Regulation (EC) No 1272/2008 of the European Parliament and Council, moving closer to the ‘one substance, one assessment’ vision as regards uniformity of hazard assessments of chemicals across the Union. This possibility should be reflected in the relevant provision providing for the resolution of diverging scientific opinions laid down in Regulation (EC) No 178/2002.		

11	Recital 10	To comply with the obligation laid down in Section 10.4.3 of Annex I to Regulation (EU) 2017/745 of the European Parliament and of the Council ⁵ , the Commission has provided the Scientific Committee on Health, Environmental and Emerging Risks ('SCHEER') with a mandate to prepare guidelines on the benefit-risk assessment		

		of the presence of phthalates which are classified as either carcinogenic, mutagenic or toxic to reproduction category 1A or 1B, or which have endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁶. The SCHEER issued those guidelines in 2019 and the Commission has issued a mandate to the SCHEER to perform a first update of those guidelines. ⁵ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1). ⁶ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1–849).		

12	Recital 11	To comply with the obligation laid out in Section 10.4.4. of Annex I to Regulation (EU) 2017/745, the Commission should mandate the relevant scientific committee to prepare guidelines for substances other than phthalates and which are classified as either carcinogenic, mutagenic or toxic to reproduction category 1A or 1B, or which have endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council.		

13	Recital 12	The European Chemicals Agency already provides scientific advice on chemical substances, including on phthalates, endocrine disruptors and carcinogens, mutagens and reproductive toxicants under Regulation (EC) No 1907/2006. Several key capacities of the agency can be reused, including hazard, risk, exposure and socio-economic assessment capacities, the Committee opinion development and IT capabilities for stakeholder consultation and dissemination. To enable timely future updates on the presence of phthalates and to ensure that the appropriate Union agency develops new guidelines on other substances on the basis of the latest		

		scientific evidence, these tasks should be attributed to the European Chemicals Agency.		

14	Recital 13	Taking account of the new hazard classes and criteria for classification, labelling and packaging of substances introduced by Commission Delegated Regulation (EU) 2023/707 of 19 December 2022⁷, reference to endocrine disruptors for human health, of Category 1, should be specified in 10.4.1., point (b) of Annex I of Regulation (EU) 2017/745 in light of the relevance of that hazard class to the type of substances in medical devices. ⁷ Commission Delegated Regulation (EU) 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures (OJ L 93, 31.3.2023, p. 7–39).		
15	Recital 14	To make best use of the European Chemicals Agency's knowledge and expertise gained through its involvement in the nomination and assessment processes under the Stockholm Convention on Persistent Organic Pollutants, the European Chemicals Agency should, upon request, assist the Commission in complying with its obligation to amend Annexes IV and V to Regulation (EU) 2019/1021⁸. Where the opinion of the Committee for Socio-		

		Economic analysis is required, and in order to allow for the necessary capacity and resources for the effective functioning of that committee, Member States should be given the opportunity to cover for the specific expertise required for the effective performance of the task by nominating experts. In order to ensure that the Committee for Socio-Economic analysis benefits from sufficient resources, when the committee appoints one of their members as a rapporteur, that person, or his employer should be remunerated. ⁸ Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45).		
16	Recital 15	In order to amend certain non-essential elements of Regulation (EU) 2019/1021 of the European Parliament and of the Council, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending Annexes IV and V in order to adapt them to the changes to the list of substances set out in the Annexes to the Stockholm Convention or the Protocol or adapt them to scientific and technical progress.		

17	Recital 16	As part of their reporting obligations under the Regulation (EU) 2019/1021 of the European Parliament and of the		
		Council, Member States must report to the European Chemicals Agency information on the presence of substances listed in Part A of Annex III in the environment. The use of the Information Platform for Chemical Monitoring ('IPCHEM') is encouraged as a means for Member States to comply with their obligations to report that chemical occurrence data and to simplify and reduce their reporting obligations. Where Member States make data available through IPCHEM, they no longer need to report it to the European Chemicals Agency, as the agency may retrieve it from the platform.		

18	Recital 17	The revision of the Directive (EU) 2020/2184 of the European Parliament and of the Council⁹ requires Member States to share with European Environmental Agency all chemical occurrence or monitoring data in water. Additionally, the monitoring data on the presence of POPs in air are already being reported by Member States to the EEA as part of the Union air quality legislation. The proposal for a Regulation of the European Parliament and the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable, and reusable and establishing a monitoring and outlook framework for chemicals¹⁰ will		

		require all chemical occurrence data to be held by the EEA. As a result, chemical occurrence data provided to and held in IPCHEM by the Commission will thus be collected and held by the EEA, instead of by the Commission. Therefore, it is necessary to simplify the reporting obligations for Member States to ensure that, where Member States have already submitted that information to the EEA as part of fulfilling obligations required by the provisions of other pieces of Union environmental legislation, Member States should be considered to have fulfilled their reporting obligations under Regulation (EU) 2019/1021. ⁹ Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast), (OJ L 435, 23.12.2020, p. 1–62). ¹⁰ [OJ Please insert reference once proposal is adopted]		
19	Recital 18	Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 should therefore be amended accordingly,		
20	Articles	HAVE ADOPTED THIS REGULATION:		

21	1	Amendments to Regulation (EC) No 178/2002		
22		Regulation (EC) No 178/2002 is amended as follows:		
23	(1)	in Article 23, the following point (m) is added:		
24		‘(m) to cooperate with the competent bodies in the Member States that carry out similar tasks to those of the Authority and to cooperate with other scientific bodies established under Union law, notably the European Chemicals Agency, the European Medicines Agency, and the European Environment Agency on the provision of relevant scientific opinions, on the exchange of data and information, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and on the development of scientific methodologies for the assessment of chemicals.’;		

25	(2)	Article 30 is replaced by the following:	Question were raised by a delegation on whether the EFSA procedure for risk assessment must not be changed as a result of this proposal and it must be ensured that the assessment of EFSA, and if applicable, other EU authorities are properly and appropriately taken into account by ECHA. How is this ensured by the provisions in Article 30? PRES: Discussion took place during WP2.	
26		‘Article 30 Diverging scientific opinions	One delegation requested an example of what could be considered diverging scientific opinions. PRES: Discussion took place during WP2.	

27		1. The Authority shall take the necessary and appropriate measures to monitor and identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks.		

28		2. Where the Authority identifies a potential source of divergence, it shall contact the body concerned in order to ensure that all relevant scientific or technical information is shared and in order to identify the potentially contentious scientific or technical issues. The Authority and the body concerned shall cooperate to resolve the divergence. If the Authority and the body concerned are not able to resolve the divergence, they shall draw up a joint report. The report shall clearly outline the contentious scientific issues and identify the relevant uncertainties in the data and be made publicly available. Where the body concerned is a Union agency or a scientific committee, the Authority shall present the joint report to the Commission.		
29		3. Where relevant, and where the divergence concerns conflicting scientific opinions of the Authority and		

		another Union body or agency on whether a substance fulfils the criteria laid out in Annex I of Regulation (EC) No 1272/2008 of the European Parliament and of the Council¹¹, the Commission may request the European Chemicals Agency to prepare a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof following the procedure laid out in Article 37 of Regulation (EC) No 1272/2008. The Authority and the Union body or agency concerned shall co-operate with the European Chemicals Agency in developing that proposal.’.		
30		¹¹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353 31.12.2008, p. 1 – 1355.		
31	2	Amendments to Regulation (EC) No 401/2009	One delegation asked for clarification why the EEA’s cooperation with ECHA is supposed to be regulated in Article 15(5) of the EEA Regulation. Systematically, paragraph 1 with a new letter c seems closer. In addition, it would be clear that	DE still asks for clarification why the EEA's cooperation with the ECHA is supposed to be regulated in Article 15(5) of the EEA Regulation. According to our reading of Article 15 para 1 ECHA is already covered by “The Agency shall

			paragraph 4 also refers to this cooperation. One delegation has doubts about the impact of the Eionet Network's involvement in this cooperation. PRES: Discussion took place during WP2.	actively seek the cooperation of other Community bodies and programmes". We do not mind to mention ECHA explicitly, but still think that para 1 is more appropriate than para 5. Systematically, Para 1 with a new letter c seems much closer, as it mentions other EU bodies. In addition, if ECHA is mentioned in para 1 it would be clear that paragraph 4 also refers to this cooperation.

32		Regulation (EC) No 401/2009 is amended as follows:		
33	(1)	in Article 2, the following point (p) is added:		
34		‘(p) to develop assessment methodologies related to chemicals in the fields falling within its mission.’;		
35	(2)	in Article 15, the following paragraph 5 is added:		

36		‘5. The Agency shall cooperate with other scientific bodies established under Union law, notably the European Chemicals Agency, the European Food Safety Authority, and the European Medicines Agency, on the exchange of data and information on chemicals, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and on the development of scientific methodologies for the assessment of chemicals.’.		
37	3	Amendments to Regulation (EU) 2017/745	One delegation questions ECHA’s expertise regarding medical devices. PRES: Discussion took place during WP2	
38		Annex I to Regulation (EU) 2017/745 is amended as follows:		
39	(1)	in Section 10.4.1, point (b) is replaced by the following:		

40		‘(b) substances which are identified as endocrine disruptors for human health, of Category 1, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ¹² and substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council or substances having endocrine disrupting properties relevant to human health identified in accordance with Regulation (EU) No 528/2012.’		
41		¹² Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006(OJ L 353 31.12.2008, p. 1).		
42	(2)	in Section 10.4.2, point (d) is replaced by the following:		
43		‘(d) where applicable and available, the latest relevant guidelines in accordance with Sections 10.4.3. and 10.4.4.’;		
44	(3)	Section 10.4.3 is replaced by the following:		

45		‘10.4.3. Guidelines on phthalates When deemed appropriate based on the latest scientific evidence, but at least every 5 years, the Commission shall request the European Chemicals Agency (ECHA) to update guidelines on the benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in Section 10.4.1., points (a) and (b). The benefit-risk assessment shall consider the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments When appropriate or when requested by the Commission, ECHA shall consult the Committee for Risk Assessment and the Committee for Socio-economic Analysis.’;		
46	(4)	Section 10.4.4 is replaced by the following:		
47		‘10.4.4. Guidelines on other CMR and endocrine-disrupting substances The Commission shall request ECHA to prepare guidelines as referred to in Section 10.4.3. and following the process described therein also for other substances referred to in Section 10.4.1., points (a) and (b), where appropriate.’.		

48	4	Amendments to Regulation (EU) 2019/1021	A delegation proposed that Article 4 of the POP Regulation would be amended to give the Commission the possibility to request ECHA to carry out the assessment required to amend the concentration limit values in the Annexes IV and V to the POP regulation It is further proposed (article 13 paragraph 2) that this provision would also introduce the adoption of amendments to Annexes IV and V by means of delegated act. Moreover, they believe that the delegation of legislative powers to the Commission in POPregulation Article 15 needs further consideration This delegation sees the role of the POP-CA (competent authorities) very important in preparation of the delegated acts. In case the above described amendments would be accepted, what would be the role of the POP-CA in the future? Would the Commission still consult the experts designated by each Member State and closely collaborate with POP-CA before adopting a delegated act? One delegation proposes that ECHA is also given the task to determine limit values and amending Annex I and not	Including methoxychlor, dechlorane plus and UV-328 in Annexes IV and V: DE thanks the COM for its comments in this regard and understands its arguments. Nonetheless, DE is critical of the COM's considerations regarding the timetable for including these substances in Annexes IV and V of the POPs Regulation. It is difficult to understand why these three substances are to be included in Annex I of the POPs Regulation by the end of 2024, but that they are not to be included in Annexes IV and V until the end of 2027. This is a gap of about 3 years. Two more substances (MCCPs and long-chained PFCA) are expected to be added to Annex A of the Stockholm Convention at the upcoming COP 2025. Are these also not to be included in Annexes IV and V until 2027? ECHA would then have to include limit values for 5 new POPs in Annex IV and V, in addition to the 5 reviews prescribed in Regulation (EU) 2022/2400. It should be noted that the requirements of Article 7 cannot be implemented as long as no limit values are set in Annex IV. This article refers to the list of substances in Annex IV.

			only Annexes IV and V to the POP regulation. They also ask whether ECHA will have the knowledge on the impact of adjusting Annex IV values on the waste and recycling phase, while another delegate questions the knowledge of SEAC on waste management. PRES: Discussion took place during WP2. PRES proposes amendments to be made to the proposal. Written comments are welcomed.	
49		Regulation (EU) 2019/1021 is amended as follows:		
50	(1)	Article 8(1) is amended as follows:		
51	(a)	the following point (i) is added:		
52		‘(i) upon request from the Commission, and within 12 months from that request, draw up and ~~provide-submit~~ a report on the human health, environmental and socio-economic impacts of introducing or modifying concentration limit values specified in Annex IV or V.’	One delegation proposes to change ‘draw up and provide a report’ to ‘draw up and submit a report.’ PRES proposed a change to the text.	DE supports this change. When does the Commission intend to commission the ECHA to draw up this report? After the inclusion of the new substances in the Annexes of the Stockholm Convention? It would be desirable for Annexes IV and V of the POPs Regulation to be amended shortly after the amendment of Annex I.
53	(2)	Article 8(1a) is added:		

54		‘1a. The report referred to in Article 8(1), point (i), shall contain the following information:		
55		(a) as appropriate, information on human health and environmental impacts of waste consisting of, containing or contaminated with POPs, including impacts on waste management		DE propose to delete “as appropriate”. It is not consistent with para 1 (a) (see Line nr. 52), according to which ECHA shall draw up and provide a report in particular on human health and environment impacts. The text should be read as follows: ~~as appropriate~~ , information on human health and environmental impacts of waste consisting of, containing or contaminated with POPs, including impacts on waste management;
56		(b) information on concentrations and mass flows of POPs in relevant waste streams and on waste treatment and treatment capacities;		
57		(c) an analysis of the impacts of the different concentration limit values considered;		
58		(d) a duly motivated proposal for concentration limit values to be introduced in Annex IV and, as appropriate, in Annex V.		DE propose to delete “as appropriate”. In Annex V, Part 2 lists mineral waste to which the exemption in Article 7 (4) (b) applies. These waste may also contain substances listed in Annex IV, for example excavated soil contaminated with PFOA, its salts or PFOA-related substances. Therefore, ECHA should propose limit values for Annex V. The text should be read as follows:

				(d) a duly motivated proposal for concentration limit values to be introduced in Annex IV and, as appropriate, in Annex V.
59		The Agency shall, as soon as it receives the request referred to ~~in the first subparagraph~~ Article 8(1) , point (i), publish on its website a notice that a report on a possible amendment of Annex IV or V will be prepared inviting all interested parties, including waste operators and users of recycled materials, to submit comments within 8 weeks. The Agency shall publish those comments on its website.	One delegation proposed to change the reference, to clarify and to use the same kind of reference as is used in the paragraph above. PRES proposed change accordingly	DE supports this change.
60		At the latest 9 months following the submission of ~~the~~ report referred to in Article (8(1), point (i)) , the Committee for Socio-economic Analysis of the Agency, set up pursuant to Article 76(1), point (d), of Regulation (EC) No 1907/2006 shall adopt an opinion on the report and on the concentration limit	One delegation proposed to clarify which submission it is referred to given that it is mentioned in several paragraphs earlier in the text. The proposed change would help to clarify this together with a consequential amendment in Article 8(1) point (i) to change the word 'provide' to 'submit' PRES proposed change.	DE supports this change.
		values proposed therein. For the purpose of adopting an opinion on the report, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.		

61		The Agency shall submit the report and the opinion of the Committee for the Socio-economic Analysis on the concentration limit values to the Commission without delay.’;		
62	(3)	in Article 13, paragraph 2 is replaced by the following:	One delegation further proposed (Article 13 paragraph 2) that this provision would also introduce the adoption of amendments to Annexes IV and V by means of delegated acts. PRES requires further clarification from FI (potential text proposal).	
63		‘2. Where a Member State shares the information referred to in paragraph 1, point (e), with the European Environmental Agency, that Member State shall indicate that in the report and the Member State shall be considered to have fulfilled its reporting obligations under that point.		
64		Where the information referred to in paragraph 1, point (e), is contained in the report of a Member State provided to the Agency, the Agency shall transmit the information to the European Environmental Agency for compiling, storing and sharing that information’;		
65	(4)	in Article 15, paragraph 2 is replaced by the following:		

66		‘2. The Commission is empowered to adopt delegated acts in accordance with Article 18, to amend Annexes IV and V to this Regulation to adapt them to the changes to the list of substances set out in the Annexes to the Convention or the Protocol or to adapt them to scientific and technical progress.’	One delegation proposed the amendment in order to clarify that the reference is to the Annexes in this Regulation. PRES changed the text. One delegation would like confirmation of the Commission’s obligation to consult MS experts before adopting delegated acts as appears to be provided in Article 18(4) of the POP Regulation. Another delegation considers it of high importance to preserve the expertise of the Meeting of the Competent Authorities for Regulation (EU) 2019/1021 on POPs and would like to know in which stage of the future amendments of the annexes the experts from the CAs will be consulted and whether additional POP experts will be incorporated to SEAC and/or RAC. One delegation asked for the delegation of legislative powers to the COM in POP regulation article 15 to be further considered. They see the role of the POP-CA very important in the preparation of the delegated acts.	

			PRES: Discussion took place during WP2. Written comments are welcome.	
67	(5)	Article 18 is amended as follows:	DK suggests no changes to be made to Article 18, they don't want to delegate this regulatory authority to the COM.	In general, DE supports the COM proposal to amend Annexes IV and V using delegated acts. It is only logical that the annexes to the POP Regulation

				should be amended using a uniform procedure.

			PRES proposes to discuss this during WP2.	
68	(a)	The first sentence of paragraph 2 is replaced by the following:		
69		‘2. The power to adopt delegated acts referred to in Articles 4(3), 10(2) and 15 shall be conferred on the Commission for a period of five years from 15 July 2019.’.	One delegation considers that this 5-year term is very likely to have passed before the proposed delegation of authority takes effect. Therefore, they suggest adjusting the period in order to have effect in practice. PRES Discussion took place during WP2. Written comments are welcome	According to Article 18 (2), the delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period. For reasons of transparency, the date could be adjusted
70	(b)	The first sentence of paragraph 3 is replaced by the following:		
71		‘3. The delegation of power referred to in Articles 4(3), 10(2) and 15 may be revoked at any time by the European Parliament or by the Council.’.		
72	(c)	Paragraph 6 is replaced by the following:		

73		‘6. A delegated act adopted pursuant to Articles 4(3), 10(2) and 15 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object.’.		
74	6	Entry into force		
		This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.		
		Done at Brussels,		
		For the European Parliament The President		
		For the Council The President		

PUBLIC

GERMANY

22nd March 2024

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

Follow-up to ad-hoc Working Party on One Substance One Assessment on

8 March 2024

Written comments by Germany

	Presidency proposals: amendments (~~deletions~~ / additions)	Presidency justification after WP1: follow-up or proposal to work on amendments, or requests for written comments	Delegates comments/proposals after WP2
Proposal Title			
1	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals)		
Formula			
2	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN		
Citation 1			
3	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114(1) thereof,		
Citation 2			
4	Having regard to the proposal from the European Commission,		
Citation 3			
5	After transmission of the draft legislative act to the national parliaments,		
Citation 4			
6	Having regard to the opinion of the European Economic and Social Committee ¹		
Citation 5			
7	Acting in accordance with the ordinary legislative procedure,		
Formula			
8	Whereas:		

Recital 1			
9	(1) The European Green Deal ³⁴ sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability ³⁵ is a crucial delivery of this zero-		
	pollution ambition and introduces the 'one substance, one assessment' approach, which aims to improve the efficiency, effectiveness, coherence, and transparency of safety assessments of chemicals across Union legislation. According to that Strategy, 'safe and sustainable by design' criteria should be developed to enable the production and use of chemicals that are safe and sustainable throughout their entire lifecycle. The Strategy also sets out that the interaction between scientific developments and policy-making should be strengthened by means of an early warning system for chemicals to ensure that Union policies address emerging chemical risks as soon as these are identified by monitoring and research, and that a framework of indicators should be developed to monitor the drivers and impacts of chemical pollution and to measure the effectiveness of chemicals legislation. This Regulation aims to implement these objectives.		
Recital 2			

10	(2) The main objective of this Regulation is to increase the level of protection of the environment and human health from the risks arising from hazardous chemicals, as well as to facilitate the functioning of the internal market for chemicals. For that purpose, this Regulation should establish a common data platform data on chemicals ('the common data platform'), to be managed by the European Chemicals Agency ('ECHA'). The common data platform is a digital infrastructure that brings together chemicals data and information generated under the Union chemicals acquis. This Regulation should also establish dedicated services within the common data platform and lay down rules on the accessibility and usability of the data contained in that platform. This Regulation aims to create a common knowledge base on chemicals available to authorities to enable better, complete, coherent and robust scientific assessments of chemicals and their impacts and to ensure the best use of existing information for the purpose of the implementation and the development of Union legislation on chemicals. Moreover, the Regulation aims to provide a one-stop-shop on chemicals data and information in the Union accessible to the general public and, thus, to increase the predictability and the transparency of regulatory processes on chemicals, as well as to strengthen public trust in the robustness of scientific decision-making.		

Recital 3			
11	(3) Under Decision (EU) 2022/591 of the European Parliament and of the Council³⁶, harnessing the potential of digital and data technologies to support environmental policy, including by delivering real-time data where possible and information on the state of ecosystems, while increasing efforts to minimise the environmental footprint of these technologies and ensuring transparency, authenticity, interoperability and public accessibility of the data and information is a long-term priority objective. Data and information on chemicals are therefore essential for the proper development and implementation of a Union environmental policy, and specifically of a chemicals policy.		
Recital 4			

12	(4) In its communication of 19 February 2020 on a European strategy for data ³⁷ , the Commission described its vision of a common European data space and highlighted the need for the development of sectoral data spaces in strategic areas, since not all sectors of the economy and society are moving at the same speed. This Regulation aims therefore to build a data space for chemicals by establishing a common data platform on chemicals ('common data platform'), which is also part of the Green Deal data space, as referred to in the European strategy for data. Furthermore, in that strategy, the Commission highlighted several issues concerning the availability of data for the public good, including data availability, data infrastructures and governance, interoperability, as well as the lack of adequate sharing of data between public authorities. This Regulation aims to increase data availability on chemicals by requiring the relevant Union agencies to make data available for integration in the common data platform on chemicals, to promote interoperability of that data by providing for the establishment of standard formats and controlled vocabularies, as well as to facilitate data exchange and use by public authorities to enable them to effectively carry out their regulatory and policy developing tasks.		
Recital 5			
13	(5) This Regulation also aims to implement into the chemicals sector the principles laid out in the proposal for an Interoperable Europe Act ³⁸ by strengthening the cross-border interoperability of network		

	and information systems used to provide or manage public services on chemicals in the Union. This Regulation will contribute to increased cross-border data flows for truly European digital services and broaden the access to publicly available chemicals data for utilisation in other sectors' applications.		
Recital 6			

14	(6) Business operators and Members States' competent authorities are required by various Union acts to submit data and information to a multitude of Union agencies, as well as to the Commission in specific cases. This generates a fragmentation of data and information on chemicals, which are held under various data sharing and use conditions and in different formats. Such fragmentation prevents public authorities, as well as the general public, from having a clear overview of what information is available on individual chemicals or groups of chemicals, of where and how information can be accessed and whether it can be used. This increases the likelihood of inconsistency between various assessments of the same chemical required by various Union acts on chemicals and of damaging the general public's trust in the scientific grounds for Union decisions on chemicals. In order to ensure that data on chemicals is easily findable, accessible, interoperable and usable, the ECHA should establish a common data platform on chemicals. The common data platform on chemicals should serve as a single point of reference and as a broadened and shared evidence base to enable the efficient delivery of coherent hazard and risk assessments of chemicals across various Union acts on chemicals, as well as to enable the timely identification of emerging chemical risks and the drivers and impact of chemical pollution.		
Recital 7			
15	The common data platform should contain chemicals-related data and information held by relevant Union agencies or the Commission generated or submitted as part of the implementation of Union chemicals legislation listed in Annex I. This includes, for instance, all regulatory dossiers or applications submitted to the relevant Union agencies, but also chemicals data on occurrence of chemicals submitted by Member States to Union agencies or the Commission in compliance with their reporting obligations. The common data		

	platform should also include chemicals data and information generated as part of Union, national or international programmes or research activities related to chemicals, where this data and information is held by the Commission or one of the relevant agencies.		
Recital 8			
16	Due to the different nature of the risk and hazard assessments performed under Union acts on medicinal products, when compared to those performed under the main Union acts on chemicals, for medicinal products, only chemicals data related to environmental risk assessments for human and veterinary medicines, non-clinical studies for human medicines and maximum residue limit values the European Medicines Agency ('EMA') holds, as well as specific reference values, should be included in the common data platform. For medicinal active substances, only data on relevant substances should be included. These concern active substances covered by the medicines legislation and also used for other applications regulated by other Union legislation identified in this Regulation, as well as other active substances with particular persistent, bio-accumulative and toxic properties or with a known high level of residues in the environment.	Some delegations expressed the need for a clarification of the scope and meaning of "relevant substances" for active substances → PRES: this is scheduled for discussion at the 2 nd WP	We also see a need for further clarification. One question to be discussed: Will this also cover data on resistance including resistance from other uses, e.g. triazole substances in plant protection, and human diseases based on chemical like Parkinson caused e.g. by paraquat (plant protection)?
Recital 9			
17	(9) These data should also be limited to data submitted to the EMA in the context of the relevant procedures that are finalised or submitted after the entry into force of this Regulation. At a later stage, it should also be possible to include in the common data platform, where relevant, data the EMA holds on procedures concluded before the entry into force of this Regulation.		
Recital 10			

18	(10) Due to the sensitivity of the information on the exact chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health or physical effects, submitted to the bodies appointed by the Member States under Article 45 of Regulation (EC) No 1272/2008 of the European Parliament and the Council ³⁹ , that information should not be included in the common data platform. Likewise, due to the commercial sensitiveness of data and information on final cosmetic products, the information related to		
	cosmetic products notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/2009 ⁴⁰ of the European Parliament and of the Council should not be included in the common data platform either. However, chemicals data and information on individual chemical ingredients of cosmetic products should be included in the common data platform.		
Recital 11			
19	(11) To safeguard the ability of the European Commission, of the Union agencies working on chemicals and of the competent Member State authorities (hereinafter ‘the Authorities’), to carry out their tasks, documents with chemicals data relating to their internal work or decision-making should in principle not be included in the common data platform.		
Recital 12			

20	(12) In order to respond to the needs of the digital economy and to ensure a high level of protection of the environment and human health, it is necessary to lay down a harmonised framework specifying who is entitled to access and use the chemicals data contained in the common data platform, under which conditions, on what basis, and for which purposes. The Authorities that are entrusted with regulatory tasks related to chemicals should be allowed and encouraged to use the chemicals data and information contained in the common data platform to effectively fulfil their regulatory duties and tasks, in order to improve the effectiveness, efficiency, and coherence of chemicalsrelated assessments as well as the development of Union chemicals policies.		
Recital 13			
21	(13) Chemicals data and information generated as a result of obligations set by Union acts on chemicals may be protected by confidentiality claims on confidential business information. The public dissemination of such data may affect the commercial interest of private parties. To ensure legal certainty for duty holders and to protect their legitimate expectations, as well as to ensure industry's		
	competitiveness on the internal market, the ECHA, as a manager of the common data platform, should grant differentiated access rights to the data and information contained in the common data platform. To this end, the Authorities should have full access to all chemicals data and information contained in the common data platform, including access to confidential information, while business operators and the general public should have restricted access to that data and information, which does not include access to confidential information.		
Recital 14			

22	(14) When using data contained in the common data platform, the Authorities should respect the originator principle. Under this principle, the confidentiality marking of chemicals data as done by the originator and as correspondingly indicated by the Agency when it provides that data to the common data platform should be respected by the Authorities using that data or information to perform their regulatory functions or fulfil their tasks.		
Recital 15			
23	(15) To ensure the protection of legitimate expectations of duty holders when generating or submitting data or information under the Union acts listed in Annex I, as well as to protect the confidentiality of that information when used by the Authorities, exceptional grounds for disclosing confidential information laid down in the Union acts listed in Annex I should apply only to the disclosure of the data and information submitted or generated in compliance with those acts. For example, under Article 39(4) of Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁴¹ , where urgent action is essential to protect human health, animal health or the environment, such as in emergency situations, the European Food Safety Authority ('EFSA') may disclose information previously considered confidential under that Regulation and the EFSA is required to make public information, previously considered confidential, that forms part of conclusions of scientific outputs of the EFSA and relates to foreseeable effects on human health, animal health or the environment. Likewise, Article 118 of Regulation (EC) No 1907/2006 of the European Parliament and of		

	the Council ⁴² provides for the possibility for the ECHA to disclose confidential information submitted to it under that Regulation if urgent action is essential to protect human health, safety or the environment, such as in emergency situations.		
Recital 16			

24	(16) Taking into account that the Agencies would be required to store scientific data, which includes confidential and personal data, it is necessary to ensure that such storage is carried out in accordance with a high level of security of information systems and that access to confidential data is auditable.		
Recital 17			
25	(17) While the ECHA should identify and develop the technical functionalities of the common data platform in stages, certain dedicated services should be defined by this Regulation. As such, the common data platform should, in addition to providing access to chemicals-related data made available by the Agencies and the Commission, provide access to the chemicals data and information made available through its dedicated services. These dedicated services should be integrated into the common data platform and consist of the existing Information Platform for Chemical Monitoring ('IPCHEM'), a repository of reference values, a database of study notifications, a database with information on regulatory processes, a database with information on applicable legal obligations, a repository of standard formats and controlled vocabularies, a database on environmental sustainability related data, as well as a dashboard of indicators on chemicals.		
Recital 18			
26	(18) The Commission should adopt an implementation plan identifying initial datasets to be made accessible via the platform and the timeline for their integration, informed by the preparatory work of the Commission and the Agencies ⁴³ . The Commission should set up a governance scheme to support and steer the common data platform's operation and evolution covering the organisation of work structures		

	and coordination between ECHA and data providers, required rules, formats and vocabularies for data integration, and maintain a rolling implementation plan to ensure the progress in identification and integration of new datasets and services for inclusion. The governance scheme should be adopted and updated as necessary by the Commission, after consultation with a newly established platform steering committee composed of representatives from Union agencies and the Commission. In order to ensure uniform conditions for the implementation of the obligations to establish an implementation plan and a governance scheme, implementing powers should be conferred on the Commission.		
Recital 19			
27	(19) The common data platform should serve the widest possible community, with the ability to address new use cases, incorporate new relevant datasets, develop new functionalities, and respond to developing tools and applications.		
Recital 20			
28	(20) In order to bring together all relevant chemicals data and information in the common data platform, the Commission and Union agencies – notably the European Agency for Safety and Health at Work ('EU-OSHA'), the ECHA, the European Environment Agency ('EEA'), the EFSA, and the EMA ('the Agencies'), should act as data providers and make available any such relevant data they have or hold to the ECHA for integration in the common data platform. The Agencies, including the ECHA itself when making its own data available, should provide the necessary standard metadata, contextual information and relevant mapping to the platform's structure, and respect rules on standard formats and controlled vocabularies where available.		
Recital 21			

29	(21) To ensure that an adequate knowledge base on chemicals is available through the common data platform, the Commission should be able to request the Agencies to host, maintain and make available, via the common data platform, data generated as part of Union,		
	national or international programmes or research activities beyond the data already flowing to the Agencies as part of the obligations under the Union acts listed in Annex I. The Commission should make such requests to the Agencies in accordance with their mandates and allocated tasks.		
Recital 22			
30	(22) Some types of data are currently not within the mandate of any of the Agencies. In order to ensure clarity of responsibilities of the Agencies and efficient management of chemicals data, the Agencies should be required to host, maintain and provide specific data types to the common data platform. To this end, the ECHA should host and be a data provider to the common data platform for workplace monitoring data, and the EEA should host and be a data provider to the common data platform for data on indoor air quality and environment monitoring data, as well as data on concentrations of chemicals in human matrices such as blood or urine ('human biomonitoring data').		Why are hazard data streams not mentioned (EFSA hosts hazard data related to feed and food and ECHA all other hazard data to be integrated into data platform)? Is this not needed anymore as these data streams are already established by existing regulations?
Recital 23			
31	(23) To improve the uptake of academic data and to expand the knowledge base for chemicals safety assessments and environmental sustainability impacts of chemicals, researchers or research consortia funded by Union framework programmes should make available, in line with the 'as open as possible, as closed as necessary' principle, any human biomonitoring data they collect or generate resulting from research and development programmes to the EEA and any environmental sustainability data on chemicals or materials they collect or generate to the ECHA.		

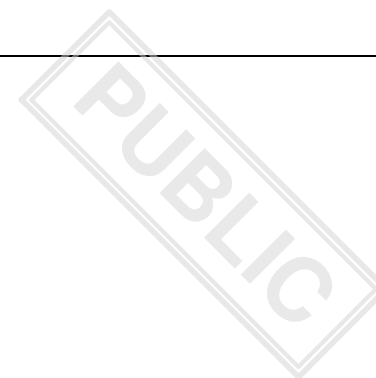
Recital 24			
32	(24) The EEA, as the agency responsible for monitoring data and information on chemicals in the environment, should also be responsible for collecting, hosting, and maintaining human biomonitoring data. To the extent that human biomonitoring data constitutes a special category of personal data, namely, health data, the EEA should process that data only where the processing is		
	necessary for reasons of substantial public interest, as required by Article 10(2)(g) of the Regulation (EU) No 2018/1725 of the European Parliament and of the Council ⁴⁴ . This Regulation lays down the cases where there is such substantial public interest in processing human biomonitoring data: namely, where the EEA processes that data to assess the impact of chemicals on human health and the environment, to monitor time and spatial trends in exposure, to develop health risk and impact indicators, to monitor the impact of regulatory intervention, and to support regulatory risk assessments.		
Recital 25			
33	(25) In order to ensure that appropriate safeguards are in place to secure the protection of this sensitive type of personal data, the EEA should only provide anonymised human biomonitoring data to the ECHA for integration in IPCHEM and the common data platform. IPCHEM, currently operated by the Commission, gathers occurrence data on chemicals in different media, including water, soil, indoor and outdoor air, biota, food and feed, humans, and products. In order to take advantage of the integration of various information systems and to ensure that occurrence data on chemicals is made available for use together with the other chemicals data, the ECHA should take over from the Commission the operation of IPCHEM and integrate it in the common data platform as one of its main dedicated services.		
Recital 26			

34	(26) In order to prevent disruption to the existing operation and functioning of the IPCHEM, the ECHA should integrate the IPCHEM in the common data platform together with the data present in IPCHEM at the moment of integration. At the same time, in order to enable optimal hosting and management of occurrence data on chemicals, the Commission should also transfer the data present in IPCHEM to the ECHA, the EEA or the EFSA for hosting and future updating in accordance with their respective mandates. In order to ensure that the ECHA takes over from the Commission the operation of the IPCHEM, integrates it into the common data platform and takes over the initial data sets and sets up adequate data flows, it is necessary to allow the		

	ECHA an appropriate period of time to carry out these actions, of up to 3 years from the date of entry into force of this Regulation.		
Recital 27			
35	In order to promote the use and harmonisation of reference values among risk assessors and risk managers across different Union acts and to facilitate compliance with, and enforcement of, regulatory reference values, the ECHA should establish and maintain a repository of reference values established or adopted under the Union acts listed in Annexes I and II The Agencies should provide the ECHA with reference values they hold or establish as part of their activities. In addition, the ECHA should regularly screen Union acts for reference values adopted under them. To facilitate automatic access of the general public to upto-date reference values, the ECHA should integrate the repository of reference values in the common data platform as a dedicated service, include in that repository all reference values together with the relevant context data it has received or retrieved and ensure that those values and that context data are machine readable.		
Recital 28			

36	(28) In order to increase transparency, as well as to enable Authorities to have complete prior knowledge of studies commissioned by business operators, irrespective of whether such studies are carried out by the business operator itself or are outsourced, business operators and laboratories should notify to a database of study notifications established and managed by the ECHA the studies on chemicals they commission for compliance with regulatory requirements under the Union acts listed in Annex I. For this purpose, the ECHA should establish and manage a database of study notifications, as a dedicated service of the common data platform, to store the information related to those studies. In order to allow business operators and laboratories sufficient time to prepare the notifications of studies, the obligation to notify studies should only start to apply two years after the date of entry into force of this Regulation.		
Recital 29			

37	(29) Under Regulation (EC) No 178/2002 of the European Parliament and of the Council, business operators and laboratories are obliged to notify to the database of study notifications established and managed by the EFSA the studies they commission to support an application or notification in relation to which Union law contains provisions for the EFSA to provide a scientific output. To avoid overburdening business operators and laboratories, they should therefore not be required to also notify those studies to the database of study notifications established and managed by the ECHA under this Regulation.		
Recital 30			



38	(30) To ensure the coherence between those two study notification mechanisms, as well as to ensure certainty for business operators submitting notifications, the rules on the public dissemination of study notifications should, where relevant, correspond in that the notifications should only be made available through the common data platform EN 27 EN once a corresponding registration, application, notification or other relevant regulatory dossier was submitted to the relevant Union or national institution and a decision on the confidentiality of the data contained in that regulatory dossier was taken by that Union or national institution. In addition, in order to facilitate compliance with the requirement to notify a study, the ECHA and the EFSA should cooperate to ensure a common approach for the identification of notified information in order to facilitate the traceability of studies notified to their respective databases.		
Recital 31			
39	(31) While the study notification obligation established in this Regulation should apply in the context of all the Union acts on chemicals listed in Annex I, the various relevant data collection and safety assessment processes under those acts may vary widely procedurally. The overarching aim of the database of study notifications established under this Regulation should be to bring together information on studies on chemicals being commissioned by business operators, such as to enable a centralised and complete		

	overview of the studies being performed to support regulatory compliance under Union acts on chemicals as listed in Annex I. On the basis of this objective and considering the fact that assessment procedures under Union acts on chemicals in Annex I may vary widely, it would be beyond the scope and aim of this Regulation to amend existing assessment processes set under those Union acts listed in Annex I by imposing additional conditions leading to potential market access consequences not foreseen in those Union acts. Consequently, it is not appropriate to introduce in this Regulation the consequences associated non-compliance with the study notification obligation as laid out in Article 32b of Regulation (EC) No 178/2002 of the European Parliament and of the Council.		
Recital 32			
40	(32) Nevertheless, to ensure compliance with the study notification obligation laid down in this Regulation, and to cater to the specificities of individual assessment processes, where existing, Member States should lay down rules on penalties applicable to the infringement of that obligation and take all necessary measures to ensure that those rules are complied with. Those penalties should be effective, proportionate, and dissuasive, since non-compliance with this Regulation could result in less robust chemicals risk assessments, creating potential risks and consequently adverse effects on human health and the environment.		
Recital 33			
41	(33) In order to facilitate enforcement by Member States, the Agencies responsible for assessing and providing scientific output, including scientific opinions, on regulatory dossiers containing studies subject to notification to ECHA should, where relevant, cooperate and exchange information with the Member State enforcement authorities on the compliance with the obligations laid out in Article 22.		
Recital 34			

42	(34) While Regulation (EC) No 178/2002 of the European Parliament and of the Council also requires the consultation of stakeholders and		

	the public following the notification to the EFSA of studies commissioned for the purposes of the renewal of an authorisation or approval, a similar requirement under this Regulation would lay a disproportionate administrative burden on the ECHA, given the wide scope of the studies that is to be notified under this Regulation.		
Recital 35			
43	(35) A mechanism related to study notifications exists in Regulation (EC) No 1907/2006 of the European Parliament and of the Council. Where registrants are required to perform studies to generate data in accordance with requirements in Annexes IX and X to that Regulation, they must first submit a testing proposal to the ECHA in order to receive a decision requiring them to perform a study. Such decision may also be issued as an outcome of compliance check or substance evaluation under that Regulation. In order to facilitate the transparency, traceability, and effective monitoring of studies commissioned or carried out pursuant to a decision of the ECHA in accordance with Articles 40, 41 or 46 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council, business operators should specify in their notifications of studies under this Regulation that those studies are being commissioned or carried out in compliance with those decisions.		
Recital 36			

44	(36) To strengthen the coordination and cooperation between the different bodies performing chemicals assessments in the Union, and to promote an increased transparency of chemicals assessments, the ECHA should establish and manage a database with information on regulatory processes or activities that are planned, ongoing or completed by Member States, the Commission and Agencies referred to in the Union acts listed in Annex III to this Regulation and integrate it into the common data platform for access by the authorities. The information on such regulatory processes or activities should include at least the substance identity and the identification, status and eventually the outcome of the regulatory process or activity. That information should also be made available without undue delay and		

	kept updated through the assessment process. Once the process or activity has formally started, that information should be shared also publicly on the common data platform.		
Recital 37			
45	(37) The existing 'The EU Chemicals Legislation Finder' ⁴⁵ project managed by the ECHA makes it easier to find and identify legal obligations related to the use of a specific chemical. The project is especially helpful for small and medium sized enterprises in identifying their legal obligations. To reinforce the supportive function of the project for business operators, it should be established on a permanent basis and more Union acts should be included in its scope. For this purpose, the ECHA should collect information on the legal obligations deriving from the Union acts on chemicals listed in Annex I to this Regulation and incorporate that information into the common data platform as a dedicated service.		
Recital 38			

46	(38) In order to ensure the interoperability and comparability of chemicals data and to facilitate their automatic and electronic exchange, the Agencies and the Commission should store chemicals data in adequate and mutually coherent and interoperable formats and use mutually coherent and interoperable controlled vocabularies. Some Union acts listed in Annex I or II set procedures to establish or make available data formats, in particular for the submission of chemicals data by business operators or Member States. Where such procedures do not exist in the Union acts listed in Annex I or II, the Agencies and the Commission should, where relevant, specify appropriate formats for chemicals data they receive and store, avoiding the use of proprietary standards while, as appropriate, using OECD or other internationally agreed formats, making use of existing formats and ensuring interoperability with existing data submission approaches.		
Recital 39			
47	(39) Likewise, the Agencies and the Commission should specify		

	appropriate controlled vocabularies for data they receive and store and, where relevant, integrate them in submission software or formats. Moreover, in order to facilitate a smooth electronic exchange of data through the common data platform, the Agencies and the Commission should agree on the required formats and controlled vocabularies for providing data to the common data platform. Whenever the Agencies or the Commission set formats or controlled vocabularies, they should cooperate with each other to ensure their coherence, consistency and interoperability. In order to ensure uniform conditions for resolving divergences in data formats and controlled vocabularies, implementing powers should be conferred on the Commission.		
Recital 40			

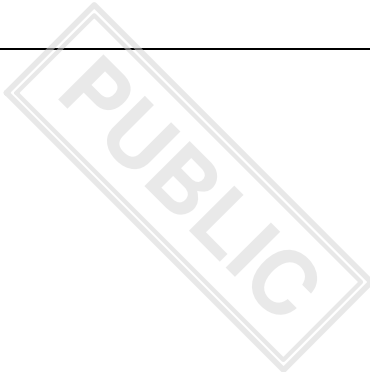
48	(40) In order to promote the interoperability of database systems on chemicals beyond the common data platform, the ECHA should establish a repository of standard formats and controlled vocabularies as part of the common data platform. The Agencies and the Commission should make the formats and controlled vocabularies they set available to the repository and the ECHA should make them available free of charge in electronic formats for use by developers of database systems and the general public.		
Recital 41			
49	(41) The International Uniform Chemical Information Database ('IUCLID') is a software application designed to record, store, maintain and exchange data on chemicals. The ECHA develops and maintains the IUCLID software and the underlying format in collaboration with the Organisation for Economic Cooperation and Development ('OECD'). The IUCLID implements all OECD-harmonised templates, which are harmonised formats agreed at the OECD level to facilitate structured and consistent documentation of test outputs and similar chemicals data. Since chemicals data is being submitted to the ECHA in IUCLID under Union acts such as Regulations (EC) No 1907/2006, (EC) No 1107/200946 and (EU) No 528/201247 of the European Parliament and of the Council, the ECHA is closely involved in the continued development of IUCLID, and IUCLID implements the standard formats		Concerning active substances for plant protection products IUCLID is used as submission tool for dossiers from applicants. The OHTs do not contain peer reviewed end points so that it is questionable how IUCLID can be used as data source.

	agreed at the OECD level, it is appropriate and necessary to require the Commission and the Agencies to use IUCLID for the relevant parts of dossiers under specified Union acts listed in Annex I when they make the data contained in those dossiers available to the ECHA .		
Recital 42			

50	(42) To increase the availability and facilitate the use of information on the environmental performance of chemicals throughout their lifecycle, and to enable a comprehensive assessment of the impacts of chemicals on the environment, the Commission should identify relevant data and information related to the environmental sustainability of chemicals, including, where available, information on their impact on climate change, for integration into the common data platform. Once the Commission has identified the relevant existing datasets on environmental sustainability related data and has designed the relevant related database functionalities, the ECHA should establish a database on environmental sustainability-related data, collect the data as made available by the Commission, the Agencies and, where relevant, by the researchers and research consortia funded by Union framework programmes, and integrate the content of that database into the common data platform as a dedicated service. In order to ensure uniform conditions for the implementation of the obligation to identify relevant environmental sustainability datasets, implementing powers should be conferred on the Commission.		
Recital 43			
51	(43) To monitor the impacts on humans and the environment, including the climate, of exposure to chemicals and to establish a knowledge base to measure the effectiveness of chemicals legislation in protecting human health and the environment, the EEA and the ECHA should jointly develop and regularly, at least every two years, update a set of indicators and present it in the form of a dashboard. The EFSA, the EMA, the EU-OSHA and the Commission shall regularly provide the EEA with any available data falling within their mandate and relevant for the establishment of the indicators. The EEA and the ECHA should integrate this dashboard of indicators into the common data platform.		
Recital 44			

52	(44) To enable the identification and evaluation of emerging chemical risks, the EEA should develop and compile information on early warning signals and draw up an annual summary report to inform regulatory follow-up actions. In its work, the EEA should include its own sources, targeted literature searches and make use of information from national early warning systems. It should also include relevant information made available by the related work of the ECHA, the EFSA, the EU-OSHA, the EMA and their networks, such as the EFSA's task of identifying and collecting information on emerging risks under Regulation 178/2002. The EEA should make the summary report and the underlying data available through the common data platform, ensuring public access and its use for further action on existing and emerging risks. In order to allow the EEA sufficient time to organise the collection of early warning signals and to compile and analyse the initial information the EEA should only deliver the first report six months after the end of the first calendar year after entry into force of this Regulation. This Regulation sets a deadline for the first report and associated data.		
Recital 45			
53	(45) In June 2017, at the Commission' request, the ECHA set up the European Observatory for Nanomaterials⁴⁸ ('EUON'), which collects existing data and information from databases, registries and studies and generates new data through studies and surveys on nanomaterials on the EU market.		
Recital 46			
54	(46) The ECHA should continue operating the EUON and transform it into an observatory for specific chemicals with potential contribution to emerging chemical risks ('the observatory'), which should cover also other chemicals and innovative (rationally designed complex 'advanced') materials selected by the Commission, using, as appropriate, signals from the early warning and action system. One of the criteria for selecting chemicals for the observatory should be their		

	novelty and disruptive potential that may contribute to an emerging chemical risk. Another criterion for that selection should be the higher degree of uncertainty surrounding them and, due to less regulatory experience regarding those chemicals, the resulting need for additional scrutiny and transparency. The observatory should facilitate regulatory implementation and responsible use of these chemicals by collecting, generating, and disseminating reliable information on selected chemicals' properties, uses and market presence to the general public.		
Recital 47			
55	(47) The observatory should not be regarded as a substitute for required risk management action on any chemical in cases where a hazard or risk has been identified. In order to provide for an efficient and consistent approach for the generation and dissemination of all such additional information, the ECHA should oversee the work of the observatory and make the regularly updated data and information it collects available through the common data platform, or by means of other communication channels, as appropriate. In order to ensure uniform conditions for the implementation of the requirement to select chemicals to be included in the observatory, implementing powers should be conferred on the Commission.		
Recital 48			



56	(48) Under Regulation (EC) No 178/2002, the EFSA is able to commission, in an open and transparent manner, the scientific studies it needs to accomplish its mission, while seeking to avoid duplication with Member States or Union research programmes. The ECHA should also be able to commission studies to obtain adequate data and information on chemicals within its mission, while maintaining the principle that the burden to prove compliance with Union chemicals legislation remains on the duty holder. Furthermore, the ECHA should commission such studies out of its own initiative or at the request of the Commission, with the objective of supporting the effective and efficient implementation and evaluation of Union acts on chemicals within its mandate and contributing the development of a Union chemicals policy.		
Recital 49			

57	(49) In order to adjust the contents of Annexes I and III to technical and scientific progress in the field of chemicals and to bring in the scope of this Regulation new Union acts under which relevant chemicals data and information is generated or submitted, and, where relevant, to expand the specific data types and reference values, listed in Annex II, to be made available by the EMA through the common data platform, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending Annexes I, II and III. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work in relation to the amendment of the Annexes by delegated act, including at expert level through the One-Substance One-Assessment Expert Group, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016⁴⁹. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.		
Recital 50			
58	(50) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States as Member States do not hold the data within the scope of this Regulation and cannot establish a Union wide common data platform, but can rather, by reason of chemicals data and information being hosted at Union level by the Agencies, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.		
Recital 51			

59	(51) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council and delivered an opinion on [OP: Please insert the date of the opinion of the EDPS].		
Formula			
60	HAVE ADOPTED THIS REGULATION:		
Chapter I			
61	Chapter I SUBJECT MATTER, SCOPE AND DEFINITIONS		
Article 1			
62	Article 1 Subject matter and scope		
Article 1(1)			
63	1. This Regulation aims to ensure the efficient delivery of coherent hazard and risk assessments of chemicals where those assessments are required by Union legal acts, to achieve a high level of protection of human health and the environment, to enable the development and use of sustainable chemicals, to ensure the proper functioning of the single market for chemicals, and to improve the Union's citizens' trust in the scientific base for the decisions taken under Union legal acts on chemicals.	One delegation proposed to include SSBD (safe and sustainable by design) as one of the roles for the platform. → PRES propose to work on an amendment introducing explicitly the safe and sustainable by design approach as one of the aims.	
Article 1(2)			
64	2. To achieve the objectives referred to in paragraph 1, this Regulation contains measures to:		
Article 1(2), point (a)			
65	(a) bring together data and information on chemicals and ensure that data and information are easily findable, accessible, interoperable and re-usable;		

Article 1(2), point (b)			
66	(b) keep records of studies commissioned or carried out by business operators in the context of fulfilling their obligations set under Union chemicals legislation;		
Article 1(2), point(c)			
67	(c) establish the widest possible scientific base for the implementation and development of Union legislation and policy on chemicals;		
Article 1(2), point (c)			
68	(d) establish an early warning and action system for emerging chemical risks.		
Article 1(3)			
69	The provisions laid down in this Regulation apply to chemicals data as laid out in Article 3(2).		
Article 2			

70	Article 2 Definitions	One delegation requested amending art.2 to clarify the meaning of “product” in this proposal. One delegation asked what is covered by the term “products” in art.7(1) One delegation requested examples of the meaning of “chemical products” in relation to mixtures, articles, substances. PRES highlights that the term occurs in recital (8), (10),(25),art.3(3), art.7(1), art.22(1). PRES highlights also that while some of those occurrences relates to cosmetic or medicinal products, other occurrences do not refer to a particular regulation and might have overlapping meaning with e.g. articles in REACH, or products under the ESPR. → PRES is working on an amendment proposal.	We agree with the need to clarify the meaning of “product” in this proposal.
Formula			
71	For the purpose of this Regulation, the following definitions shall apply:		
Article			

2(1)			
72	1. ‘Agencies’ means the European Chemicals Agency (‘ECHA’), the European Environment Agency (‘EEA’), the European Food Safety Authority (‘EFSA’) and the European Medicines Agency (‘EMA’) and the European Agency for Safety and Health at Work (‘EU-OSHA’);		
Article 2(2)			
73	2. ‘Authorities’ means the European Commission, the competent authorities of the Member States as referred to in any of the Union acts listed in Annexes I and III, and the Agencies, excluding their management boards;		
Article 2(3)			
74	3. ‘duty holder’ means a natural or legal person responsible for meeting obligations under the Union acts listed in Annex I or II;		

Article 2(4)			
75	4. 'business operators' means duty holders which are private or public undertakings;	One delegation suggests to “use ‘economic operators’ instead of ‘business operators’ to ensure alignment with other relevant legislation”. PRES highlights that the term “business operator” is used in recital (8),(13),(28),(29),(30),(31),(35),(37),(38), and articles 1(2), 22, 25, and 26. Those articles relate to studies commissioned, studies notifications, and related enforcement/penalties. PRES highlights that the term “duty holder” is defined in art. 2(3) in relation to obligations in acts mentioned in annex I or II. The term is per se used in recital (13), (15), (48), art 2(4), 15(5), and 17(2). Those later articles relate to the use of the controlled vocabularies, as well as the prohibition for Authorities to use data from the platform to fulfil legal obligations of duty holders. → PRES seeks written comments on the following: ESPR has a definition of “economic operator”: ‘economic operator’	We agree with Presidency not to change the wording.

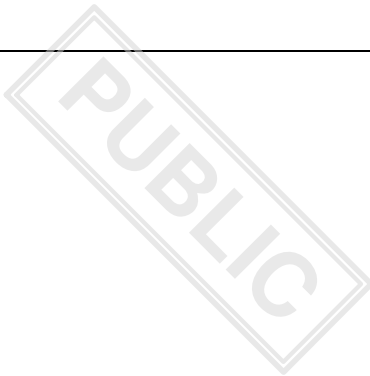
		means the manufacturer, the authorised representative, the importer, the distributor, the dealer and the fulfilment service provider. PRES understands that in the present regulation the meaning of it is much more narrow, and relates only to duty holders that at the same time are undertakings. → PRES seeks for agreement that in consequence there is no correspondence with other EU regulations, and thus no amendment here should be done.	
Article 2(5)			

76	5. 'human biomonitoring data' means concentrations of chemicals measured in human matrices such as blood or urine;		
Article 2(6)			
77	6. 'reference value' means an estimate of a maximum exposure to or emission level of a chemical below which no or only acceptable adverse effects on human health or the environment are expected, or below which risks related to the adverse effects on human health or the environment are considered acceptable or tolerable;	One delegation commented about “acceptable or tolerable” in relation to non-threshold cancerogenic substances. PRES understands that the intention is to avoid that reference values for non-threshold substances are published without mentioning as metadata the actual statistical risk they represent. → PRES proposes to work on an amendment of art 2(6), 8 and 14 for this.	Could this problem be overcome by adding the uncertainty (analysis) to the data?
Article 2(7)			
78	7. 'originator' means the Commission, Agency, or Member State competent authority responsible for confidentiality assessments under any Union act listed in Annex I or Annex II;		
Article 2(8)			
79	8. 'originating Union act' means the Union act under which chemicals data and information were generated or submitted;		
Article 2(9)			
80	9. 'controlled vocabularies' means standardised and organised arrangements of words and phrases presented as lists of terms or as thesaurus and taxonomies with a hierarchical structure of broader and narrower terms;		
Article 2(10)			

81	10. 'chemicals data' means any representation of facts or information relating to chemicals and any compilation of such facts or information, including information on physico-chemical properties, hazard properties, use, exposure, risk, occurrence, emissions and manufacturing process of the chemicals, as well as environmental sustainability related information, including climate change related information, on those chemicals, regulatory process-related information on chemicals, standard formats, controlled vocabularies, or any information on applicable legal obligations related to chemicals;		
Article 2(11)			
82	11. 'environmental sustainability related data' means any data relevant for the environmental sustainability assessment of a chemical or material throughout its entire life cycle, including:	One delegation finds this definition vague, and proposes to add an annex (e.g. in Art. 13) which can be updated on a regular basis by means of Delegated Acts. This annex should contain the respective legal acts as well as the associated sustainability information. PRES highlights that the definition here is used in a broader sense than the information available in legal acts (e.g. research in art.5(6), art 13(3) and potentially art.13(4)). → PRES requests written comments on the necessity to add a reference to a new annex IV, containing a list legal acts relevant for environmental sustainability related data. Such a reference would be added here as a new point 2(11)(d) along with related delegated powers in Chapter VIII. → PRES would also like to have comments on the provisions of art.13(4) as this partially overlaps with the concern raised by one delegation (by having the COM adopting an implementing decision for data not already hosted or hold by agencies/COM or not coming from EU research). Which relevant data are generated through legal	Given that the definition here is used in a broader sense and this is a relatively new topic, addition of an annex might be a good way forward, and therefore is supported.
		acts but are not hold or hosted by COM/agencies listed in this proposal?	

Article 2(11), point (a)			
83	(a) data on resources, including raw materials, water, energy, fossil fuels and land;		
Article 2(11), point (b)			
84	(b) data on emissions, including greenhouse gases, eutrophicationrelevant substances, dust and all other polluting substances; and		
Article 2(11), point (c)			
85	(c) data on by-products originating during the chemical's life cycle that can be used as resources for other production processes, including hydrogen and carbon monoxide.		
Article 2(12)			
86	12. 'personal data' means personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679 of the European Parliament and of the Council and as defined in Article 3, ~~point (16), of Regulation (EU) 2018/175~~ point (1), of Regulation (EU) 2018/1725 of the European Parliament and of the Council;	One delegation highlighted that this definition is specified in Article 3, point (1) of Regulation 2018/1725 and not in Article 3, point (16) of Regulation 2018/175. → PRES sees this as an editorial amendment and proposes to modify Article 2 (12) consequently.	
Article 2(13)			
87	13. 'processing' means processing as defined in Article 4, point (2), of Regulation (EU) 2016/679 of the European Parliament and of the Council and as defined in Article 3, point (3), of ~~Regulation (EU) 2018/175~~ Regulation (EU) 2018/1725	One delegation highlighted that the reference is to Regulation 2018/1725 and not to Regulation 2018/175. → PRES sees that this is an editorial amendment and proposes to modify Article 2 (13) consequently.	

	of the European Parliament and of the Council;		
Article 2(14)			
88	14. 'data controller' means controller as defined in Article 4, point (7), of Regulation (EU) 2016/679 and as defined in Article 3, point (8), of ~~Regulation (EU) 2018/175~~ Regulation (EU) 2018/1725 of the European Parliament and of the Council;	One delegation highlighted that the reference is to Regulation 2018/1725 and not to Regulation 2018/175. → PRES sees that this is an editorial amendment and proposes to modify Article 2 (14) consequently.	
Article 2(15)			
89	15. 'interoperability' means the ability of two or more data spaces or communication networks, systems, products, applications or components to exchange and use data in order to perform their functions.	One delegation asked if advanced programming interfaces (API) will be used. PRES highlights that API are tools that MSs may use amongst others in order to query the data platform from their own advanced knowledge management systems (i.e. machine readability) instead of relying on "manual" queries in a web interface like in ECHA web site today. PRES highlights that in the explanatory memorandum the COM mentions that "The proposal also contributes to the objectives of EU data and digital policies by promoting interoperability and machine readability ". However only interoperability is explicitly mentioned here. → PRES requests written comments on this and on the necessity to amend the proposal to explicitly mention APIs and the conditions of their use for MS and the public.	In the interest of legal certainty, we suggest to include a definition of the term 'study'. The practical arrangements by EFSA under GFL also refer to the general definition provided by OECD (Point 2.3 para 1 of OECD Council Decision 26 November 1997, C(97)186/FINAL). We suggest to include the OECD definition in the legal text. Drafting suggestion: "16. 'study' means an experiment or set of experiments in which a test item is examined under laboratory conditions or in



			the environment to obtain data on its properties or its safety, intended for submission to appropriate regulatory authorities.” Application Programming Interface (API) means a set of functions, procedures, definitions and protocols for machine-to-machine communication and seamless data exchange. They foster and facilitate the management of data according to the FAIR principles. We suggest that the proposal be amended to include an explicit reference to promoting the provision of data via APIs, their terms of use and documentation as is the case in other data-related legislation (e.g. Commission Implementation Regulation 2023/138).
Chapter II			
90	Chapter II INFORMATION SYSTEMS AND PLATFORMS		
Article 3			

91	Article 3 Common Data Platform on Chemicals		
Article 3(1)			
92	1. The ECHA shall establish and manage a common data platform on chemicals ('the common data platform').		
Article 3(2)			
93	2. The common data platform shall provide access to all chemicals data:	One delegation highlights that it is difficult to assess the exhaustiveness of annexes I and III. PRES request written comments on any potentially missing relevant regulations in those annexes. One delegation questioned the differentiated approach between medicinal products and biocidal and phytopharmaceutical products. → PRES would like to receive further clarity in writing.	
Article 3(2), point (a)			
94	(a) generated or submitted as part of the implementation of the Union acts listed in Annex I to this Regulation and held by the Agencies or the Commission;		
Article 3(2), point (b)			
95	(b) generated as part of Union, national or international programmes or research activities in the sphere of chemicals and held by the ECHA, the EEA, the EFSA, the EU-OSHA or the Commission;		

Article 3(2), point (c)			
96	(c) listed in Annex II and held by the EMA;		
Article 3(3)			

97	3. The following information shall not be included in the common data platform:		
Article 3(3), point (a)			
98	(a) the information referred to in Article 45 of Regulation (EC) No 1272/2008 ⁵⁰ ; 50 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).		
Article 3(3), point (b)			
99	(b) the information related to cosmetic products and notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/2009 ⁵¹ of the European Parliament and of the Council. 51 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November on cosmetic products (OJ L 342 22.12.2009, p. 59).		
Article 3(4)			

100	4. Documents relating to Authorities' internal work or decision-making processes need not be included in the common data platform, unless required under Article 10.		
Article 3(5)			
101	5. The common data platform shall provide the dedicated services identified in the governance scheme referred to in Article 4(3) including:		
Article 3(5), point (a)			
102	(a) the Information Platform for Chemical Monitoring ('IPCHEM')		

	referred to in Article 7;		
Article 3(5), point (b)			
103	(b) the repository of reference values referred to in Article 8;		
Article 3(5), point (c)			
104	(c) the database of study notifications referred to in Article 9;		
Article 3(5), point (d)			
105	(d) information on regulatory processes referred to in Article 10;		
Article 3(5), point (e)			
106	(e) information on obligations under Union chemicals legislation referred to in Article 11;		

Article 3(5), point (f)			
107	(f) the repository of standard formats and controlled vocabularies referred to in Article 12;		
Article 3(5), point (g)			
108	(g) the database on environmental sustainability-related data referred to in Article 13.		
Article 3(6)			
109	6. The Authorities and the general public shall have access to the data contained in the common data platform in accordance with Article 16.		
Article 3(7)			
110	7. The data contained in the common data platform may be used in		

	accordance with Article 17.		
Article 3(8)			
111	8. The data contained in the common data platform shall be made available in standard formats, where developed, and through controlled vocabularies where available.		
Article 3(9)			

112	9. The data contained in the common data platform shall be electronically accessible and searchable. The ECHA shall take measures to ensure a high standard of security appropriate to the security risks at stake for the storage of chemicals data in and transmission of chemicals data to the common data platform. The ECHA shall design the common data platform in a way that guarantees that any access to confidential data is auditable.		
Article 3(10)			
113	10. The Commission or Agency under whose authority chemicals data is included in the common data platform on chemicals shall remain responsible for handling any requests for access to documents made under Regulation (EC) No 1049/200152. 52 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (. OJ L 145, 31.5.2001, p. 43).		
Article 3(11)			
114	11. The common data platform and its dedicated services shall be established by [OP: please insert date: three years after the date of entry into force of this Regulation], unless specified otherwise. The relevant datasets shall be integrated progressively into the common data platform by [OP please insert date: ten years from the date of entry into force of this Regulation] according to the implementation plan referred to in Article 4 (1), first sentence. Upon integration of those datasets in the common data platform, when the ECHA receives	One delegation requested clarifications on this paragraph (timing for the notification service, lack of specification of the timing for the rolling plans). This delegation proposed amendments accordingly → PRES: a more general discussion at the 2d WP took place regarding the timelines	

	chemicals data in accordance with Article 5, it shall make that data available through the common data platform without undue delay.		
Article 4			

115	Article 4 Implementation plan and governance of the common data platform	One delegation proposed to include new provisions 5a,5b,5c in art.4., requesting that the COM prepares and presents a recommendation on “how to amend legislation listed in the Annexes to this regulation”. → PRES would like to receive written comments on this as it is not clear for us if this means amending the annexes of the data platform proposal, or if the delegation meant to amend the listed regulations. One delegation raised concerns about the wording “implementing” appearing at several places and which is seen as “misleading” with respect to the legal definition of “implementing acts”. → PRES seeks legal advice on this. The Council legal services provided an opinion on this at the 2nd WP.	
Article 4(1)			
116	1. By [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall adopt and publish an implementation plan identifying datasets for inclusion in the common data platform together with a timeline for their inclusion by means of an implementing decision. Subsequent rolling implementation plans shall be adopted in line with the governance scheme referred to in paragraph 3.	One delegation questioned the procedure for adopting the plan, the consultation procedures and MS involvement. → PRES: WP2 discussion on the desired level of and procedures for MS participation took place.	Remarks are supported
Article 4(2)			
117	2. The Commission shall, by means of an implementing decision, establish and manage a platform steering committee, which shall include one representative from the ECHA, one representative from the EEA, one representative from the EFSA, one representative from the EMA, one representative from the EU-OSHA and five representatives from the Commission.		For the pharmaceutical sector, it is essential to ensure that ISO IDMP (Identification of medicinal products) compatibility for the data platform and that the terms and IDs of the EU SRS (Substance Registration System) for

			pharmaceutical substances are used. The Platform Steering Committee is responsible for establishing and managing the platform and also covers the topics of data management and standard formats. At least, these important technical details should be defined by the Platform Steering Committee provided for in Art. 4 (2) (Implementation plan and governance of the common data platform) of the draft Regulation, with representatives of the authorities (ECHA, EEA, EFSA, EMA, EU-OSHA and the Commission) as a suitable body for detailed technical issues.
Article 4(3)			
118	3. The platform steering committee shall advise the Commission in the		
	preparation of the common data platform's governance scheme.		
Article 4(4)			

119	4. The Commission shall adopt and publish the governance scheme referred to in paragraph 3 and any revision thereof by means of an implementing decision		
Article 4(5)			
120	5. That governance scheme shall describe:		
Article 4(5), point (a)			
121	(a) the organisation of the main work structures supporting the development and implementation of the common data platform;		
Article 4(5), point (b)			
122	(b) the preparation and adoption of rolling implementation plans for the common data platform;		
Article 4(5), point (c)			
123	(c) the principles on data governance and the required standard formats, controlled vocabularies and further conditions for the provision of information and context data to the common data platform;		
Article 4(5), point (d)			
124	(d) the decision-making procedures for the development of new dedicated services and the inclusion of new functionalities of the platform;		
Article 4(5), point(e)			

125	(e) any other rules or requirements necessary for the operation of the common data platform such as the data update, archiving and deletion policy;		
Article 4(5), point (f)			
126	(f) the operation of the steering committee itself.		
Article 5			
127	Article 5 Data Flows for the purpose of the common data platform		
Article 5(1)			
128	1. At the Commission's request, the Agencies shall host and maintain chemicals data generated as part of Union, national or international legislation, programmes or research activities, corresponding to their mandate and the type of data they already hold.		We suggest to include a reference to data which are provided by third parties (i.e. MS, their agencies of scientific bodies). According to COM's reply, it is in general possible to suggest data for inclusion in the CDPC. This should be reflected in the legal text. Drafting suggestion of a new second sentence: "Upon suggestion of a Member State, a national Authority or a scientific body of a Member State, after approval of the Commission, the Agencies shall host and maintain chemical data which are

			additional to the data mentioned in the first sentence.”
Article 5(2)			
129	2. Where the Commission or the Agencies hold data or information referred to in Article 3(2), they shall make that data available to the ECHA, in a standard format, where available, together with the relevant context data as ~~referred to in Article 4(4), point (c).~~ referred to in Article 4(5), point (c). The Commission and the Agencies shall indicate whether that data or information is made available to the public under the originating Union act.	One delegation highlighted that the reference should be to Article 4(5), point (c) and not Article 4(4), point (c). → PRES sees this as an editorial amendment and proposes to modify Article 5(2) consequently.	
Article 5(3)			
130	3. The ECHA shall host and maintain occurrence data related to workplace monitoring.		
Article 5(4)			
131	4. The EEA shall host and maintain human biomonitoring data, occurrence data for the environment and occurrence data related to indoor air quality.	One delegation asked if Commission pursues plans for systematic or regular surveys of indoor air quality data → PRES is requesting written comments on this.	Does this include also hosting and maintaining non-target screening information? Not only substances produced or manufactured for the EU market are relevant but also transformation and degradation products are relevant for assessment purposes.
Article			
5(5)			

132	5. Researchers or research consortia funded by Union framework programmes shall make available to the EEA any human biomonitoring data they collect or generate from [OP please insert: date of the entry into force of this Regulation].		
Article 5(6)			
133	6. Researchers or research consortia funded by Union framework programmes shall make available to the ECHA any environmental sustainability data on chemicals or materials they collect or generate from [OP please insert: date of the entry into force of this Regulation].		
Article 5(7)			
134	7. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of the chemicals data provided in accordance with paragraph 2 in the common data platform as well as its publication through that platform.		
Article 5(8)			
135	8. For the purpose of paragraph 2, the Commission and the Agencies shall make chemicals data available to the ECHA without undue delay after collection or receipt of the data, after performance of validity and confidentiality assessments in accordance with applicable rules and once the corresponding dataset has been integrated in the common data platform.		
Article 5(9)			
136	9. The Commission and the Agencies shall ensure that data made available to the ECHA shall be downloadable, machine readable and interoperable. They shall appropriately curate and validate the data before providing them to the ECHA.		
Article 6			

137	Article 6 Human biomonitoring data	→ PRES: given the numerous comments, questions and clarification requests received, PRES set this as a discussion point at the 2 nd WP (8/3), and invites MS and the COM to react to the EDPS recommendations.	

Article 6(1)			
138	1. The EEA shall collect, host, and maintain human biomonitoring data generated within the territory of the EEA's member and cooperating countries.		
Article 6(2)			
139	2. At the latest by [OP please insert date: 3 years after entry into force of this Regulation] the Commission shall transfer any human biomonitoring data it holds to the EEA.		
Article 6(3)			
140	3. The EEA may process human biomonitoring data constituting personal data to support the Commission in its policy making or to support the Agencies in fulfilling their missions.		
Article 6(4)			
141	4. Human biomonitoring data constituting personal data may be processed by the EEA for the following purposes:		
Article 6(4), point (a)			
142	(a) assessing the impact of chemicals on human health and the environment;		
Article 6(4), point (b)			
143	(b) monitoring time and spatial trends in exposure;		

Article 6(4), point (c)			
144	(c) developing health risk and impact indicators;		
Article 6(4), point (d)			
145	(d) monitoring the impact of regulatory intervention;		

Article 6(4), point (e)			
146	(e) supporting regulatory risk assessments.		
146.a	<i>(f) supporting regulatory risk management</i>	One delegation proposed to add this amendment. PRES understands that HBM data are indeed useful for risk management, e.g. trend analysis will give an idea if policy actions are having an impact or not on reducing exposure → PRES proposes thus to add this paragraph (f)	This is the result of supporting regulatory risk assessment and thus acceptable. Is it necessary to have an exchange on the measures taken with other MS and the Commission?
Article 6(5)			
147	5. The EEA shall make human biomonitoring data they hold or host publicly available in anonymised form through the Information Platform for Chemical Monitoring.		
Article 6(6)			

148	6. The EEA shall act as data controller for the human biomonitoring personal data it holds or hosts and processes for the purposes referred to in paragraph 2. in paragraph 4.	Some delegations highlighted that the reference should be to para. 4. → PRES sees this as an editorial amendment and proposes to modify art.6(6) in consequence. One delegation proposed to add an additional reference to art.3 and 5 here. → PRES, up to his knowledge, understands that from the definition of a data controller this is logical, but seeks for written opinions on this and will request a legal advice. Discussions at the 2nd WP on the EDPS recommendations might also contribute clarifications on this proposal. One delegation suggested to “include the same reference to Articles 6(3) and 6(4)” → PRES is keen to receive a written rationale for this as it seems to introduce a circular reference in the text.	DE supports the recommendation of the EDPS according to which the reference to paragraph 2 should be replaced by a reference to para 3 to 5. The different purposes are mentioned in those paragraphs.
Article 7			

149	Article 7 Information Platform for Chemical Monitoring		
Article 7(1)			
150	1. The ECHA shall operate and maintain the Information Platform for Chemical Monitoring containing occurrence data on chemicals across different media, including water, soil, indoor air, outdoor air, biota, food and feed, humans, and products as part of the common data platform.	→ PRES: regarding the meaning of “products”, cfr art.2 (here in line 70).	From an analytical point of view this are matrices. In plant protection or biocidal uses a product is a formulation used by an applicant.
Article 7(2)			

151	2. At the latest by [OP please insert date: 3 years after the date of entry into force of this Regulation], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring at that moment to the ECHA for integration in the common data platform.		
Article 7(3)			
152	3. At the latest by [OP please insert date: 3 years after entry into force of this Regulation], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring to the ECHA, the EEA or the EFSA for hosting in accordance with the respective agencies' mandate and in accordance with Article 5.		
Article 7(4)			
153	4. After the completion of the transfer referred to in paragraph 3, where the Commission or the Agencies host or hold occurrence data on chemicals and related chemicals data, they shall make that data available to the ECHA without undue delay for integration in the Information Platform for Chemical Monitoring.		
Article 7(5)			
154	5. The Commission and Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration and publication of occurrence data and related chemicals data they host or hold through the common data platform.		
Article			

7(6)			
155	6. The ECHA shall ensure that the data contained in the Information Platform for Chemical Monitoring is machine readable and downloadable.		
Article 8			

156	Article 8 Repository of reference values	One delegation requested a amendment about the statistical (cancer) risk associated with some reference values. → PRES: see our proposal in art 2(6) here line 77	
Article 8(1)			
157	1. The ECHA shall establish and manage a repository of reference values as part of the common data platform.		
Article 8(2)			
158	2. The ECHA shall include any reference value adopted under Union acts listed in Annex I or Annex II, Part 1, in the repository of reference values without undue delay.		
Article 8(3)			
159	3. For reference values not falling under paragraph 2, the Agencies holding or establishing reference values as part of their activities under Union acts listed in Annex I, or the reference values referred to in Annex II, Part 2, shall make those reference values available to the ECHA, in the standard formats provided for in Article 14, where developed, and without undue delay, for integration in the repository of reference values.		
Article 8(4)			
160	4. For the purpose of paragraph 3, where reference values are included in a regulatory dossier submitted to the Agencies, the Agencies shall share those reference values in the standard formats with ECHA without undue delay and once relevant validity and confidentiality assessments have been completed by the originator in accordance with applicable rules.		
Article 8(5)			

161	5. The ECHA shall ensure that the data contained in the repository of reference values is machine readable.		
Article 9			
162	Article 9 Database of Study Notifications		
Article 9(1)			
163	1. The ECHA shall establish and operate a Database of Study Notifications by [OP please insert date: two years after the date of entry into force of this Regulation].		
Article 9(2)			
164	2. The ECHA shall store in the Database of Study Notifications the data notified to it in accordance with Article 22.		
Article 9(3)			
165	3. The ECHA shall integrate the data contained in the Database of Study Notifications in the common data platform once a corresponding registration, application, notification or other relevant regulatory dossier was submitted to the relevant Union or national institution, agency, or body in accordance with corresponding Union law and after a decision was taken by that Union or national institution, agency, or body on the disclosure of the accompanying studies in accordance with the applicable rules on confidentiality.	One delegation considers that this deserves clarification as it seems to prevent Member States authorities from getting relevant information on notified studies in time. PRES notes that this might be related to enforcement. → PRES seeks further written comments on this → PRES is working on an amendment proposal	For PPP, it is already the case that only limited data are provided to MS to check NOS. Unfortunately, this affects the benefits of NOS check.
Article 9(4)			
166	4. The EFSA shall make the data contained in the database referred to in Article 32b of Regulation (EC) No 178/2002 available to the ECHA for integration in the common data platform once it has received a corresponding application and after it has decided on the disclosure of the accompanying studies in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002.		

Article 9(5)			
167	5. The ECHA and the EFSA shall cooperate to ensure a common approach for the identification of information notified to them in		

	accordance with Article 22 of this Regulation and Article 32b of Regulation (EC) No 178/2002, respectively and facilitate the traceability of the studies notified to their respective databases.		
Article 10			
168	Article 10 Information on regulatory processes on chemicals	→ PRES is seeking written comments on one delegation's question about already existing communication channels in certain regulations, related to the stage of evaluation, and the potential need to modify those regulations. → PRES highlights that this might be the case for TRIS notifications.	
Article 10(1)			
169	1. The ECHA shall establish and manage, as part of the common data platform, a new database containing information on regulatory processes on individual substances or groups of substances that are planned, ongoing or have been completed since the entry into force of this Regulation by the Member States or the Union institutions, agencies or committees referred to in the Union acts listed in Annex III.	→ PRES is seeking for written comments on one delegation's comment that it is not clear whether the scope of art 10(1) includes national regulations processes.	
Article 10(2)			
170	2. Where Member State competent authorities as referred to in any of the Union acts listed in Annex III hold the information referred to in paragraph 1, they shall make that information available to the Union agency responsible under the respective Union act listed in Annex III without undue delay.	→ PRES is seeking for written comments on one delegation's request to clarify the COM reference (during the 1 st WP) to voluntary notifications, including examples.	
Article 10(3)			

171	3. Where the ECHA, EEA, EFSA, EU-OSHA or the Commission hold the information referred to in paragraph 1, they shall make that information available to the ECHA for integration in the common data platform in the standard formats provided for in Article 14 without undue delay and, where relevant, once the responsible agency or the Commission has performed the validity assessment. For each regulatory process or activity, at least the following information shall be included:	→ PRES is seeking written comments on one delegation's question about which information EEA might have to make available to ECHA in this context, as EEA has no competences about chemical products.	
Article			

10(3), point (a)			
172	(a) substance identity;		
Article 10(3), point (b)			
173	(b) the Union act and the regulatory process under which the activity takes place;		
Article 10(3), point (c)			
174	(c) submitter or actor responsible for the regulatory process or activity;		
Article 10(3), point (d)			
175	(d) status of the regulatory process or activity;		
Article 10(3), point (e)			

176	(e) where applicable , outcome of the regulatory process or activity ~~, including, where applicable, and~~ reports or opinions adopted;	☐ PRES understand from one delegation's comment that it is not always possible to indicate the (future) outcome, so this provision is not always applicable. → PRES propose to amend art 10(3) by inserting "where applicable" as we see it more precise than "where appropriate"	
Article 10(3), point (f)			
177	(f) where applicable, date of intention to start the regulatory process or activity, completion and latest update.		
Article 10(4)			
178	4. The information referred to in paragraph 3, points (a) to (f), on a specific regulatory process or activity shall be made available to the public once that process or activity has formally started.		
Article 11			
179	Article 11	☐ PRES notes one delegation's comment on the potentiality of	

	Information on the obligations under Union acts on chemicals	IA in this context.	
Article 11(1)			
180	1. The ECHA shall establish and manage, as part of the common data platform, a database with information on the provisions and legal obligations applicable to chemicals under the Union acts listed in Annex I.		
Article 11(2)			
181	2. The ECHA shall update the information in the database on a regular basis and in accordance with the governance scheme referred to in Article 4(3).		
Article 12			

182	Article 12 Repository of standards formats and controlled vocabularies		
Article 12(1)			
183	1. The ECHA shall establish and manage as part of the common data platform a repository of standard formats and controlled vocabularies.		
Article 12(2)			
184	2. Where standard data formats are established under the Union acts listed in Annexes I and II, the ECHA shall include them in the common data platform.		
Article 12(3)			
185	3. Where the Commission or the Agencies specify a standard format or controlled vocabulary in accordance with Articles 14 or 15, the Commission or the Agency shall make it available to the ECHA without undue delay for integration in the common data platform.		
Article 13			
186	Article 13 Database on environmental sustainability related data	One delegation requested for a new annex on relevant legal acts, see discussion of Article 2(11) → PRES: see line 82 here above □ About the role of EIONET in this	Having a look to the EIONET webpage, it is the aim of EEA Strategy 2021-2030 to reach the targets on environment and sustainability.

		→ PRES included this in the discussion at the WP2 (effort needed by MS)	
Article 13(1)			
187	1. At the latest within three years after the publication of the decision referred to in paragraph 4, the ECHA shall establish and manage, as part of the common data platform, a database containing environmental sustainability related data.		

Article 13(2)			
188	2. Where the Commission or the Agencies host or hold environmental sustainability related data in addition to the chemicals data already available in the common data platform, they shall make that data available to the ECHA without undue delay once the Commission or the Agency hosting or holding that data has completed, where relevant, validity and confidentiality assessments. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of environmental sustainability related data in the database on environmental sustainability related data.		
Article 13(3)			
189	3. Where researchers or research consortia funded by Union framework programmes make available to the ECHA, under Article 5(6), any environmental sustainability data on chemicals or materials they collect or generate, the ECHA shall integrate the relevant data in the database on environmental sustainability related data.		
Article 13(4)			
190	4. By [OP please insert date: three years after the date of entry into force of this Regulation], the Commission shall adopt an implementing decision identifying existing datasets on environmental sustainability related data, other than those referred to in paragraph 2, for inclusion in the common data platform and shall design relevant related database functionalities.	→ PRES is seeking legal advice about the wording “implementing decision” (cfr delegation comment). Council legal services provided an opinion on this at the 2 nd WP.	
Chapter III			

191	Chapter III DATA FORMATS AND CONTROLLED VOCABULARIES	→ PRES seeks written comments on one delegation's request to eventually have study reports and raw data provided → PRES seek written comments on the request by one delegation to investigate that there is no impact on the use of INCI names for cosmetics regulation, and no impact on substance identification and product labelling in that regulation.	Sanitized reports as background information sounds good, Raw data are not necessarily needed and when only on request. It should be stated (as minimum in the recitals) that the knowledge and input of end users such as MS agencies and other stakeholders should be consulted in the process of developing data formats and controlled vocabularies.
Article 14			
192	Article 14 Standard formats	One delegation amendment proposal on statistical risk: → PRES: see here Article 2(6) line 77	
Article 14(1)			
193	1. Without prejudice to Union provisions providing for the development or making available of data formats, the Commission and the Agencies shall specify, where relevant, for the data referred to in Article 3 (2) and falling within their mandate, standard formats and software packages and make them available free of charge through the common data platform.		
Article 14(2)			
194	2. The standard formats referred to in paragraph 1 shall, to the extent possible:		
Article 14(2), point (a)			

195	(a) avoid the use of proprietary standards;		
Article 14(2), point (b)			
196	(b) re-use existing data formats or parts of them;		
Article 14(2), point (c)			
197	(c) use OECD or other internationally agreed formats;		
Article 14(2), point (d)			

198	(d) be coherent with other existing data formats;		
Article 14(2), point (e)			
199	(e) ensure interoperability with existing data submission approaches.		
Article 14(3)			
200	3. Those standard formats shall be interoperable with the common data platform and be user-friendly.		
Article 14(4)			
201	4. The Commission and the Agencies shall exchange data contained in the common data platform in the relevant standard format.		
Article 14(5)			
202	5. The Commission and the Agencies shall use the International Uniform Chemical Information Database format (IUCLID) for making available to the ECHA for integration in the common data platform the relevant parts of dossiers under the following Union acts:		Why are Regulation (EC) No 1272/2008, Regulation (EC) No 1107/2009, Regulation (EC) No 396/2005, and

			Regulation (EU) No 528/2012 not mentioned?
Article 14(5), point (a)			
203	(a) Regulation (EC) No 1831/2003 of the European Parliament and of the Council ⁵³ ; ⁵³ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268 18.20.2003, p. 29).		
Article 14(5), point (b)			
204	(b) Regulation (EC) No 1935/2004 of the European Parliament and of the Council ⁵⁴ ; ⁵⁴ Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and		

	89/109/EEC (OJ L 338 13.11.2004, p. 4).		
Article 14(5), point (c)			
205	(c) Regulation (EC) No 1331/2008 of the European Parliament and of the Council ⁵⁵ ; ⁵⁵ Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354 31.12.2008. p. 1).		

Article 14(5), point (d)			
206	(d) Regulation (EC) No 1332/2008 of the European Parliament and of the Council ⁵⁶ ; ⁵⁶ Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354 31.12.2008, p. 7).		
Article 14(5), point (e)			
207	(e) Regulation (EC) No 1333/2008 of the European Parliament and of the Council ⁵⁷ ; ⁵⁷ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354 31.12.2008, p. 16).		
Article 14(5), point (f)			
208	(f) Regulation (EC) No 1334/2008 of the European Parliament and of the Council ⁵⁸ ; ⁵⁸ Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food		
	ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354 31.12.2008, p. 34).		
Article 14(5), point (g)			

209	(g) Regulation (EC) No 1223/2009 of the European Parliament and of the Council 59; ⁵⁹ Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342 22.12.2009. p, 59).		
Article 14(5), point (h)			
210	(h) Commission Regulation (EU) No 234/2011⁶⁰; ⁶⁰ Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 064 11.3.2011, p. 15).		
Article 14(5), point (i)			
211	(i) Directive 2009/48/EC of the European Parliament and of the Council.⁶¹ ⁶¹ Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170 30.6.2009, p. 1).		
Article 14(6)			
212	6. The Commission and the Agencies shall cooperate when setting standard formats to ensure coherence with other formats and the interoperability of the standard formats with the common data platform and with existing data submission approaches.		
Article 14(7)			

213	7. The Commission and the Agencies shall take the necessary and appropriate measures to monitor and identify at an early stage any potential divergence between data formats that could cause interoperability problems. If a divergence is identified, the Agencies concerned shall cooperate to resolve it or, where the divergence is justified, explain the underlying reasons. Where the Agencies concerned are not able to resolve that divergence, they shall draw up a joint report and present it to the Commission. The report shall clearly outline the reasons for the divergence, clarify any underlying technical issue and make a proposal to remedy the divergence.		
Article 14(8)			
214	8. The Commission shall adopt an implementing decision to remedy the divergence.		
Article 15			
215	Article 15 Controlled vocabularies	→ PRES is seeking written comments on the remarks by one delegation about the difficulties related to differences in vocabularies between legislations. → PRES seeks for comments on the difficulties related to substances identification inconsistencies between regulations (see delegation comment). PRES highlights that this problem is also relevant for art.22,25,26 on studies notification (a lack of correct identification might render difficult to implement them)	Different substance names make it difficult to find identical substances in different legislation and thus to find out whether an assessment has taken place.- Controlled vocabularies and especially how substances are identified are essential. The problem of unambiguously and uniquely describing a substance across regulations still appears unresolved, as Art. 15 allows the Commission and EU agencies to specify and update the controlled vocabulary within the

			scope of their mandate, even if they are supposed to coordinate this. An establishment of a universal substance ID should be reconsidered.
Article 15(1)			
216	1. The Commission and the Agencies shall specify and regularly update controlled vocabularies within their mandate for the data referred to in Article 3(2), where relevant.		
Article 15(2)			
217	2. The Commission and the Agencies shall prioritise specifying controlled vocabularies for the identification of chemicals and the characterisation of their forms.		

Article 15(3)			
218	3. Those controlled vocabularies shall:		
Article 15(3), point (a)			
219	(a) avoid the use of proprietary controlled vocabularies to the extent possible;		
Article 15(3), point (b)			
220	(b) re-use existing substance identifiers and controlled vocabularies or parts of them to the extent possible;		

Article 15(3), point (c)			
221	(c) use OECD or other internationally agreed controlled vocabularies to the extent possible;		
Article 15(3), point (d)			
222	(d) ensure coherence with other relevant controlled vocabularies including by preparing alignment tables.		
Article 15(4)			
223	4. Those controlled vocabularies shall be interoperable with the common data platform.		
Article 15(5)			
224	5. Where controlled vocabularies are specified, the Commission and the Agencies shall:		
Article 15(5), point (a)			
225	(a) make them available free of charge through the common data		

	platform and as open datasets;		
Article 15(5), point (b)			
226	(b) integrate them in any submission software or template to be used by duty holders under the Union acts listed in Annex I and referred to in Article 3(2); and		

Article 15(5), point (c)			
227	(c) use them when exchanging data between them through the common data platform.		
Article 15(6)			
228	6. The Commission and the Agencies shall cooperate with each other in setting the controlled vocabularies.		
Article 15(7)			
229	7. The Commission and the Agencies shall take the necessary and appropriate measures to monitor and identify at an early stage any potential divergence between controlled vocabularies. If a divergence is identified, the Agencies concerned shall cooperate to resolve it or, where the divergence is justified, explain the underlying reasons. Where the Agencies concerned are not able to resolve that divergence, they shall draw up a joint report and present it to the Commission. The report shall clearly outline the reasons for the divergence, clarify any underlying technical issue and make a proposal to remedy the divergence.		
Article 15(8)			
230	8. The Commission shall adopt an implementing decision to remedy the divergence.		
Chapter IV			
231	Chapter IV	→ PRES: some delegation's comments here were discussed at the	

	CHEMICALS DATA CONFIDENTIALITY AND USE	WP2.	
Article 16			

232	Article 16 Access rights and transparency	→ PRES: One delegation request and questions (line 232 of the comments file) were discussed at the WP2.	
Article 16(1)			
233	1. The Authorities shall have access to all the chemicals data contained in the common data platform, including data which is deemed to be confidential under Article 5(2), second sentence.		
Article 16(2)			
234	2. The Authorities shall take the necessary measures to ensure that information contained in the common data platform marked as confidential in accordance with Article 5(2) is not made public.	→ PRES: One delegation comment and questions were discussed at the WP2 (line 234 of the comments file)	Only sanitized versions of studies but results from assessments of the agencies are normally already published and thus data from these publication can be made available to the public.
Article 16(3)			
235	3. The general public shall have access to all the chemicals data contained in the common data platform and considered as available to the public in accordance with the Union act under which the data was generated or submitted.		
Article 17			
236	Article 17 Use of chemicals data contained in the common data platform	One delegation comment on the meaning of “products” is addressed here in art.2 (see line 70). PRES: Regarding the other comments: → PRES seeks written comments on one delegation’s concern on the identification in the data platform of cosmetics ingredients that may have been tested on animals. → PRES invites the COM to update MS on the possibility of an overview table on confidentiality provisions requested by one delegation.	
Article 17(1)			

237	1. The Authorities may use the chemicals data contained in the common data platform in the performance of any of their activities, where those activities support the development or implementation of	→ PRES: one delegation requested for amendment to explicitly allow national use of the data was set for discussion at WP2.	
	chemicals legislation and policy.		
Article 17(2)			
238	2. Without prejudice to existing provisions enabling the sharing and use of chemicals data under the Union acts listed in Annexes I and II, Authorities shall not use chemicals data contained in the common data platform to fulfil any legal obligations of duty holders.	One delegation requested clarifications on the use of data in relation to duty holders obligations. → PRES invites for written comments on this.	From COM's explanation we understand that it is possible for the Agencies to check the data provided by the duty holders in fulfilling their obligations against the data which is included in the CDPC. If the data included in the CDPC gives reason to doubt the integrity and plausibility of the data provided by the duty holder, the Agencies could in our understanding request further clarifications from the duty holder.
Article 17(3)			
239	3. When using chemicals data contained in the common data platform that is deemed confidential under Article 5(2), second sentence, the Authorities shall respect the confidentiality of information data as marked by the originator and shall not disclose that data to the public without the consent of the originator.		See comment above to Article 16 para 2 and 3. In every reference to Article 5 (2) Sentence 2, the wording should be aligned. Drafting suggestion: "3. When using chemicals data contained in the common data platform

			that is <u>marked as confidential in accordance with</u> Article 5(2), second sentence, the Authorities shall respect the confidentiality of information data as marked by the originator and shall not disclose that data to the public without the consent of the originator.”
Chapter V			
240	Chapter V MONITORING AND OUTLOOK FRAMEWORK FOR CHEMICALS		
Article 18			
241	Article 18 Framework of indicators	One delegation questioning the MS involvement was set for discussion at the 2nd WP → PRES put the question on EIONET impacts for discussion at the 2nd WP. One delegation comments on cosmetics: → PRES invites for written comments on questions raised by one delegation on cosmetics aspects (notification of undesirable effects, link to the Communication System for Market Surveillance (ICSMS) Art 23 Reg 1223/2009, consequences on the allowance of use for critical circumstances). One delegation comment on the relation to existing statistics systems → PRES invites for written comments	
Article 18(1)			

242	1. The EEA, in collaboration with the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission, shall establish, operate, and maintain a framework of indicators to monitor the drivers and impacts of exposure to chemicals, measure the effectiveness of chemicals legislation and measure the transition towards the production of safe and sustainable chemicals.		We see the need to formally include the need for consulting the Member States before establishing the framework of indicators in the legal text. Drafting suggestion: "1. The EEA, in collaboration with the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission, shall after consulting the Member States establish, operate, and maintain a framework of indicators to monitor the drivers and impacts of exposure to chemicals, measure the effectiveness of chemicals legislation and measure the transition towards the production of safe and sustainable chemicals."
Article 18(2)			
243	2. The framework of indicators referred to in paragraph 1 shall be accessible in the form of an indicator dashboard, which the EEA shall establish and which the ECHA shall make available through the common data platform.		
Article 18(3)			

243.b	3. The framework of indicators referred to in paragraph 1 shall be established, operated, and maintained by [OP: please insert date: 3 years after the end of the first calendar year after entry into force of this Regulation].	One delegation expressed concerns on the timescale for establishing the framework PRES highlights that several other articles contain indications on the timeframe → PRES submits this amendment for consideration, and discussion took place at the 2nd WP.	
Article 19			
244	Article 19 Early warning and action system for emerging chemical risks	→ PRES: One delegation's question on MS experts and RAC involvement was set for discussion at 2nd WP → PRES: One delegation's request for clarification on implications/role of EIONET and MS was set for discussion at the 2nd WP □ Regarding the other comments: → PRES seeks written comments about one delegation's question on the relation between the indicators and the early warning system (art.18,19). → PRES invites for written comments on the question regarding the level of ambition of the system in relation to complex systemic risks.	

		→ PRES invites written comment on the proposal to include the word "prevention" in the proposal	
Article 19(1)			
245	1. The EEA shall establish, operate and maintain a Union early warning system for emerging chemical risks by [OP please insert date: one year after the date of entry into force of this Regulation].		
Article 19(2)			

246	2. For the purpose of paragraph 1, the EEA shall compile early warning signals, which shall include at least signals from:		Would it not be beneficial to also consider non-target screening information on substances in the early warning and action system?
Article 19(2), point (a)			
247	(a) the EFSA's emerging risks exchange network;		
Article 19(2), point (b)			
248	(b) existing national early warning systems;		
Article 19(2), point (c)			
249	(c) data that the EEA holds;		
Article 19(2), point (d)			
250	(d) targeted literature searches performed by the EEA;		
Article 19(2), point (e)			
251	(e) data made available by the ECHA, the EFSA, the EU-OSHA and the EMA in accordance with paragraph 3.		
Article 19(2)			
252	The early warning signals compiled by the EEA under the first		

	subparagraph may be based on a positive identification of an emerging risk or on an uncertainty in the data leading to a potential positive identification of an emerging risk.		
Article 19(3)			
253	3. The ECHA, the EFSA, the EU-OSHA and the EMA shall identify and gather relevant available data on early warning signals from the field falling within their mandate and provide this data to the EEA.		
Article 19(4)			
254	4. The EEA shall draw up an annual report, compiling and analysing the data on early warning signals gathered in accordance with paragraphs 2 and 3. [The first report shall be prepared by [OP: please insert date: 6 months after the end of the first calendar year after entry into force of this Regulation]. The EEA shall present this report to the Commission, relevant Union agencies and ~~Member State competent authorities for consideration of the need~~ Member State competent authorities who shall consider the need for regulatory or policy action related to the early warning signals.	One delegation expressed questions the request to EEA to highlight areas on which to FOCUS, in the report. PRES suppose that this may be solved by a change in the wording (mostly editorial) → PRES proposes for consideration a proposed amendment to the text.	The analysis should be done in close cooperation with ECHA, EFSA, EU-OSHA and EMA as these authorities are in a better position to assess this.
Article 19(5)			
255	5. The EEA shall make all relevant data on early warning signals that it holds or hosts as well as the report referred to in paragraph 4 available to the ECHA for integration in the common data platform.		
Article 20			
256	Article 20 Observatory for specific chemicals with potential contribution to emerging chemical risks	PRES seeks written comments on one delegation's question about the type of risks covered here, and the interplay with existing chemicals legislation.	
Article 20(1)			

257	1. The ECHA shall establish, operate and maintain an observatory for specific chemicals that the Commission considers as requiring additional scrutiny. The observatory shall include reliable information on the chemicals' properties, safety aspects, uses and market presence.		
Article			

20(2)			
258	2. By [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall adopt and publish a list of the selected chemicals by means of an implementing decision. The Commission shall review the list of selected chemicals regularly and adopt any revision thereof by the same means.	One delegation highlighted that the linking word "and" is missing before the proposal "adopt any revision thereof by the same means". à PRES sees this as an editorial amendment and proposes to modify article 20(2) consequently (see <i>bold italic</i>). One delegation requested for amendments (implementing "decisions"). → PRES: questions on the meaning of "implementing", and MS participation were discussed at the 2nd WP.	
Article 20(3)			
259	3. The Commission shall select the chemicals referred to in paragraph 1 based on the scientific and technical progress and using the signals of the early warning system referred to in Article 19. The selection shall include potential contributors to new and emerging chemical risks among innovative rationally designed materials with new or enhanced properties or targeted or enhanced structural features at nanoscale.		
Article 20(4)			
260	4. For the purpose of operating the observatory referred to in paragraph 1, the ECHA shall:		
Article 20(4), point (a)			

261	(a) make use of relevant datasets integrated in the common data platform, and compile, analyse and curate further available data on selected chemicals or classes of chemicals;		
Article 20(4), point (b)			
262	(b) commission studies and, where relevant, use the data generation mechanism established under Article 21 to address knowledge gaps or significant uncertainties;		
Article			

20(4), point (c)			
263	(c) make compiled data publicly available through the common data platform or other communication and outreach tools as appropriate, to facilitate informed societal discussion and increase public awareness on the properties, use and safety aspects of specific chemicals, and regularly update that information.		
Chapter VI			
264	Chapter VI DATA GENERATION MECHANISM		
Article 21			

265	Article 21 Data generation mechanism	One delegation raised the question of the promotion of animal testing in relation to article 1. PRES understands that the type of tests are prescribed in each regulation mentioned in annex I, and thus this regulation is not modifying that. However, art.21 here is new, and thus the question of the minimization of animal testing might be relevant here. One delegation would like to know if commissioned animal studies will be notified → PRES requests written reactions and proposals on this matter. One delegation expressed the need to frame the mandate in such a way that the burden of proof on companies is preserved. One delegation insisted also on the burden of proof on industry and highlights the need for clarity on procedures and financing. → PRES invites for written comments and amendments proposals. Some Comments were received in relation to the involvement of MS, industry, stakeholders in the data generation mechanism. → PRES: discussion during the 2nd WP	The burden of proof should be always with those who want to put chemicals on the European market. This would be preferred to avoid duplication of work
Article 21(1)			
266	1. Using the best independent resources available, the ECHA may commission scientific studies to support the implementation of Union acts on chemicals listed in Annex I within its mandate and to contribute	One delegation requested clarity on the meaning of scientific studies, and which ones will not be covered. → PRES invites for written comments on this	This might be an exceptional case where no stakeholder is known for putting the chemical on the market especially in case of naturally occurring substances.
	to the support, evaluation or development of a Union chemicals policy.		
Article 21(2)			
267	2. The Commission may request the ECHA to commission the scientific studies referred to in paragraph 1.		

Article 21(3)			
268	3. The ECHA shall only commission scientific studies when results cannot be obtained through existing legal provisions or processes under Union legislation listed in Annex I. It shall not commission studies with a predominant research objective.		
Article 21(4)			
269	4. The ECHA shall seek to avoid duplication with Member State or Union research or implementation programmes.		
Article 21(5)			
270	5. The ECHA shall commission these scientific studies in an open and transparent manner.	One delegation suggested to amend this to introduce compulsory prior MS consultation. → PRES scheduled this for discussion at the 2 nd WP	
Article 21(6)			
271	6. The ECHA and the EFSA shall closely cooperate with each other on the planning and commissioning of scientific studies undertaken by the ECHA in accordance with paragraph 1 and of studies undertaken by the EFSA in accordance with Article 32 of Regulation (EC) No 178/2002.		
Article 21(7)			
272	7. The ECHA shall make the results of the scientific studies performed under this Article available through the common data platform.		
Chapter VII			
273	Chapter VII NOTIFICATION OF STUDIES	Several comments were received on this chapter: on the legal scope and definition of studies to be notified, duplications, studies conducted outside the EU, late notifications, absence of a transitional period, practical arrangements for companies, the need	The discussion in the WP is highly welcomed.

		for early access before publication in the data platform. → PRES scheduled this for discussion at the 2 nd WP	
Article 22			
274	Article 22 Notification of studies		
Article 22(1)			
275	1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, without undue delay, any studies on chemicals they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment, prior to placing on the market, under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.		As already put forward by a MS, it is necessary that laboratories and testing facilities are informed about the fact that a study commissioned by a business operator falls under the notification obligation under Article 22 (3). Therefore, it is necessary to include a duty of the business operator to inform the laboratory about the regulatory purposes of the study. Drafting suggestion for a new third sentence to para 1: "Business operators shall inform the laboratory or testing facility in which the study is carried out without undue delay about the fact that the study falls under the notification obligation of para 3."
Article 22(2)			

276	2. For the purposes of paragraph 1, business operators shall notify to the Database of Study Notifications referred to in Article 9 the title, scope, laboratory, or testing facility carrying out the study, the intended starting and planned completion dates and, where relevant, whether the study is commissioned to comply with a decision of the ECHA pursuant to Articles 40, 41 or 46 of Regulation (EC) No 1907/2006.		
Article 22(3)			
277	3. Laboratories and testing facilities shall also, without undue delay, notify any study commissioned by business operators to support a regulatory dossier on which an Agency is required to provide a scientific output, including a scientific opinion, under the Union acts listed in Annex I. However, laboratories and testing facilities shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.		It seems unclear why the wording with respect to the purpose of the studies differs from the wording in para 1. Para 3 only covers “regulatory dossiers”. In what way is the scope of the notification obligation for laboratories and testing facilities intended to be different from the obligation for business operators?
Article 22(4)			

278	4. For the purposes of paragraph 3, laboratories and testing facilities shall notify to the Database of Study Notifications referred to in Article 9 the title, scope, intended starting and planned completion dates of any test they carry out, as well as the name of the business operator who commissioned the test.		
Article 22(5)			

279	5. Paragraphs 3 and 4 shall apply, mutatis mutandis, to laboratories and testing facilities located in third countries insofar as set out in relevant agreements with those third countries.		
Article 22(6)			
280	6. The obligations set under this article shall apply from [OP please insert date: 24 months after the date of entry into force of this Regulation].		
Article 22(7)			
281	7. The ECHA shall lay down the practical arrangements for implementing the provisions of this Article.		
Chapter VIII			
282	Chapter VIII DELEGATED POWERS		
Article 23			
283	Article 23 Amendment of Annexes I, II and III		
Article 23(1)			
284	1. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex I in order to adjust the content of that Annex to technical and scientific progress in the field of chemicals or, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it new Union acts under which relevant chemicals data is generated or submitted.		
Article			
23(2)			

285	2. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex II by adding, where relevant, new categories of data types.		
Article 23(3)			
286	3. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex III in order to adjust the content of that Annex to technical and scientific and technical progress in the field of chemicals and, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it Union acts relevant for data on new regulatory processes on chemicals.		
Article 24			
287	Article 24 Exercise of the delegation		
Article 24 (1)			
288	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.		
Article 24(2)			
289	2. The power to adopt delegated acts referred to in Article 23 shall be conferred on the Commission for a period of five years from [OP please insert: the date of the entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each five-year period.		
Article 24(3)			

290	3. The delegation of power referred to in Article 23 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that		
	decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.		
Article 24(4)			
291	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.		
Article 24(5)			
292	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.		
Article 24(6)			
293	6. A delegated act adopted pursuant to Article 23 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.		
Chapter IX			

294	Chapter IX ENFORCEMENT AND PENALTIES	One delegation expressed concerns on enforcement for third countries; one delegation questioned the effectiveness of national sanctions. → PRES scheduled this for discussion at the 2 nd WP	—
Article 25			
295	Article 25 Enforcement		
	The Agencies shall cooperate with Member States' enforcement authorities and exchange information on the compliance, by business operators and laboratories, with the obligation to notify studies in accordance with Article 22.		
Article 26			
296	Article 26 Penalties for non-compliance		
Article 26(1)			
297	1. Member States shall introduce penalties for non-compliance, by business operators and laboratories, with the obligations laid out in Article 22 and shall take all necessary measures to ensure that they are implemented. The penalties provided for shall be effective, proportionate, and dissuasive.		
Article 26(2)			
298	2. Member States shall notify the Commission of those rules and of those measures by 30 June 2025 and shall notify to the Commission without delay any subsequent amendment affecting them.		
Article 27			

299	Article 27 Entry into force and application in time This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.		
Formula			
300	This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels, For the European Parliament For the Council The President The President		

	Presidency proposals: amendments (~~deletions~~ / additions)	Presidency proposals: follow-up or proposal to work on amendments, or requests for written comments	Reactions from the Commission and MS
Annex I			

301	Annex I UNION ACTS REFERRED TO IN ARTICLES 2, 3, 8, 11, 12, 15, 17, 21, 22 AND 23 Reference to each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.		
302	1. Council Directive 91/271/EEC of 21 May 1991 concerning urban wastewater treatment (OJ L 135, 30.5.1991, p. 40)		
303	2. Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources (OJ L 375,		

	31.12.1991, p.1)		
304	3. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1)		
305	4. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste		

306	5. Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11)		
307	6. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50)		
308	7. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34)		
309	8. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for the Community action in the field of water policy (OJ L 327, 22.12.2000, p.1)		
310	9. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate		
	release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1)		

311	10. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p. 1)		
312	11. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10)		
313	12. Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51)		
314	13. Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1)		
315	14. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29)		
316	15. Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (OJ L 309, 26.11.2003, p. 1)		

317	16. Regulation (EC) No 853/2004 of the European		
	Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55)		
318	17. Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1)		
319	18. Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1)		
320	19. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)		
321	20. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3)		

322	21. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 070, 16.3.2005, p. 1)		
323	22. Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant		
	Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC (OJ L 033, 4.2.2006, p. 1)		
324	23. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19)		

325	24. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)		
326	25. Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9)		
327	26. Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26)		
328	27. Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an		
	Infrastructure for Spatial Information in the European Community (INSPIRE) (OJ L 108, 25.4.2007, p. 1)		

329	~~28. Regulation (EC) No 108/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 39, 13.2.2008, p. 11)~~	One delegation highlighted the fact that regulation 108/2008 is mentioned in point 28 of Annex I, whereas this regulation is already covered by regulation 1925/2006 mentioned in point 26 of Annex I. →PRES proposes to amend the text (deleting point 28).	Supported, this Regulation is an amendment of Regulation (EC) No. 1925/2006 in incorporated in the consolidated version
330	29. Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19)		
331	30. Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1)		
332	31. Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3)		
333	32. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive		

	2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84)		
334	33. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)		
335	34. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)		
336	35. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC, and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p.7)		
337	36. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16)		

338	37. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91,		
	Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34)		
339	38. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energyrelated products		
340	39. Regulation (EC) No 401/2009 of the European Parliament and of the Council of 23 April 2009 on the European Environment Agency and the European Environment Information and Observation Network (OJ L 126, 21.5.2009, p. 13)		
341	40. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3)		

342	41. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1)		
343	42. Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal byproducts and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (OJ L 300, 14.11.2009, p. 1)		
344	43. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009		

	concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)		
345	44. Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71)		

346	45. Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28)		
347	46. Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community ecomanagement and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC (OJ L 342, 22.12.2009, p. 1)		
348	47. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)		
349	48. Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17)		
350	49. Regulation (EC) No 66/210 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel (OJ L 027, 30.1.2010, p. 1)		

351	50. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)		
352	51. Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18)		
353	52. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)		
354	53. Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.7.2012, p. 1)		
355	54. Directive 2012/19/EU of the European Parliament		

	and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38)		
356	55. Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the import and export of hazardous chemicals (OJ L 201, 27.7.2012, p. 60)		
357	56. Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35)		
358	57. Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (OJ L 96, 29.3.2014, p. 1)		

359	58. Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1)		
360	59. Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006 (OJ L 150, 20.5.2014, p. 195)		
361	60. Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1)		
362	61. Directive (EU) 2016/2284 of the European Parliament and of the Council of 14 December 2016 on the reduction of national emissions of certain atmospheric pollutants, amending Directive 2003/35/EC and repealing Directive 2001/81/EC (OJ L 344, 17.12.2016, p. 1)		

363	62. Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council		
	Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 095, 7.4.2017, p. 1)		
364	63. Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1)		

365	64. Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008 (OJ L 137, 24.5.2017, p. 1)		
366	65. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).		
367	66. Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing		
	Regulation (EC) No 2003/2003 (OJ L 170, 25.6.2019, p. 1)		
368	67. Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45)		

369	68. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435, 23.12.2020, p. 1)		
370	69. Regulation (EU) .../... of the European Parliament and of the Council on nature restoration (OJ .../ELI: ... [OP: please add number and publication reference].		
371	70. Regulation (EU) .../... of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (OJ .../ELI: ... [OP: please add number and publication reference]		
ANNEX II			
372	ANNEX II UNION ACTS REFERRED TO IN ARTICLES 2, 3, 12, 17 AND 23 AND REFERENCE VALUES REFERRED TO IN ARTICLE 8		
Part 1			
373	Part 1 - Specific data on relevant active substances to be identified in accordance with Article 4(5)(b) falling under the scope of this Regulation for the purposes of		
	Article 3 for human and veterinary medicinal products		



374	1. Non-clinical safety data, including data related to environmental risk assessments, compiled pursuant to Directive 2001/83/EC of the European Parliament and of the Council¹ and Regulation (EC) No 726/2004 of the European Parliament and of the Council²; ¹ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67). ² Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).		
375	2. Data related to environmental risk assessments, compiled pursuant to Regulation (EU) 2019/6 of the European Parliament and of the Council³; and ³ Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).		
376	3. Maximum residue levels data compiled pursuant to Regulation (EC) No 470/2009 of		

	the European Parliament and of the Council⁴. ⁴ Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).		
377	These data shall be limited to data submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation. Where relevant, the data held by the EMA resulting from procedures concluded before the entry into force of this Regulation may also be considered for inclusion into the common data platform.		

Part 2			
378	Part 2 - Reference values to be included in the repository of reference values following Article 8(3)		
379	1. Predicted no effect concentrations derived as part of the environmental risk assessment under Directive 2001/83/EC of the European Parliament and of the Council, Regulation (EC) No 726/2004 of the European Parliament and of the Council and Regulation (EU) 2019/6 of the European Parliament and of the Council.		
380	These data shall be limited to data submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation. Where relevant, data held by the EMA resulting from procedures concluded before the date of entry into force of this Regulation shall also be considered for inclusion into the common data platform.		
Annex III			
381	Annex III UNION ACTS REFERRED TO IN ARTICLES 2, 10 AND 23		

382	Reference to each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.		
383	1. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1)		
384	2. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste		
385	3. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50)		
386	4. Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11)		
387	5. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34)		

388	6. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p. 1)		
389	7. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10)		
390	8. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29)		
391	9. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)		
392	10. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3)		

393	11. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1)		
394	12. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19)		
395	13. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)		
396	14. Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38)		

397	15. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84)		
398	16. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)		
399	17. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)		
380	18. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC, and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008,		

	p.7)		
381	19. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16)		
382	20. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34)		
383	~~21. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)~~	Some delegations highlighted the fact that Regulation 1331/2008 is mentioned twice: in points 17 and 21 of Annex III. → PRES proposes to amend the text (deleting this repetition).	
384	22. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3)		

385	23. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energyrelated products		
386	24. Directive 2009/48/EC of the European Parliament		

	and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1)		
387	25. Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer (OJ L 286, 31.10.2009, p. 1)		
388	26. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)		
389	27. Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28)		

390	28. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)		
391	29. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)		
392	30. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)		
393	31. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).		
394	32. Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45)		
395	33. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435, 23.12.2020, p. 1)		

396	34. Regulation (EU) .../... of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (OJ .../ELI: ... [OP: please add number and publication reference].		



IRELAND

Responses to MS Comments on Proposed Amendments to the ROHS Directive (new comments in blue):

Summary:

During first consultation round comments from **ES, DE, DK, FR, HU, IE, NL, PT, SE, SI** were received. Some delegations highlighted the scrutiny reservation indicating that further comments can still be submitted at the later stage.

In general, all delegations welcomed the proposal of the Commission to amend the ROHS Directive. It is believed that the proposed changes will improve and refine the process of restricting new substances, granting new exemptions, and therefore increase transparency and legal certainty.

Number of delegations (**HU, DE, IE, NL**) however expressed their concern regarding the increase of the workload of the ECHA's scientific committees (SEAC and RAC). In their comments delegations therefore recommended the Commission to ensure sufficient resources to ECHA. **HU** underlined *the importance to have a draft of ECHA basic regulation available as soon as possible, to have a sound basis for decisions on certain issues related to this legislative package* **IE**: *We would support HU's comment here*, while **IE** proposed not to put too much emphasis on the ECHA Committees, but rather to re-attribute this task to ECHA (and its already existing Expert Groups **IE**: *To clarify, not necessary existing expert groups but to allow ECHA to decide (if the needed it) to establish a ROHS expert group*). **IE** believes that the change proposed by them would not preclude the Executive Director from requesting the assistance of the ECHA Scientific Committees on a case by-case basis. Moreover, **NL** underlined that attributing ECHA new tasks under ROHS Directive will require additional in-house expertise in the evaluation of the life cycle of the substance in the refurbishment, waste and recycling stage, which is according to the Commission staff document currently not available. (**IE**: *This supports our point that the Committees will not have the capability to do these new additional tasks- there is already enough work under REACH for the RAC/SEAC*)

Some delegations appreciated the alignment of the ROHS directive with REACH Regulation (**SI, DE**), while others expressed some concerns related to that alignment (**SE, DK**).

PT is concerned about the confidentiality of the request of the companies regarding the substance requirements.

Additionally, in the view of **ES**, a clarity is needed on whether the proposal of the COM to amend the ROHS Directive requires transposition.

List of general questions to the COM:

SE: Would it be possible to amend the proposal so that exemptions will be adopted by delegated regulations instead of delegated directives? That would mean a harmonization within the EU when an exemption enters into force and would facilitate matters for actors concerned.

IE- *We see merit in this proposal from SE.*

NL: Could the Commission elaborate how ECHA will be equipped to enable sufficient knowledge on assessing the impact of a restriction on refurbishment, and the waste and recycling phase?

IE- Also how will the RAC and SEAC be equipped?

HU: We would like to ask for the opinion of the Council Legal Service as to whether it is justified to include in the proposal specific provisions on transposition by Member States into their national law, taking into account that, for example, our relevant national legislation refers to procedures such as applications for exemption.

Additional suggestions:

IE: We also recommend the OSOA legislation package amends **Article 85 & 87 of REACH** to provide for additional experts to cover the additional work and its associated remuneration. Some possible changes are suggested below:

*Each Member State may nominate candidates to membership of the Committee for Risk Assessment and or expert working groups established by ECHA. The Executive Director shall establish a list of the nominees, which shall be published on the Agency's website, without prejudice to Article 88(1). The Management Board shall appoint the members of the Committee from this list, including at least one member but not more than **three or four** ~~two~~ from the nominees of each Member State that has nominated candidates. Members shall be appointed **to the Committee or to an expert working group** for their role and experience in performing the tasks specified in Article 77(3) **(insert relevant Articles from other legislation that assigns ECHA tasks here)**.*

*Each Member State may nominate candidates to membership of the Committee for Socio-economic Analysis and or relevant expert working groups established by ECHA. The Executive Director shall establish a list of the nominees, which shall be published on the Agency's website, without prejudice to Article 88(1). The Management Board shall appoint the members of the Committee from this list, including at least one member but not more than **three or four** ~~two~~ from the nominees of each Member State that has nominated candidates. Members shall be appointed **to the Committee or to an expert working groups** for their role and experience in performing the tasks specified in Article 77(3) **(insert relevant Articles from other legislation that assigns ECHA tasks here)**.*

*The Committees shall aim to have a broad range of relevant expertise among their members. To this end each Committee may co-opt a maximum of **eight** ~~five~~ additional members chosen on the basis of their specific competence.*

Article 87

Rapporteurs of Committees and use of experts

1. Where, in accordance with Article 77 **(the other relevant articles under this regulation and the Regulation of CLP that assign a role to the Committee would need to be included)**, a Committee is required to provide an opinion or consider whether a Member State dossier conforms with the requirements of Annex XV **(CLH etc)** it shall appoint one of its members **or their advisor** as a rapporteur. The Committee concerned may appoint a ~~second~~ **additional** member(s) **or their advisors** to act as co-rapporteur. For each case, rapporteurs and corapporteurs shall undertake to act in the interests of the Community and shall make a declaration of commitment to fulfil their duties and a declaration of interests in writing. A member of a Committee **or their advisor(s)** shall not be appointed rapporteur for a particular case if he indicates any interest that might be prejudicial to the independent consideration of that case. The Committee concerned may replace the rapporteur or co-rapporteur by another one of its members at any time, if, for example, they are unable to fulfil their duties within the prescribed time limits, or if a potentially prejudicial interest comes to light.

2. Member States shall transmit to the Agency the names of experts with proven experience in the tasks required by Article 77 **(insert other relevant articles)**, who would be available to serve on **ECHA expert groups or** working groups of the Committees, together with an indication of their qualifications and specific areas of expertise.

The Agency shall keep an up-to-date list of experts. The list shall include the experts referred to in the first subparagraph and other experts identified directly by the Secretariat.

3. The provision of services by Committee members or any advisor or expert serving on an expert group or working group of the Committees or Forum, or performing any other task for the Agency shall be governed by a written contract between the Agency and the person concerned, or where appropriate between the Agency and the employer of the person concerned.

The person concerned, or his employer, shall be remunerated by the Agency in accordance with a scale of fees to be included in the financial arrangements established by the Management Board. Where the person concerned fails to fulfil his duties, the Executive Director has the right to terminate or suspend the contract or withhold remuneration.

4. The provision of services for which there are several potential providers may require a call for an expression of interest:

- (a) if the scientific and technical context allows; and
- (b) if it is compatible with the duties of the Agency, in particular the need to provide a high level of protection of human health and the environment.

The Management Board shall adopt the appropriate procedures on a proposal from the Executive Director.

5. The Agency may use the services of experts for the discharge of other specific tasks for which it is responsible. Experts or their employer, shall be remunerated by the Agency in accordance with a scale of fees to be included in the financial arrangements established by the ECHA Management Board. Where the person concerned fails to fulfil his duties, the Executive Director has the right to terminate or suspend the contract or withhold remuneration

IRELAND

14/3/2024

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

establishing a common **data platform** on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

(Text with EEA relevance)



	Presidency proposals: amendments (~~deletions~~ / additions)	Presidency justification after WP1: follow-up or proposal to work on amendments, or requests for written comments	Delegates comments/proposals after WP2
Proposal Title			
1	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals)		
Formula			
2	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN		
Citation 1			
3	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114(1) thereof,		
Citation 2			
4	Having regard to the proposal from the European Commission,		
Citation 3			
5	After transmission of the draft legislative act to the national parliaments,		
Citation 4			
6	Having regard to the opinion of the European Economic and Social Committee ¹		
Citation 5			
7	Acting in accordance with the ordinary legislative procedure,		
Formula			
8	Whereas:		

Recital 1			
9	(1) The European Green Deal ³⁴ sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability ³⁵ is a crucial delivery of this zero-		
	pollution ambition and introduces the 'one substance, one assessment' approach, which aims to improve the efficiency, effectiveness, coherence, and transparency of safety assessments of chemicals across Union legislation. According to that Strategy, 'safe and sustainable by design' criteria should be developed to enable the production and use of chemicals that are safe and sustainable throughout their entire lifecycle. The Strategy also sets out that the interaction between scientific developments and policy-making should be strengthened by means of an early warning system for chemicals to ensure that Union policies address emerging chemical risks as soon as these are identified by monitoring and research, and that a framework of indicators should be developed to monitor the drivers and impacts of chemical pollution and to measure the effectiveness of chemicals legislation. This Regulation aims to implement these objectives.		
Recital 2			

10	(2) The main objective of this Regulation is to increase the level of protection of the environment and human health from the risks arising from hazardous chemicals, as well as to facilitate the functioning of the internal market for chemicals. For that purpose, this Regulation should establish a common data platform data on chemicals ('the common data platform'), to be managed by the European Chemicals Agency ('ECHA'). The common data platform is a digital infrastructure that brings together chemicals data and information generated under the Union chemicals acquis. This Regulation should also establish dedicated services within the common data platform and lay down rules on the accessibility and usability of the data contained in that platform. This Regulation aims to create a common knowledge base on chemicals available to authorities to enable better, complete, coherent and robust scientific assessments of chemicals and their impacts and to ensure the best use of existing information for the purpose of the implementation and the development of Union legislation on chemicals. Moreover, the Regulation aims to provide a one-stop-shop on chemicals data and information in the Union accessible to the general public and, thus, to increase the predictability and the transparency of regulatory processes on chemicals, as well as to strengthen public trust in the robustness of scientific decision-making.		

Recital 3			
11	(3) Under Decision (EU) 2022/591 of the European Parliament and of the Council³⁶, harnessing the potential of digital and data technologies to support environmental policy, including by delivering real-time data where possible and information on the state of ecosystems, while increasing efforts to minimise the environmental footprint of these technologies and ensuring transparency, authenticity, interoperability and public accessibility of the data and information is a long-term priority objective. Data and information on chemicals are therefore essential for the proper development and implementation of a Union environmental policy, and specifically of a chemicals policy.		
Recital 4			

12	(4) In its communication of 19 February 2020 on a European strategy for data ³⁷ , the Commission described its vision of a common European data space and highlighted the need for the development of sectoral data spaces in strategic areas, since not all sectors of the economy and society are moving at the same speed. This Regulation aims therefore to build a data space for chemicals by establishing a common data platform on chemicals ('common data platform'), which is also part of the Green Deal data space, as referred to in the European strategy for data. Furthermore, in that strategy, the Commission highlighted several issues concerning the availability of data for the public good, including data availability, data infrastructures and governance, interoperability, as well as the lack of adequate sharing of data between public authorities. This Regulation aims to increase data availability on chemicals by requiring the relevant Union agencies to make data available for integration in the common data platform on chemicals, to promote interoperability of that data by providing for the establishment of standard formats and controlled vocabularies, as well as to facilitate data exchange and use by public authorities to enable them to effectively carry out their regulatory and policy developing tasks.		
Recital 5			
13	(5) This Regulation also aims to implement into the chemicals sector the principles laid out in the proposal for an Interoperable Europe Act ³⁸ by strengthening the cross-border interoperability of network		

	and information systems used to provide or manage public services on chemicals in the Union. This Regulation will contribute to increased cross-border data flows for truly European digital services and broaden the access to publicly available chemicals data for utilisation in other sectors' applications.		
Recital 6			

14	(6) Business operators and Member States' competent authorities are required by various Union acts to submit data and information to a multitude of Union agencies, as well as to the Commission in specific cases. This generates a fragmentation of data and information on chemicals, which are held under various data sharing and use conditions and in different formats. Such fragmentation prevents public authorities, as well as the general public, from having a clear overview of what information is available on individual chemicals or groups of chemicals, of where and how information can be accessed and whether it can be used. This increases the likelihood of inconsistency between various assessments of the same chemical required by various Union acts on chemicals and of damaging the general public's trust in the scientific grounds for Union decisions on chemicals. In order to ensure that data on chemicals is easily findable, accessible, interoperable and usable, the ECHA should establish a common data platform on chemicals. The common data platform on chemicals should serve as a single point of reference and as a broadened and shared evidence base to enable the efficient delivery of coherent hazard and risk assessments of chemicals across various Union acts on chemicals, as well as to enable the timely identification of emerging chemical risks and the drivers and impact of chemical pollution.		
Recital 7			
15	The common data platform should contain chemicals-related data and information held by relevant Union agencies or the Commission generated or submitted as part of the implementation of Union chemicals legislation listed in Annex I. This includes, for instance, all regulatory dossiers or applications submitted to the relevant Union agencies, but also chemicals data on occurrence of chemicals submitted by Member States to Union agencies or the Commission in compliance with their reporting obligations. The common data		
	platform should also include chemicals data and information generated as part of Union, national or international programmes or research activities related to chemicals, where this data and information is held by the Commission or one of the relevant agencies.		

Recital 8			
16	Due to the different nature of the risk and hazard assessments performed under Union acts on medicinal products, when compared to those performed under the main Union acts on chemicals, for medicinal products, only chemicals data related to environmental risk assessments for human and veterinary medicines, non-clinical studies for human medicines and maximum residue limit values the European Medicines Agency ('EMA') holds, as well as specific reference values, should be included in the common data platform. For medicinal active substances, only data on relevant substances should be included. These concern active substances covered by the medicines legislation and also used for other applications regulated by other Union legislation identified in this Regulation, as well as other active substances with particular persistent, bio-accumulative and toxic properties or with a known high level of residues in the environment.	Some delegations expressed the need for a clarification of the scope and meaning of "relevant substances" for active substances → PRES: this is scheduled for discussion at the 2 nd WP	
Recital 9			
17	(9) These data should also be limited to data submitted to the EMA in the context of the relevant procedures that are finalised or submitted after the entry into force of this Regulation. At a later stage, it should also be possible to include in the common data platform, where relevant, data the EMA holds on procedures concluded before the entry into force of this Regulation.		
Recital 10			
18	(10) Due to the sensitivity of the information on the exact chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health or physical effects, submitted to the bodies appointed by the Member States under Article 45 of Regulation (EC) No 1272/2008 of the European Parliament and the Council ³⁹ , that information should not be included in the common data platform. Likewise, due to the commercial sensitiveness of data and information on final cosmetic products, the information related to		

	cosmetic products notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/200940 of the European Parliament and of the Council should not be included in the common data platform either. However, chemicals data and information on individual chemical ingredients of cosmetic products should be included in the common data platform.		
Recital 11			
19	(11) To safeguard the ability of the European Commission, of the Union agencies working on chemicals and of the competent Member State authorities (hereinafter 'the Authorities'), to carry out their tasks, documents with chemicals data relating to their internal work or decision-making should in principle not be included in the common data platform.		
Recital 12			
20	(12) In order to respond to the needs of the digital economy and to ensure a high level of protection of the environment and human health, it is necessary to lay down a harmonised framework specifying who is entitled to access and use the chemicals data contained in the common data platform, under which conditions, on what basis, and for which purposes. The Authorities that are entrusted with regulatory tasks related to chemicals should be allowed and encouraged to use the chemicals data and information contained in the common data platform to effectively fulfil their regulatory duties and tasks, in order to improve the effectiveness, efficiency, and coherence of chemicalsrelated assessments as well as the development of Union chemicals policies.		
Recital 13			

21	(13) Chemicals data and information generated as a result of obligations set by Union acts on chemicals may be protected by confidentiality claims on confidential business information. The public dissemination of such data may affect the commercial interest of private parties. To ensure legal certainty for duty holders and to protect their legitimate expectations, as well as to ensure industry's		
	competitiveness on the internal market, the ECHA, as a manager of the common data platform, should grant differentiated access rights to the data and information contained in the common data platform. To this end, the Authorities should have full access to all chemicals data and information contained in the common data platform, including access to confidential information, while business operators and the general public should have restricted access to that data and information, which does not include access to confidential information.		
Recital 14			
22	(14) When using data contained in the common data platform, the Authorities should respect the originator principle. Under this principle, the confidentiality marking of chemicals data as done by the originator and as correspondingly indicated by the Agency when it provides that data to the common data platform should be respected by the Authorities using that data or information to perform their regulatory functions or fulfil their tasks.		
Recital 15			

23	(15) To ensure the protection of legitimate expectations of duty holders when generating or submitting data or information under the Union acts listed in Annex I, as well as to protect the confidentiality of that information when used by the Authorities, exceptional grounds for disclosing confidential information laid down in the Union acts listed in Annex I should apply only to the disclosure of the data and information submitted or generated in compliance with those acts. For example, under Article 39(4) of Regulation (EC) No 178/2002 of the European Parliament and of the Council⁴¹, where urgent action is essential to protect human health, animal health or the environment, such as in emergency situations, the European Food Safety Authority ('EFSA') may disclose information previously considered confidential under that Regulation and the EFSA is required to make public information, previously considered confidential, that forms part of conclusions of scientific outputs of the EFSA and relates to foreseeable effects on human health, animal health or the environment. Likewise, Article 118 of Regulation (EC) No 1907/2006 of the European Parliament and of		

	the Council ⁴² provides for the possibility for the ECHA to disclose confidential information submitted to it under that Regulation if urgent action is essential to protect human health, safety or the environment, such as in emergency situations.		
Recital 16			
24	(16) Taking into account that the Agencies would be required to store scientific data, which includes confidential and personal data, it is necessary to ensure that such storage is carried out in accordance with a high level of security of information systems and that access to confidential data is auditable.		
Recital 17			

25	(17) While the ECHA should identify and develop the technical functionalities of the common data platform in stages, certain dedicated services should be defined by this Regulation. As such, the common data platform should, in addition to providing access to chemicals-related data made available by the Agencies and the Commission, provide access to the chemicals data and information made available through its dedicated services. These dedicated services should be integrated into the common data platform and consist of the existing Information Platform for Chemical Monitoring ('IPCHEM'), a repository of reference values, a database of study notifications, a database with information on regulatory processes, a database with information on applicable legal obligations, a repository of standard formats and controlled vocabularies, a database on environmental sustainability related data, as well as a dashboard of indicators on chemicals.		
Recital 18			
26	(18) The Commission should adopt an implementation plan identifying initial datasets to be made accessible via the platform and the timeline for their integration, informed by the preparatory work of the Commission and the Agencies ⁴³ . The Commission should set up a governance scheme to support and steer the common data platform's operation and evolution covering the organisation of work structures		
	and coordination between ECHA and data providers, required rules, formats and vocabularies for data integration, and maintain a rolling implementation plan to ensure the progress in identification and integration of new datasets and services for inclusion. The governance scheme should be adopted and updated as necessary by the Commission, after consultation with a newly established platform steering committee composed of representatives from Union agencies and the Commission. In order to ensure uniform conditions for the implementation of the obligations to establish an implementation plan and a governance scheme, implementing powers should be conferred on the Commission.		

Recital 19			
27	(19) The common data platform should serve the widest possible community, with the ability to address new use cases, incorporate new relevant datasets, develop new functionalities, and respond to developing tools and applications.		
Recital 20			
28	(20) In order to bring together all relevant chemicals data and information in the common data platform, the Commission and Union agencies – notably the European Agency for Safety and Health at Work ('EU-OSHA'), the ECHA, the European Environment Agency ('EEA'), the EFSA, and the EMA ('the Agencies'), should act as data providers and make available any such relevant data they have or hold to the ECHA for integration in the common data platform. The Agencies, including the ECHA itself when making its own data available, should provide the necessary standard metadata, contextual information and relevant mapping to the platform's structure, and respect rules on standard formats and controlled vocabularies where available.		
Recital 21			
29	(21) To ensure that an adequate knowledge base on chemicals is available through the common data platform, the Commission should be able to request the Agencies to host, maintain and make available, via the common data platform, data generated as part of Union,		
	national or international programmes or research activities beyond the data already flowing to the Agencies as part of the obligations under the Union acts listed in Annex I. The Commission should make such requests to the Agencies in accordance with their mandates and allocated tasks.		
Recital 22			

30	(22) Some types of data are currently not within the mandate of any of the Agencies. In order to ensure clarity of responsibilities of the Agencies and efficient management of chemicals data, the Agencies should be required to host, maintain and provide specific data types to the common data platform. To this end, the ECHA should host and be a data provider to the common data platform for workplace monitoring data, and the EEA should host and be a data provider to the common data platform for data on indoor air quality and environment monitoring data, as well as data on concentrations of chemicals in human matrices such as blood or urine ('human biomonitoring data').		
Recital 23			
31	(23) To improve the uptake of academic data and to expand the knowledge base for chemicals safety assessments and environmental sustainability impacts of chemicals, researchers or research consortia funded by Union framework programmes should make available, in line with the 'as open as possible, as closed as necessary' principle, any human biomonitoring data they collect or generate resulting from research and development programmes to the EEA and any environmental sustainability data on chemicals or materials they collect or generate to the ECHA.		
Recital 24			
32	(24) The EEA, as the agency responsible for monitoring data and information on chemicals in the environment, should also be responsible for collecting, hosting, and maintaining human biomonitoring data. To the extent that human biomonitoring data constitutes a special category of personal data, namely, health data, the EEA should process that data only where the processing is		

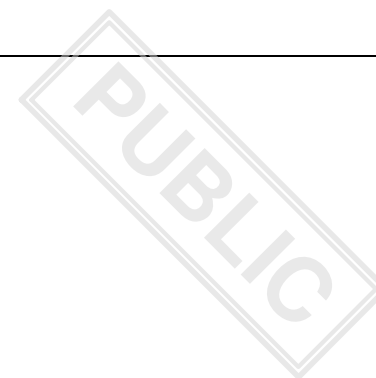
	necessary for reasons of substantial public interest, as required by Article 10(2)(g) of the Regulation (EU) No 2018/1725 of the European Parliament and of the Council ⁴⁴ . This Regulation lays down the cases where there is such substantial public interest in processing human biomonitoring data: namely, where the EEA processes that data to assess the impact of chemicals on human health and the environment, to monitor time and spatial trends in exposure, to develop health risk and impact indicators, to monitor the impact of regulatory intervention, and to support regulatory risk assessments.		
Recital 25			
33	(25) In order to ensure that appropriate safeguards are in place to secure the protection of this sensitive type of personal data, the EEA should only provide anonymised human biomonitoring data to the ECHA for integration in IPCHEM and the common data platform. IPCHEM, currently operated by the Commission, gathers occurrence data on chemicals in different media, including water, soil, indoor and outdoor air, biota, food and feed, humans, and products. In order to take advantage of the integration of various information systems and to ensure that occurrence data on chemicals is made available for use together with the other chemicals data, the ECHA should take over from the Commission the operation of IPCHEM and integrate it in the common data platform as one of its main dedicated services.		
Recital 26			

34	(26) In order to prevent disruption to the existing operation and functioning of the IPCHEM, the ECHA should integrate the IPCHEM in the common data platform together with the data present in IPCHEM at the moment of integration. At the same time, in order to enable optimal hosting and management of occurrence data on chemicals, the Commission should also transfer the data present in IPCHEM to the ECHA, the EEA or the EFSA for hosting and future updating in accordance with their respective mandates. In order to ensure that the ECHA takes over from the Commission the operation of the IPCHEM, integrates it into the common data platform and takes over the initial data sets and sets up adequate data flows, it is necessary to allow the		

	ECHA an appropriate period of time to carry out these actions, of up to 3 years from the date of entry into force of this Regulation.		
Recital 27			
35	In order to promote the use and harmonisation of reference values among risk assessors and risk managers across different Union acts and to facilitate compliance with, and enforcement of, regulatory reference values, the ECHA should establish and maintain a repository of reference values established or adopted under the Union acts listed in Annexes I and II The Agencies should provide the ECHA with reference values they hold or establish as part of their activities. In addition, the ECHA should regularly screen Union acts for reference values adopted under them. To facilitate automatic access of the general public to upto-date reference values, the ECHA should integrate the repository of reference values in the common data platform as a dedicated service, include in that repository all reference values together with the relevant context data it has received or retrieved and ensure that those values and that context data are machine readable.		
Recital 28			

36	(28) In order to increase transparency, as well as to enable Authorities to have complete prior knowledge of studies commissioned by business operators, irrespective of whether such studies are carried out by the business operator itself or are outsourced, business operators and laboratories should notify to a database of study notifications established and managed by the ECHA the studies on chemicals they commission for compliance with regulatory requirements under the Union acts listed in Annex I. For this purpose, the ECHA should establish and manage a database of study notifications, as a dedicated service of the common data platform, to store the information related to those studies. In order to allow business operators and laboratories sufficient time to prepare the notifications of studies, the obligation to notify studies should only start to apply two years after the date of entry into force of this Regulation.		
Recital 29			

37	(29) Under Regulation (EC) No 178/2002 of the European Parliament and of the Council, business operators and laboratories are obliged to notify to the database of study notifications established and managed by the EFSA the studies they commission to support an application or notification in relation to which Union law contains provisions for the EFSA to provide a scientific output. To avoid overburdening business operators and laboratories, they should therefore not be required to also notify those studies to the database of study notifications established and managed by the ECHA under this Regulation.		
Recital 30			



38	(30) To ensure the coherence between those two study notification mechanisms, as well as to ensure certainty for business operators submitting notifications, the rules on the public dissemination of study notifications should, where relevant, correspond in that the notifications should only be made available through the common data platform EN 27 EN once a corresponding registration, application, notification or other relevant regulatory dossier was submitted to the relevant Union or national institution and a decision on the confidentiality of the data contained in that regulatory dossier was taken by that Union or national institution. In addition, in order to facilitate compliance with the requirement to notify a study, the ECHA and the EFSA should cooperate to ensure a common approach for the identification of notified information in order to facilitate the traceability of studies notified to their respective databases.		
Recital 31			
39	(31) While the study notification obligation established in this Regulation should apply in the context of all the Union acts on chemicals listed in Annex I, the various relevant data collection and safety assessment processes under those acts may vary widely procedurally. The overarching aim of the database of study notifications established under this Regulation should be to bring together information on studies on chemicals being commissioned by business operators, such as to enable a centralised and complete		

	overview of the studies being performed to support regulatory compliance under Union acts on chemicals as listed in Annex I. On the basis of this objective and considering the fact that assessment procedures under Union acts on chemicals in Annex I may vary widely, it would be beyond the scope and aim of this Regulation to amend existing assessment processes set under those Union acts listed in Annex I by imposing additional conditions leading to potential market access consequences not foreseen in those Union acts. Consequently, it is not appropriate to introduce in this Regulation the consequences associated non-compliance with the study notification obligation as laid out in Article 32b of Regulation (EC) No 178/2002 of the European Parliament and of the Council.		
Recital 32			
40	(32) Nevertheless, to ensure compliance with the study notification obligation laid down in this Regulation, and to cater to the specificities of individual assessment processes, where existing, Member States should lay down rules on penalties applicable to the infringement of that obligation and take all necessary measures to ensure that those rules are complied with. Those penalties should be effective, proportionate, and dissuasive, since non-compliance with this Regulation could result in less robust chemicals risk assessments, creating potential risks and consequently adverse effects on human health and the environment.		
Recital 33			
41	(33) In order to facilitate enforcement by Member States, the Agencies responsible for assessing and providing scientific output, including scientific opinions, on regulatory dossiers containing studies subject to notification to ECHA should, where relevant, cooperate and exchange information with the Member State enforcement authorities on the compliance with the obligations laid out in Article 22.		
Recital 34			

42	(34) While Regulation (EC) No 178/2002 of the European Parliament and of the Council also requires the consultation of stakeholders and		

	the public following the notification to the EFSA of studies commissioned for the purposes of the renewal of an authorisation or approval, a similar requirement under this Regulation would lay a disproportionate administrative burden on the ECHA, given the wide scope of the studies that is to be notified under this Regulation.		
Recital 35			
43	(35) A mechanism related to study notifications exists in Regulation (EC) No 1907/2006 of the European Parliament and of the Council. Where registrants are required to perform studies to generate data in accordance with requirements in Annexes IX and X to that Regulation, they must first submit a testing proposal to the ECHA in order to receive a decision requiring them to perform a study. Such decision may also be issued as an outcome of compliance check or substance evaluation under that Regulation. In order to facilitate the transparency, traceability, and effective monitoring of studies commissioned or carried out pursuant to a decision of the ECHA in accordance with Articles 40, 41 or 46 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council, business operators should specify in their notifications of studies under this Regulation that those studies are being commissioned or carried out in compliance with those decisions.		
Recital 36			

44	(36) To strengthen the coordination and cooperation between the different bodies performing chemicals assessments in the Union, and to promote an increased transparency of chemicals assessments, the ECHA should establish and manage a database with information on regulatory processes or activities that are planned, ongoing or completed by Member States, the Commission and Agencies referred to in the Union acts listed in Annex III to this Regulation and integrate it into the common data platform for access by the authorities. The information on such regulatory processes or activities should include at least the substance identity and the identification, status and eventually the outcome of the regulatory process or activity. That information should also be made available without undue delay and		

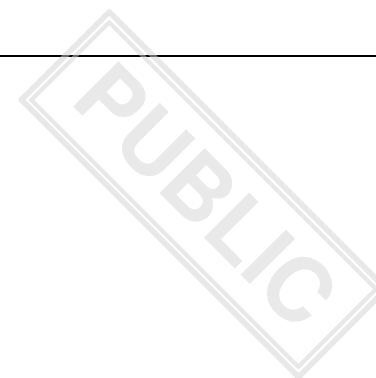
	kept updated through the assessment process. Once the process or activity has formally started, that information should be shared also publicly on the common data platform.		
Recital 37			
45	(37) The existing 'The EU Chemicals Legislation Finder' ⁴⁵ project managed by the ECHA makes it easier to find and identify legal obligations related to the use of a specific chemical. The project is especially helpful for small and medium sized enterprises in identifying their legal obligations. To reinforce the supportive function of the project for business operators, it should be established on a permanent basis and more Union acts should be included in its scope. For this purpose, the ECHA should collect information on the legal obligations deriving from the Union acts on chemicals listed in Annex I to this Regulation and incorporate that information into the common data platform as a dedicated service.		
Recital 38			

46	(38) In order to ensure the interoperability and comparability of chemicals data and to facilitate their automatic and electronic exchange, the Agencies and the Commission should store chemicals data in adequate and mutually coherent and interoperable formats and use mutually coherent and interoperable controlled vocabularies. Some Union acts listed in Annex I or II set procedures to establish or make available data formats, in particular for the submission of chemicals data by business operators or Member States. Where such procedures do not exist in the Union acts listed in Annex I or II, the Agencies and the Commission should, where relevant, specify appropriate formats for chemicals data they receive and store, avoiding the use of proprietary standards while, as appropriate, using OECD or other internationally agreed formats, making use of existing formats and ensuring interoperability with existing data submission approaches.		
Recital 39			
47	(39) Likewise, the Agencies and the Commission should specify		

	appropriate controlled vocabularies for data they receive and store and, where relevant, integrate them in submission software or formats. Moreover, in order to facilitate a smooth electronic exchange of data through the common data platform, the Agencies and the Commission should agree on the required formats and controlled vocabularies for providing data to the common data platform. Whenever the Agencies or the Commission set formats or controlled vocabularies, they should cooperate with each other to ensure their coherence, consistency and interoperability. In order to ensure uniform conditions for resolving divergences in data formats and controlled vocabularies, implementing powers should be conferred on the Commission.		
Recital 40			

48	(40) In order to promote the interoperability of database systems on chemicals beyond the common data platform, the ECHA should establish a repository of standard formats and controlled vocabularies as part of the common data platform. The Agencies and the Commission should make the formats and controlled vocabularies they set available to the repository and the ECHA should make them available free of charge in electronic formats for use by developers of database systems and the general public.		
Recital 41			
49	(41) The International Uniform Chemical Information Database ('IUCLID') is a software application designed to record, store, maintain and exchange data on chemicals. The ECHA develops and maintains the IUCLID software and the underlying format in collaboration with the Organisation for Economic Cooperation and Development ('OECD'). The IUCLID implements all OECD-harmonised templates, which are harmonised formats agreed at the OECD level to facilitate structured and consistent documentation of test outputs and similar chemicals data. Since chemicals data is being submitted to the ECHA in IUCLID under Union acts such as Regulations (EC) No 1907/2006, (EC) No 1107/200946 and (EU) No 528/201247 of the European Parliament and of the Council, the ECHA is closely involved in the continued development of IUCLID, and IUCLID implements the standard formats		

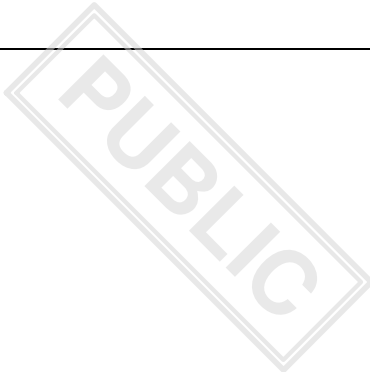
	agreed at the OECD level, it is appropriate and necessary to require the Commission and the Agencies to use IUCLID for the relevant parts of dossiers under specified Union acts listed in Annex I when they make the data contained in those dossiers available to the ECHA .		
Recital 42			



50	(42) To increase the availability and facilitate the use of information on the environmental performance of chemicals throughout their lifecycle, and to enable a comprehensive assessment of the impacts of chemicals on the environment, the Commission should identify relevant data and information related to the environmental sustainability of chemicals, including, where available, information on their impact on climate change, for integration into the common data platform. Once the Commission has identified the relevant existing datasets on environmental sustainability related data and has designed the relevant related database functionalities, the ECHA should establish a database on environmental sustainability-related data, collect the data as made available by the Commission, the Agencies and, where relevant, by the researchers and research consortia funded by Union framework programmes, and integrate the content of that database into the common data platform as a dedicated service. In order to ensure uniform conditions for the implementation of the obligation to identify relevant environmental sustainability datasets, implementing powers should be conferred on the Commission.		
Recital 43			
51	(43) To monitor the impacts on humans and the environment, including the climate, of exposure to chemicals and to establish a knowledge base to measure the effectiveness of chemicals legislation in protecting human health and the environment, the EEA and the ECHA should jointly develop and regularly, at least every two years, update a set of indicators and present it in the form of a dashboard. The EFSA, the EMA, the EU-OSHA and the Commission shall regularly provide the EEA with any available data falling within their mandate and relevant for the establishment of the indicators. The EEA and the ECHA should integrate this dashboard of indicators into the common data platform.		
Recital 44			

52	(44) To enable the identification and evaluation of emerging chemical risks, the EEA should develop and compile information on early warning signals and draw up an annual summary report to inform regulatory follow-up actions. In its work, the EEA should include its own sources, targeted literature searches and make use of information from national early warning systems. It should also include relevant information made available by the related work of the ECHA, the EFSA, the EU-OSHA, the EMA and their networks, such as the EFSA's task of identifying and collecting information on emerging risks under Regulation 178/2002. The EEA should make the summary report and the underlying data available through the common data platform, ensuring public access and its use for further action on existing and emerging risks. In order to allow the EEA sufficient time to organise the collection of early warning signals and to compile and analyse the initial information the EEA should only deliver the first report six months after the end of the first calendar year after entry into force of this Regulation. This Regulation sets a deadline for the first report and associated data.		
Recital 45			
53	(45) In June 2017, at the Commission' request, the ECHA set up the European Observatory for Nanomaterials⁴⁸ ('EUON'), which collects existing data and information from databases, registries and studies and generates new data through studies and surveys on nanomaterials on the EU market.		
Recital 46			
54	(46) The ECHA should continue operating the EUON and transform it into an observatory for specific chemicals with potential contribution to emerging chemical risks ('the observatory'), which should cover also other chemicals and innovative (rationally designed complex 'advanced') materials selected by the Commission, using, as appropriate, signals from the early warning and action system. One of the criteria for selecting chemicals for the observatory should be their		

	novelty and disruptive potential that may contribute to an emerging chemical risk. Another criterion for that selection should be the higher degree of uncertainty surrounding them and, due to less regulatory experience regarding those chemicals, the resulting need for additional scrutiny and transparency. The observatory should facilitate regulatory implementation and responsible use of these chemicals by collecting, generating, and disseminating reliable information on selected chemicals' properties, uses and market presence to the general public.		
Recital 47			
55	(47) The observatory should not be regarded as a substitute for required risk management action on any chemical in cases where a hazard or risk has been identified. In order to provide for an efficient and consistent approach for the generation and dissemination of all such additional information, the ECHA should oversee the work of the observatory and make the regularly updated data and information it collects available through the common data platform, or by means of other communication channels, as appropriate. In order to ensure uniform conditions for the implementation of the requirement to select chemicals to be included in the observatory, implementing powers should be conferred on the Commission.		
Recital 48			



56	(48) Under Regulation (EC) No 178/2002, the EFSA is able to commission, in an open and transparent manner, the scientific studies it needs to accomplish its mission, while seeking to avoid duplication with Member States or Union research programmes. The ECHA should also be able to commission studies to obtain adequate data and information on chemicals within its mission, while maintaining the principle that the burden to prove compliance with Union chemicals legislation remains on the duty holder. Furthermore, the ECHA should commission such studies out of its own initiative or at the request of the Commission, with the objective of supporting the effective and efficient implementation and evaluation of Union acts on chemicals within its mandate and contributing the development of a Union chemicals policy.		
Recital 49			

57	(49) In order to adjust the contents of Annexes I and III to technical and scientific progress in the field of chemicals and to bring in the scope of this Regulation new Union acts under which relevant chemicals data and information is generated or submitted, and, where relevant, to expand the specific data types and reference values, listed in Annex II, to be made available by the EMA through the common data platform, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending Annexes I, II and III. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work in relation to the amendment of the Annexes by delegated act, including at expert level through the One-Substance One-Assessment Expert Group, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016⁴⁹. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.		
Recital 50			
58	(50) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States as Member States do not hold the data within the scope of this Regulation and cannot establish a Union wide common data platform, but can rather, by reason of chemicals data and information being hosted at Union level by the Agencies, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.		
Recital 51			

59	(51) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council and delivered an opinion on [OP: Please insert the date of the opinion of the EDPS].		
Formula			
60	HAVE ADOPTED THIS REGULATION:		
Chapter I			
61	Chapter I SUBJECT MATTER, SCOPE AND DEFINITIONS		
Article 1			
62	Article 1 Subject matter and scope		IE: In relation to there being no specific reference to the promotion of data from non-animal methods in Article 1, while we appreciate that COM indicated that this regulation is not the most appropriate place to promote non animal methods, we nonetheless ask if consideration could be given to referencing it in the recitals. This would give recognition within this Regulation to this important issue.
Article 1(1)			

63	1. This Regulation aims to ensure the efficient delivery of coherent hazard and risk assessments of chemicals where those assessments are required by Union legal acts, to achieve a high level of protection of human health and the environment, to enable the development and use of sustainable chemicals, to ensure the proper functioning of the single market for chemicals, and to improve the Union's citizens' trust in the scientific base for the decisions taken under Union legal acts on chemicals.	One delegation proposed to include SSBD (safe and sustainable by design) as one of the roles for the platform. → PRES propose to work on an amendment introducing explicitly the safe and sustainable by design approach as one of the aims.	
Article 1(2)			
64	2. To achieve the objectives referred to in paragraph 1, this Regulation contains measures to:		
Article 1(2), point (a)			
65	(a) bring together data and information on chemicals and ensure that data and information are easily findable, accessible, interoperable and re-usable;		
Article 1(2), point (b)			
66	(b) keep records of studies commissioned or carried out by business operators in the context of fulfilling their obligations set under Union chemicals legislation;		
Article 1(2), point(c)			
67	(c) establish the widest possible scientific base for the implementation and development of Union legislation and policy on chemicals;		
Article 1(2), point (c)			

68	(d) establish an early warning and action system for emerging chemical risks.		
Article 1(3)			
69	The provisions laid down in this Regulation apply to chemicals data as laid out in Article 3(2).		
Article 2			
70	Article 2 Definitions	One delegation requested amending art.2 to clarify the meaning of “product” in this proposal. One delegation asked what is covered by the term “products” in art.7(1) One delegation requested examples of the meaning of “chemical products” in relation to mixtures, articles, substances. PRES highlights that the term occurs in recital (8), (10),(25),art.3(3), art.7(1), art.22(1). PRES highlights also that while some of those occurrences relates to cosmetic or medicinal products, other occurrences do not refer to a particular regulation and might have overlapping meaning with e.g. articles in REACH, or products under the ESPR. → PRES is working on an amendment proposal.	IE: We still ask what is meant by the term ‘products’ here as the term on its own is too vague.
Formula			
71	For the purpose of this Regulation, the following definitions shall apply:		
Article			

2(1)			
72	1. ‘Agencies’ means the European Chemicals Agency (‘ECHA’), the European Environment Agency (‘EEA’), the European Food Safety Authority (‘EFSA’) and the European Medicines Agency (‘EMA’) and the European Agency for Safety and Health at Work (‘EU-OSHA’);		
Article 2(2)			

73	2. 'Authorities' means the European Commission, the competent authorities of the Member States as referred to in any of the Union acts listed in Annexes I and III, and the Agencies, excluding their management boards;		
Article 2(3)			
74	3. 'duty holder' means a natural or legal person responsible for meeting obligations under the Union acts listed in Annex I or II;		
Article 2(4)			
75	4. 'business operators' means duty holders which are private or public undertakings;	One delegation suggests to "use 'economic operators' instead of 'business operators' to ensure alignment with other relevant legislation". PRES highlights that the term "business operator" is used in recital (8),(13),(28),(29),(30),(31),(35),(37),(38), and articles 1(2), 22, 25, and 26. Those articles relate to studies commissioned, studies notifications, and related enforcement/penalties. PRES highlights that the term "duty holder" is defined in art. 2(3) in relation to obligations in acts mentioned in annex I or II. The terms are per se used in recital (13), (15), (48), art 2(4), 15(5), and 17(2). Those later articles relate to the use of the controlled vocabularies, as well as the prohibition for Authorities to use data from the platform to fulfil legal obligations of duty holders. → PRES seeks written comments on the following: ESPR has a definition of "economic operator": 'economic operator'	IE: Response is noted but we would welcome further clarity as to why the aim is to reduce the scope of those covered? Our comment was to align the definition with the EU Market Surveillance Regulation of 2019 in the context of compliance/enforcement.

		means the manufacturer, the authorised representative, the importer, the distributor, the dealer and the fulfilment service provider. PRES understands that in the present regulation the meaning of it is much more narrow, and relates only to duty holders that at the same time are undertakings. → PRES seeks for agreement that in consequence there is no correspondence with other EU regulations, and thus no amendment here should be done.	
Article 2(5)			
76	5. 'human biomonitoring data' means concentrations of chemicals measured in human matrices such as blood or urine;		
Article 2(6)			
77	6. 'reference value' means an estimate of a maximum exposure to or emission level of a chemical below which no or only acceptable adverse effects on human health or the environment are expected, or below which risks related to the adverse effects on human health or the environment are considered acceptable or tolerable;	One delegation commented about "acceptable or tolerable" in relation to non-threshold cancerogenic substances. PRES understands that the intention is to avoid that reference values for non-threshold substances are published without mentioning as metadata the actual statistical risk they represent. → PRES proposes to work on an amendment of art 2(6), 8 and 14 for this.	
Article 2(7)			
78	7. 'originator' means the Commission, Agency, or Member State competent authority responsible for confidentiality assessments under any Union act listed in Annex I or Annex II;		
Article 2(8)			
79	8. 'originating Union act' means the Union act under which chemicals data and information were generated or submitted;		

Article 2(9)			
80	9. 'controlled vocabularies' means standardised and organised arrangements of words and phrases presented as lists of terms or as thesaurus and taxonomies with a hierarchical structure of broader and narrower terms;		
Article 2(10)			
81	10. 'chemicals data' means any representation of facts or information relating to chemicals and any compilation of such facts or information, including information on physico-chemical properties, hazard properties, use, exposure, risk, occurrence, emissions and manufacturing process of the chemicals, as well as environmental sustainability related information, including climate change related information, on those chemicals, regulatory process-related information on chemicals, standard formats, controlled vocabularies, or any information on applicable legal obligations related to chemicals;		
Article 2(11)			

82	11. 'environmental sustainability related data' means any data relevant for the environmental sustainability assessment of a chemical or material throughout its entire life cycle, including:	One delegation finds this definition vague, and proposes to add an annex (e.g. in Art. 13) which can be updated on a regular basis by means of Delegated Acts. This annex should contain the respective legal acts as well as the associated sustainability information. PRES highlights that the definition here is used in a broader sense than the information available in legal acts (e.g. research in art.5(6), art 13(3) and potentially art.13(4)). → PRES requests written comments on the necessity to add a reference to a new annex IV, containing a list legal acts relevant for environmental sustainability related data. Such a reference would be added here as a new point 2(11)(d) along with related delegated powers in Chapter VIII. → PRES would also like to have comments on the provisions of art.13(4) as this partially overlaps with the concern raised by one delegation (by having the COM adopting an implementing decision for data not already hosted or hold by agencies/COM or not coming from EU research). Which relevant data are generated through legal	

		acts but are not hold or hosted by COM/agencies listed in this proposal?	
Article 2(11), point (a)			
83	(a) data on resources, including raw materials, water, energy, fossil fuels and land;		
Article 2(11), point (b)			
84	(b) data on emissions, including greenhouse gases, eutrophicationrelevant substances, dust and all other polluting substances; and		

Article 2(11), point (c)			
85	(c) data on by-products originating during the chemical's life cycle that can be used as resources for other production processes, including hydrogen and carbon monoxide.		
Article 2(12)			
86	12. 'personal data' means personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679 of the European Parliament and of the Council and as defined in Article 3, ~~point (16), of Regulation (EU) 2018/175~~ point (1), of Regulation (EU) 2018/1725 of the European Parliament and of the Council;	One delegation highlighted that this definition is specified in Article 3, point (1) of Regulation 2018/1725 and not in Article 3, point (16) of Regulation 2018/175. → PRES sees this as an editorial amendment and proposes to modify Article 2 (12) consequently.	
Article 2(13)			
87	13. 'processing' means processing as defined in Article 4, point (2), of Regulation (EU) 2016/679 of the European Parliament and of the Council and as defined in Article 3, point (3), of ~~Regulation (EU) 2018/175~~ Regulation (EU) 2018/1725	One delegation highlighted that the reference is to Regulation 2018/1725 and not to Regulation 2018/175. → PRES sees that this is an editorial amendment and proposes to modify Article 2 (13) consequently.	

	of the European Parliament and of the Council;		
Article 2(14)			
88	14. 'data controller' means controller as defined in Article 4, point (7), of Regulation (EU) 2016/679 and as defined in Article 3, point (8), of ~~Regulation (EU) 2018/175~~ Regulation (EU) 2018/1725 of the European Parliament and of the Council;	One delegation highlighted that the reference is to Regulation 2018/1725 and not to Regulation 2018/175. → PRES sees that this is an editorial amendment and proposes to modify Article 2 (14) consequently.	

Article 2(15)			
89	15. 'interoperability' means the ability of two or more data spaces or communication networks, systems, products, applications or components to exchange and use data in order to perform their functions.	One delegation asked if advanced programming interfaces (API) will be used. PRES highlights that API are tools that MSs may use amongst others in order to query the data platform from their own advanced knowledge management systems (i.e. machine readability) instead of relying on "manual" queries in a web interface like in ECHA web site today. PRES highlights that in the explanatory memorandum the COM mentions that "The proposal also contributes to the objectives of EU data and digital policies by promoting interoperability and machine readability". However only interoperability is explicitly mentioned here. → PRES requests written comments on this and on the necessity to amend the proposal to explicitly mention APIs and the conditions of their use for MS and the public.	
Chapter II			
90	Chapter II INFORMATION SYSTEMS AND PLATFORMS		
Article 3			
91	Article 3 Common Data Platform on Chemicals		

Article 3(1)			
92	1. The ECHA shall establish and manage a common data platform on chemicals ('the common data platform').		

Article 3(2)			
93	2. The common data platform shall provide access to all chemicals data:	One delegation highlights that it is difficult to assess the exhaustiveness of annexes I and III. PRES request written comments on any potentially missing relevant regulations in those annexes. One delegation questioned the differentiated approach between medicinal products and biocidal and phytopharmaceutical products. → PRES would like to receive further clarity in writing.	
Article 3(2), point (a)			
94	(a) generated or submitted as part of the implementation of the Union acts listed in Annex I to this Regulation and held by the Agencies or the Commission;		
Article 3(2), point (b)			
95	(b) generated as part of Union, national or international programmes or research activities in the sphere of chemicals and held by the ECHA, the EEA, the EFSA, the EU-OSHA or the Commission;		
Article 3(2), point (c)			
96	(c) listed in Annex II and held by the EMA;		
Article 3(3)			

97	3. The following information shall not be included in the common data platform:		
Article 3(3), point (a)			
98	(a) the information referred to in Article 45 of Regulation (EC) No 1272/2008 ⁵⁰ ; 50 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).		
Article 3(3), point (b)			
99	(b) the information related to cosmetic products and notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/2009 ⁵¹ of the European Parliament and of the Council. 51 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November on cosmetic products (OJ L 342 22.12.2009, p. 59).		
Article 3(4)			
100	4. Documents relating to Authorities' internal work or decision-making processes need not be included in the common data platform, unless required under Article 10.		
Article 3(5)			
101	5. The common data platform shall provide the dedicated services identified in the governance scheme referred to in Article 4(3) including:		

Article 3(5), point (a)			
102	(a) the Information Platform for Chemical Monitoring ('IPCHEM')		

	referred to in Article 7;		
Article 3(5), point (b)			
103	(b) the repository of reference values referred to in Article 8;		
Article 3(5), point (c)			
104	(c) the database of study notifications referred to in Article 9;		
Article 3(5), point (d)			
105	(d) information on regulatory processes referred to in Article 10;		
Article 3(5), point (e)			
106	(e) information on obligations under Union chemicals legislation referred to in Article 11;		
Article 3(5), point (f)			
107	(f) the repository of standard formats and controlled vocabularies referred to in Article 12;		
Article 3(5), point (g)			

108	(g) the database on environmental sustainability-related data referred to in Article 13.		
Article 3(6)			
109	6. The Authorities and the general public shall have access to the data contained in the common data platform in accordance with Article 16.		
Article 3(7)			
110	7. The data contained in the common data platform may be used in		

	accordance with Article 17.		
Article 3(8)			
111	8. The data contained in the common data platform shall be made available in standard formats, where developed, and through controlled vocabularies where available.		
Article 3(9)			
112	9. The data contained in the common data platform shall be electronically accessible and searchable. The ECHA shall take measures to ensure a high standard of security appropriate to the security risks at stake for the storage of chemicals data in and transmission of chemicals data to the common data platform. The ECHA shall design the common data platform in a way that guarantees that any access to confidential data is auditable.		
Article 3(10)			

113	10. The Commission or Agency under whose authority chemicals data is included in the common data platform on chemicals shall remain responsible for handling any requests for access to documents made under Regulation (EC) No 1049/2001⁵². ⁵² Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (. OJ L 145, 31.5.2001, p. 43).		
Article 3(11)			
114	11. The common data platform and its dedicated services shall be established by [OP: please insert date: three years after the date of entry into force of this Regulation], unless specified otherwise. The relevant datasets shall be integrated progressively into the common data platform by [OP please insert date: ten years from the date of entry into force of this Regulation] according to the implementation plan referred to in Article 4 (1), first sentence. Upon integration of those datasets in the common data platform, when the ECHA receives	One delegation requested clarifications on this paragraph (timing for the notification service, lack of specification of the timing for the rolling plans). This delegation proposed amendments accordingly → PRES: a more general discussion at the 2d WP took place regarding the timelines	
	chemicals data in accordance with Article 5, it shall make that data available through the common data platform without undue delay.		
Article 4			

115	Article 4 Implementation plan and governance of the common data platform	One delegation proposed to include new provisions 5a,5b,5c in art.4., requesting that the COM prepares and presents a recommendation on “how to amend legislation listed in the Annexes to this regulation”. → PRES would like to receive written comments on this as it is not clear for us if this means amending the annexes of the data platform proposal, or if the delegation meant to amend the listed regulations. One delegation raised concerns about the wording “implementing” appearing at several places and which is seen as “misleading” with respect to the legal definition of “implementing acts”. → PRES seeks legal advice on this. The Council legal services provided an opinion on this at the 2nd WP.	
Article 4(1)			
116	1. By [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall adopt and publish an implementation plan identifying datasets for inclusion in the common data platform together with a timeline for their inclusion by means of an implementing decision. Subsequent rolling implementation plans shall be adopted in line with the governance scheme referred to in paragraph 3.	One delegation questioned the procedure for adopting the plan, the consultation procedures and MS involvement. → PRES: WP2 discussion on the desired level of and procedures for MS participation took place.	IE: In general, we also support MS consultation on this and ask for information of the process by which that consultation will happen (e.g. will it be via the OSOA expert working group?)
Article 4(2)			
117	2. The Commission shall, by means of an implementing decision, establish and manage a platform steering committee, which shall include one representative from the ECHA, one representative from the EEA, one representative from the EFSA, one representative from the EMA, one representative from the EU-OSHA and five representatives from the Commission.		
Article 4(3)			

118	3. The platform steering committee shall advise the Commission in the		
	preparation of the common data platform's governance scheme.		
Article 4(4)			
119	4. The Commission shall adopt and publish the governance scheme referred to in paragraph 3 and any revision thereof by means of an implementing decision		
Article 4(5)			
120	5. That governance scheme shall describe:		
Article 4(5), point (a)			
121	(a) the organisation of the main work structures supporting the development and implementation of the common data platform;		
Article 4(5), point (b)			
122	(b) the preparation and adoption of rolling implementation plans for the common data platform;		
Article 4(5), point (c)			
123	(c) the principles on data governance and the required standard formats, controlled vocabularies and further conditions for the provision of information and context data to the common data platform;		
Article 4(5), point (d)			

124	(d) the decision-making procedures for the development of new dedicated services and the inclusion of new functionalities of the platform;		
Article 4(5), point(e)			

125	(e) any other rules or requirements necessary for the operation of the common data platform such as the data update, archiving and deletion policy;		
Article 4(5), point (f)			
126	(f) the operation of the steering committee itself.		
Article 5			
127	Article 5 Data Flows for the purpose of the common data platform		
Article 5(1)			
128	1. At the Commission's request, the Agencies shall host and maintain chemicals data generated as part of Union, national or international legislation, programmes or research activities, corresponding to their mandate and the type of data they already hold.		
Article 5(2)			
129	2. Where the Commission or the Agencies hold data or information referred to in Article 3(2), they shall make that data available to the ECHA, in a standard format, where available, together with the relevant context data as ~~referred to in Article 4(4), point (c).~~ referred to in Article 4(5), point (c). The Commission and the Agencies shall indicate whether that data or information is made available to the public under the originating Union act.	One delegation highlighted that the reference should be to Article 4(5), point (c) and not Article 4(4), point (c). → PRES sees this as an editorial amendment and proposes to modify Article 5(2) consequently.	

Article 5(3)			
130	3. The ECHA shall host and maintain occurrence data related to workplace monitoring.		
Article 5(4)			
131	4. The EEA shall host and maintain human biomonitoring data, occurrence data for the environment and occurrence data related to indoor air quality.	One delegation asked if Commission pursues plans for systematic or regular surveys of indoor air quality data → PRES is requesting written comments on this.	
Article			

5(5)			
132	5. Researchers or research consortia funded by Union framework programmes shall make available to the EEA any human biomonitoring data they collect or generate from [OP please insert: date of the entry into force of this Regulation].		
Article 5(6)			
133	6. Researchers or research consortia funded by Union framework programmes shall make available to the ECHA any environmental sustainability data on chemicals or materials they collect or generate from [OP please insert: date of the entry into force of this Regulation].		
Article 5(7)			
134	7. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of the chemicals data provided in accordance with paragraph 2 in the common data platform as well as its publication through that platform.		
Article 5(8)			

135	8. For the purpose of paragraph 2, the Commission and the Agencies shall make chemicals data available to the ECHA without undue delay after collection or receipt of the data, after performance of validity and confidentiality assessments in accordance with applicable rules and once the corresponding dataset has been integrated in the common data platform.		
Article 5(9)			
136	9. The Commission and the Agencies shall ensure that data made available to the ECHA shall be downloadable, machine readable and interoperable. They shall appropriately curate and validate the data before providing them to the ECHA.		
Article 6			
137	Article 6 Human biomonitoring data	→ PRES: given the numerous comments, questions and clarification requests received, PRES set this as a discussion point at the 2 nd WP (8/3), and invites MS and the COM to react to the EDPS recommendations.	

Article 6(1)			
138	1. The EEA shall collect, host, and maintain human biomonitoring data generated within the territory of the EEA's member and cooperating countries.		
Article 6(2)			
139	2. At the latest by [OP please insert date: 3 years after entry into force of this Regulation] the Commission shall transfer any human biomonitoring data it holds to the EEA.		
Article 6(3)			
140	3. The EEA may process human biomonitoring data constituting personal data to support the Commission in its policy making or to support the Agencies in fulfilling their missions.		

Article 6(4)			
141	4. Human biomonitoring data constituting personal data may be processed by the EEA for the following purposes:		
Article 6(4), point (a)			
142	(a) assessing the impact of chemicals on human health and the environment;		
Article 6(4), point (b)			
143	(b) monitoring time and spatial trends in exposure;		
Article 6(4), point (c)			
144	(c) developing health risk and impact indicators;		
Article 6(4), point (d)			
145	(d) monitoring the impact of regulatory intervention;		
Article 6(4), point (e)			
146	(e) supporting regulatory risk assessments.		

146.a	(f) supporting regulatory risk management	One delegation proposed to add this amendment. PRES understands that HBM data are indeed useful for risk management, e.g. trend analysis will give an idea if policy actions are having an impact or not on reducing exposure → PRES proposes thus to add this paragraph (f)	IE: Addition noted, with thanks
Article 6(5)			
147	5. The EEA shall make human biomonitoring data they hold or host publicly available in anonymised form through the Information Platform for Chemical Monitoring.		
Article 6(6)			
148	6. The EEA shall act as data controller for the human biomonitoring personal data it holds or hosts and processes for the purposes referred to in paragraph 2. in paragraph 4.	Some delegations highlighted that the reference should be to para. 4. → PRES sees this as an editorial amendment and proposes to modify art.6(6) in consequence. One delegation proposed to add an additional reference to art.3 and 5 here. → PRES, up to his knowledge, understands that from the definition of a data controller this is logical, but seeks for written opinions on this and will request a legal advice. Discussions at the 2nd WP on the EDPS recommendations might also contribute clarifications on this proposal. One delegation suggested to “include the same reference to Articles 6(3) and 6(4)” → PRES is keen to receive a written rationale for this as it seems to introduce a circular reference in the text.	
Article 7			

149	Article 7 Information Platform for Chemical Monitoring		
Article 7(1)			
150	1. The ECHA shall operate and maintain the Information Platform for Chemical Monitoring containing occurrence data on chemicals across different media, including water, soil, indoor air, outdoor air, biota, food and feed, humans, and products as part of the common data platform.	→ PRES: regarding the meaning of “products”, cfr art.2 (here in line 70).	IE: Can further clarity be given as to what is meant by the term ‘product’ as on its own, this term is too vague.
Article 7(2)			
151	2. At the latest by [OP please insert date: 3 years after the date of entry into force of this Regulation], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring at that moment to the ECHA for integration in the common data platform.		
Article 7(3)			
152	3. At the latest by [OP please insert date: 3 years after entry into force of this Regulation], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring to the ECHA, the EEA or the EFSA for hosting in accordance with the respective agencies’ mandate and in accordance with Article 5.		
Article 7(4)			
153	4. After the completion of the transfer referred to in paragraph 3, where the Commission or the Agencies host or hold occurrence data on chemicals and related chemicals data, they shall make that data available to the ECHA without undue delay for integration in the Information Platform for Chemical Monitoring.		
Article 7(5)			

154	5. The Commission and Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration and publication of occurrence data and related chemicals data they host or hold through the common data platform.		
Article			

7(6)			
155	6. The ECHA shall ensure that the data contained in the Information Platform for Chemical Monitoring is machine readable and downloadable.		
Article 8			
156	Article 8 Repository of reference values	One delegation requested a amendment about the statistical (cancer) risk associated with some reference values. → PRES: see our proposal in art 2(6) here line 77	
Article 8(1)			
157	1. The ECHA shall establish and manage a repository of reference values as part of the common data platform.		
Article 8(2)			
158	2. The ECHA shall include any reference value adopted under Union acts listed in Annex I or Annex II, Part 1, in the repository of reference values without undue delay.		
Article 8(3)			
159	3. For reference values not falling under paragraph 2, the Agencies holding or establishing reference values as part of their activities under Union acts listed in Annex I, or the reference values referred to in Annex II, Part 2, shall make those reference values available to the ECHA, in the standard formats provided for in Article 14, where developed, and without undue delay, for integration in the repository of reference values.		

Article 8(4)			
160	4. For the purpose of paragraph 3, where reference values are included in a regulatory dossier submitted to the Agencies, the Agencies shall share those reference values in the standard formats with ECHA without undue delay and once relevant validity and confidentiality assessments have been completed by the originator in accordance with applicable rules.		
Article 8(5)			

161	5. The ECHA shall ensure that the data contained in the repository of reference values is machine readable.		
Article 9			
162	Article 9 Database of Study Notifications		
Article 9(1)			
163	1. The ECHA shall establish and operate a Database of Study Notifications by [OP please insert date: two years after the date of entry into force of this Regulation].		
Article 9(2)			
164	2. The ECHA shall store in the Database of Study Notifications the data notified to it in accordance with Article 22.		
Article 9(3)			

165	3. The ECHA shall integrate the data contained in the Database of Study Notifications in the common data platform once a corresponding registration, application, notification or other relevant regulatory dossier was submitted to the relevant Union or national institution, agency, or body in accordance with corresponding Union law and after a decision was taken by that Union or national institution, agency, or body on the disclosure of the accompanying studies in accordance with the applicable rules on confidentiality.	One delegation considers that this deserves clarification as it seems to prevent Member States authorities from getting relevant information on notified studies in time. PRES notes that this might be related to enforcement. → PRES seeks further written comments on this → PRES is working on an amendment proposal	
Article 9(4)			
166	4. The EFSA shall make the data contained in the database referred to in Article 32b of Regulation (EC) No 178/2002 available to the ECHA for integration in the common data platform once it has received a corresponding application and after it has decided on the disclosure of the accompanying studies in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002.		
Article 9(5)			
167	5. The ECHA and the EFSA shall cooperate to ensure a common approach for the identification of information notified to them in		

	accordance with Article 22 of this Regulation and Article 32b of Regulation (EC) No 178/2002, respectively and facilitate the traceability of the studies notified to their respective databases.		
Article 10			
168	Article 10 Information on regulatory processes on chemicals	→ PRES is seeking written comments on one delegation's question about already existing communication channels in certain regulations, related to the stage of evaluation, and the potential need to modify those regulations. → PRES highlights that this might be the case for TRIS notifications.	
Article 10(1)			

169	1. The ECHA shall establish and manage, as part of the common data platform, a new database containing information on regulatory processes on individual substances or groups of substances that are planned, ongoing or have been completed since the entry into force of this Regulation by the Member States or the Union institutions, agencies or committees referred to in the Union acts listed in Annex III.	→ PRES is seeking for written comments on one delegation's comment that it is not clear whether the scope of art 10(1) includes national regulations processes.	
Article 10(2)			
170	2. Where Member State competent authorities as referred to in any of the Union acts listed in Annex III hold the information referred to in paragraph 1, they shall make that information available to the Union agency responsible under the respective Union act listed in Annex III without undue delay.	→ PRES is seeking for written comments on one delegation's request to clarify the COM reference (during the 1 st WP) to voluntary notifications, including examples.	
Article 10(3)			
171	3. Where the ECHA, EEA, EFSA, EU-OSHA or the Commission hold the information referred to in paragraph 1, they shall make that information available to the ECHA for integration in the common data platform in the standard formats provided for in Article 14 without undue delay and, where relevant, once the responsible agency or the Commission has performed the validity assessment. For each regulatory process or activity, at least the following information shall be included:	→ PRES is seeking written comments on one delegation's question about which information EEA might have to make available to ECHA in this context, as EEA has no competences about chemical products.	
Article			

10(3), point (a)			
172	(a) substance identity;		
Article 10(3), point (b)			

173	(b) the Union act and the regulatory process under which the activity takes place;		
Article 10(3), point (c)			
174	(c) submitter or actor responsible for the regulatory process or activity;		
Article 10(3), point (d)			
175	(d) status of the regulatory process or activity;		
Article 10(3), point (e)			
176	(e) where applicable , outcome of the regulatory process or activity ~~, including, where applicable, and~~ reports or opinions adopted;	☐ PRES understand from one delegation's comment that it is not always possible to indicate the (future) outcome, so this provision is not always applicable. → PRES propose to amend art 10(3) by inserting "where applicable" as we see it more precise than "where appropriate"	
Article 10(3), point (f)			
177	(f) where applicable, date of intention to start the regulatory process or activity, completion and latest update.		
Article 10(4)			
178	4. The information referred to in paragraph 3, points (a) to (f), on a specific regulatory process or activity shall be made available to the public once that process or activity has formally started.		
Article 11			
179	Article 11	☐ PRES notes one delegation's comment on the potentiality of	

	Information on the obligations under Union acts on chemicals	IA in this context.	

Article 11(1)			
180	1. The ECHA shall establish and manage, as part of the common data platform, a database with information on the provisions and legal obligations applicable to chemicals under the Union acts listed in Annex I.		
Article 11(2)			
181	2. The ECHA shall update the information in the database on a regular basis and in accordance with the governance scheme referred to in Article 4(3).		
Article 12			
182	Article 12 Repository of standards formats and controlled vocabularies		
Article 12(1)			
183	1. The ECHA shall establish and manage as part of the common data platform a repository of standard formats and controlled vocabularies.		
Article 12(2)			
184	2. Where standard data formats are established under the Union acts listed in Annexes I and II, the ECHA shall include them in the common data platform.		
Article 12(3)			
185	3. Where the Commission or the Agencies specify a standard format or controlled vocabulary in accordance with Articles 14 or 15, the Commission or the Agency shall make it available to the ECHA without undue delay for integration in the common data platform.		
Article 13			

186	Article 13 Database on environmental sustainability related data	One delegation requested for a new annex on relevant legal acts, see discussion of Article 2(11) → PRES: see line 82 here above □ About the role of EIONET in this	

		→ PRES included this in the discussion at the WP2 (effort needed by MS)	
Article 13(1)			
187	1. At the latest within three years after the publication of the decision referred to in paragraph 4, the ECHA shall establish and manage, as part of the common data platform, a database containing environmental sustainability related data.		
Article 13(2)			
188	2. Where the Commission or the Agencies host or hold environmental sustainability related data in addition to the chemicals data already available in the common data platform, they shall make that data available to the ECHA without undue delay once the Commission or the Agency hosting or holding that data has completed, where relevant, validity and confidentiality assessments. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of environmental sustainability related data in the database on environmental sustainability related data.		
Article 13(3)			
189	3. Where researchers or research consortia funded by Union framework programmes make available to the ECHA, under Article 5(6), any environmental sustainability data on chemicals or materials they collect or generate, the ECHA shall integrate the relevant data in the database on environmental sustainability related data.		
Article 13(4)			

190	4. By [OP please insert date: three years after the date of entry into force of this Regulation], the Commission shall adopt an implementing decision identifying existing datasets on environmental sustainability related data, other than those referred to in paragraph 2, for inclusion in the common data platform and shall design relevant related database functionalities.	→ PRES is seeking legal advice about the wording “implementing decision” (cfr delegation comment). Council legal services provided an opinion on this at the 2 nd WP.	
Chapter III			

191	Chapter III DATA FORMATS AND CONTROLLED VOCABULARIES	→ PRES seeks written comments on one delegation’s request to eventually have study reports and raw data provided → PRES seek written comments on the request by one delegation to investigate that there is no impact on the use of INCI names for cosmetics regulation, and no impact on substance identification and product labelling in that regulation.	
Article 14			
192	Article 14 Standard formats	One delegation amendment proposal on statistical risk: → PRES: see here Article 2(6) line 77	
Article 14(1)			
193	1. Without prejudice to Union provisions providing for the development or making available of data formats, the Commission and the Agencies shall specify, where relevant, for the data referred to in Article 3 (2) and falling within their mandate, standard formats and software packages and make them available free of charge through the common data platform.		
Article 14(2)			
194	2. The standard formats referred to in paragraph 1 shall, to the extent possible:		
Article 14(2), point (a)			

195	(a) avoid the use of proprietary standards;		
Article 14(2), point (b)			
196	(b) re-use existing data formats or parts of them;		
Article 14(2), point (c)			
197	(c) use OECD or other internationally agreed formats;		
Article 14(2), point (d)			

198	(d) be coherent with other existing data formats;		
Article 14(2), point (e)			
199	(e) ensure interoperability with existing data submission approaches.		
Article 14(3)			
200	3. Those standard formats shall be interoperable with the common data platform and be user-friendly.		
Article 14(4)			
201	4. The Commission and the Agencies shall exchange data contained in the common data platform in the relevant standard format.		
Article 14(5)			
202	5. The Commission and the Agencies shall use the International Uniform Chemical Information Database format (IUCLID) for making available to the ECHA for integration in the common data platform the relevant parts of dossiers under the following Union acts:		

Article 14(5), point (a)			
203	(a) Regulation (EC) No 1831/2003 of the European Parliament and of the Council ⁵³ ; ⁵³ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268 18.20.2003, p. 29).		
Article 14(5), point (b)			
204	(b) Regulation (EC) No 1935/2004 of the European Parliament and of the Council ⁵⁴ ; ⁵⁴ Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and		

	89/109/EEC (OJ L 338 13.11.2004, p. 4).		
Article 14(5), point (c)			
205	(c) Regulation (EC) No 1331/2008 of the European Parliament and of the Council ⁵⁵ ; ⁵⁵ Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354 31.12.2008, p. 1).		
Article 14(5), point (d)			

206	(d) Regulation (EC) No 1332/2008 of the European Parliament and of the Council ⁵⁶ ; ⁵⁶ Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354 31.12.2008, p. 7).		
Article 14(5), point (e)			
207	(e) Regulation (EC) No 1333/2008 of the European Parliament and of the Council ⁵⁷ ; ⁵⁷ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354 31.12.2008, p. 16).		
Article 14(5), point (f)			
208	(f) Regulation (EC) No 1334/2008 of the European Parliament and of the Council ⁵⁸ ; ⁵⁸ Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food		

	ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354 31.12.2008, p. 34).		
Article 14(5), point (g)			

209	(g) Regulation (EC) No 1223/2009 of the European Parliament and of the Council 59; ⁵⁹ Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342 22.12.2009. p, 59).		
Article 14(5), point (h)			
210	(h) Commission Regulation (EU) No 234/2011⁶⁰; ⁶⁰ Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 064 11.3.2011, p. 15).		
Article 14(5), point (i)			
211	(i) Directive 2009/48/EC of the European Parliament and of the Council.⁶¹ ⁶¹ Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170 30.6.2009, p. 1).		
Article 14(6)			
212	6. The Commission and the Agencies shall cooperate when setting standard formats to ensure coherence with other formats and the interoperability of the standard formats with the common data platform and with existing data submission approaches.		
Article 14(7)			

213	7. The Commission and the Agencies shall take the necessary and appropriate measures to monitor and identify at an early stage any potential divergence between data formats that could cause interoperability problems. If a divergence is identified, the Agencies concerned shall cooperate to resolve it or, where the divergence is justified, explain the underlying reasons. Where the Agencies concerned are not able to resolve that divergence, they shall draw up a joint report and present it to the Commission. The report shall clearly outline the reasons for the divergence, clarify any underlying technical issue and make a proposal to remedy the divergence.		
Article 14(8)			
214	8. The Commission shall adopt an implementing decision to remedy the divergence.		
Article 15			
215	Article 15 Controlled vocabularies	→ PRES is seeking written comments on the remarks by one delegation about the difficulties related to differences in vocabularies between legislations. → PRES seeks for comments on the difficulties related to substances identification inconsistencies between regulations (see delegation comment). PRES highlights that this problem is also relevant for art.22,25,26 on studies notification (a lack of correct identification might render difficult to implement them)	
Article 15(1)			
216	1. The Commission and the Agencies shall specify and regularly update controlled vocabularies within their mandate for the data referred to in Article 3(2), where relevant.		
Article 15(2)			
217	2. The Commission and the Agencies shall prioritise specifying controlled vocabularies for the identification of chemicals and the characterisation of their forms.		

Article 15(3)			
218	3. Those controlled vocabularies shall:		
Article 15(3), point (a)			
219	(a) avoid the use of proprietary controlled vocabularies to the extent possible;		
Article 15(3), point (b)			
220	(b) re-use existing substance identifiers and controlled vocabularies or parts of them to the extent possible;		
Article 15(3), point (c)			
221	(c) use OECD or other internationally agreed controlled vocabularies to the extent possible;		
Article 15(3), point (d)			
222	(d) ensure coherence with other relevant controlled vocabularies including by preparing alignment tables.		
Article 15(4)			
223	4. Those controlled vocabularies shall be interoperable with the common data platform.		
Article 15(5)			
224	5. Where controlled vocabularies are specified, the Commission and the Agencies shall:		

Article 15(5), point (a)			
225	(a) make them available free of charge through the common data		

	platform and as open datasets;		
Article 15(5), point (b)			
226	(b) integrate them in any submission software or template to be used by duty holders under the Union acts listed in Annex I and referred to in Article 3(2); and		
Article 15(5), point (c)			
227	(c) use them when exchanging data between them through the common data platform.		
Article 15(6)			
228	6. The Commission and the Agencies shall cooperate with each other in setting the controlled vocabularies.		
Article 15(7)			

229	7. The Commission and the Agencies shall take the necessary and appropriate measures to monitor and identify at an early stage any potential divergence between controlled vocabularies. If a divergence is identified, the Agencies concerned shall cooperate to resolve it or, where the divergence is justified, explain the underlying reasons. Where the Agencies concerned are not able to resolve that divergence, they shall draw up a joint report and present it to the Commission. The report shall clearly outline the reasons for the divergence, clarify any underlying technical issue and make a proposal to remedy the divergence.		
Article 15(8)			
230	8. The Commission shall adopt an implementing decision to remedy the divergence.		
Chapter IV			
231	Chapter IV	→ PRES: some delegation's comments here were discussed at the	

	CHEMICALS DATA CONFIDENTIALITY AND USE	WP2.	
Article 16			
232	Article 16 Access rights and transparency	→ PRES: One delegation request and questions (line 232 of the comments file) were discussed at the WP2.	
Article 16(1)			
233	1. The Authorities shall have access to all the chemicals data contained in the common data platform, including data which is deemed to be confidential under Article 5(2), second sentence.		
Article 16(2)			
234	2. The Authorities shall take the necessary measures to ensure that information contained in the common data platform marked as confidential in accordance with Article 5(2) is not made public.	→ PRES: One delegation comment and questions were discussed at the WP2 (line 234 of the comments file)	IE: We welcome further discussion and clarity on the issue of confidentiality of data and the re-use of

PUBLIC

			data. Regarding Article 16(2), we would like clarification as to whether it is expected that MSs will access the platform in a similar manner as to how they currently access REACH IT and ECHA MSCA applications and so be required to have similar security requirements in place, be subject to audit, etc. We would also like clarification as to how the provision of information in the common data platform will align itself with article 25(3) of REACH and the 12 year rule on access to data? In that regard, what processes will be put in place to prevent a company using publicly available data to fulfil their legal obligations that was submitted (e.g. under REACH) and is owned by another company?
Article 16(3)			

235	3. The general public shall have access to all the chemicals data contained in the common data platform and considered as available to the public in accordance with the Union act under which the data was generated or submitted.		
Article 17			
236	Article 17 Use of chemicals data contained in the common data platform	One delegation comment on the meaning of “products” is addressed here in art.2 (see line 70). PRES: Regarding the other comments: → PRES seeks written comments on one delegation’s concern on the identification in the data platform of cosmetics ingredients that may have been tested on animals. → PRES invites the COM to update MS on the possibility of an overview table on confidentiality provisions requested by one delegation.	
Article 17(1)			
237	1. The Authorities may use the chemicals data contained in the common data platform in the performance of any of their activities, where those activities support the development or implementation of	→ PRES: one delegation requested for amendment to explicitly allow national use of the data was set for discussion at WP2.	

	chemicals legislation and policy.		
Article 17(2)			
238	2. Without prejudice to existing provisions enabling the sharing and use of chemicals data under the Union acts listed in Annexes I and II, Authorities shall not use chemicals data contained in the common data platform to fulfil any legal obligations of duty holders.	One delegation requested clarifications on the use of data in relation to duty holders obligations. → PRES invites for written comments on this.	
Article 17(3)			

239	3. When using chemicals data contained in the common data platform that is deemed confidential under Article 5(2), second sentence, the Authorities shall respect the confidentiality of information data as marked by the originator and shall not disclose that data to the public without the consent of the originator.		
Chapter V			
240	Chapter V MONITORING AND OUTLOOK FRAMEWORK FOR CHEMICALS		
Article 18			
241	Article 18 Framework of indicators	One delegation questioning the MS involvement was set for discussion at the 2nd WP → PRES put the question on EIONET impacts for discussion at the 2nd WP. One delegation comments on cosmetics: → PRES invites for written comments on questions raised by one delegation on cosmetics aspects (notification of undesirable effects, link to the Communication System for Market Surveillance (ICSMS) Art 23 Reg 1223/2009, consequences on the allowance of use for critical circumstances). One delegation comment on the relation to existing statistics systems → PRES invites for written comments	
Article 18(1)			
242	1. The EEA, in collaboration with the ECHA, the EFSA, the EMA, the EUOSHA and the Commission, shall establish, operate, and maintain a framework of indicators to monitor the drivers and impacts of exposure to chemicals, measure the effectiveness of chemicals legislation and measure the transition towards the production of safe and sustainable chemicals.		

Article 18(2)			
243	2. The framework of indicators referred to in paragraph 1 shall be accessible in the form of an indicator dashboard, which the EEA shall establish and which the ECHA shall make available through the common data platform.		
Article 18(3)			
243.b	3. The framework of indicators referred to in paragraph 1 shall be shall established, operated, and maintained by [OP: please insert date: 3 years after the end of the first calendar year after entry into force of this Regulation].	One delegation expressed concerns on the timescale for establishing the framework PRES highlights that several other articles contain indications on the timeframe → PRES submits this amendment for consideration, and discussion took place at the 2nd WP.	
Article 19			
244	Article 19 Early warning and action system for emerging chemical risks	→ PRES: One delegation's question on MS experts and RAC involvement was set for discussion at 2nd WP → PRES: One delegation's request for clarification on implications/role of EIONET and MS was set for discussion at the 2nd WP □ Regarding the other comments: → PRES seeks written comments about one delegation's question on the relation between the indicators and the early warning system (art.18,19). → PRES invites for written comments on the question regarding the level of ambition of the system in relation to complex systemic risks.	
		→ PRES invites written comment on the proposal to include the word "prevention" in the proposal	

Article 19(1)			
245	1. The EEA shall establish, operate and maintain a Union early warning system for emerging chemical risks by [OP please insert date: one year after the date of entry into force of this Regulation].		
Article 19(2)			
246	2. For the purpose of paragraph 1, the EEA shall compile early warning signals, which shall include at least signals from:		
Article 19(2), point (a)			
247	(a) the EFSA's emerging risks exchange network;		
Article 19(2), point (b)			
248	(b) existing national early warning systems;		
Article 19(2), point (c)			
249	(c) data that the EEA holds;		
Article 19(2), point (d)			
250	(d) targeted literature searches performed by the EEA;		
Article 19(2), point (e)			

251	(e) data made available by the ECHA, the EFSA, the EU-OSHA and the EMA in accordance with paragraph 3.		
Article 19(2)			
252	The early warning signals compiled by the EEA under the first		

	subparagraph may be based on a positive identification of an emerging risk or on an uncertainty in the data leading to a potential positive identification of an emerging risk.		
Article 19(3)			
253	3. The ECHA, the EFSA, the EU-OSHA and the EMA shall identify and gather relevant available data on early warning signals from the field falling within their mandate and provide this data to the EEA.		
Article 19(4)			
254	4. The EEA shall draw up an annual report, compiling and analysing the data on early warning signals gathered in accordance with paragraphs 2 and 3. [The first report shall be prepared by [OP: please insert date: 6 months after the end of the first calendar year after entry into force of this Regulation]. The EEA shall present this report to the Commission, relevant Union agencies and ~~Member State competent authorities for consideration of the need~~ Member State competent authorities who shall consider the need for regulatory or policy action related to the early warning signals.	One delegation expressed questions the request to EEA to highlight areas on which to FOCUS, in the report. PRES suppose that this may be solved by a change in the wording (mostly editorial) → PRES proposes for consideration a proposed amendment to the text.	
Article 19(5)			
255	5. The EEA shall make all relevant data on early warning signals that it holds or hosts as well as the report referred to in paragraph 4 available to the ECHA for integration in the common data platform.		
Article 20			

256	Article 20 Observatory for specific chemicals with potential contribution to emerging chemical risks	PRES seeks written comments on one delegation's question about the type of risks covered here, and the interplay with existing chemicals legislation.	
Article 20(1)			
257	1. The ECHA shall establish, operate and maintain an observatory for specific chemicals that the Commission considers as requiring additional scrutiny. The observatory shall include reliable information on the chemicals' properties, safety aspects, uses and market presence.		
Article			

20(2)			
258	2. By [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall adopt and publish a list of the selected chemicals by means of an implementing decision. The Commission shall review the list of selected chemicals regularly and adopt any revision thereof by the same means.	One delegation highlighted that the linking word "and" is missing before the proposal "adopt any revision thereof by the same means". à PRES sees this as an editorial amendment and proposes to modify article 20(2) consequently (see <i>bold italic</i>). One delegation requested for amendments (implementing "decisions"). → PRES: questions on the meaning of "implementing", and MS participation were discussed at the 2nd WP.	
Article 20(3)			
259	3. The Commission shall select the chemicals referred to in paragraph 1 based on the scientific and technical progress and using the signals of the early warning system referred to in Article 19. The selection shall include potential contributors to new and emerging chemical risks among innovative rationally designed materials with new or enhanced properties or targeted or enhanced structural features at nanoscale.		
Article 20(4)			

260	4. For the purpose of operating the observatory referred to in paragraph 1, the ECHA shall:		
Article 20(4), point (a)			
261	(a) make use of relevant datasets integrated in the common data platform, and compile, analyse and curate further available data on selected chemicals or classes of chemicals;		
Article 20(4), point (b)			
262	(b) commission studies and, where relevant, use the data generation mechanism established under Article 21 to address knowledge gaps or significant uncertainties;		
Article			

20(4), point (c)			
263	(c) make compiled data publicly available through the common data platform or other communication and outreach tools as appropriate, to facilitate informed societal discussion and increase public awareness on the properties, use and safety aspects of specific chemicals, and regularly update that information.		
Chapter VI			
264	Chapter VI DATA GENERATION MECHANISM		
Article 21			

265	Article 21 Data generation mechanism	One delegation raised the question of the promotion of animal testing in relation to article 1. PRES understands that the type of tests are prescribed in each regulation mentioned in annex I, and thus this regulation is not modifying that. However, art.21 here is new, and thus the question of the minimization of animal testing might be relevant here. One delegation would like to know if commissioned animal studies will be notified → PRES requests written reactions and proposals on this matter. One delegation expressed the need to frame the mandate in such a way that the burden of proof on companies is preserved. One delegation insisted also on the burden of proof on industry and highlights the need for clarity on procedures and financing. → PRES invites for written comments and amendments proposals. Some Comments were received in relation to the involvement of MS, industry, stakeholders in the data generation mechanism. → PRES: discussion during the 2nd WP	IE: We support that consideration be given to including text in relation to the minimisation of animal testing here. We support the comments raised by NL and ES in relation to the burden of proof remaining with industry.
Article 21(1)			
266	1. Using the best independent resources available, the ECHA may commission scientific studies to support the implementation of Union acts on chemicals listed in Annex I within its mandate and to contribute	One delegation requested clarity on the meaning of scientific studies, and which ones will not be covered. → PRES invites for written comments on this	

	to the support, evaluation or development of a Union chemicals policy.		
Article 21(2)			
267	2. The Commission may request the ECHA to commission the scientific studies referred to in paragraph 1.		
Article 21(3)			

268	3. The ECHA shall only commission scientific studies when results cannot be obtained through existing legal provisions or processes under Union legislation listed in Annex I. It shall not commission studies with a predominant research objective.		
Article 21(4)			
269	4. The ECHA shall seek to avoid duplication with Member State or Union research or implementation programmes.		
Article 21(5)			
270	5. The ECHA shall commission these scientific studies in an open and transparent manner.	One delegation suggested to amend this to introduce compulsory prior MS consultation. → PRES scheduled this for discussion at the 2nd WP	IE: We support DK's comment here. We question as to whether there will be MS 'agreement' of the study to be carried out as is the case for example currently under the REACH evaluation process. Also, will the impacted industry stakeholders be consulted on the proposed studies to be commissioned? Overall, we would like clarification on the envisaged process that will be put in place to ensure that the studies are commissioned by ECHA in an 'open and transparent manner'.

Article 21(6)			
271	6. The ECHA and the EFSA shall closely cooperate with each other on the planning and commissioning of scientific studies undertaken by the ECHA in accordance with paragraph 1 and of studies undertaken by the EFSA in accordance with Article 32 of Regulation (EC) No 178/2002.		
Article 21(7)			
272	7. The ECHA shall make the results of the scientific studies performed under this Article available through the common data platform.		
Chapter VII			
273	Chapter VII NOTIFICATION OF STUDIES	Several comments were received on this chapter: on the legal scope and definition of studies to be notified, duplications, studies conducted outside the EU, late notifications, absence of a transitional period, practical arrangements for companies, the need	IE: We welcome further discussions generally on this chapter in line with the comments raised by MSs. Can it also be clarified as to the overlap, if any, between the obligation to notify a study under this Regulation and the obligation to submit a testing proposal under REACH in certain circumstances. Will the two processes run in parallel? Or, for example, would an operator need to have received a testing proposal decision from ECHA before notifying to the database of study notifications?

		for early access before publication in the data platform. → PRES scheduled this for discussion at the 2 nd WP	
Article 22			
274	Article 22 Notification of studies		
Article 22(1)			
275	1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, without undue delay, any studies on chemicals they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment, prior to placing on the market, under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.		
Article 22(2)			
276	2. For the purposes of paragraph 1, business operators shall notify to the Database of Study Notifications referred to in Article 9 the title, scope, laboratory, or testing facility carrying out the study, the intended starting and planned completion dates and, where relevant, whether the study is commissioned to comply with a decision of the ECHA pursuant to Articles 40, 41 or 46 of Regulation (EC) No 1907/2006.		
Article 22(3)			
277	3. Laboratories and testing facilities shall also, without undue delay, notify any study commissioned by business operators to support a regulatory dossier on which an Agency is required to provide a scientific output, including a scientific opinion, under the Union acts listed in Annex I. However, laboratories and testing facilities shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.		

Article 22(4)			
278	4. For the purposes of paragraph 3, laboratories and testing facilities shall notify to the Database of Study Notifications referred to in Article 9 the title, scope, intended starting and planned completion dates of any test they carry out, as well as the name of the business operator who commissioned the test.		
Article 22(5)			
279	5. Paragraphs 3 and 4 shall apply, mutatis mutandis, to laboratories and testing facilities located in third countries insofar as set out in relevant agreements with those third countries.		
Article 22(6)			
280	6. The obligations set under this article shall apply from [OP please insert date: 24 months after the date of entry into force of this Regulation].		
Article 22(7)			
281	7. The ECHA shall lay down the practical arrangements for implementing the provisions of this Article.		
Chapter VIII			
282	Chapter VIII DELEGATED POWERS		
Article 23			
283	Article 23 Amendment of Annexes I, II and III		
Article 23(1)			

284	1. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex I in order to adjust the content of that Annex to technical and scientific progress in the field of chemicals or, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it new Union acts under which relevant chemicals data is generated or submitted.		
Article			

23(2)			
285	2. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex II by adding, where relevant, new categories of data types.		
Article 23(3)			
286	3. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex III in order to adjust the content of that Annex to technical and scientific and technical progress in the field of chemicals and, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it Union acts relevant for data on new regulatory processes on chemicals.		
Article 24			
287	Article 24 Exercise of the delegation		
Article 24 (1)			
288	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.		
Article 24(2)			

289	2. The power to adopt delegated acts referred to in Article 23 shall be conferred on the Commission for a period of five years from [OP please insert: the date of the entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each five-year period.		
Article 24(3)			
290	3. The delegation of power referred to in Article 23 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that		

	decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.		
Article 24(4)			
291	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.		
Article 24(5)			
292	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.		
Article 24(6)			

293	6. A delegated act adopted pursuant to Article 23 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.		
Chapter IX			
294	Chapter IX ENFORCEMENT AND PENALTIES	One delegation expressed concerns on enforcement for third countries; one delegation questioned the effectiveness of national sanctions. → PRES scheduled this for discussion at the 2 nd WP	IE: Enforcement of the notification provision may be difficult for MSs who do not have fines in place for example (IE does not have such a fines system). The breach would be that the study will have been conducted without having been notified. What then would the 'penalty' be on the company instead of a fine? It is a similar case to studies conducted under REACH without a testing proposal, which is a difficult issue to enforce retrospectively.
Article 25			
295	Article 25 Enforcement The Agencies shall cooperate with Member States' enforcement		

	authorities and exchange information on the compliance, by business operators and laboratories, with the obligation to notify studies in accordance with Article 22.		
Article 26			
296	Article 26 Penalties for non-compliance		
Article 26(1)			
297	1. Member States shall introduce penalties for non-compliance, by business operators and laboratories, with the obligations laid out in Article 22 and shall take all necessary measures to ensure that they are implemented. The penalties provided for shall be effective, proportionate, and dissuasive.		
Article 26(2)			
298	2. Member States shall notify the Commission of those rules and of those measures by 30 June 2025 and shall notify to the Commission without delay any subsequent amendment affecting them.		
Article 27			
299	Article 27 Entry into force and application in time This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.		
Formula			
300	This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels, For the European Parliament For the Council The President The President		

PUBLIC

	Presidency proposals: amendments (~~deletions~~ / additions)	Presidency proposals: follow-up or proposal to work on amendments, or requests for written comments	Reactions from the Commission and MS
Annex I			
301	Annex I UNION ACTS REFERRED TO IN ARTICLES 2, 3, 8, 11, 12, 15, 17, 21, 22 AND 23 Reference to each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.		
302	1. Council Directive 91/271/EEC of 21 May 1991 concerning urban wastewater treatment (OJ L 135, 30.5.1991, p. 40)		

303	2. Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources (OJ L 375, 31.12.1991, p.1)		
304	3. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1)		
305	4. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste		
306	5. Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11)		
307	6. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50)		

308	7. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34)		
309	8. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for the Community action in the field of water policy (OJ L 327, 22.12.2000, p.1)		
310	9. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate		
	release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1)		
311	10. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p. 1)		
312	11. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10)		

313	12. Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51)		
314	13. Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1)		
315	14. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29)		
316	15. Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (OJ L 309, 26.11.2003, p. 1)		
317	16. Regulation (EC) No 853/2004 of the European		
	Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55)		
318	17. Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1)		

319	18. Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1)		
320	19. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)		
321	20. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3)		
322	21. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 070, 16.3.2005, p. 1)		
323	22. Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant		

	Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC (OJ L 033, 4.2.2006, p. 1)		
324	23. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19)		
325	24. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)		
326	25. Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9)		
327	26. Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26)		

328	27. Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an		
	Infrastructure for Spatial Information in the European Community (INSPIRE) (OJ L 108, 25.4.2007, p. 1)		
329	~~28. Regulation (EC) No 108/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 39, 13.2.2008, p. 11)~~	One delegation highlighted the fact that regulation 108/2008 is mentioned in point 28 of Annex I, whereas this regulation is already covered by regulation 1925/2006 mentioned in point 26 of Annex I. →PRES proposes to amend the text (deleting point 28).	
330	29. Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19)		
331	30. Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1)		

332	31. Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3)		
333	32. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive		
	2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84)		
334	33. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)		
335	34. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)		

336	35. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC, and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p.7)		
337	36. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16)		
338	37. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91,		
	Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34)		
339	38. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energyrelated products		

340	39. Regulation (EC) No 401/2009 of the European Parliament and of the Council of 23 April 2009 on the European Environment Agency and the European Environment Information and Observation Network (OJ L 126, 21.5.2009, p. 13)		
341	40. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3)		
342	41. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1)		
343	42. Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal byproducts and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (OJ L 300, 14.11.2009, p. 1)		
344	43. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009		

	concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)		
345	44. Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71)		
346	45. Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28)		
347	46. Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community ecomanagement and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC (OJ L 342, 22.12.2009, p. 1)		
348	47. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)		

349	48. Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17)		
350	49. Regulation (EC) No 66/210 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel (OJ L 027, 30.1.2010, p. 1)		
351	50. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)		
352	51. Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18)		

353	52. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)		
354	53. Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.7.2012, p. 1)		
355	54. Directive 2012/19/EU of the European Parliament		
	and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38)		
356	55. Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the import and export of hazardous chemicals (OJ L 201, 27.7.2012, p. 60)		

357	56. Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35)		
358	57. Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (OJ L 96, 29.3.2014, p. 1)		
359	58. Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1)		

360	59. Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006 (OJ L 150, 20.5.2014, p. 195)		
361	60. Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1)		
362	61. Directive (EU) 2016/2284 of the European Parliament and of the Council of 14 December 2016 on the reduction of national emissions of certain atmospheric pollutants, amending Directive 2003/35/EC and repealing Directive 2001/81/EC (OJ L 344, 17.12.2016, p. 1)		

363	62. Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council		
	Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 095, 7.4.2017, p. 1)		
364	63. Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1)		

365	64. Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008 (OJ L 137, 24.5.2017, p. 1)		
366	65. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).		
367	66. Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing		
	Regulation (EC) No 2003/2003 (OJ L 170, 25.6.2019, p. 1)		
368	67. Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45)		

369	68. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435, 23.12.2020, p. 1)		
370	69. Regulation (EU) .../... of the European Parliament and of the Council on nature restoration (OJ .../ELI: ... [OP: please add number and publication reference].		
371	70. Regulation (EU) .../... of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (OJ .../ELI: ... [OP: please add number and publication reference]		
ANNEX II			
372	ANNEX II UNION ACTS REFERRED TO IN ARTICLES 2, 3, 12, 17 AND 23 AND REFERENCE VALUES REFERRED TO IN ARTICLE 8		
Part 1			
373	Part 1 - Specific data on relevant active substances to be identified in accordance with Article 4(5)(b) falling under the scope of this Regulation for the purposes of		
	Article 3 for human and veterinary medicinal products		



374	1. Non-clinical safety data, including data related to environmental risk assessments, compiled pursuant to Directive 2001/83/EC of the European Parliament and of the Council¹ and Regulation (EC) No 726/2004 of the European Parliament and of the Council²; ¹ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67). ² Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).		
375	2. Data related to environmental risk assessments, compiled pursuant to Regulation (EU) 2019/6 of the European Parliament and of the Council³; and ³ Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).		
376	3. Maximum residue levels data compiled pursuant to Regulation (EC) No 470/2009 of		

	the European Parliament and of the Council⁴. ⁴ Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).		
377	These data shall be limited to data submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation. Where relevant, the data held by the EMA resulting from procedures concluded before the entry into force of this Regulation may also be considered for inclusion into the common data platform.		

Part 2			
378	Part 2 - Reference values to be included in the repository of reference values following Article 8(3)		
379	1. Predicted no effect concentrations derived as part of the environmental risk assessment under Directive 2001/83/EC of the European Parliament and of the Council, Regulation (EC) No 726/2004 of the European Parliament and of the Council and Regulation (EU) 2019/6 of the European Parliament and of the Council.		
380	These data shall be limited to data submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation. Where relevant, data held by the EMA resulting from procedures concluded before the date of entry into force of this Regulation shall also be considered for inclusion into the common data platform.		
Annex III			
381	Annex III UNION ACTS REFERRED TO IN ARTICLES 2, 10 AND 23		

382	Reference to each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.		
383	1. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1)		
384	2. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste		
385	3. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50)		
386	4. Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11)		
387	5. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34)		

388	6. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p. 1)		
389	7. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10)		
390	8. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29)		
391	9. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)		
392	10. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3)		

393	11. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1)		
394	12. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19)		
395	13. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)		
396	14. Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38)		

397	15. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84)		
398	16. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)		
399	17. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)		
380	18. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC, and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008,		

	p.7)		
381	19. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16)		
382	20. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34)		
383	~~21. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)~~	Some delegations highlighted the fact that Regulation 1331/2008 is mentioned twice: in points 17 and 21 of Annex III. → PRES proposes to amend the text (deleting this repetition).	
384	22. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3)		

385	23. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energyrelated products		
386	24. Directive 2009/48/EC of the European Parliament		

	and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1)		
387	25. Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer (OJ L 286, 31.10.2009, p. 1)		
388	26. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)		
389	27. Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28)		

390	28. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)		
391	29. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)		
392	30. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)		
393	31. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).		
394	32. Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45)		
395	33. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435, 23.12.2020, p. 1)		

396	34. Regulation (EU) .../... of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (OJ .../ELI: ... [OP: please add number and publication reference].		

14/03/2024

Proposal for a

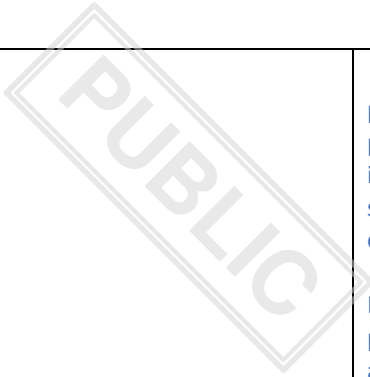
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the **re-attribution** of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals

(Text with EEA relevance)

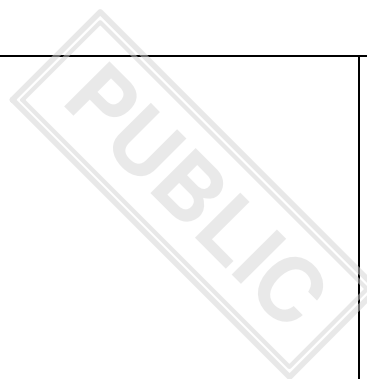


Line nr.		Presidency proposal: amendments (~~deletions~~ /additions)	Presidency justification after WP1: follow-up or proposal to work on amendments, or requests for written comments	Delegates comments/proposals after WP2

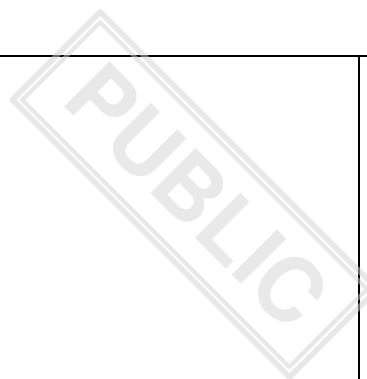
1		THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 43, 114, 168(4)(c), 192(1) and 207 thereof, Having regard to the proposal from the European Commission, After transmission of the draft legislative act to the national parliaments, Having regard to the opinion of the European Economic and Social Committee, Having regard to the opinion of the Committee of the Regions, Acting in accordance with the ordinary legislative procedure, Whereas:		IE: Overall, we support that the legislative proposal needs to provide for the Agency to provide the Member States and the institutions of the Community with the scientific/technical advice relating to chemicals. However, we are not convinced that the proposal to assign the tasks to ECHA's RAC and SEAC is the right approach. These committees were established for the purpose of undertaking REACH tasks. We are already concerned with the workload of the Committee. The proposed extra workload for these committees will impact the institutions/authorities who have provided the members and experts for the RAC and SEAC. While we acknowledge the thinking behind the possible benefits of the Commission's proposal, we are mindful of the impacts of it, particularly for ECHA Committee members. While there will be impacts on ECHA and we support the calls for adequate resourcing of ECHA, the most significant impacts on the ECHA Committees will fall back on the members nominated by the Member States, thus impacting the Member State resources significantly. Experts are generally experts in a particular area. It will be impossible to find two sufficient experts nominations in all areas for RAC/SEAC.

2	Recital 1	The European Green Deal ¹ sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability ² ('the Strategy') is a crucial delivery of the zero-pollution ambition and introduces the 'one		
		substance, one assessment' approach, which aims to improve the efficiency, effectiveness, coherence, and transparency of safety assessments of chemicals across Union legislation. ¹Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal. COM (2019) 640 final. ²Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability Towards a ToxicFree Environment. COM (2020) 667 final		

3	Recital 2	In order to achieve this objective, a part of the scientific and technical work on chemicals performed at Union level in support of Union legislation needs to be consolidated in the relevant Union agencies, while obligations on Union agencies to cooperate for the development of assessment methodologies and exchange of data and information should be introduced. This would simplify the current set-up, improve quality and coherence of safety assessments across Union legislation and ensure more efficient use of existing resources.		
4	Recital 3	The reattribution of certain existing scientific and technical tasks to the	Many concerns were raised during the commenting about:	IE: We thank PRES for noting our concerns here and we welcome further discussion on this proposal. We have indicated our general view on this above (line Nr 1) and include our key concerns and proposals again below for the discussions. The mandate of the RAC was extended in 2008 to include opinions on harmonised classification and that classification workload has now been broadened with the recent introduction of new hazard classes in CLP. The RAC's mandate was then further extended to developing occupational exposure limits under occupational health and safety legislation and limits for drinking water, despite the REACH legislation only



			providing for two expert nominations per Member State. While we acknowledge that the Committee membership is not at full capacity the assigning of additional tasks to the Committee may in fact further discourage further uptake by new members of the existing vacant positions, as experts do not have the technical competence in the newly assigned areas. It would seem to be more appropriate to allow ECHA the scope to establish expert groups (Committees) outside of the current RAC & SEAC mandates. Expert participation could be encouraged by allowing a greater number of experts to cover different aspects of ECHA's opinion making tasks. In some instances, we believe it would be more appropriate to assign the task(s) to prepare an opinion to ECHA rather than RAC & SEAC, and allow ECHA to best determine the most efficient and appropriate way to deliver the opinion. For example, ECHA's technical experts could draft opinions and establish technical expert working groups to consult with in order for scientific opinions to be delivered. In certain cases, the Executive Director can still use their powers under Article 77 (3) to issue a request to RAC and SEAC, thus negating the need for all tasks to have a RAC and/or SEAC opinion. In support of our intervention we recall a presentation given by the RAC chair to the



			CARACAL meeting in November 2023, in which it was indicated that the RAC meeting days have increased from about 30 meetings days per year in 2015 to about 50 per year currently, also noting that with the members committee production cannot be increased. It was a similar story from the SEAC chair, who noted a falling number of members since the peak in 2015 and difficulties in filling co-opted members slots. We hold similar views to other Member States, our concern is with the capacity of the individual members to deliver on the expected workload, even if both Committees were at full capacity. Therefore, we see a need for provisions to be included in legislation to amend the composition of the ECHA's committees to cover any ad-hoc Article 77 (3) requests from the Executive Director or to allow ECHA to establish expert groups to undertake additional tasks beyond what has already been assigned to RAC and SEAC. Additionally, remuneration of rapporteurs for all tasks needs to be provided for. We suggest that the OSOA legislative package amends Articles 85 & 87 of REACH to provide for additional experts to cover the additional work and remuneration. We have already suggested some possible legislative changes in this regard. We do appreciate that resourcing is a matter for ECHA's Founding Regulation. However,

				as that Regulation is yet to be published, it is difficult to agree it as a solution when the current proposed legislation is clearly assigning the additional tasks to ECHA's Committees rather than simply to ECHA.

PUBLIC

		European Chemicals Agency, as well as the attribution of new tasks, were proposed as part of ongoing revisions of Union acts. This horizontal proposal aims to provide for further attribution of tasks in respect of those Union acts which are not in the process of being revised and is necessary in order to ensure that the European Chemicals Agency is involved in tasks pertaining to its expertise and developed capacities on chemicals. This is in line with the ‘one substance, one assessment’ aim to ensure that technical and scientific work is performed by the appropriate Union agency, benefiting from demonstrated experience and established tools in its field. The proposal for a Regulation is accompanied by a proposal for a Directive for the amendment of Directive 2011/65/EU of the European Parliament and of the Council³, aiming to achieve the same objectives. ³Directive 2011/65/EU of the European Parliament and of the Council as regards the reattribution of scientific and technical tasks to the European Chemicals Agency	Concerns on ECHA’s capacity, budget (including budget for technical and infrastructure requirements and training), workload, committees, expertise to take on the extra tasks. This relates amongst others to the expertise of committee members (and not only the number of experts), potential establishment of technical expert groups (and how they relate to the Committees’ role), what is to be left for the founding regulation, potential targeted REACH amendments, ECHA and committees expertise in medical devices and in POP-waste. Some specific elements for discussion: One delegation proposed it would be more appropriate to assign the task(s) to prepare opinions to ECHA, and allow ECHA to best determine the most efficient and appropriate way to deliver a robust opinion. For example, ECHA’s technical experts could draft opinions and establish technical expert working groups to consult with in order for scientific opinions to be delivered. In certain cases, the Executive Director can still use their powers under REACH’s Article 77 (3) to issue a request to RAC and SEAC, thus negating the need for all tasks to have a RAC and/or SEAC opinion. This delegation also prefers that the legislative package makes provisions for	

			ECHA to prepare opinions in some circumstances without the explicit need for those opinions to be drafted by RAC and SEAC. In addition, they explained that their concern is with the capacity of the individual members to deliver the expected workload, even if both Committees were at full capacity. Therefore, they see a need for provisions to be included to allow for amending the composition of the current ECHA's committees to cover also any ad-hoc Article 77(3) requests in light of requests from the Executive Director. Finally, the inclusion of remuneration for Committee Rapporteurs for all tasks needs to be provided for. They also recommend the OSOA legislation package amends Article 85 and 87 of REACH to provide for additional experts to cover the additional work and its associated remuneration. PRES: Discussion took place during WP2	

5	Recital 4	As part of the coordinated consolidation and attribution of tasks under the ‘one substance, one assessment’ approach, provisions to allocate a mandate to the European Medicines Agency to develop and cooperate on the development of assessment methodologies, standard		

		formats and controlled vocabularies and exchange of data and information on chemicals have been introduced in Article 138(1), subparagraphs (zd) and (ze), as well as new procedures for ensuring the coherence between scientific opinions in Article 139 of the proposal for a Regulation amending Union pharmaceutical legislation.⁴ ⁴Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006, COM(2023) 193 final. [OJ:Please insert correct reference once the Regulation is adopted].		

6	Recital 5	To ensure the coherence of methodologies for assessments related to chemicals at Union level, all relevant Union agencies should have an equal mandate to develop such methodologies in the areas falling within their respective missions and should be subject to the same obligations to cooperate amongst each other to develop such methodologies.		
7	Recital 6	To ensure the coherence and efficiency of assessments related to chemicals		

		across Union legislation, it is also important to enable data interoperability and easy exchange of data between the relevant Union agencies, as well as to encourage cooperation on the development of standard formats and controlled vocabularies. Thus, to facilitate data exchange between agencies, any new data formats defined by the European Food Safety Authority or by the European Environmental Agency should be set in cooperation with other relevant Union agencies working on chemicals. To this end, relevant provisions should be introduced in Regulation (EC) No 401/2009 of the European Parliament and of the Council and, in Regulation (EC) No 178/2002 of the European Parliament and of the Council, existing provisions should be strengthened and, where relevant, new ones be introduced. Similar provisions should also be considered to be proposed for a strengthened mandate of the European Chemicals Agency in its founding regulation.	

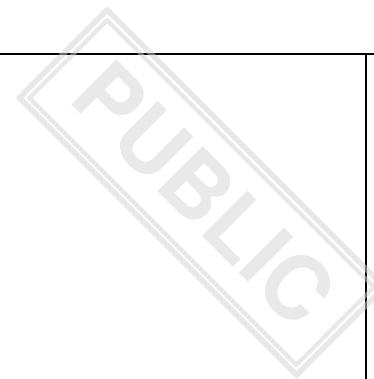
8	Recital 7	To promote the coherence and efficiency of assessments related to chemicals across Union legislation, steps should be taken by the relevant Union agencies to avoid divergent scientific opinions. Existing cases of divergent opinions have lead to increased uncertainty for operators, as well as to declined public		
		trust in the scientific robustness and coherence of scientific decision making. Proposals to address and strengthen procedures for resolving divergence of scientific opinions concerning the European Medicines Agency with other scientific bodies is proposed as part of the revision of Union pharmaceutical legislation. Similar provisions should also be considered to be proposed for a strengthened mandate of the European Chemicals Agency in its founding regulation, whilst such provisions are not relevant and applicable to the European Environmental Agency, since this agency does not issue scientific opinions on individual chemicals such as to be part in divergent outcomes.		

9	Recital 8	Correspondingly, this Regulation aims to address the eventual divergence between scientific opinions of the European Food Safety Authority and those of other Union agencies. Regulation (EC) No 178/2002 of the European Parliament and Council already contains provisions establishing a procedure to solve divergent scientific opinions. Those resolution procedures should be reinforced, in that the European Food Safety Authority and the other dissenting agency should be bound to make their best effort to resolve the divergence on general scientific issues, and only when they are not able to resolve the		
		divergence, should they refer to risk managers.		

10	Recital 9	In the more specific case of scientific divergence pertaining to the hazard identification of chemical substances, a new procedure enabling the resolution of the divergence should be established. This procedure should enable the Commission to request the European Chemicals Agency, as the Union agency most equipped with expertise and capacity in hazard assessment, as well as long-standing experience with the harmonised classification and labelling process, to develop a proposal for harmonised classification and labelling, in accordance the Regulation (EC) No 1272/2008 of the European Parliament and Council, moving closer to the ‘one substance, one assessment’ vision as regards uniformity of hazard assessments of chemicals across the Union. This possibility should be reflected in the relevant provision providing for the resolution of diverging scientific opinions laid down in Regulation (EC) No 178/2002.		
11	Recital 10	To comply with the obligation laid down in Section 10.4.3 of Annex I to Regulation (EU) 2017/745 of the European Parliament and of the Council⁵, the Commission has provided the Scientific Committee on Health,		

		Environmental and Emerging Risks ('SCHEER') with a mandate to prepare guidelines on the benefit-risk assessment of the presence of phthalates which are classified as either carcinogenic, mutagenic or toxic to reproduction category 1A or 1B, or which have endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁶. The SCHEER issued those guidelines in 2019 and the Commission has issued a mandate to the SCHEER to perform a first update of those guidelines. ⁵ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1). ⁶ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation	

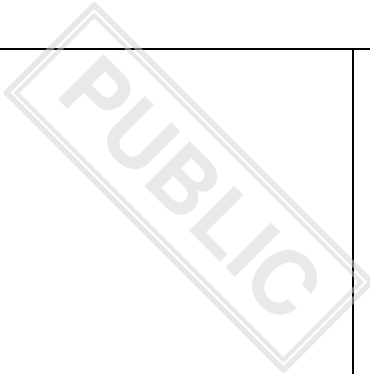
		(EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives		



		91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1–849).		
12	Recital 11	To comply with the obligation laid out in Section 10.4.4. of Annex I to Regulation (EU) 2017/745, the Commission should mandate the relevant scientific committee to prepare guidelines for substances other than phthalates and which are classified as either carcinogenic, mutagenic or toxic to reproduction category 1A or 1B, or which have endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council.		

13	Recital 12	The European Chemicals Agency already provides scientific advice on chemical substances, including on phthalates, endocrine disruptors and carcinogens, mutagens and reproductive toxicants under Regulation (EC) No 1907/2006. Several key capacities of the agency can be reused, including hazard, risk, exposure and socio-economic assessment capacities, the Committee opinion development and IT capabilities for stakeholder consultation and dissemination. To enable timely future updates on the presence of phthalates and		
		to ensure that the appropriate Union agency develops new guidelines on other substances on the basis of the latest scientific evidence, these tasks should be attributed to the European Chemicals Agency.		

14	Recital 13	Taking account of the new hazard classes and criteria for classification, labelling and packaging of substances introduced by Commission Delegated Regulation (EU) 2023/707 of 19 December 2022⁷, reference to endocrine disruptors for human health, of Category 1, should be specified in 10.4.1., point (b) of Annex I of Regulation (EU) 2017/745 in light of the relevance of that hazard class to the type of substances in medical devices. ⁷ Commission Delegated Regulation (EU) 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures (OJ L 93, 31.3.2023, p. 7–39).		
15	Recital 14	To make best use of the European Chemicals Agency's knowledge and expertise gained through its involvement in the nomination and assessment processes under the Stockholm Convention on Persistent Organic Pollutants, the European Chemicals Agency should, upon request, assist the Commission in complying with its		



		obligation to amend Annexes IV and V to Regulation (EU) 2019/1021⁸. Where the opinion of the Committee for SocioEconomic analysis is required, and in order to allow for the necessary capacity and resources for the effective functioning of that committee, Member States should be given the opportunity to cover for the specific expertise required for the effective performance of the task by nominating experts. In order to ensure that the Committee for Socio-Economic analysis benefits from sufficient resources, when the committee appoints one of their members as a rapporteur, that person, or his employer should be remunerated. ⁸ Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45).		

16	Recital 15	In order to amend certain non-essential elements of Regulation (EU) 2019/1021 of the European Parliament and of the Council, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending Annexes IV and V in order to adapt them to the changes to the list of substances set out in the Annexes to the Stockholm Convention or the Protocol or adapt them to scientific and technical progress.		
17	Recital 16	As part of their reporting obligations under the Regulation (EU) 2019/1021 of the European Parliament and of the Council, Member States must report to the European Chemicals Agency information on the presence of substances listed in Part A of Annex III in the environment. The use of the Information Platform for Chemical Monitoring ('IPCHEM') is encouraged as a means for Member States to comply with their obligations to report that chemical occurrence data and to simplify and reduce their reporting obligations. Where Member States make data available through IPCHEM, they no longer need to report it to the European Chemicals Agency, as the agency may retrieve it from the platform.		

18	Recital 17	The revision of the Directive (EU) 2020/2184 of the European Parliament and of the Council⁹ requires Member States to share with European Environmental Agency all chemical occurrence or monitoring data in water. Additionally, the monitoring data on the presence of POPs in air are already being reported by Member States to the EEA as part of the Union air quality legislation. The proposal for a Regulation of the European Parliament and the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable,		

		accessible, interoperable, and reusable and establishing a monitoring and outlook framework for chemicals¹⁰ will require all chemical occurrence data to be held by the EEA. As a result, chemical occurrence data provided to and held in IPCHEM by the Commission will thus be collected and held by the EEA, instead of by the Commission. Therefore, it is necessary to simplify the reporting obligations for Member States to ensure that, where Member States have already submitted that information to the EEA as part of fulfilling obligations required by the provisions of other pieces of Union environmental legislation, Member States should be considered to have fulfilled their reporting obligations under Regulation (EU) 2019/1021. ⁹ Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast), (OJ L 435, 23.12.2020, p. 1–62). ¹⁰ [OJ Please insert reference once proposal is adopted]		
19	Recital 18	Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 should therefore be amended accordingly,		

20	Articles	HAVE ADOPTED THIS REGULATION:		

21	1	Amendments to Regulation (EC) No 178/2002		
22		Regulation (EC) No 178/2002 is amended as follows:		
23	(1)	in Article 23, the following point (m) is added:		
24		‘(m) to cooperate with the competent bodies in the Member States that carry out similar tasks to those of the Authority and to cooperate with other scientific bodies established under Union law, notably the European Chemicals Agency, the European Medicines Agency, and the European Environment Agency on the provision of relevant scientific opinions, on the exchange of data and information, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and on the development of scientific methodologies for the assessment of chemicals.’;		

25	(2)	Article 30 is replaced by the following:	Question were raised by a delegation on whether the EFSA procedure for risk assessment must not be changed as a result of this proposal and it must be ensured that the assessment of EFSA, and if applicable, other EU authorities are properly and appropriately taken into account by ECHA. How is this ensured by the provisions in Article 30?	

			PRES: Discussion took place during WP2	
26		‘Article 30 Diverging scientific opinions	One delegation requested an example of what could be considered diverging scientific opinions. PRES: Discussion took place during WP2.	IE: We support the comment from DE and agree that a discussion on such examples would be beneficial.
27		1. The Authority shall take the necessary and appropriate measures to monitor and identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks.		

28		2. Where the Authority identifies a potential source of divergence, it shall contact the body concerned in order to ensure that all relevant scientific or technical information is shared and in order to identify the potentially contentious scientific or technical issues. The Authority and the body concerned shall cooperate to resolve the divergence. If the Authority and the body concerned are not able to resolve the divergence, they shall draw up a joint report. The report shall clearly outline the contentious scientific issues and identify the relevant uncertainties in the data and be made publicly available. Where the body concerned is a Union agency or a scientific committee, the		

		Authority shall present the joint report to the Commission.		

29		3. Where relevant, and where the divergence concerns conflicting scientific opinions of the Authority and another Union body or agency on whether a substance fulfils the criteria laid out in Annex I of Regulation (EC) No 1272/2008 of the European Parliament and of the Council¹¹, the Commission may request the European Chemicals Agency to prepare a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof following the procedure laid out in Article 37 of Regulation (EC) No 1272/2008. The Authority and the Union body or agency concerned shall co-operate with the European Chemicals Agency in developing that proposal.’.		
30		¹¹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353 31.12.2008, p. 1 – 1355.		
31	2	Amendments to Regulation (EC) No 401/2009	One delegation asked for clarification why the EEA’s cooperation with ECHA is	

			supposed to be regulated in Article 15(5) of the EEA Regulation. Systematically, paragraph 1 with a new letter c seems closer. In addition, it would be clear that paragraph 4 also refers to this cooperation. One delegation has doubts about the impact of the Eionet Network's involvement in this cooperation. PRES: Discussion took place during WP2	
32		Regulation (EC) No 401/2009 is amended as follows:		
33	(1)	in Article 2, the following point (p) is added:		
34		‘(p) to develop assessment methodologies related to chemicals in the fields falling within its mission.’;		
35	(2)	in Article 15, the following paragraph 5 is added:		
36		‘5. The Agency shall cooperate with other scientific bodies established under Union law, notably the European Chemicals Agency, the European Food Safety Authority, and the European Medicines Agency, on the exchange of data and information on chemicals, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and on the development of		

		scientific methodologies for the assessment of chemicals.’.		
37	3	Amendments to Regulation (EU) 2017/745	One delegation questions ECHA’s expertise regarding medical devices. PRES: Discussion took place during WP2	
38		Annex I to Regulation (EU) 2017/745 is amended as follows:		
39	(1)	in Section 10.4.1, point (b) is replaced by the following:		
40		‘(b) substances which are identified as endocrine disruptors for human health, of Category 1, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ¹² and substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council or substances having endocrine disrupting properties relevant to human health identified in accordance with Regulation (EU) No 528/2012.’		

41		¹² Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending		

		Regulation (EC) No 1907/2006(OJ L 353 31.12.2008, p. 1).		
42	(2)	in Section 10.4.2, point (d) is replaced by the following:		
43		‘(d) where applicable and available, the latest relevant guidelines in accordance with Sections 10.4.3. and 10.4.4.’;		
44	(3)	Section 10.4.3 is replaced by the following:		

45		‘10.4.3. Guidelines on phthalates When deemed appropriate based on the latest scientific evidence, but at least every 5 years, the Commission shall request the European Chemicals Agency (ECHA) to update guidelines on the benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in Section 10.4.1., points (a) and (b). The benefit-risk assessment shall consider the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments When appropriate or when requested by the Commission, ECHA shall consult the Committee for Risk Assessment and the Committee for Socio-economic Analysis.’;		
46	(4)	Section 10.4.4 is replaced by the following:		
47		‘10.4.4. Guidelines on other CMR and endocrine-disrupting substances		
		The Commission shall request ECHA to prepare guidelines as referred to in Section 10.4.3. and following the process described therein also for other substances referred to in Section 10.4.1., points (a) and (b), where appropriate.’.		

48	4	Amendments to Regulation (EU) 2019/1021	A delegation proposed that Article 4 of the POP Regulation would be amended to give the Commission the possibility to request ECHA to carry out the assessment required to amend the concentration limit values in the Annexes IV and V to the POP regulation It is further proposed (article 13 paragraph 2) that this provision would also introduce the adoption of amendments to Annexes IV and V by means of delegated act. Moreover, they believe that the delegation of legislative powers to the Commission in POPregulation Article 15 needs further consideration This delegation sees the role of the POP-CA (competent authorities) very important in preparation of the delegated acts. In case the above described amendments would be accepted, what would be the role of the POP-CA in the future? Would the Commission still consult the experts	

			designated by each Member State and closely collaborate with POP-CA before adopting a delegated act? One delegation proposes that ECHA is also given the task to determine limit values and amending Annex I and not only Annexes IV and V to the POP regulation. They also ask whether ECHA will have the knowledge on the impact of adjusting Annex IV values on the waste and recycling phase, while another delegate questions the knowledge of SEAC on waste management. PRES: Discussion took place during WP2. PRES proposes amendments to be made to the proposal. Written comments are welcomed.	
49		Regulation (EU) 2019/1021 is amended as follows:		
50	(1)	Article 8(1) is amended as follows:		
51	(a)	the following point (i) is added:		

52		‘(i) upon request from the Commission, and within 12 months from that request, draw up and ~~provide-submit~~ a report on the human health, environmental and socio-economic impacts of introducing or modifying concentration limit values specified in Annex IV or V.’	One delegation proposes to change ‘draw up and provide a report’ to ‘draw up and submit a report.’ PRES proposed a change to the text.	

53	(2)	Article 8(1a) is added:		
54		‘1a. The report referred to in Article 8(1), point (i), shall contain the following information:		
55		(a) as appropriate, information on human health and environmental impacts of waste consisting of, containing or contaminated with POPs, including impacts on waste management;		
56		(b) information on concentrations and mass flows of POPs in relevant waste streams and on waste treatment and treatment capacities;		
57		(c) an analysis of the impacts of the different concentration limit values considered;		
58		(d) a duly motivated proposal for concentration limit values to be introduced in Annex IV and, as appropriate, in Annex V.		

59		The Agency shall, as soon as it receives the request referred to ~~in the first subparagraph~~ Article 8(1), point (i), publish on its website a notice that a report on a possible amendment of Annex IV or V will be prepared inviting all interested parties, including waste operators and users of recycled materials, to submit comments within 8 weeks. The Agency shall publish those comments on its website.	One delegation proposed to change the reference, to clarify and to use the same kind of reference as is used in the paragraph above. PRES proposed change accordingly	
60		At the latest 9 months following the submission of ~~the~~ report <i>referred to in Article (8(1), point (i))</i>, the Committee for Socio-economic Analysis of the Agency, set up pursuant to Article 76(1), point (d), of Regulation (EC) No 1907/2006 shall adopt an opinion on the report and on the concentration limit values proposed therein. For the purpose of adopting an opinion on the report, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.	One delegation proposed to clarify which submission it is referred to given that it is mentioned in several paragraphs earlier in the text. The proposed change would help to clarify this together with a consequential amendment in Article 8(1) point (i) to change the word 'provide' to 'submit' PRES proposed change.	
61		The Agency shall submit the report and the opinion of the Committee for the Socio-economic Analysis on the concentration limit values to the Commission without delay.';		

62	(3)	in Article 13, paragraph 2 is replaced by the following:	One delegation further proposed (Article 13 paragraph 2) that this provision would also introduce the adoption of amendments to Annexes IV and V by means of delegated acts. PRES requires further clarification (potential text proposal).	
63		‘2. Where a Member State shares the information referred to in paragraph 1, point (e), with the European Environmental Agency, that Member State shall indicate that in the report and the Member State shall be considered to have fulfilled its reporting obligations under that point.		
64		Where the information referred to in paragraph 1, point (e), is contained in the report of a Member State provided to the Agency, the Agency shall transmit the information to the European Environmental Agency for compiling, storing and sharing that information’;		
65	(4)	in Article 15, paragraph 2 is replaced by the following:		

66		‘2. The Commission is empowered to adopt delegated acts in accordance with Article 18, to amend Annexes IV and V to this Regulation to adapt them to the changes to the list of substances set out in the Annexes to the Convention or the Protocol or to adapt them to scientific and technical progress.’	One delegation proposed the amendment in order to clarify that the reference is to the Annexes in this Regulation. PRES changed the text. One delegation would like confirmation of the Commission’s obligation to consult MS experts before adopting delegated acts as appears to be provided in Article 18(4) of the POP Regulation. Another delegation considers it of high importance to preserve the expertise of the Meeting of the Competent Authorities for Regulation (EU) 2019/1021 on POPs and would like to know in which stage of the future amendments of the annexes the experts from the CAs will be consulted and whether additional POP experts will be incorporated to SEAC and/or RAC.	

			One delegation asked for the delegation of legislative powers to the COM in POP regulation article 15 to be further considered. They see the role of the POP-CA very important in the preparation of the delegated acts. PRES: Discussion took place during WP2. Written comments are welcome.	
67	(5)	Article 18 is amended as follows:	One delegation suggests no changes to be made to Article 18, they don't want to delegate this regulatory authority to the COM. PRES: Discussion took place during WP2. Written comments are welcome.	
68	(a)	The first sentence of paragraph 2 is replaced by the following:		
69		'2. The power to adopt delegated acts referred to in Articles 4(3), 10(2) and 15 shall be conferred on the Commission for a period of five years from 15 July 2019.'	A delegation considers that this 5-year term is very likely to have passed before the proposed delegation of authority takes effect. Therefore, they suggest adjusting the period in order to have effect in practice. PRES: Discussion took place during WP2. Written comments are welcome.	
70	(b)	The first sentence of paragraph 3 is replaced by the following:		
71		'3. The delegation of power referred to in Articles 4(3), 10(2) and 15 may be		

		revoked at any time by the European Parliament or by the Council.’.		
72	(c)	Paragraph 6 is replaced by the following:		
73		‘6. A delegated act adopted pursuant to Articles 4(3), 10(2) and 15 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object.’.		
74	6	Entry into force		
		This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.		
		Done at Brussels,		
		For the European Parliament The President For the Council The President		

PUBLIC

Proposal for a
DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
amending Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European
Chemicals Agency
(Text with EEA relevance)



PRESIDENCY PROPOSALS for written comments by 22 March 2024 1 PM

Delegations will find attached a **revised** Presidency compromise proposal on the above-mentioned Proposal.

Changes in comparison to the previous compromise proposal, document COM(2023) 781, are marked in **red bold underline** for additions and in ~~red strikethrough~~ for deletions.

	Commission Proposal	Presidency Justification	Delegations comments

Proposal Title			
1	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL Amending Directive 2011/65/EU control of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency (Text with EEA relevance)		
Formula			
2	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,		
Citation 1			
3	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,		
Citation 2			
4	Having regard to the proposal from the European Commission,		

Citation 3			
5	After transmission of the draft legislative act to the national parliaments,		
Citation 4			
6	Having regard to the opinion of the European Economic and Social Committee ¹		
Footnote 1			
7	¹ OJ C [...], [...], p. [...].		
Citation 5			
8	After consulting the Committee of the Regions,		
Citation 6			
9	Acting in accordance with the ordinary legislative procedure,		
Formula			
10	Whereas:		
Recital 1			

11	(1) The Commission has, in its Communication 'European Green Deal'², set an objective that chemical safety assessments should move towards a process of 'one-substance, oneassessment', calling for more transparent and simpler risk assessment processes in order to reduce the burden on all stakeholders, accelerate decisionmaking, as well as to increase consistency and predictability of scientific decisions and opinions. The Commission, in its Communication on Chemicals Strategy for Sustainability³ concludes that, in order to achieve that objective, part of the scientific and technical work on chemicals performed at Union level in support of Union legislation needs to be reattributed to the most suitable Union agencies. This would simplify the current set-up, improve quality and coherence of safety assessments across Union legislation, and ensure more efficient use of existing resources.	

Footnote 2

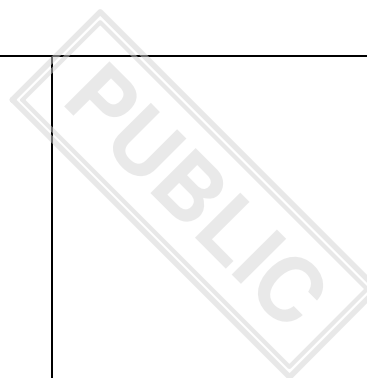
	² Communication from the Commission to the European		

12	Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal (COM (2019) 640 final of 11 December 2019).		

Footnote 3

13	³ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability Towards a ToxicFree Environment (COM (2020) 667 final of 14 October 2020).		

Recital 2



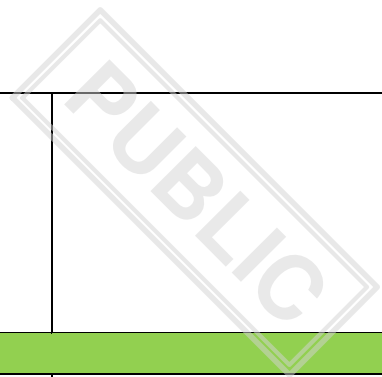
14	(2) The reattribution of certain scientific and technical tasks to the European Chemicals Agency is necessary in order to align processes and levels of scientific scrutiny and digitalisation with current standards and processes of the European Chemicals Agency. This is also necessary in order to ensure a consistent standard of scientific quality, transparency, data searchability and interoperability, in line with		

	the 'one-substance, oneassessment' ambition.		

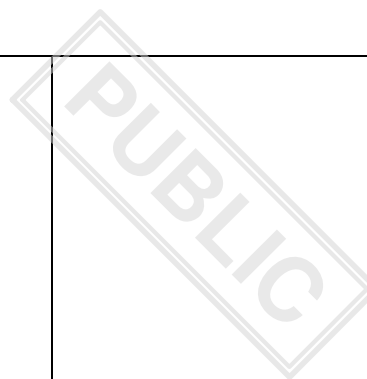
Recital 3

15	(3) Directive 2011/65/EU of the European Parliament and of the Council⁴ contains two procedures related to the assessment of chemicals: the evaluation of economic operators' applications for granting, renewing or revoking an exemption from the substance restrictions pursuant to Article 5 of that Directive and the review of substances to be added to the list of restricted substances pursuant to Article 6 of that Directive. There is a need to increase transparency by setting detailed procedural steps for the process to review substances for a potential inclusion in the list of restricted substances.		
Footnote 4			
16	⁴ Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment – OJ L 174 1.7.2011, p 88.		

17	(4) Data and information held by the European Chemicals Agency in the context of regulatory processes under Titles VII and VIII of Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁵ can be usefully deployed for the assessment of potential substance restrictions and for assessing applications for exemption under Directive 2011/65/EU. Established structures and procedures can help to build on the existing knowledge base, maximise synergies, and make the best use of available expertise and resources.		
Footnote 5			
18	⁵ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as		



	well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC - OJ L 396 30.12.2006, p. 1.		
Recital 5			
19	(5) To ensure consistency between the evaluation of economic operators' applications for granting, renewing or revoking an exemption pursuant to Article 5 of the Directive 2011/65/EU, as well as to make the best use of existing chemicals-related expertise, the technical evaluation to assess the justification of such exemption requests should be carried out by the European Chemicals Agency and its committees in close coordination with the Commission.		
Recital 6			



	(6) To ensure that the restriction process referred to Article 6 in Directive 2011/65/EU is consistent with the restriction processes under other legislation related to chemicals, in particular with the substance restriction process laid down in Articles 69		

20	to 73 of Regulation (EC) No 1907/2006, it is necessary to amend Directive 2011/65/EU to formally task the European Chemicals Agency with a role in the restriction process. In the light of experience obtained when carrying out substance reviews, it is essential for the quality of the related technical assessment, and for enabling synergies, to make use of information and tools being used in the context of assessments for chemical restrictions under Regulation (EC) No 1907/2006.		

Recital 7

21	(7) The two procedures described under Article 5 and Article 6 are applicable at the EU level. National provisions should not deviate from these Articles set in Directive 2011/65/EU.		
Recital 8			
22	(8) For amending procedural provisions under Directive 2011/65/EU, a transitional period of 12 months is necessary to allow for appropriate resource and task allocation for the European Chemicals Agency. That timeframe is considered sufficient		
	to allow for amending procedural provisions under Directive 2011/65/EU, a transitional period of 12 months is necessary to allow for appropriate resource and task allocation for the European Chemicals Agency. That timeframe is considered sufficient to allow potential applicants or Member States to adjust to the modified procedural steps under that Directive.		
Recital 9			

23	(9) Directive 2011/65/EU should therefore be amended accordingly,		
Formula			
24	HAVE ADOPTED THIS DIRECTIVE:		
Article 1			
25	<i>Article 1</i> Amendments to Directive 2011/65/EU Directive 2011/65/EU is amended as follows:		
Article 1(1)			
26	(1)Article 5 is amended as follows:		
Article 1(1), point (a)			
27	(a) paragraphs 3 and 4 are replaced by the following		
Article 1(1), point (a), paragraph 3			

28	'3. An application for granting, renewing or revoking an exemption shall be made to the European Chemicals Agency set up pursuant to Article 75(1) of Regulation (EC) No 1907/2006 ('the Agency') in accordance with Annex V.		
Article 1(1), point (a), paragraph 4a			
29	4. The Agency shall: (a) acknowledge receipt of an application within 15 days of its receipt, stating the date of receipt of the application;		
Article 1(1), point (a), paragraph 4b			
	30 (b) verify that the in Annex V;	application contains all the elements laid out	
Article 1(1), point (a), paragraph 4c			
	(c) if necessary, request the applicant to complete the application <u>within 45 days of</u>	Change proposed based on the comments from two delegations.	

31	<u>receipt of the application</u>, and provide an appropriate deadline <u>of maximum 60 days</u>;	One delegation suggested replacing the word “appropriate” with a specific deadline in order to improve legal certainty for the actors concerned. They motivated that this would also ensure that current applications are published on the Agency’s website in a timely manner. Additionally, other delegation motivated that the applicant should be given a deadline within which the application should be completed, since the exemption continue to apply during the process of evaluation of the application. The 45 days and 60 days were proposed based on the deadlines given in REACH Article 69 (4) for restrictions proposals, as there are no similar deadlines under the authorisation scheme in REACH. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(1), point (a), paragraph 4d			
32	(d) make the application and any supplementary information supplied by the applicant available to Member States;		
Article 1(1), point (a), paragraph 4e			

33	(e) make a summary of the application and a nonconfidential version of the application as submitted by the applicant, as well as the date when the application is		

PUBLIC

	considered complete, available to the public on the Agency's website;		
Article 1(1), point (a), paragraph 4f			
34	(f) invite interested parties to submit information within 3 months of its publication on the Agency's website.		
Article 1(1), point (a), paragraph 4			

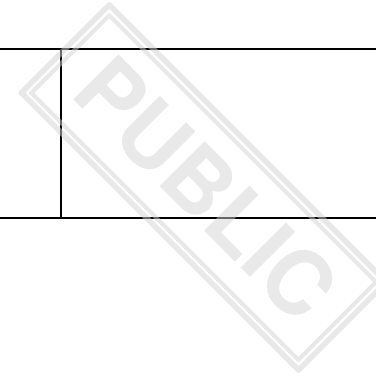
PUBLIC

35	Where the applicant does not complete the application with the missing elements identified by the Agency in compliance with Annex V within the deadline provided in accordance with the first subparagraph, point (c), the Agency may reject such application. The Agency shall establish and communicate to the applicant without undue delay the date when the application is considered complete. Upon receipt of an application, the Agency shall notify the Commission of the application and keep it informed of any of the procedural steps under points (b) to (f).';		
Article 1(1), point (b)			
36	b) the following paragraph 4a is inserted after paragraph 4:		
Article 1(1), point (b), regarding inclusion of article 4a			

37	4a. The Agency shall, after verifying the completeness of the application, request the opinion of the Committee for Socioeconomic Analysis, set up pursuant to Article 76(1), point (d) of Regulation (EC) No 1907/2006. It shall request the opinion of the Committee for Risk Assessment, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006, in the case of an application for a new exemption or where otherwise considered appropriate. The Committee for Socioeconomic Analysis and, where relevant, the Committee for Risk Assessment:	Two delegations suggested that it needs to be clearer when RAC shall evaluate an application for exemption. Therefore, they considered that it may be good to clarify that RAC shall evaluate applications for renewal of exemptions that have previously been evaluated by external consultants or where there are amendments in the exemption that have not been evaluated before. This would have the effect of increasing consistency between the evaluations. Alternatively, other delegation proposed in their comments to rather assign the tasks to ECHA (and its Expert Groups) than directly to RAC and SEAC. Their proposal was motivated by a concern related to the capacity of SEAC and RAC to perform the tasks under Art. 5 (lack of expertise in RoHS within the Committees, insufficient staff). In their opinion, the proposed change in the text would not preclude the Executive Director from requesting the assistance of the Committees of ECHA on a case-by-case basis. PRES did not modify the proposal and welcomes delegations' views/comments.	IE Comment: We maintain our position that the "ROHS tasks" should not be assigned to the Committees established under the REACH Regulation to deal with REACH authorisations and REACH restrictions. It isn't appropriate for the scope and remit of the Committees to be continually expanded particularly when they already have more tasks to deliver than they have capacity for. (The scope and mandate of the Committees has been expanded already with CLP, OEL's and drinking water positive list now it is proposed to expand even further to POPs, ROHS etc.). It is critical that the risk management provisions within REACH (authorisation/restriction) are progressed and implemented. This is the rationale behind why IE is proposing to assign the ROHS tasks to the agencies' own staff (ECHA) instead of assigning to the persons nominations by member states to the RAC and SEAC. If COM feels there is still a need to have a formal "Committee" and process named within the legislation, then the draft legislation can note that ECHA have the power to establish a ROHS Expert Group or the legislation could establish a ROHS Assessment Committee to deal with these ROHS tasks. The draft legislation would then include provisions as to how such an expert groups is established and how experts are nominated.

		Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(1), point (b), regarding inclusion of article 4a (a)			
	(a) shall draw up draft opinions deadline within 9 months of assessment of application has authorisation scheme and of authorisation under the paragraph 4, point (b); Regulation (Article 64 (1) of Regulation). 38	One delegation proposed to align the the date the for RAC and SEAC for the been considered exemptions with the complete by the Agency under assessment REACH- the REACH Other delegation proposed to specify that the opinions drawn shall be scientific and technical. This proposal is a consequence of their proposal above (line 37 of this document), where it is considered that tasks should be rather assigned to ECHA (and its Expert Groups) than directly to RAC and SEAC. PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	IE: The proposal of IE to insert the specify words “scientific and technical” is connected with our proposal not to assign ROHS tasks to the REACH RAC/SEAC Committees. It was a suggestion to possibly indicate in the legislation when an opinion (RoHS) is a scientific or technical opinion prepared by the ECHA Staff and/or an opinion prepared by an ECHA (RoHS) expert group in contrast to an opinion prepared by RAC or SEAC
Article 1(1), point (b), regarding inclusion of article 4a (b)			

39	(b) shall assess whether the criteria in Article 5(1), point (a), are met and shall provide clear guidance to the Commission on		



	granting, renewing or revoking an exemption;		
Article 1(1), point (b), regarding inclusion of article 4a (c)			
40	(c) may request the applicant or third parties to submit, within a specified period, additional information;		
Article 1(1), point (b), regarding inclusion of article 4a (d)			
41	(d) upon adopting the draft opinions, shall communicate those draft opinions to the applicant and shall allow the applicant the opportunity to comment within 4 weeks of the communication of the draft opinions to the applicant;	One delegation proposed to specify that the opinions drawn shall be scientific and technical. This proposal is a consequence of their proposal above (line 37 of this document), where it is considered that tasks should be rather assigned to ECHA (and its Expert Groups) than directly to RAC and SEAC. PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	IE: As noted above this proposal is to align with the proposal not to assign tasks to RAC/SEAC. It would make a distinction when ECHA prepare the opinion rather than an opinion of the Committees.
Article 1(1), point (b), regarding inclusion of article 4a (e)			
42	(e) shall adopt their final opinions, taking into account the comments from the applicant.		

Article 1(1), point (b), regarding inclusion of article 4a			

PUBLIC

43	Each Committee shall take into account any information submitted by third parties in accordance with the second subparagraph, point (c). The Agency shall send the final opinion(s) of the Committees to the Commission within 12 months from the date an application has been considered complete by the Agency. The Agency shall identify which parts of its opinions and of any attachments thereto should be made publicly available on its website and shall make those parts publicly available on its website. For the purpose of adopting opinions pursuant to this paragraph, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.'	One delegation proposed to align the deadline for RAC and SEAC for the assessment of exemptions with the authorisation scheme and assessment of authorisation under the REACH Regulation. Therefore, in their view the deadline for sending the final opinion to the Commission should be set to 14 months. This will assure that ECHA will have at least the same time period as is given under Article 64 (5) in REACH, where the Committees shall adopt their final opinion within two months after receiving the comments from the applicant and send it to the Commission within 15 days after this. Additionally, other delegation proposed to specify that the opinions drawn shall be scientific and technical. This proposal is a consequence of their proposal above (line 37 of this document), where it is considered that tasks should be rather assigned to ECHA (and its Expert Groups) than directly to RAC and SEAC. PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(1), point (c)			

44	(c) paragraph 8 is replaced by the following:		

PUBLIC

Article 1(1), point (c), paragraph 8

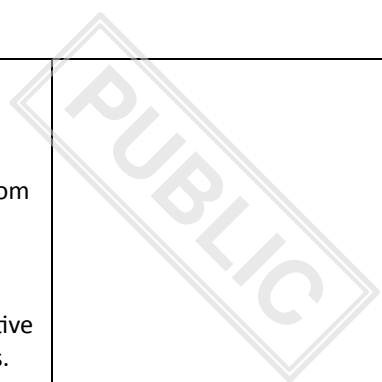
PUBLIC

45	8. The Agency shall, in agreement with the Commission, provide a harmonised format for the applications referred to in paragraph 3 of this Article as well as comprehensive guidelines for such applications, taking into account the situation of SMEs. Any submission to the Agency shall be made using the format and the submission tools made available by the Agency.’;	One delegation considered that a clarification is needed in relation to third criterion in Art. 5(1)(a) of the RoHS Directive: <i>‘the total negative environmental, health and consumer protection impact as a result of the substitution is likely to be greater than the total environmental, health and consumer protection benefits thereof’.</i> In their view many exemptions are granted or renewed with reference to this criterion, not infrequently, where the other criterions do not apply i.e. where substitution is possible or reliable alternatives are available, in spite of the weight of substitution in RoHS as reflected in recital 8 <i>the most effective way of ensuring a significant reduction of risks to health and the environment relating to those substances, in order to achieve the chosen level of protection in the Union, is the substitution of those substances in EEE by safe or safer materials.</i> The criterion is often applied based on energy considerations. It is unclear if this was the intention of this criteria and, which weight to assign energy considerations compared to chemicals considerations within the frame of RoHS. In light of the experienced difficulty concerning collection of information from applicants as identified during the RoHS review process, priority should be given to clarifying the applicability of this criterion.	

		Therefore, there is a need to clarify the applicability of this criteria and it is important that ECHA does so through following this reattribution of tasks. ECHA should revise this guidance and that the guidance should be adopted by the expert committee (see proposal for reference to this committee in under article 20). PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(2)			
46	(2) in Annex V, the following paragraph is added: 'In cases referred to in the first paragraph, point (h), the applicant shall submit a nonconfidential version of the application.'		
Article 1(3)			
	47 (3) Article 6 is amended as	follows:	
Article 1(3), point (a)			

PUBLIC

|



48	(a) in paragraph 1, the first subparagraph is replaced by the following: ‘With a view to achieving the objectives set out in Article 1 and taking account of the precautionary principle, a review, based on a thorough assessment, and an amendment of the list of restricted substances in Annex II shall be considered by the Commission <u>every five years</u> ~~periodically~~ on its own initiative or following the submission of a restriction dossier prepared by a Member State containing the information referred to in paragraph 2.’;	Change proposed based on the comment from one delegation. One delegation considered that the list of substances restricted under the ROHS directive should be evaluated on a more regular basis. Here a 5-year period is suggested. It is not paramount that it should be a 5-year period, however, a timeline is needed. Staff working document p. 119 assesses the impact for ECHA. Here it says: <i>As the assessments are to be done ca. every 5 years.</i> Therefore, a time limit of 5 years is considered appropriate. eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52023SC0850 One delegation proposed also some additional changes (introduction of subparagraph 1a) as they considered that the substances restricted in the POP-regulation, and where the use in EEE is exempted, should be considered for Annex II in the RoHS-Directive. PRES did not modify the proposal and welcomes delegations’ views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	

PUBLIC

Article 1(3), point (b)

PUBLIC

49	(b) in paragraph 1, the fourth subparagraph is deleted.		
Article 1(3), point (c)			

PUBLIC

50	(c) paragraph 2 is replaced by the following: '2. The review and amendment of the list of restricted substances, <u>or a group of similar substances,</u> in Annex II shall be based on restriction dossiers prepared by the Agency at the request of the Commission or prepared by a Member State. The Agency or a Member State shall take into account any available information and any relevant risk assessment submitted for the purposes of other Union legislation covering the life cycle of the substance used in EEE, in particular the waste phase. To this end, other bodies established under Union law and carrying out a similar task shall, on request, provide information to the Agency or Member State concerned.	Change proposed based on the comment of one delegation. One delegation considered that the reference to the assessment of groups of substances should not be deleted as it is in the current COM's proposal. Additionally, one delegation considered that any relevant assessment, including assessments of waste handling, should be included in a restriction dossier, therefore DK proposed to delete "risk" from the text. PRES did not modify the proposal and welcomes delegations' views/comments. Change based on the proposal of the COM received prior to the 2nd Ad Hoc WP and discussed during that meeting. This proposal intended to accommodate the	

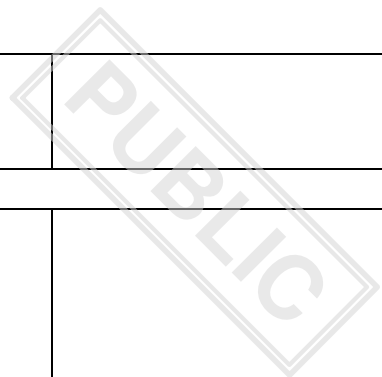
	The restriction dossier shall comply with the requirements set out in Part II, point 3, of Annex XV to Regulation (EC) No 1907/2006 <u>for those requirements that relate to the criteria set out in Article 6(1)</u> and shall, in addition, contain the following information: (a) information on the use of the substance or the group of similar substances in EEE; (b) information on detrimental effects and exposure in particular during waste EEE management operations.'	concern of one delegation regarding reshifting of focus of assessment required under the RoHS Directive when aligning restriction procedure with the REACH restriction. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(4)			
51	(4) the following Articles 6a, 6b and 6c are inserted:		
Article 1(4), regarding insertion of Article 6a			
52	'Article 6a Initiation of procedure for review and amendment of the list of restricted substances		
Article 1(4), regarding insertion of Article 6a, point (1)			

53	1. Within 12 months of receipt of the request from the Commission referred to in Article 6(2), first subparagraph, the Agency shall prepare a restriction dossier		
	conforming to the requirements referred to in Article 6(2), third subparagraph, and suggest restrictions in order to initiate the restriction process.		
Article 1(4), regarding insertion of Article 6a, point (2)			
54	2. A Member State shall notify the Agency that it proposes to prepare a restriction dossier which conforms to the requirements referred to in Article 6(2), third subparagraph, within 12 months. If that dossier demonstrates that action on a Union-wide basis is necessary, beyond any measures already in place, the Member State shall submit it to the Agency in order to initiate the restriction process.		
Article 1(4), regarding insertion of Article 6a, point (3)			

55	3. The Agency shall publish without delay the intention of the Commission or the Member State to initiate the process to review and amend the list of restricted substances in Annex II <u>on the Agency's website</u> .	Change proposed based on the comment from one delegation and in line with the text proposed in Art. 5 (see line 28 of this document). One delegation considered that it was not clear where the intention to review and amend the list of restricted substances will be published.	

PUBLIC

		Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(4), regarding insertion of Article 6a, point (4)			
56	4. The Agency shall establish and maintain a list of substances for which a restriction dossier conforming to the requirements of Article 6(2) is planned or underway by either the Agency or a Member State for the purposes of a proposed restriction.		
Article 1(4), regarding insertion of Article 6a, point (5), paragraph 1			
57	5. The Agency shall consult the Committee for Risk Assessment, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006, and the Committee for Socio-economic Analysis, set up pursuant to Article 76(1), point (d), of that Regulation. The Committees shall verify whether the restriction dossier submitted conforms to the requirements referred to in Article 6(2), third subparagraph.		
Article 1(4), regarding insertion of Article 6a, point (5), paragraph 2			



	Within 30 days of receipt of the restriction dossier, the respective		

58	Committee shall inform the Agency or the Member State proposing restrictions whether the dossier conforms to the requirements referred to in Article 6(2), third subparagraph. If the dossier does not conform to those requirements, the reasons shall be given to the Agency or the Member State in writing within 45 days of receipt of that dossier. The Agency or the Member State shall bring the dossier into conformity within 60 days of the date of receipt of the reasons from the Committees, otherwise the procedure under this Article shall be terminated.		

Article 1(4), regarding insertion of Article 6a, point (6)

59	Where the dossier meets the requirements referred to in Article 6(2), third subparagraph, the Agency shall make it publicly available without delay, clearly indicating the date of publication. The Agency shall invite all interested parties, including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations to submit, individually or jointly, within 4 months from the date of the		
	publication of the dossier, the following:		
Article 1(4), regarding insertion of Article 6a, point (6a)			
60	(a) comments on dossiers and the suggested restrictions;		
Article 1(4), regarding insertion of Article 6a, point (6b)			
	(b) a socio-economic analysis including an analysis of 61 alternatives, or information answer to the proposal made the document WK 3533 2024 drawbacks of the proposed	Changes partially modified based on the comment from one delegation. which can contribute to ~~one of~~ Note: COM can the suggested restrictions, be found in Rev. examining the advantages and 1. restriction ~~s~~ .	

Article 1(4), regarding insertion of Article 6a

62	The analysis referred to in the first subparagraph, point (b), shall conform to the requirements in Annex XVI to Regulation (EC) No 1907/2006.	One delegation suggested to delete this text, as they consider that the restriction process in RoHS may be too extensive compared to the restriction process in REACH. They were also concerned that having in mind future revision of the REACH Regulation, it is not clear how the restriction process will look like in the future. PRES did not modify the proposal and welcomes delegations' views/comments.	

		Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(4), regarding insertion of Article 6b			
63	Article 6b Opinion of the Agency's Committees		
Article 1(4), regarding insertion of Article 6b, point (1)			
64	1. Within 12 months from the date of publication referred to in Article 6a(6), the Committee for Risk Assessment shall adopt an opinion as to whether the restriction is appropriate in reducing the risk to human health or the environment, specifically ~~by reference to the risks set out in Article 6(1)~~ <u>for those requirements that relate to the criteria set out in Article 6(1)</u>, third subparagraph, based on its consideration of the relevant parts of the dossier. This opinion shall take account of the restriction dossier prepared by the Agency at the request of the Commission or by the Member State, and the views of interested parties referred to in Article 6a(6), point (a).	Change proposed by PRES to align the text with Article 1(3), point (c) (line 50 of this document). This proposal intended to accommodate the concern of one delegation regarding re-shifting of focus of assessment required under the RoHS Directive when aligning restriction procedure with the REACH restriction. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	

Article 1(4), regarding insertion of Article 6b, point (2)

PUBLIC

65	2. Within 15 months from the date of publication referred to in Article 6a(6), the Committee for Socio-economic Analysis, shall adopt an opinion on the proposed restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. Prior to that, it shall prepare a draft opinion on the suggested restrictions and on the related socio-economic impact, taking account any existing analysis or information according to Article 6a(6), point (b).		
Article 1(4), regarding insertion of Article 6b, point (3)			
66	3. The Agency shall publish the draft opinion of the Committee for Socio-economic Analysis on its website without delay and invite interested parties to provide their comments on the draft opinion no later than 60 days from its publication.		
Article 1(4), regarding insertion of Article 6b, point (4)			

67	4. The Committee for Socioeconomic Analysis shall without delay adopt its opinion, taking into account where appropriate further comments received by		

	the deadline set in paragraph 3. This opinion shall take into account the comments of interested parties submitted under Article 6a(6), point (a), and paragraph 3 of this Article.		

Article 1(4), regarding insertion of Article 6b, point (5)

68	5. Where the opinion of the Committee for Risk Assessment diverges significantly from the restrictions proposed, the Agency shall postpone the deadline for the opinion of the Committee responsible for Socio-economic Analysis by a maximum of 90 days.		

Article 1(4), regarding insertion of Article 6b, point (6)

69	6. For the purpose of adopting opinions pursuant to this article, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.	One delegation proposed some additional suggestions to provide for legislative provisions for the remuneration of tasks by Rapporteurs within the OSOA Package. PRES did not modify the proposal, as this is covered by mutatis mutandis application of Art. 87 of Regulation (EC) No 1907/2006 . Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	IE: Again all IE proposals are aligned to the principle that these ROHS tasks are not assigned to the RAC and SEAC Committees. This proposal of remuneration is therefore needed to address remuneration of tasks outside of RAC/SEAC Committees if they are undertaken by experts who are not staff or contractors of ECHA.
Article 1(4), regarding insertion of Article 6c			

70	Article 6c Submission of an opinion to the Commission		
Article 1(4), regarding insertion of Article 6c, point (1)			

PUBLIC

71	1. The Agency shall submit to the Commission, without delay, the opinions of the Committees for Risk Assessment and Socioeconomic Analysis on the restrictions suggested pursuant to Article 6b. Where the opinions of the Committees for Risk Assessment and Socio-economic Analysis diverge significantly from the restrictions suggested by the dossier, the Agency shall submit an explanatory note to the Commission providing a detailed explanation of the reasons for such differences. If one or both of the Committees do not adopt an opinion by the deadlines set in Article 6b(1) and (2) the Agency shall inform the Commission accordingly, stating the reasons.		
Article 1(4), regarding insertion of Article 6c, point (2)			
72	2. The Agency shall publish the opinions of both Committees on its website without delay.		
Article 1(4), regarding insertion of Article 6c, point (3)			

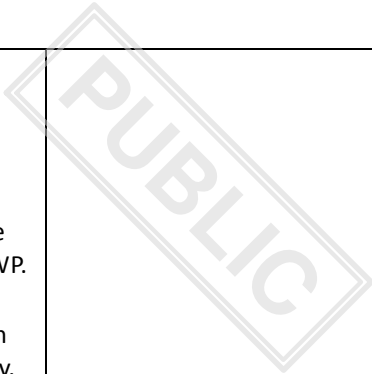
73	3. The Agency shall, on request, provide the Commission or Member State with all documents and evidence submitted to or considered by it.;		
Article 2			
74	The provisions under this Directive shall be applicable from [OJ: 12 months after the publication of this Directive].		
Article 3			
	This Directive shall enter into force on the twentieth day following that of its publication in the <i>Official Journal of the European Union</i> .		
Article 4			
76	This Directive is addressed to the Member States. Done at Brussels, <i>For the European Parliament For the Council</i> <i>The President The President</i>		

Additional recommendations (changes proposed regarding articles that were not included in the current COM's proposal)

Concerning amendments of Article 5(5):

77	An application for renewal of an exemption shall be made no later than 18 months before the exemption expires.	One delegation proposed extension of the deadline to 24 months as they are concerned that by aligning the exemptions assessment process with REACH, the Commission will be phased with the issue of expediting delegated directives before the expiration of the concerned exemption. Therefore it was suggested to increase the deadline in order to leave more room for the assessment procedure. PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	

Concerning amendments of Article 20:

78	Exercise of the delegation 1. The powers to adopt the delegated acts referred to in Article 4(2), Article 5(1) and Article 6 shall be conferred on the Commission for a period of 5 years from 21 July 2011. The Commission shall draw up a report in respect of delegated powers at the latest 6 months before the end of the 5-year period. The delegation of power shall be ~~automatically~~ <u>tacitly</u> extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 21. <u>1a. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of</u>	Change proposed based on the comments from one delegation. The COM agreed to the proposed changes, prior to the 2nd Ad Hoc WP. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	

|

	<u>13 April 2016 on Better LawMaking.</u>		

PUBLIC

SPAIN

14/03/2024

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the **re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals**

(Text with EEA relevance)



Line nr.		Presidency proposal: amendments (~~deletions~~ /additions)	Presidency justification after WP1: follow-up or proposal to work on amendments, or requests for written comments	Delegates comments/proposals after WP2
1		THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 43, 114, 168(4)(c), 192(1) and 207 thereof, Having regard to the proposal from the European Commission, After transmission of the draft legislative act to the national parliaments, Having regard to the opinion of the European Economic and Social Committee, Having regard to the opinion of the Committee of the Regions, Acting in accordance with the ordinary legislative procedure, Whereas:		
2	Recital 1	The European Green Deal¹ sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability² ('the Strategy') is a crucial delivery of the zero-pollution ambition and introduces the 'one		

		substance, one assessment' approach, which aims to improve the efficiency, effectiveness, coherence, and transparency of safety assessments of chemicals across Union legislation. ¹Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal. COM (2019) 640 final. ²Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment. COM (2020) 667 final		
3	Recital 2	In order to achieve this objective, a part of the scientific and technical work on chemicals performed at Union level in support of Union legislation needs to be consolidated in the relevant Union agencies, while obligations on Union agencies to cooperate for the development of assessment methodologies and exchange of data and information should be introduced. This would simplify the current set-up, improve quality and coherence of safety assessments across Union legislation and ensure more efficient use of existing resources.		
4	Recital 3	The reattribution of certain existing scientific and technical tasks to the	Many concerns were raised during the commenting about:	

		European Chemicals Agency, as well as the attribution of new tasks, were proposed as part of ongoing revisions of Union acts. This horizontal proposal aims to provide for further attribution of tasks in respect of those Union acts which are not in the process of being revised and is necessary in order to ensure that the European Chemicals Agency is involved in tasks pertaining to its expertise and developed capacities on chemicals. This is in line with the ‘one substance, one assessment’ aim to ensure that technical and scientific work is performed by the appropriate Union agency, benefiting from demonstrated experience and established tools in its field. The proposal for a Regulation is accompanied by a proposal for a Directive for the amendment of Directive 2011/65/EU of the European Parliament and of the Council³, aiming to achieve the same objectives. ³Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency	Concerns on ECHA’s capacity, budget (including budget for technical and infrastructure requirements and training), workload, committees, expertise to take on the extra tasks. This relates amongst others to the expertise of committee members (and not only the number of experts), potential establishment of technical expert groups (and how they relate to the Committees’ role), what is to be left for the founding regulation, potential targeted REACH amendments, ECHA and committees expertise in medical devices and in POP-waste. Some specific elements for discussion: One delegation proposed it would be more appropriate to assign the task(s) to prepare opinions to ECHA, and allow ECHA to best determine the most efficient and appropriate way to deliver a robust opinion. For example, ECHA’s technical experts could draft opinions and establish technical expert working groups to consult with in order for scientific opinions to be delivered. In certain cases, the Executive Director can still use their powers under REACH’s Article 77 (3) to issue a request to RAC and SEAC, thus negating the need for all tasks to have a RAC and/or SEAC opinion. This delegation also prefers that the legislative package makes provisions for	

			ECHA to prepare opinions in some circumstances without the explicit need for those opinions to be drafted by RAC and SEAC. In addition, they explained that their concern is with the capacity of the individual members to deliver the expected workload, even if both Committees were at full capacity. Therefore, they see a need for provisions to be included to allow for amending the composition of the current ECHA's committees to cover also any ad-hoc Article 77(3) requests in light of requests from the Executive Director. Finally, the inclusion of remuneration for Committee Rapporteurs for all tasks needs to be provided for. They also recommend the OSOA legislation package amends Article 85 and 87 of REACH to provide for additional experts to cover the additional work and its associated remuneration. PRES: Discussion took place during WP2	
5	Recital 4	As part of the coordinated consolidation and attribution of tasks under the 'one substance, one assessment' approach, provisions to allocate a mandate to the European Medicines Agency to develop and cooperate on the development of assessment methodologies, standard		

		formats and controlled vocabularies and exchange of data and information on chemicals have been introduced in Article 138(1), subparagraphs (zd) and (ze), as well as new procedures for ensuring the coherence between scientific opinions in Article 139 of the proposal for a Regulation amending Union pharmaceutical legislation.⁴ ⁴Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006, COM(2023) 193 final. [OJ:Please insert correct reference once the Regulation is adopted].		
6	Recital 5	To ensure the coherence of methodologies for assessments related to chemicals at Union level, all relevant Union agencies should have an equal mandate to develop such methodologies in the areas falling within their respective missions and should be subject to the same obligations to cooperate amongst each other to develop such methodologies.		
7	Recital 6	To ensure the coherence and efficiency of assessments related to chemicals		

		across Union legislation, it is also important to enable data interoperability and easy exchange of data between the relevant Union agencies, as well as to encourage cooperation on the development of standard formats and controlled vocabularies. Thus, to facilitate data exchange between agencies, any new data formats defined by the European Food Safety Authority or by the European Environmental Agency should be set in cooperation with other relevant Union agencies working on chemicals. To this end, relevant provisions should be introduced in Regulation (EC) No 401/2009 of the European Parliament and of the Council and, in Regulation (EC) No 178/2002 of the European Parliament and of the Council, existing provisions should be strengthened and, where relevant, new ones be introduced. Similar provisions should also be considered to be proposed for a strengthened mandate of the European Chemicals Agency in its founding regulation.		
8	Recital 7	To promote the coherence and efficiency of assessments related to chemicals across Union legislation, steps should be taken by the relevant Union agencies to avoid divergent scientific opinions. Existing cases of divergent opinions have lead to increased uncertainty for operators, as well as to declined public		

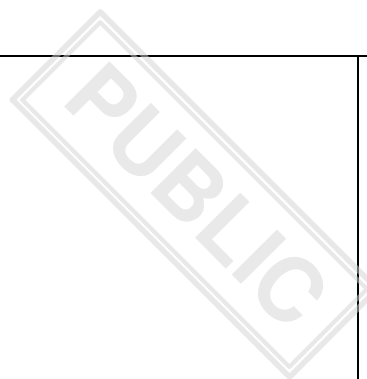
		trust in the scientific robustness and coherence of scientific decision making. Proposals to address and strengthen procedures for resolving divergence of scientific opinions concerning the European Medicines Agency with other scientific bodies is proposed as part of the revision of Union pharmaceutical legislation. Similar provisions should also be considered to be proposed for a strengthened mandate of the European Chemicals Agency in its founding regulation, whilst such provisions are not relevant and applicable to the European Environmental Agency, since this agency does not issue scientific opinions on individual chemicals such as to be part in divergent outcomes.		
9	Recital 8	Correspondingly, this Regulation aims to address the eventual divergence between scientific opinions of the European Food Safety Authority and those of other Union agencies. Regulation (EC) No 178/2002 of the European Parliament and Council already contains provisions establishing a procedure to solve divergent scientific opinions. Those resolution procedures should be reinforced, in that the European Food Safety Authority and the other dissenting agency should be bound to make their best effort to resolve the divergence on general scientific issues, and only when they are not able to resolve the		

		divergence, should they refer to risk managers.		
10	Recital 9	In the more specific case of scientific divergence pertaining to the hazard identification of chemical substances, a new procedure enabling the resolution of the divergence should be established. This procedure should enable the Commission to request the European Chemicals Agency, as the Union agency most equipped with expertise and capacity in hazard assessment, as well as long-standing experience with the harmonised classification and labelling process, to develop a proposal for harmonised classification and labelling, in accordance the Regulation (EC) No 1272/2008 of the European Parliament and Council, moving closer to the ‘one substance, one assessment’ vision as regards uniformity of hazard assessments of chemicals across the Union. This possibility should be reflected in the relevant provision providing for the resolution of diverging scientific opinions laid down in Regulation (EC) No 178/2002.		
11	Recital 10	To comply with the obligation laid down in Section 10.4.3 of Annex I to Regulation (EU) 2017/745 of the European Parliament and of the Council ⁵ , the Commission has provided the Scientific Committee on Health,		

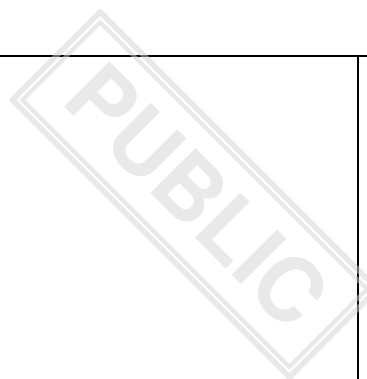
	Environmental and Emerging Risks ('SCHEER') with a mandate to prepare guidelines on the benefit-risk assessment of the presence of phthalates which are classified as either carcinogenic, mutagenic or toxic to reproduction category 1A or 1B, or which have endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁶. The SCHEER issued those guidelines in 2019 and the Commission has issued a mandate to the SCHEER to perform a first update of those guidelines. ⁵ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1). ⁶ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives	

		91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1–849).		
12	Recital 11	To comply with the obligation laid out in Section 10.4.4. of Annex I to Regulation (EU) 2017/745, the Commission should mandate the relevant scientific committee to prepare guidelines for substances other than phthalates and which are classified as either carcinogenic, mutagenic or toxic to reproduction category 1A or 1B, or which have endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council.		
13	Recital 12	The European Chemicals Agency already provides scientific advice on chemical substances, including on phthalates, endocrine disruptors and carcinogens, mutagens and reproductive toxicants under Regulation (EC) No 1907/2006. Several key capacities of the agency can be reused, including hazard, risk, exposure and socio-economic assessment capacities, the Committee opinion development and IT capabilities for stakeholder consultation and dissemination. To enable timely future updates on the presence of phthalates and		

		to ensure that the appropriate Union agency develops new guidelines on other substances on the basis of the latest scientific evidence, these tasks should be attributed to the European Chemicals Agency.		
14	Recital 13	Taking account of the new hazard classes and criteria for classification, labelling and packaging of substances introduced by Commission Delegated Regulation (EU) 2023/707 of 19 December 2022⁷, reference to endocrine disruptors for human health, of Category 1, should be specified in 10.4.1., point (b) of Annex I of Regulation (EU) 2017/745 in light of the relevance of that hazard class to the type of substances in medical devices. ⁷ Commission Delegated Regulation (EU) 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures (OJ L 93, 31.3.2023, p. 7–39).		
15	Recital 14	To make best use of the European Chemicals Agency's knowledge and expertise gained through its involvement in the nomination and assessment processes under the Stockholm Convention on Persistent Organic Pollutants, the European Chemicals Agency should, upon request, assist the Commission in complying with its		



		obligation to amend Annexes IV and V to Regulation (EU) 2019/1021⁸. Where the opinion of the Committee for Socio-Economic analysis is required, and in order to allow for the necessary capacity and resources for the effective functioning of that committee, Member States should be given the opportunity to cover for the specific expertise required for the effective performance of the task by nominating experts. In order to ensure that the Committee for Socio-Economic analysis benefits from sufficient resources, when the committee appoints one of their members as a rapporteur, that person, or his employer should be remunerated. ⁸ Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45).		
16	Recital 15	In order to amend certain non-essential elements of Regulation (EU) 2019/1021 of the European Parliament and of the Council, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending Annexes IV and V in order to adapt them to the changes to the list of substances set out in the Annexes to the Stockholm Convention or the Protocol or adapt them to scientific and technical progress.		



17	Recital 16	As part of their reporting obligations under the Regulation (EU) 2019/1021 of the European Parliament and of the Council, Member States must report to the European Chemicals Agency information on the presence of substances listed in Part A of Annex III in the environment. The use of the Information Platform for Chemical Monitoring ('IPCHEM') is encouraged as a means for Member States to comply with their obligations to report that chemical occurrence data and to simplify and reduce their reporting obligations. Where Member States make data available through IPCHEM, they no longer need to report it to the European Chemicals Agency, as the agency may retrieve it from the platform.		
18	Recital 17	The revision of the Directive (EU) 2020/2184 of the European Parliament and of the Council⁹ requires Member States to share with European Environmental Agency all chemical occurrence or monitoring data in water. Additionally, the monitoring data on the presence of POPs in air are already being reported by Member States to the EEA as part of the Union air quality legislation. The proposal for a Regulation of the European Parliament and the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable,		

		accessible, interoperable, and reusable and establishing a monitoring and outlook framework for chemicals¹⁰ will require all chemical occurrence data to be held by the EEA. As a result, chemical occurrence data provided to and held in IPCHEM by the Commission will thus be collected and held by the EEA, instead of by the Commission. Therefore, it is necessary to simplify the reporting obligations for Member States to ensure that, where Member States have already submitted that information to the EEA as part of fulfilling obligations required by the provisions of other pieces of Union environmental legislation, Member States should be considered to have fulfilled their reporting obligations under Regulation (EU) 2019/1021. ⁹ Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast), (OJ L 435, 23.12.2020, p. 1–62). ¹⁰ [OJ Please insert reference once proposal is adopted]		
19	Recital 18	Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 should therefore be amended accordingly,		
20	Articles	HAVE ADOPTED THIS REGULATION:		

21	1	Amendments to Regulation (EC) No 178/2002		
22		Regulation (EC) No 178/2002 is amended as follows:		
23	(1)	in Article 23, the following point (m) is added:		
24		‘(m) to cooperate with the competent bodies in the Member States that carry out similar tasks to those of the Authority and to cooperate with other scientific bodies established under Union law, notably the European Chemicals Agency, the European Medicines Agency, and the European Environment Agency on the provision of relevant scientific opinions, on the exchange of data and information, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and on the development of scientific methodologies for the assessment of chemicals.’;		
25	(2)	Article 30 is replaced by the following:	Question were raised by a delegation on whether the EFSA procedure for risk assessment must not be changed as a result of this proposal and it must be ensured that the assessment of EFSA, and if applicable, other EU authorities are properly and appropriately taken into account by ECHA. How is this ensured by the provisions in Article 30?	

			PRES: Discussion took place during WP2	
26		‘Article 30 Diverging scientific opinions	One delegation requested an example of what could be considered diverging scientific opinions. PRES: Discussion took place during WP2.	
27		1. The Authority shall take the necessary and appropriate measures to monitor and identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks.		
28		2. Where the Authority identifies a potential source of divergence, it shall contact the body concerned in order to ensure that all relevant scientific or technical information is shared and in order to identify the potentially contentious scientific or technical issues. The Authority and the body concerned shall cooperate to resolve the divergence. If the Authority and the body concerned are not able to resolve the divergence, they shall draw up a joint report. The report shall clearly outline the contentious scientific issues and identify the relevant uncertainties in the data and be made publicly available. Where the body concerned is a Union agency or a scientific committee, the		

		Authority shall present the joint report to the Commission.		
29		3. Where relevant, and where the divergence concerns conflicting scientific opinions of the Authority and another Union body or agency on whether a substance fulfils the criteria laid out in Annex I of Regulation (EC) No 1272/2008 of the European Parliament and of the Council ¹¹ , the Commission may request the European Chemicals Agency to prepare a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof following the procedure laid out in Article 37 of Regulation (EC) No 1272/2008. The Authority and the Union body or agency concerned shall co-operate with the European Chemicals Agency in developing that proposal.’.		
30		¹¹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353 31.12.2008, p. 1 – 1355.		
31	2	Amendments to Regulation (EC) No 401/2009	One delegation asked for clarification why the EEA’s cooperation with ECHA is	

			supposed to be regulated in Article 15(5) of the EEA Regulation. Systematically, paragraph 1 with a new letter c seems closer. In addition, it would be clear that paragraph 4 also refers to this cooperation. One delegation has doubts about the impact of the Eionet Network's involvement in this cooperation. PRES: Discussion took place during WP2	
32		Regulation (EC) No 401/2009 is amended as follows:		
33	(1)	in Article 2, the following point (p) is added:		
34		‘(p) to develop assessment methodologies related to chemicals in the fields falling within its mission.’;		
35	(2)	in Article 15, the following paragraph 5 is added:		
36		‘5. The Agency shall cooperate with other scientific bodies established under Union law, notably the European Chemicals Agency, the European Food Safety Authority, and the European Medicines Agency, on the exchange of data and information on chemicals, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and on the development of		

		scientific methodologies for the assessment of chemicals.’.		
37	3	Amendments to Regulation (EU) 2017/745	One delegation questions ECHA’s expertise regarding medical devices. PRES: Discussion took place during WP2	
38		Annex I to Regulation (EU) 2017/745 is amended as follows:		
39	(1)	in Section 10.4.1, point (b) is replaced by the following:		
40		‘(b) substances which are identified as endocrine disruptors for human health, of Category 1, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ¹² and substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council or substances having endocrine disrupting properties relevant to human health identified in accordance with Regulation (EU) No 528/2012.’		ES: scrutiny reservation We have requested information to DG Santé about the added text on section 10.4.1 point (b) <i>substances which are identified as endocrine disruptors for human health, of Category 1, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council¹²</i>
41		¹² Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending		

		Regulation (EC) No 1907/2006(OJ L 353 31.12.2008, p. 1).		
42	(2)	in Section 10.4.2, point (d) is replaced by the following:		
43		‘(d) where applicable and available, the latest relevant guidelines in accordance with Sections 10.4.3. and 10.4.4.’;		
44	(3)	Section 10.4.3 is replaced by the following:		
45		‘10.4.3. Guidelines on phthalates When deemed appropriate based on the latest scientific evidence, but at least every 5 years, the Commission shall request the European Chemicals Agency (ECHA) to update guidelines on the benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in Section 10.4.1., points (a) and (b). The benefit-risk assessment shall consider the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments When appropriate or when requested by the Commission, ECHA shall consult the Committee for Risk Assessment and the Committee for Socio-economic Analysis.’;		ES: ECHA's assessment should consider not only the chemical perspective, but also the benefit-risk balance of medical devices, taking into account the opinion of experts in the field of medical devices. The risk-benefit assessment should take into account the intended purpose and context of use of the product, as well as any available alternative substances and alternative medical materials, designs or treatments. The Scientific Committee on Health, Environmental and Emerging Risks (SCHER), which now carries out these assessments, does take this into account. We understand the principle of one substance, one assessment, but it has to be adapted to each situation taking into account the risk-benefit ratio, as mentioned above. We also consider important that if this work it is going to be done by ECHA, this

				Agency should have experts on medical devices. Proposed text: 10.4.3. Guidelines on phthalates When deemed appropriate based on the latest scientific evidence, but at least every 5 years, the Commission shall request the European Chemicals Agency (ECHA) to update guidelines on the benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in Section 10.4.1., points (a) and (b). The benefit-risk assessment shall consider the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments. The assessment shall take into account the opinion of experts in the field of medical devices When appropriate or when requested by the Commission, ECHA shall consult the Committee for Risk Assessment and the Committee for Socio-economic Analysis.'
46	(4)	Section 10.4.4 is replaced by the following:		
47		'10.4.4. Guidelines on other CMR and endocrine-disrupting substances		ES. Same comment as in line 45 above. Proposed text:

		The Commission shall request ECHA to prepare guidelines as referred to in Section 10.4.3. and following the process described therein also for other substances referred to in Section 10.4.1., points (a) and (b), where appropriate.’		The following text should be added as a second paragraph to point 10.4.4 The benefit-risk assessment shall consider the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments. The assessment shall take into account the opinion of experts in the field of medical devices When appropriate or when requested by the Commission, ECHA shall consult the Committee for Risk Assessment and the Committee for Socio-economic Analysis.’;
48	4	Amendments to Regulation (EU) 2019/1021	A delegation proposed that Article 4 of the POP Regulation would be amended to give the Commission the possibility to request ECHA to carry out the assessment required to amend the concentration limit values in the Annexes IV and V to the POP regulation It is further proposed (article 13 paragraph 2) that this provision would also introduce the adoption of amendments to Annexes IV and V by means of delegated act. Moreover, they believe that the delegation of legislative	

			powers to the Commission in POP-regulation Article 15 needs further consideration This delegation sees the role of the POP-CA (competent authorities) very important in preparation of the delegated acts. In case the above described amendments would be accepted, what would be the role of the POP-CA in the future? Would the Commission still consult the experts designated by each Member State and closely collaborate with POP-CA before adopting a delegated act? One delegation proposes that ECHA is also given the task to determine limit values and amending Annex I and not only Annexes IV and V to the POP regulation. They also ask whether ECHA will have the knowledge on the impact of adjusting Annex IV values on the waste and recycling phase, while another delegate questions the knowledge of SEAC on waste management. PRES: Discussion took place during WP2. PRES proposes amendments to be made to the proposal. Written comments are welcomed.	

49		Regulation (EU) 2019/1021 is amended as follows:		
50	(1)	Article 8(1) is amended as follows:		
51	(a)	the following point (i) is added:		
52		‘(i) upon request from the Commission, and within 12 months from that request, draw up and ~~provide~~ submit a report on the human health, environmental and socio-economic impacts of introducing or modifying concentration limit values specified in Annex IV or V.’	One delegation proposes to change ‘draw up and provide a report’ to ‘draw up and submit a report.’ PRES proposed a change to the text.	
53	(2)	Article 8(1a) is added:		
54		‘1a. The report referred to in Article 8(1), point (i), shall contain the following information:		
55		(a) as appropriate, information on human health and environmental impacts of waste consisting of, containing or contaminated with POPs, including impacts on waste management;		
56		(b) information on concentrations and mass flows of POPs in relevant waste streams and on waste treatment and treatment capacities;		
57		(c) an analysis of the impacts of the different concentration limit values considered;		
58		(d) a duly motivated proposal for concentration limit values to be		

		introduced in Annex IV and, as appropriate, in Annex V.		
59		The Agency shall, as soon as it receives the request referred to ~~in the first subparagraph~~ Article 8(1) , point (i), publish on its website a notice that a report on a possible amendment of Annex IV or V will be prepared inviting all interested parties, including waste operators and users of recycled materials, to submit comments within 8 weeks. The Agency shall publish those comments on its website.	One delegation proposed to change the reference, to clarify and to use the same kind of reference as is used in the paragraph above. PRES proposed change accordingly	
60		At the latest 9 months following the submission of ~~the~~ report referred to in Article (8(1), point (i)) , the Committee for Socio-economic Analysis of the Agency, set up pursuant to Article 76(1), point (d), of Regulation (EC) No 1907/2006 shall adopt an opinion on the report and on the concentration limit values proposed therein. For the purpose of adopting an opinion on the report, Article 87 of Regulation (EC) No 1907/2006 shall apply <i>mutatis mutandis</i> .	One delegation proposed to clarify which submission it is referred to given that it is mentioned in several paragraphs earlier in the text. The proposed change would help to clarify this together with a consequential amendment in Article 8(1) point (i) to change the word 'provide' to 'submit' PRES proposed change.	
61		The Agency shall submit the report and the opinion of the Committee for the Socio-economic Analysis on the concentration limit values to the Commission without delay.';		
62	(3)	in Article 13, paragraph 2 is replaced by the following:	One delegation further proposed (Article 13 paragraph 2) that this provision would also introduce the adoption of	

			amendments to Annexes IV and V by means of delegated acts. PRES requires further clarification (potential text proposal).	
63		‘2. Where a Member State shares the information referred to in paragraph 1, point (e), with the European Environmental Agency, that Member State shall indicate that in the report and the Member State shall be considered to have fulfilled its reporting obligations under that point.		
64		Where the information referred to in paragraph 1, point (e), is contained in the report of a Member State provided to the Agency, the Agency shall transmit the information to the European Environmental Agency for compiling, storing and sharing that information’;		
65	(4)	in Article 15, paragraph 2 is replaced by the following:		
66		‘2. The Commission is empowered to adopt delegated acts in accordance with Article 18, to amend Annexes IV and V to this Regulation to adapt them to the changes to the list of substances set out in the Annexes to the Convention or the Protocol or to adapt them to scientific and technical progress.’	One delegation proposed the amendment in order to clarify that the reference is to the Annexes in this Regulation. PRES changed the text. One delegation would like confirmation of the Commission’s obligation to consult MS experts before adopting delegated	ES: We agree with the amendment of Annexes IV and V by delegated acts, but underline the importance of the group of competent authorities being informed and able to express their opinion at an early stage of the process. Although this is a political issue (as it involves decision-making), in the end the solution must be adopted on the basis of technical and

			acts as appears to be provided in Article 18(4) of the POP Regulation. Another delegation considers it of high importance to preserve the expertise of the Meeting of the Competent Authorities for Regulation (EU) 2019/1021 on POPs and would like to know in which stage of the future amendments of the annexes the experts from the CAs will be consulted and whether additional POP experts will be incorporated to SEAC and/or RAC. One delegation asked for the delegation of legislative powers to the COM in POP regulation article 15 to be further considered. They see the role of the POP-CA very important in the preparation of the delegated acts. PRES: Discussion took place during WP2. Written comments are welcome.	practical criteria (and ECHA's experience will facilitate the process).
67	(5)	Article 18 is amended as follows:	One delegation suggests no changes to be made to Article 18, they don't want to delegate this regulatory authority to the COM. PRES: Discussion took place during WP2. Written comments are welcome.	
68	(a)	The first sentence of paragraph 2 is replaced by the following:		

69		‘2. The power to adopt delegated acts referred to in Articles 4(3), 10(2) and 15 shall be conferred on the Commission for a period of five years from 15 July 2019.’.	A delegation considers that this 5-year term is very likely to have passed before the proposed delegation of authority takes effect. Therefore, they suggest adjusting the period in order to have effect in practice. PRES: Discussion took place during WP2 Written comments are welcome	
70	(b)	The first sentence of paragraph 3 is replaced by the following:		
71		‘3. The delegation of power referred to in Articles 4(3), 10(2) and 15 may be revoked at any time by the European Parliament or by the Council.’.		
72	(c)	Paragraph 6 is replaced by the following:		
73		‘6. A delegated act adopted pursuant to Articles 4(3), 10(2) and 15 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object.’.		
74	6	Entry into force		
		This Regulation shall enter into force on the twentieth day following that of its		

[illegible]

SPAIN

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

establishing a common **data platform** on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

(Text with EEA relevance)



COMMENTS FROM SPAIN

	Presidency proposals: amendments (~~deletions~~ /additions)	Presidency proposals: follow-up or proposal to work on amendments, or requests for written comments	Reactions from the Commission and MS
Proposal Title			
1	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals)		
Formula			
2	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN		
Citation 1			
3	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114(1) thereof,		
Citation 2			
4	Having regard to the proposal from the European Commission,		
Citation 3			
5	After transmission of the draft legislative act to the national parliaments,		
Citation 4			
6	Having regard to the opinion of the European Economic and Social Committee ¹		
Citation 5			
7	Acting in accordance with the ordinary legislative procedure,		
Formula			
8	Whereas:		

Recital 1			
9	(1) The European Green Deal³⁴ sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability³⁵ is a crucial delivery of this zero-pollution ambition and introduces the ‘one substance, one assessment’ approach, which aims to improve the efficiency, effectiveness, coherence, and transparency of safety assessments of chemicals across Union legislation. According to that Strategy, ‘safe and sustainable by design’ criteria should be developed to enable the production and use of chemicals that are safe and sustainable throughout their entire lifecycle. The Strategy also sets out that the interaction between scientific developments and policy-making should be strengthened by means of an early warning system for chemicals to ensure that Union policies address emerging chemical risks as soon as these are identified by monitoring and research, and that a framework of indicators should be developed to monitor the drivers and impacts of chemical pollution and to measure the effectiveness of chemicals legislation. This Regulation aims to implement these objectives.		
Recital 2			
10	(2) The main objective of this Regulation is to increase the level of protection of the environment and human health from the risks arising from hazardous chemicals, as well as to facilitate the functioning of the internal market for chemicals. For that purpose, this Regulation should establish a common data platform data on chemicals (‘the common data platform’), to be managed by the European Chemicals Agency (‘ECHA’). The common data platform is a digital infrastructure that brings together chemicals data and information generated under the Union chemicals acquis. This Regulation should also establish dedicated services within the common data platform and lay down rules on the accessibility and usability of the data contained in that platform. This Regulation aims to create a common knowledge base on chemicals available to authorities to enable better, complete, coherent and robust scientific assessments of chemicals and their impacts and to ensure the best use of existing information for the purpose of the implementation and the development of Union legislation on chemicals. Moreover, the Regulation aims to provide a one-stop-shop on chemicals data and		

	information in the Union accessible to the general public and, thus, to increase the predictability and the transparency of regulatory processes on chemicals, as well as to strengthen public trust in the robustness of scientific decision-making.		
Recital 3			
11	(3) Under Decision (EU) 2022/591 of the European Parliament and of the Council ³⁶ , harnessing the potential of digital and data technologies to support environmental policy, including by delivering real-time data where possible and information on the state of ecosystems, while increasing efforts to minimise the environmental footprint of these technologies and ensuring transparency, authenticity, interoperability and public accessibility of the data and information is a long-term priority objective. Data and information on chemicals are therefore essential for the proper development and implementation of a Union environmental policy, and specifically of a chemicals policy.		
Recital 4			
12	(4) In its communication of 19 February 2020 on a European strategy for data ³⁷ , the Commission described its vision of a common European data space and highlighted the need for the development of sectoral data spaces in strategic areas, since not all sectors of the economy and society are moving at the same speed. This Regulation aims therefore to build a data space for chemicals by establishing a common data platform on chemicals ('common data platform'), which is also part of the Green Deal data space, as referred to in the European strategy for data. Furthermore, in that strategy, the Commission highlighted several issues concerning the availability of data for the public good, including data availability, data infrastructures and governance, interoperability, as well as the lack of adequate sharing of data between public authorities. This Regulation aims to increase data availability on chemicals by requiring the relevant Union agencies to make data available for integration in the common data platform on chemicals, to promote interoperability of that data by providing for the establishment of standard formats and controlled vocabularies, as well as to facilitate data exchange and use by public authorities to enable them to effectively carry out their regulatory and policy developing tasks.		

Recital 5			
13	(5) This Regulation also aims to implement into the chemicals sector the principles laid out in the proposal for an Interoperable Europe Act ³⁸ by strengthening the cross-border interoperability of network and information systems used to provide or manage public services on chemicals in the Union. This Regulation will contribute to increased cross-border data flows for truly European digital services and broaden the access to publicly available chemicals data for utilisation in other sectors' applications.		
Recital 6			
14	(6) Business operators and Member States' competent authorities are required by various Union acts to submit data and information to a multitude of Union agencies, as well as to the Commission in specific cases. This generates a fragmentation of data and information on chemicals, which are held under various data sharing and use conditions and in different formats. Such fragmentation prevents public authorities, as well as the general public, from having a clear overview of what information is available on individual chemicals or groups of chemicals, of where and how information can be accessed and whether it can be used. This increases the likelihood of inconsistency between various assessments of the same chemical required by various Union acts on chemicals and of damaging the general public's trust in the scientific grounds for Union decisions on chemicals. In order to ensure that data on chemicals is easily findable, accessible, interoperable and usable, the ECHA should establish a common data platform on chemicals. The common data platform on chemicals should serve as a single point of reference and as a broadened and shared evidence base to enable the efficient delivery of coherent hazard and risk assessments of chemicals across various Union acts on chemicals, as well as to enable the timely identification of emerging chemical risks and the drivers and impact of chemical pollution.		
Recital 7			
15	The common data platform should contain chemicals-related data and information held by relevant Union agencies or the Commission generated or submitted as part of the implementation of Union chemicals legislation listed in Annex I. This includes, for instance, all		

	regulatory dossiers or applications submitted to the relevant Union agencies, but also chemicals data on occurrence of chemicals submitted by Member States to Union agencies or the Commission in compliance with their reporting obligations. The common data platform should also include chemicals data and information generated as part of Union, national or international programmes or research activities related to chemicals, where this data and information is held by the Commission or one of the relevant agencies.		
Recital 8			
16	Due to the different nature of the risk and hazard assessments performed under Union acts on medicinal products, when compared to those performed under the main Union acts on chemicals, for medicinal products, only chemicals data related to environmental risk assessments for human and veterinary medicines, non-clinical studies for human medicines and maximum residue limit values the European Medicines Agency ('EMA') holds, as well as specific reference values, should be included in the common data platform. For medicinal active substances, only data on relevant substances should be included. These concern active substances covered by the medicines legislation and also used for other applications regulated by other Union legislation identified in this Regulation, as well as other active substances with particular persistent, bio-accumulative and toxic properties or with a known high level of residues in the environment.	Some MS expressed the need for a clarification of the scope and meaning of "relevant substances" for active substances → PRES: this is scheduled for discussion at the 2 nd WP	ES: What kind of non-clinical studies is the proposal referring to? Repeated dose toxicity studies, genotoxicity...? In Annex II it is mentioned as 'non-clinical safety data'.
Recital 9			
17	(9) These data should also be limited to data submitted to the EMA in the context of the relevant procedures that are finalised or submitted after the entry into force of this Regulation. At a later stage, it should also be possible to include in the common data platform, where relevant, data the EMA holds on procedures concluded before the entry into force of this Regulation.		
Recital 10			
18	(10) Due to the sensitivity of the information on the exact chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health or physical effects, submitted to the bodies appointed by the Member States under Article 45 of		

	Regulation (EC) No 1272/2008 of the European Parliament and the Council ³⁹ , that information should not be included in the common data platform. Likewise, due to the commercial sensitiveness of data and information on final cosmetic products, the information related to cosmetic products notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/2009 ⁴⁰ of the European Parliament and of the Council should not be included in the common data platform either. However, chemicals data and information on individual chemical ingredients of cosmetic products should be included in the common data platform.		
Recital 11			
19	(11) To safeguard the ability of the European Commission, of the Union agencies working on chemicals and of the competent Member State authorities (hereinafter 'the Authorities'), to carry out their tasks, documents with chemicals data relating to their internal work or decision-making should in principle not be included in the common data platform.		
Recital 12			
20	(12) In order to respond to the needs of the digital economy and to ensure a high level of protection of the environment and human health, it is necessary to lay down a harmonised framework specifying who is entitled to access and use the chemicals data contained in the common data platform, under which conditions, on what basis, and for which purposes. The Authorities that are entrusted with regulatory tasks related to chemicals should be allowed and encouraged to use the chemicals data and information contained in the common data platform to effectively fulfil their regulatory duties and tasks, in order to improve the effectiveness, efficiency, and coherence of chemicals-related assessments as well as the development of Union chemicals policies.		
Recital 13			
21	(13) Chemicals data and information generated as a result of obligations set by Union acts on chemicals may be protected by		

	confidentiality claims on confidential business information. The public dissemination of such data may affect the commercial interest of private parties. To ensure legal certainty for duty holders and to protect their legitimate expectations, as well as to ensure industry's competitiveness on the internal market, the ECHA, as a manager of the common data platform, should grant differentiated access rights to the data and information contained in the common data platform. To this end, the Authorities should have full access to all chemicals data and information contained in the common data platform, including access to confidential information, while business operators and the general public should have restricted access to that data and information, which does not include access to confidential information.		
Recital 14			
22	(14) When using data contained in the common data platform, the Authorities should respect the originator principle. Under this principle, the confidentiality marking of chemicals data as done by the originator and as correspondingly indicated by the Agency when it provides that data to the common data platform should be respected by the Authorities using that data or information to perform their regulatory functions or fulfil their tasks.		
Recital 15			
23	(15) To ensure the protection of legitimate expectations of duty holders when generating or submitting data or information under the Union acts listed in Annex I, as well as to protect the confidentiality of that information when used by the Authorities, exceptional grounds for disclosing confidential information laid down in the Union acts listed in Annex I should apply only to the disclosure of the data and information submitted or generated in compliance with those acts. For example, under Article 39(4) of Regulation (EC) No 178/2002 of the European Parliament and of the Council⁴¹, where urgent action is essential to protect human health, animal health or the environment, such as in emergency situations, the European Food Safety Authority ('EFSA') may disclose information previously considered confidential under that Regulation and the EFSA is required to make public information,		

	previously considered confidential, that forms part of conclusions of scientific outputs of the EFSA and relates to foreseeable effects on human health, animal health or the environment. Likewise, Article 118 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁴² provides for the possibility for the ECHA to disclose confidential information submitted to it under that Regulation if urgent action is essential to protect human health, safety or the environment, such as in emergency situations.		
Recital 16			
24	(16) Taking into account that the Agencies would be required to store scientific data, which includes confidential and personal data, it is necessary to ensure that such storage is carried out in accordance with a high level of security of information systems and that access to confidential data is auditable.		
Recital 17			
25	(17) While the ECHA should identify and develop the technical functionalities of the common data platform in stages, certain dedicated services should be defined by this Regulation. As such, the common data platform should, in addition to providing access to chemicals-related data made available by the Agencies and the Commission, provide access to the chemicals data and information made available through its dedicated services. These dedicated services should be integrated into the common data platform and consist of the existing Information Platform for Chemical Monitoring ('IPCHEM'), a repository of reference values, a database of study notifications, a database with information on regulatory processes, a database with information on applicable legal obligations, a repository of standard formats and controlled vocabularies, a database on environmental sustainability related data, as well as a dashboard of indicators on chemicals.		
Recital 18			
26	(18) The Commission should adopt an implementation plan identifying initial datasets to be made accessible via the platform and the timeline		

	for their integration, informed by the preparatory work of the Commission and the Agencies ⁴³ . The Commission should set up a governance scheme to support and steer the common data platform's operation and evolution covering the organisation of work structures and coordination between ECHA and data providers, required rules, formats and vocabularies for data integration, and maintain a rolling implementation plan to ensure the progress in identification and integration of new datasets and services for inclusion. The governance scheme should be adopted and updated as necessary by the Commission, after consultation with a newly established platform steering committee composed of representatives from Union agencies and the Commission. In order to ensure uniform conditions for the implementation of the obligations to establish an implementation plan and a governance scheme, implementing powers should be conferred on the Commission.		
Recital 19			
27	(19) The common data platform should serve the widest possible community, with the ability to address new use cases, incorporate new relevant datasets, develop new functionalities, and respond to developing tools and applications.		
Recital 20			
28	(20) In order to bring together all relevant chemicals data and information in the common data platform, the Commission and Union agencies – notably the European Agency for Safety and Health at Work ('EU-OSHA'), the ECHA, the European Environment Agency ('EEA'), the EFSA, and the EMA ('the Agencies'), should act as data providers and make available any such relevant data they have or hold to the ECHA for integration in the common data platform. The Agencies, including the ECHA itself when making its own data available, should provide the necessary standard metadata, contextual information and relevant mapping to the platform's structure, and respect rules on standard formats and controlled vocabularies where available.		
Recital 21			

29	(21) To ensure that an adequate knowledge base on chemicals is available through the common data platform, the Commission should be able to request the Agencies to host, maintain and make available, via the common data platform, data generated as part of Union, national or international programmes or research activities beyond the data already flowing to the Agencies as part of the obligations under the Union acts listed in Annex I. The Commission should make such requests to the Agencies in accordance with their mandates and allocated tasks.		
Recital 22			
30	(22) Some types of data are currently not within the mandate of any of the Agencies. In order to ensure clarity of responsibilities of the Agencies and efficient management of chemicals data, the Agencies should be required to host, maintain and provide specific data types to the common data platform. To this end, the ECHA should host and be a data provider to the common data platform for workplace monitoring data, and the EEA should host and be a data provider to the common data platform for data on indoor air quality and environment monitoring data, as well as data on concentrations of chemicals in human matrices such as blood or urine ('human biomonitoring data').		
Recital 23			
31	(23) To improve the uptake of academic data and to expand the knowledge base for chemicals safety assessments and environmental sustainability impacts of chemicals, researchers or research consortia funded by Union framework programmes should make available, in line with the 'as open as possible, as closed as necessary' principle, any human biomonitoring data they collect or generate resulting from research and development programmes to the EEA and any environmental sustainability data on chemicals or materials they collect or generate to the ECHA.		
Recital 24			
32	(24) The EEA, as the agency responsible for monitoring data and information on chemicals in the environment, should also be		

	responsible for collecting, hosting, and maintaining human biomonitoring data. To the extent that human biomonitoring data constitutes a special category of personal data, namely, health data, the EEA should process that data only where the processing is necessary for reasons of substantial public interest, as required by Article 10(2)(g) of the Regulation (EU) No 2018/1725 of the European Parliament and of the Council ⁴⁴ . This Regulation lays down the cases where there is such substantial public interest in processing human biomonitoring data: namely, where the EEA processes that data to assess the impact of chemicals on human health and the environment, to monitor time and spatial trends in exposure, to develop health risk and impact indicators, to monitor the impact of regulatory intervention, and to support regulatory risk assessments.		
Recital 25			
33	(25) In order to ensure that appropriate safeguards are in place to secure the protection of this sensitive type of personal data, the EEA should only provide anonymised human biomonitoring data to the ECHA for integration in IPCHEM and the common data platform. IPCHEM, currently operated by the Commission, gathers occurrence data on chemicals in different media, including water, soil, indoor and outdoor air, biota, food and feed, humans, and products. In order to take advantage of the integration of various information systems and to ensure that occurrence data on chemicals is made available for use together with the other chemicals data, the ECHA should take over from the Commission the operation of IPCHEM and integrate it in the common data platform as one of its main dedicated services.		
Recital 26			
34	(26) In order to prevent disruption to the existing operation and functioning of the IPCHEM, the ECHA should integrate the IPCHEM in the common data platform together with the data present in IPCHEM at the moment of integration. At the same time, in order to enable optimal hosting and management of occurrence data on chemicals, the Commission should also transfer the data present in IPCHEM to the ECHA, the EEA or the EFSA for hosting and future updating in		

	accordance with their respective mandates. In order to ensure that the ECHA takes over from the Commission the operation of the IPCHEM, integrates it into the common data platform and takes over the initial data sets and sets up adequate data flows, it is necessary to allow the ECHA an appropriate period of time to carry out these actions, of up to 3 years from the date of entry into force of this Regulation.		
Recital 27			
35	In order to promote the use and harmonisation of reference values among risk assessors and risk managers across different Union acts and to facilitate compliance with, and enforcement of, regulatory reference values, the ECHA should establish and maintain a repository of reference values established or adopted under the Union acts listed in Annexes I and II The Agencies should provide the ECHA with reference values they hold or establish as part of their activities. In addition, the ECHA should regularly screen Union acts for reference values adopted under them. To facilitate automatic access of the general public to up-to-date reference values, the ECHA should integrate the repository of reference values in the common data platform as a dedicated service, include in that repository all reference values together with the relevant context data it has received or retrieved and ensure that those values and that context data are machine readable.		
Recital 28			
36	(28) In order to increase transparency, as well as to enable Authorities to have complete prior knowledge of studies commissioned by business operators, irrespective of whether such studies are carried out by the business operator itself or are outsourced, business operators and laboratories should notify to a database of study notifications established and managed by the ECHA the studies on chemicals they commission for compliance with regulatory requirements under the Union acts listed in Annex I. For this purpose, the ECHA should establish and manage a database of study notifications, as a dedicated service of the common data platform, to store the information related to those studies. In order to allow business operators and laboratories sufficient time to prepare the notifications of studies, the obligation to		

	notify studies should only start to apply two years after the date of entry into force of this Regulation.		
Recital 29			
37	(29) Under Regulation (EC) No 178/2002 of the European Parliament and of the Council, business operators and laboratories are obliged to notify to the database of study notifications established and managed by the EFSA the studies they commission to support an application or notification in relation to which Union law contains provisions for the EFSA to provide a scientific output. To avoid overburdening business operators and laboratories, they should therefore not be required to also notify those studies to the database of study notifications established and managed by the ECHA under this Regulation.		
Recital 30			
38	(30) To ensure the coherence between those two study notification mechanisms, as well as to ensure certainty for business operators submitting notifications, the rules on the public dissemination of study notifications should, where relevant, correspond in that the notifications should only be made available through the common data platform EN 27 EN once a corresponding registration, application, notification or other relevant regulatory dossier was submitted to the relevant Union or national institution and a decision on the confidentiality of the data contained in that regulatory dossier was taken by that Union or national institution. In addition, in order to facilitate compliance with the requirement to notify a study, the ECHA and the EFSA should cooperate to ensure a common approach for the identification of notified information in order to facilitate the traceability of studies notified to their respective databases.		
Recital 31			
39	(31) While the study notification obligation established in this Regulation should apply in the context of all the Union acts on chemicals listed in Annex I, the various relevant data collection and safety assessment processes under those acts may vary widely		

	procedurally. The overarching aim of the database of study notifications established under this Regulation should be to bring together information on studies on chemicals being commissioned by business operators, such as to enable a centralised and complete overview of the studies being performed to support regulatory compliance under Union acts on chemicals as listed in Annex I. On the basis of this objective and considering the fact that assessment procedures under Union acts on chemicals in Annex I may vary widely, it would be beyond the scope and aim of this Regulation to amend existing assessment processes set under those Union acts listed in Annex I by imposing additional conditions leading to potential market access consequences not foreseen in those Union acts. Consequently, it is not appropriate to introduce in this Regulation the consequences associated non-compliance with the study notification obligation as laid out in Article 32b of Regulation (EC) No 178/2002 of the European Parliament and of the Council.		
Recital 32			
40	(32) Nevertheless, to ensure compliance with the study notification obligation laid down in this Regulation, and to cater to the specificities of individual assessment processes, where existing, Member States should lay down rules on penalties applicable to the infringement of that obligation and take all necessary measures to ensure that those rules are complied with. Those penalties should be effective, proportionate, and dissuasive, since non-compliance with this Regulation could result in less robust chemicals risk assessments, creating potential risks and consequently adverse effects on human health and the environment.		
Recital 33			
41	(33) In order to facilitate enforcement by Member States, the Agencies responsible for assessing and providing scientific output, including scientific opinions, on regulatory dossiers containing studies subject to notification to ECHA should, where relevant, cooperate and exchange information with the Member State enforcement authorities on the compliance with the obligations laid out in Article 22.		

Recital 34			
42	(34) While Regulation (EC) No 178/2002 of the European Parliament and of the Council also requires the consultation of stakeholders and the public following the notification to the EFSA of studies commissioned for the purposes of the renewal of an authorisation or approval, a similar requirement under this Regulation would lay a disproportionate administrative burden on the ECHA, given the wide scope of the studies that is to be notified under this Regulation.		
Recital 35			
43	(35) A mechanism related to study notifications exists in Regulation (EC) No 1907/2006 of the European Parliament and of the Council. Where registrants are required to perform studies to generate data in accordance with requirements in Annexes IX and X to that Regulation, they must first submit a testing proposal to the ECHA in order to receive a decision requiring them to perform a study. Such decision may also be issued as an outcome of compliance check or substance evaluation under that Regulation. In order to facilitate the transparency, traceability, and effective monitoring of studies commissioned or carried out pursuant to a decision of the ECHA in accordance with Articles 40, 41 or 46 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council, business operators should specify in their notifications of studies under this Regulation that those studies are being commissioned or carried out in compliance with those decisions.		
Recital 36			
44	(36) To strengthen the coordination and cooperation between the different bodies performing chemicals assessments in the Union, and to promote an increased transparency of chemicals assessments, the ECHA should establish and manage a database with information on regulatory processes or activities that are planned, ongoing or completed by Member States, the Commission and Agencies referred to in the Union acts listed in Annex III to this Regulation and integrate it into the common data platform for access by the authorities. The		

	information on such regulatory processes or activities should include at least the substance identity and the identification, status and eventually the outcome of the regulatory process or activity. That information should also be made available without undue delay and kept updated through the assessment process. Once the process or activity has formally started, that information should be shared also publicly on the common data platform.		
Recital 37			
45	(37) The existing 'The EU Chemicals Legislation Finder' ⁴⁵ project managed by the ECHA makes it easier to find and identify legal obligations related to the use of a specific chemical. The project is especially helpful for small and medium sized enterprises in identifying their legal obligations. To reinforce the supportive function of the project for business operators, it should be established on a permanent basis and more Union acts should be included in its scope. For this purpose, the ECHA should collect information on the legal obligations deriving from the Union acts on chemicals listed in Annex I to this Regulation and incorporate that information into the common data platform as a dedicated service.		
Recital 38			
46	(38) In order to ensure the interoperability and comparability of chemicals data and to facilitate their automatic and electronic exchange, the Agencies and the Commission should store chemicals data in adequate and mutually coherent and interoperable formats and use mutually coherent and interoperable controlled vocabularies. Some Union acts listed in Annex I or II set procedures to establish or make available data formats, in particular for the submission of chemicals data by business operators or Member States. Where such procedures do not exist in the Union acts listed in Annex I or II, the Agencies and the Commission should, where relevant, specify appropriate formats for chemicals data they receive and store, avoiding the use of proprietary standards while, as appropriate, using OECD or other internationally agreed formats, making use of existing formats and ensuring interoperability with existing data submission		

	approaches.		
Recital 39			
47	(39) Likewise, the Agencies and the Commission should specify appropriate controlled vocabularies for data they receive and store and, where relevant, integrate them in submission software or formats. Moreover, in order to facilitate a smooth electronic exchange of data through the common data platform, the Agencies and the Commission should agree on the required formats and controlled vocabularies for providing data to the common data platform. Whenever the Agencies or the Commission set formats or controlled vocabularies, they should cooperate with each other to ensure their coherence, consistency and interoperability. In order to ensure uniform conditions for resolving divergences in data formats and controlled vocabularies, implementing powers should be conferred on the Commission.		
Recital 40			
48	(40) In order to promote the interoperability of database systems on chemicals beyond the common data platform, the ECHA should establish a repository of standard formats and controlled vocabularies as part of the common data platform. The Agencies and the Commission should make the formats and controlled vocabularies they set available to the repository and the ECHA should make them available free of charge in electronic formats for use by developers of database systems and the general public.		
Recital 41			
49	(41) The International Uniform Chemical Information Database ('IUCLID') is a software application designed to record, store, maintain and exchange data on chemicals. The ECHA develops and maintains the IUCLID software and the underlying format in collaboration with the Organisation for Economic Cooperation and Development ('OECD'). The IUCLID implements all OECD-harmonised templates, which are harmonised formats agreed at the OECD level to facilitate structured and consistent documentation of test outputs and similar chemicals data. Since chemicals data is being submitted to the ECHA in IUCLID		

	under Union acts such as Regulations (EC) No 1907/2006, (EC) No 1107/200946 and (EU) No 528/201247 of the European Parliament and of the Council, the ECHA is closely involved in the continued development of IUCLID, and IUCLID implements the standard formats agreed at the OECD level, it is appropriate and necessary to require the Commission and the Agencies to use IUCLID for the relevant parts of dossiers under specified Union acts listed in Annex I when they make the data contained in those dossiers available to the ECHA .		
Recital 42			
50	(42) To increase the availability and facilitate the use of information on the environmental performance of chemicals throughout their lifecycle, and to enable a comprehensive assessment of the impacts of chemicals on the environment, the Commission should identify relevant data and information related to the environmental sustainability of chemicals, including, where available, information on their impact on climate change, for integration into the common data platform. Once the Commission has identified the relevant existing datasets on environmental sustainability related data and has designed the relevant related database functionalities, the ECHA should establish a database on environmental sustainability-related data, collect the data as made available by the Commission, the Agencies and, where relevant, by the researchers and research consortia funded by Union framework programmes, and integrate the content of that database into the common data platform as a dedicated service. In order to ensure uniform conditions for the implementation of the obligation to identify relevant environmental sustainability datasets, implementing powers should be conferred on the Commission.		
Recital 43			
51	(43) To monitor the impacts on humans and the environment, including the climate, of exposure to chemicals and to establish a knowledge base to measure the effectiveness of chemicals legislation in protecting human health and the environment, the EEA and the ECHA should jointly develop and regularly, at least every two years, update a set of indicators and present it in the form of a dashboard. The EFSA, the		

	EMA, the EU-OSHA and the Commission shall regularly provide the EEA with any available data falling within their mandate and relevant for the establishment of the indicators. The EEA and the ECHA should integrate this dashboard of indicators into the common data platform.		
Recital 44			
52	(44) To enable the identification and evaluation of emerging chemical risks, the EEA should develop and compile information on early warning signals and draw up an annual summary report to inform regulatory follow-up actions. In its work, the EEA should include its own sources, targeted literature searches and make use of information from national early warning systems. It should also include relevant information made available by the related work of the ECHA, the EFSA, the EU-OSHA, the EMA and their networks, such as the EFSA's task of identifying and collecting information on emerging risks under Regulation 178/2002. The EEA should make the summary report and the underlying data available through the common data platform, ensuring public access and its use for further action on existing and emerging risks. In order to allow the EEA sufficient time to organise the collection of early warning signals and to compile and analyse the initial information the EEA should only deliver the first report six months after the end of the first calendar year after entry into force of this Regulation. This Regulation sets a deadline for the first report and associated data.		
Recital 45			
53	(45) In June 2017, at the Commission' request, the ECHA set up the European Observatory for Nanomaterials ⁴⁸ ('EUON'), which collects existing data and information from databases, registries and studies and generates new data through studies and surveys on nanomaterials on the EU market.		
Recital 46			
54	(46) The ECHA should continue operating the EUON and transform it into an observatory for specific chemicals with potential contribution to emerging chemical risks ('the observatory'), which should cover also		

	other chemicals and innovative (rationally designed complex 'advanced') materials selected by the Commission, using, as appropriate, signals from the early warning and action system. One of the criteria for selecting chemicals for the observatory should be their novelty and disruptive potential that may contribute to an emerging chemical risk. Another criterion for that selection should be the higher degree of uncertainty surrounding them and, due to less regulatory experience regarding those chemicals, the resulting need for additional scrutiny and transparency. The observatory should facilitate regulatory implementation and responsible use of these chemicals by collecting, generating, and disseminating reliable information on selected chemicals' properties, uses and market presence to the general public.		
Recital 47			
55	(47) The observatory should not be regarded as a substitute for required risk management action on any chemical in cases where a hazard or risk has been identified. In order to provide for an efficient and consistent approach for the generation and dissemination of all such additional information, the ECHA should oversee the work of the observatory and make the regularly updated data and information it collects available through the common data platform, or by means of other communication channels, as appropriate. In order to ensure uniform conditions for the implementation of the requirement to select chemicals to be included in the observatory, implementing powers should be conferred on the Commission.		
Recital 48			
56	(48) Under Regulation (EC) No 178/2002, the EFSA is able to commission, in an open and transparent manner, the scientific studies it needs to accomplish its mission, while seeking to avoid duplication with Member States or Union research programmes. The ECHA should also be able to commission studies to obtain adequate data and information on chemicals within its mission, while maintaining the principle that the burden to prove compliance with Union chemicals legislation remains on the duty holder. Furthermore, the ECHA should commission such studies out of its own initiative or at the request of		

	the Commission, with the objective of supporting the effective and efficient implementation and evaluation of Union acts on chemicals within its mandate and contributing the development of a Union chemicals policy.		
Recital 49			
57	(49) In order to adjust the contents of Annexes I and III to technical and scientific progress in the field of chemicals and to bring in the scope of this Regulation new Union acts under which relevant chemicals data and information is generated or submitted, and, where relevant, to expand the specific data types and reference values, listed in Annex II, to be made available by the EMA through the common data platform, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending Annexes I, II and III. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work in relation to the amendment of the Annexes by delegated act, including at expert level through the One-Substance One-Assessment Expert Group, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016 ⁴⁹ . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.		
Recital 50			
58	(50) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States as Member States do not hold the data within the scope of this Regulation and cannot establish a Union wide common data platform, but can rather, by reason of chemicals data and information being hosted at Union level by the Agencies, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as		

	set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.		
Recital 51			
59	(51) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council and delivered an opinion on [OP: Please insert the date of the opinion of the EDPS].		
Formula			
60	HAVE ADOPTED THIS REGULATION:		
Chapter I			
61	Chapter I SUBJECT MATTER, SCOPE AND DEFINITIONS		ES GENERAL COMMENT: Given the new competences that ECHA assumes with this new proposal, it is important that ECHA's tasks are clearly defined in the future proposal for the basic ECHA Regulation, avoiding overlaps with the competences of other Agencies or Competent Authorities. In addition, this Regulation should clearly state that there will be no change in the authorisation competences for chemicals. It seems to us that the text needs to be improved in this respect. For example, in the case of medicines and medical devices, it is vital to continue to maintain the Commission/EMA competences for centrally authorised medicinal products through its Pharmaceutical Committee and the national competent authorities (regulatory agencies) for nationally authorised medicinal products.
Article 1			

62	Article 1 Subject matter and scope		
Article 1(1)			
63	1. This Regulation aims to ensure the efficient delivery of coherent hazard and risk assessments of chemicals where those assessments are required by Union legal acts, to achieve a high level of protection of human health and the environment, to enable the development and use of sustainable chemicals, to ensure the proper functioning of the single market for chemicals, and to improve the Union's citizens' trust in the scientific base for the decisions taken under Union legal acts on chemicals.	NL propose to include SSBD (safe and sustainable by design) as one of the roles for the platform. → PRES propose to work on an amendment introducing explicitly the safe and sustainable by design approach as one of the aims.	
Article 1(2)			
64	2. To achieve the objectives referred to in paragraph 1, this Regulation contains measures to:		
Article 1(2), point (a)			
65	(a) bring together data and information on chemicals and ensure that data and information are easily findable, accessible, interoperable and		

	re-usable;		
Article 1(2), point (b)			
66	(b) keep records of studies commissioned or carried out by business operators in the context of fulfilling their obligations set under Union chemicals legislation;		
Article 1(2), point(c)			
67	(c) establish the widest possible scientific base for the implementation and development of Union legislation and policy on chemicals;		
Article 1(2), point (c)			
68	(d) establish an early warning and action system for emerging chemical risks.		
Article 1(3)			
69	The provisions laid down in this Regulation apply to chemicals data as laid out in Article 3(2).		
Article 2			
70	Article 2 Definitions	• AT request amending art.2 to clarify the meaning of “product” in this proposal. • IE query what is covered by the term “products” in art.7(1) • DK request examples of the meaning of “chemical products” in relation to mixtures, articles, substances. • PRES highlights that the term occurs in recital (8), (10),(25),art.3(3), art.7(1), art.22(1). • PRES highlights also that while some of those occurrences relates to cosmetic or medicinal products, other occurrences do not refer to a particular regulation and might have overlapping meaning with e.g. articles in REACH, or products under the ESPR. → PRES is working on an amendment proposal.	ES: Agree to clarify the definition of "product".

Formula			
71	For the purpose of this Regulation, the following definitions shall apply:		
Article 2(1)			
72	1. 'Agencies' means the European Chemicals Agency ('ECHA'), the European Environment Agency ('EEA'), the European Food Safety Authority ('EFSA') and the European Medicines Agency ('EMA') and the European Agency for Safety and Health at Work ('EU-OSHA');		
Article 2(2)			
73	2. 'Authorities' means the European Commission, the competent authorities of the Member States as referred to in any of the Union acts listed in Annexes I and III, and the Agencies, excluding their management boards;		
Article 2(3)			
74	3. 'duty holder' means a natural or legal person responsible for meeting obligations under the Union acts listed in Annex I or II;		
Article 2(4)			
75	4. 'business operators' means duty holders which are private or public undertakings;	• IE suggests to "use 'economic operators' instead of 'business operators' to ensure alignment with other relevant legislation". • PRES highlights that the term "business operator" is used in recital (8),(13),(28),(29),(30),(31),(35),(37),(38), and articles 1(2), 22, 25, and 26. Those articles relates to studies commissioned, studies notifications, and related enforcement/penalties. • PRES highlights that the term "duty holder" is defined in art. 2(3) in relation to obligations in acts mentioned in annex I or II. The terms is per se used in recital (13), (15), (48),art 2(4), 15(5), and 17(2). Those later articles relate to the use of the controlled vocabularies, as well as the prohibition for Authorities to use data from the platform to fulfil legal	

		obligations of duty holders. → PRES seeks written comments on the following: ESPR has a definition of “economic operator”: ‘economic operator’ means the manufacturer, the authorised representative, the importer, the distributor, the dealer and the fulfilment service provider. PRES understands that in the present regulation the meaning of it is much more narrow, and relates only to duty holders that at the same time are undertakings. → PRES seeks for agreement that in consequence there is no correspondence with other EU regulations, and thus no amendment here should be done.	
Article 2(5)			
76	5. ‘human biomonitoring data’ means concentrations of chemicals measured in human matrices such as blood or urine;		
Article 2(6)			
77	6. ‘reference value’ means an estimate of a maximum exposure to or emission level of a chemical below which no or only acceptable adverse effects on human health or the environment are expected, or below which risks related to the adverse effects on human health or the environment are considered acceptable or tolerable;	• AT commented about “acceptable or tolerable” in relation to non-threshold cancerogenic substances. • PRES understands that the intention is to avoid that reference values for non-threshold substances are published without mentioning as metadata the actual statistical risk they represent. → PRES proposes to work on an amendment of art 2(6), 8 and 14 for this.	
Article 2(7)			
78	7. ‘originator’ means the Commission, Agency, or Member State competent authority responsible for confidentiality assessments under any Union act listed in Annex I or Annex II;		
Article 2(8)			

79	8. 'originating Union act' means the Union act under which chemicals data and information were generated or submitted;		
Article 2(9)			
80	9. 'controlled vocabularies' means standardised and organised arrangements of words and phrases presented as lists of terms or as thesaurus and taxonomies with a hierarchical structure of broader and narrower terms;		
Article 2(10)			
81	10. 'chemicals data' means any representation of facts or information relating to chemicals and any compilation of such facts or information, including information on physico-chemical properties, hazard properties, use, exposure, risk, occurrence, emissions and manufacturing process of the chemicals, as well as environmental sustainability related information, including climate change related information, on those chemicals, regulatory process-related information on chemicals, standard formats, controlled vocabularies, or any information on applicable legal obligations related to chemicals;		
Article 2(11)			
82	11. 'environmental sustainability related data' means any data relevant for the environmental sustainability assessment of a chemical or material throughout its entire life cycle, including:	• AT finds this definition vague, and proposes to add an annex (e.g. in Art. 13) which can be updated on a regular basis by means of Delegated Acts. This annex should contain the respective legal acts as well as the associated sustainability information. • PRES highlights that the definition here is used in a broader sense than the information available in legal acts (e.g. research in art.5(6), art 13(3) and potentially art.13(4)). → PRES requests written comments on the necessity to add a reference to a new annex IV, containing a list legal acts relevant for environmental sustainability related data. Such a reference would be added here as a new point 2(11)(d) along with related delegated powers in Chapter VIII. → PRES would also like to have comments on the provisions of art.13(4) as this partially overlaps with the concern raised by AT (by	ES: in agreement with AT's comment To the questions raised by the PRES: We agree with the incorporation of an Annex IV in the Regulation referring to the standards from which environmental sustainability data is subtracted. The objectives of the delegated act are not clear. Furthermore, we have doubts about the scope of this delegated act, which should be made more concrete.

		having the COM adopting an implementing decision for data not already hosted or hold by agencies/COM or not coming from EU research). Which relevant data are generated through legal acts but are not hold or hosted by COM/agencies listed in this proposal?	
Article 2(11), point (a)			
83	(a) data on resources, including raw materials, water, energy, fossil fuels and land;		
Article 2(11), point (b)			
84	(b) data on emissions, including greenhouse gases, eutrophication-relevant substances, dust and all other polluting substances; and		
Article 2(11), point (c)			
85	(c) data on by-products originating during the chemical's life cycle that can be used as resources for other production processes, including hydrogen and carbon monoxide.		
Article 2(12)			
86	12. 'personal data' means personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679 of the European Parliament and of the Council and as defined in Article 3, ~~point (16), of Regulation (EU) 2018/175~~ point (1), of Regulation (EU) 2018/1725 of the European Parliament and of the Council;	FR highlighted that this definition is specified in Article 3, point (1) of Regulation 2018/1725 and not in Article 3, point (16) of Regulation 2018/175. → PRES sees this as an editorial amendment and proposes to modify Article 2 (12) consequently.	ES supports this editorial amendment
Article 2(13)			
87	13. 'processing' means processing as defined in Article 4, point (2), of Regulation (EU) 2016/679 of the European Parliament and of the Council and as defined in Article 3, point (3), of	FR highlighted that the reference is to Regulation 2018/1725 and not to Regulation 2018/175. → PRES sees that this is an editorial amendment and proposes to	ES supports this editorial amendment

	~~Regulation (EU) 2018/175~~ Regulation (EU) 2018/1725 of the European Parliament and of the Council;	modify Article 2 (13) consequently.	
Article 2(14)			
88	14. ‘data controller’ means controller as defined in Article 4, point (7), of Regulation (EU) 2016/679 and as defined in Article 3, point (8), of ~~Regulation (EU) 2018/175~~ Regulation (EU) 2018/1725 of the European Parliament and of the Council;	FR highlighted that the reference is to Regulation 2018/1725 and not to Regulation 2018/175. → PRES sees that this is an editorial amendment and proposes to modify Article 2 (14) consequently.	ES supports this editorial amendment
Article 2(15)			
89	15. ‘interoperability’ means the ability of two or more data spaces or communication networks, systems, products, applications or components to exchange and use data in order to perform their functions.	- DE asks if advanced programming interfaces (API) will be used. - PRES highlights that API are tools that MS may use amongst others in order to query the data platform from their own advanced knowledge management systems (i.e. machine readability) instead of relying on “manual” queries in a web interface like in ECHA web site today. - PRES highlights that in the explanatory memorandum the COM mentions that “The proposal also contributes to the objectives of EU data and digital policies by promoting interoperability and machine readability”. However only interoperability is explicitly mentioned here. → PRES requests written comments on this and on the necessity to amend the proposal to explicitly mention APIs and the conditions of their use for MS and the public.	
Chapter II			
90	Chapter II INFORMATION SYSTEMS AND PLATFORMS		
Article 3			
91	Article 3 Common Data Platform on Chemicals		
Article			

3(1)			
92	1. The ECHA shall establish and manage a common data platform on chemicals ('the common data platform').		
Article 3(2)			
93	2. The common data platform shall provide access to all chemicals data:	- FR highlights that it is difficult to assess the exhaustiveness of annexes I and III. → PRESID request written comments on any potentially missing relevant regulations in those annexes. - FR question the differentiated approach between medicinal products and biocidal and phytopharmaceutical products. → PRESID would like to know if FR may bring this topic during the corresponding agenda point at the 2nd WP as it is not clear for us which could be the proposal that could be made on this basis.	
Article 3(2), point (a)			
94	(a) generated or submitted as part of the implementation of the Union acts listed in Annex I to this Regulation and held by the Agencies or the Commission;		
Article 3(2), point (b)			
95	(b) generated as part of Union, national or international programmes or research activities in the sphere of chemicals and held by the ECHA, the EEA, the EFSA, the EU-OSHA or the Commission;		
Article 3(2), point (c)			
96	(c) listed in Annex II and held by the EMA;		
Article 3(3)			
97	3. The following information shall not be included in the common data		

	platform:		
Article 3(3), point (a)			
98	(a) the information referred to in Article 45 of Regulation (EC) No 1272/2008 ⁵⁰ ; 50 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).		
Article 3(3), point (b)			
99	(b) the information related to cosmetic products and notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/2009 ⁵¹ of the European Parliament and of the Council. 51 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November on cosmetic products (OJ L 342 22.12.2009, p. 59).		
Article 3(4)			
100	4. Documents relating to Authorities' internal work or decision-making processes need not be included in the common data platform, unless required under Article 10.		
Article 3(5)			
101	5. The common data platform shall provide the dedicated services identified in the governance scheme referred to in Article 4(3) including:		
Article 3(5), point (a)			
102	(a) the Information Platform for Chemical Monitoring ('IPCHEM')		

	referred to in Article 7;		
Article 3(5), point (b)			
103	(b) the repository of reference values referred to in Article 8;		
Article 3(5), point (c)			
104	(c) the database of study notifications referred to in Article 9;		
Article 3(5), point (d)			
105	(d) information on regulatory processes referred to in Article 10;		
Article 3(5), point (e)			
106	(e) information on obligations under Union chemicals legislation referred to in Article 11;		
Article 3(5), point (f)			
107	(f) the repository of standard formats and controlled vocabularies referred to in Article 12;		
Article 3(5), point (g)			
108	(g) the database on environmental sustainability-related data referred to in Article 13.		
Article 3(6)			
109	6. The Authorities and the general public shall have access to the data contained in the common data platform in accordance with Article 16.		
Article 3(7)			
110	7. The data contained in the common data platform may be used in		

	accordance with Article 17.		
Article 3(8)			
111	8. The data contained in the common data platform shall be made available in standard formats, where developed, and through controlled vocabularies where available.		
Article 3(9)			
112	9. The data contained in the common data platform shall be electronically accessible and searchable. The ECHA shall take measures to ensure a high standard of security appropriate to the security risks at stake for the storage of chemicals data in and transmission of chemicals data to the common data platform. The ECHA shall design the common data platform in a way that guarantees that any access to confidential data is auditable.		
Article 3(10)			
113	10. The Commission or Agency under whose authority chemicals data is included in the common data platform on chemicals shall remain responsible for handling any requests for access to documents made under Regulation (EC) No 1049/200152. 52 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (. OJ L 145, 31.5.2001, p. 43).		
Article 3(11)			
114	11. The common data platform and its dedicated services shall be established by [OP: please insert date: three years after the date of entry into force of this Regulation], unless specified otherwise. The relevant datasets shall be integrated progressively into the common data platform by [OP please insert date: ten years from the date of entry into force of this Regulation] according to the implementation plan referred to in Article 4 (1), first sentence. Upon integration of those datasets in the common data platform, when the ECHA receives	- FR requested clarifications on this paragraph (timing for the notification service, lack of specification of the timing for the rolling plans). - FR proposed or suggests amendments accordingly → PRES: we suggest to integrate this into a more general discussion at the 2d WP about the entire timeline of the proposal.	

	chemicals data in accordance with Article 5, it shall make that data available through the common data platform without undue delay.		
Article 4			
115	Article 4 Implementation plan and governance of the common data platform	- DK proposed to include new provisions 5a,5b,5c in art.4., requesting that the COM prepares and presents a recommendation on “how to amend legislation listed in the Annexes to this regulation”. → PRES would like to receive written comments on this as it is not clear for us if this means amending the annexes of the data platform proposal, or if DK meant to amend the listed regulations. - DK raises concerns about the wording “implementing” appearing at several places and which is seen as “misleading” with respect to the legal definition of “implementing acts”. → PRES seeks legal advice on this. The Council legal services agreed to give an opinion on this at the 2nd WP.	
Article 4(1)			
116	1. By [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall adopt and publish an implementation plan identifying datasets for inclusion in the common data platform together with a timeline for their inclusion by means of an implementing decision. Subsequent rolling implementation plans shall be adopted in line with the governance scheme referred to in paragraph 3.	FR questions the procedure for adopting the plan, the consultation procedures and MS involvement. → PRES proposes to integrate this in a WP discussion on the desired level of and procedures for MS participation.	
Article 4(2)			
117	2. The Commission shall, by means of an implementing decision, establish and manage a platform steering committee, which shall include one representative from the ECHA, one representative from the EEA, one representative from the EFSA, one representative from the EMA, one representative from the EU-OSHA and five representatives from the Commission.		
Article 4(3)			

118	3. The platform steering committee shall advise the Commission in the preparation of the common data platform's governance scheme.		
Article 4(4)			
119	4. The Commission shall adopt and publish the governance scheme referred to in paragraph 3 and any revision thereof by means of an implementing decision		
Article 4(5)			
120	5. That governance scheme shall describe:		
Article 4(5), point (a)			
121	(a) the organisation of the main work structures supporting the development and implementation of the common data platform;		
Article 4(5), point (b)			
122	(b) the preparation and adoption of rolling implementation plans for the common data platform;		
Article 4(5), point (c)			
123	(c) the principles on data governance and the required standard formats, controlled vocabularies and further conditions for the provision of information and context data to the common data platform;		
Article 4(5), point (d)			
124	(d) the decision-making procedures for the development of new dedicated services and the inclusion of new functionalities of the platform;		
Article 4(5),			

point(e)			
125	(e) any other rules or requirements necessary for the operation of the common data platform such as the data update, archiving and deletion policy;		
Article 4(5), point (f)			
126	(f) the operation of the steering committee itself.		
Article 5			
127	Article 5 Data Flows for the purpose of the common data platform		
Article 5(1)			
128	1. At the Commission's request, the Agencies shall host and maintain chemicals data generated as part of Union, national or international legislation, programmes or research activities, corresponding to their mandate and the type of data they already hold.		
Article 5(2)			
129	2. Where the Commission or the Agencies hold data or information referred to in Article 3(2), they shall make that data available to the ECHA, in a standard format, where available, together with the relevant context data as ~~referred to in Article 4(4), point (c).~~ referred to in Article 4(5), point (c). The Commission and the Agencies shall indicate whether that data or information is made available to the public under the originating Union act.	FR highlighted that the reference should be to Article 4(5), point (and not Article 4(4), point (c). → PRES sees this as an editorial amendment and proposes to modify Article 5(2) consequently.	ES supports this editorial amendment.
Article 5(3)			
130	3. The ECHA shall host and maintain occurrence data related to workplace monitoring.		
Article 5(4)			
131	4. The EEA shall host and maintain human biomonitoring data, occurrence data for the environment and occurrence data related to indoor air quality.	DE ask if Commission pursue plans for systematic or regular surveys of indoor air quality data → PRES is requesting written comments on this.	

Article 5(5)			
132	5. Researchers or research consortia funded by Union framework programmes shall make available to the EEA any human biomonitoring data they collect or generate from [OP please insert: date of the entry into force of this Regulation].		ES: With regard to Art. 5(5) and (6), how will this obligation be established, will the regulation of these framework programmes have to be amended or will it be specifically established in the agreement with the consortium without having to go through an amendment of any framework programme? Will this Regulation create or establish any mechanism for this?
Article 5(6)			
133	6. Researchers or research consortia funded by Union framework programmes shall make available to the ECHA any environmental sustainability data on chemicals or materials they collect or generate from [OP please insert: date of the entry into force of this Regulation].		ES: Same comment as above
Article 5(7)			
134	7. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of the chemicals data provided in accordance with paragraph 2 in the common data platform as well as its publication through that platform.		
Article 5(8)			
135	8. For the purpose of paragraph 2, the Commission and the Agencies shall make chemicals data available to the ECHA without undue delay after collection or receipt of the data, after performance of validity and confidentiality assessments in accordance with applicable rules and once the corresponding dataset has been integrated in the common data platform.		
Article 5(9)			

136	9. The Commission and the Agencies shall ensure that data made available to the ECHA shall be downloadable, machine readable and interoperable. They shall appropriately curate and validate the data before providing them to the ECHA.		
Article 6			
137	Article 6 Human biomonitoring data	→ PRES: given the numerous comments, questions and clarification requests received, PRES proposes to set this as a discussion point at the 2 nd WP (8/3), and invites MS and the COM to react to the EDPS	

		recommendations.	
Article 6(1)			
138	1. The EEA shall collect, host, and maintain human biomonitoring data generated within the territory of the EEA's member and cooperating countries.		
Article 6(2)			
139	2. At the latest by [OP please insert date: 3 years after entry into force of this Regulation] the Commission shall transfer any human biomonitoring data it holds to the EEA.		
Article 6(3)			
140	3. The EEA may process human biomonitoring data constituting personal data to support the Commission in its policy making or to support the Agencies in fulfilling their missions.		
Article 6(4)			
141	4. Human biomonitoring data constituting personal data may be processed by the EEA for the following purposes:		
Article 6(4), point (a)			
142	(a) assessing the impact of chemicals on human health and the environment;		
Article 6(4), point (b)			
143	(b) monitoring time and spatial trends in exposure;		
Article 6(4), point (c)			
144	(c) developing health risk and impact indicators;		
Article 6(4), point (d)			

145	(d) monitoring the impact of regulatory intervention;		
Article 6(4), point (e)			
146	(e) supporting regulatory risk assessments.		
146.a	(f) supporting regulatory risk management	• IE proposed to add this amendment. • PRES understands that HBM data are indeed useful for risk management, e.g. trend analysis will give an idea if policy actions are having an impact or not on reducing exposure → PRES proposes thus to add this paragraph (f)	ES supports this addition.
Article 6(5)			
147	5. The EEA shall make human biomonitoring data they hold or host publicly available in anonymised form through the Information Platform for Chemical Monitoring.		
Article 6(6)			
148	6. The EEA shall act as data controller for the human biomonitoring personal data it holds or hosts and processes for the purposes referred to in paragraph 2. in paragraph 4.	• FR and SI highlighted that the reference should be to para. 4. → PRES sees this as an editorial amendment and proposes to modify art.6(6) in consequence. • SI proposes to add an additional reference to art.3 and 5 here. → PRES, up to his knowledge, understands that from the definition of a data controller this is logical, but seeks for written opinions on this and will request a legal advice. Discussions at the 2nd WP on the EDPS recommendations might also contribute clarifications on this proposal. • SI suggests to “include the same reference to Articles 6(3) and 6(4)” → PRES is keen to receive a written rationale for this as it seems to introduce a circular reference in the text.	
Article 7			

149	Article 7 Information Platform for Chemical Monitoring		
Article 7(1)			
150	1. The ECHA shall operate and maintain the Information Platform for Chemical Monitoring containing occurrence data on chemicals across different media, including water, soil, indoor air, outdoor air, biota, food and feed, humans, and products as part of the common data platform.	→ PRES: regarding the meaning of “products”, cfr art.2 (here in line 70).	
Article 7(2)			
151	2. At the latest by [OP please insert date: 3 years after the date of entry into force of this Regulation], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring at that moment to the ECHA for integration in the common data platform.		
Article 7(3)			
152	3. At the latest by [OP please insert date: 3 years after entry into force of this Regulation], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring to the ECHA, the EEA or the EFSA for hosting in accordance with the respective agencies’ mandate and in accordance with Article 5.		
Article 7(4)			
153	4. After the completion of the transfer referred to in paragraph 3, where the Commission or the Agencies host or hold occurrence data on chemicals and related chemicals data, they shall make that data available to the ECHA without undue delay for integration in the Information Platform for Chemical Monitoring.		
Article 7(5)			
154	5. The Commission and Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration and publication of occurrence data and related chemicals data they host or hold through the common data platform.		
Article			

7(6)			
155	6. The ECHA shall ensure that the data contained in the Information Platform for Chemical Monitoring is machine readable and downloadable.		
Article 8			
156	Article 8 Repository of reference values	• AT requested and amendment about the statistical (cancer) risk associated with some reference values. → PRES: see our proposal in art 2(6) here line 77	
Article 8(1)			
157	1. The ECHA shall establish and manage a repository of reference values as part of the common data platform.		
Article 8(2)			
158	2. The ECHA shall include any reference value adopted under Union acts listed in Annex I or Annex II, Part 1, in the repository of reference values without undue delay.		
Article 8(3)			
159	3. For reference values not falling under paragraph 2, the Agencies holding or establishing reference values as part of their activities under Union acts listed in Annex I, or the reference values referred to in Annex II, Part 2, shall make those reference values available to the ECHA, in the standard formats provided for in Article 14, where developed, and without undue delay, for integration in the repository of reference values.		
Article 8(4)			
160	4. For the purpose of paragraph 3, where reference values are included in a regulatory dossier submitted to the Agencies, the Agencies shall share those reference values in the standard formats with ECHA without undue delay and once relevant validity and confidentiality assessments have been completed by the originator in accordance with applicable rules.		
Article 8(5)			

161	5. The ECHA shall ensure that the data contained in the repository of reference values is machine readable.		
Article 9			
162	Article 9 Database of Study Notifications		
Article 9(1)			
163	1. The ECHA shall establish and operate a Database of Study Notifications by [OP please insert date: two years after the date of entry into force of this Regulation].		
Article 9(2)			
164	2. The ECHA shall store in the Database of Study Notifications the data notified to it in accordance with Article 22.		
Article 9(3)			
165	3. The ECHA shall integrate the data contained in the Database of Study Notifications in the common data platform once a corresponding registration, application, notification or other relevant regulatory dossier was submitted to the relevant Union or national institution, agency, or body in accordance with corresponding Union law and after a decision was taken by that Union or national institution, agency, or body on the disclosure of the accompanying studies in accordance with the applicable rules on confidentiality.	• AT considers that this deserves clarification as it seems to prevent Member States authorities from getting relevant information on notified studies in time. • PRES notes that this might be related to enforcement. → PRES seeks further written comments on this → PRES is working on an amendment proposal	
Article 9(4)			
166	4. The EFSA shall make the data contained in the database referred to in Article 32b of Regulation (EC) No 178/2002 available to the ECHA for integration in the common data platform once it has received a corresponding application and after it has decided on the disclosure of the accompanying studies in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002.		
Article 9(5)			
167	5. The ECHA and the EFSA shall cooperate to ensure a common approach for the identification of information notified to them in		

	accordance with Article 22 of this Regulation and Article 32b of Regulation (EC) No 178/2002, respectively and facilitate the traceability of the studies notified to their respective databases.		
Article 10			
168	Article 10 Information on regulatory processes on chemicals	→ PRES is seeking written comments on ES question about already existing communication channels in certain regulations, related to the stage of evaluation, and the potential need to modify those regulations. → PRES highlights that this might be the case for TRIS notifications.	
Article 10(1)			
169	1. The ECHA shall establish and manage, as part of the common data platform, a new database containing information on regulatory processes on individual substances or groups of substances that are planned, ongoing or have been completed since the entry into force of this Regulation by the Member States or the Union institutions, agencies or committees referred to in the Union acts listed in Annex III.	→ PRES is seeking for written comments on DK comment that it is not clear whether the scope of art 10(1) includes national regulations processes.	
Article 10(2)			
170	2. Where Member State competent authorities as referred to in any of the Union acts listed in Annex III hold the information referred to in paragraph 1, they shall make that information available to the Union agency responsible under the respective Union act listed in Annex III without undue delay.	→ PRES is seeking for written comments on DK request to clarify the COM reference (during the 1 st WP) to voluntary notifications, including examples.	
Article 10(3)			
171	3. Where the ECHA, EEA, EFSA, EU-OSHA or the Commission hold the information referred to in paragraph 1, they shall make that information available to the ECHA for integration in the common data platform in the standard formats provided for in Article 14 without undue delay and, where relevant, once the responsible agency or the Commission has performed the validity assessment. For each regulatory process or activity, at least the following information shall be included:	→ PRES is seeking written comments on PT question about which information EEA might have to make available to ECHA in this context, as EEA has no competences about chemical products.	
Article			

10(3), point (a)			
172	(a) substance identity;		
Article 10(3), point (b)			
173	(b) the Union act and the regulatory process under which the activity takes place;		
Article 10(3), point (c)			
174	(c) submitter or actor responsible for the regulatory process or activity;		
Article 10(3), point (d)			
175	(d) status of the regulatory process or activity;		
Article 10(3), point (e)			
176	(e) where applicable , outcome of the regulatory process or activity ~~, including, where applicable, and~~ reports or opinions adopted;	- PRES understand from FR comment that it is not always possible to indicate the (future) outcome, so this provision is not always applicable. → PRES propose to amend art 10(3) by inserting “where applicable” as we see it more precise than “where appropriate”	
Article 10(3), point (f)			
177	(f) where applicable, date of intention to start the regulatory process or activity, completion and latest update.		
Article 10(4)			
178	4. The information referred to in paragraph 3, points (a) to (f), on a specific regulatory process or activity shall be made available to the public once that process or activity has formally started.		
Article 11			
179	Article 11	PRES notes FR comment on the potentiality of IA in this	

	Information on the obligations under Union acts on chemicals	context.	
Article 11(1)			
180	1. The ECHA shall establish and manage, as part of the common data platform, a database with information on the provisions and legal obligations applicable to chemicals under the Union acts listed in Annex I.		
Article 11(2)			
181	2. The ECHA shall update the information in the database on a regular basis and in accordance with the governance scheme referred to in Article 4(3).		
Article 12			
182	Article 12 Repository of standards formats and controlled vocabularies		
Article 12(1)			
183	1. The ECHA shall establish and manage as part of the common data platform a repository of standard formats and controlled vocabularies.		
Article 12(2)			
184	2. Where standard data formats are established under the Union acts listed in Annexes I and II, the ECHA shall include them in the common data platform.		
Article 12(3)			
185	3. Where the Commission or the Agencies specify a standard format or controlled vocabulary in accordance with Articles 14 or 15, the Commission or the Agency shall make it available to the ECHA without undue delay for integration in the common data platform.		
Article 13			

186	Article 13 Database on environmental sustainability related data	• AT request for a new annex on relevant legal acts, see discussion of Article 2(11) → PRES: see line 82 here above • About the role of EIONET in this (cfr PT question)	ES: According to the Commission's presentations and explanations, this data Regulation does not impose any new obligations for MS, apart from the ones we already have under each of the regulations included in the Annexes of the proposal. On WP 2 what we understood is that MS are not obliged to share EIONET related data with the common data platform. We would appreciate to know what additional effort the Presidency is referring to.

		→ PRES include this in the discussion at the WP (effort needed by MS)	
Article 13(1)			
187	1. At the latest within three years after the publication of the decision referred to in paragraph 4, the ECHA shall establish and manage, as part of the common data platform, a database containing environmental sustainability related data.		
Article 13(2)			
188	2. Where the Commission or the Agencies host or hold environmental sustainability related data in addition to the chemicals data already available in the common data platform, they shall make that data available to the ECHA without undue delay once the Commission or the Agency hosting or holding that data has completed, where relevant, validity and confidentiality assessments. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of environmental sustainability related data in the database on environmental sustainability related data.		
Article 13(3)			
189	3. Where researchers or research consortia funded by Union framework programmes make available to the ECHA, under Article 5(6), any environmental sustainability data on chemicals or materials they collect or generate, the ECHA shall integrate the relevant data in the database on environmental sustainability related data.		ES: Please see Article 5(6).
Article 13(4)			
190	4. By [OP please insert date: three years after the date of entry into force of this Regulation], the Commission shall adopt an implementing decision identifying existing datasets on environmental sustainability related data, other than those referred to in paragraph 2, for inclusion in the common data platform and shall design relevant related database functionalities.	→ PRES is seeking legal advice about the wording “implanting decision” (cfr DK comment). Council legal services will give an opinion on this at the 2 nd WP.	
Chapter III			

191	Chapter III DATA FORMATS AND CONTROLLED VOCABULARIES	→ PRES seeks written comments on FR request to eventually have study reports and raw data provided → PRES seek written comments on the request by IE to investigate that there is no impact on the use of INCI names for cosmetics regulation, and no impact on substance identification and product labelling in that regulation.	
Article 14			
192	Article 14 Standard formats	• AT amendment proposal on statistical risk: → PRES: see here Article 2(6) line 77	
Article 14(1)			
193	1. Without prejudice to Union provisions providing for the development or making available of data formats, the Commission and the Agencies shall specify, where relevant, for the data referred to in Article 3 (2) and falling within their mandate, standard formats and software packages and make them available free of charge through the common data platform.		
Article 14(2)			
194	2. The standard formats referred to in paragraph 1 shall, to the extent possible:		
Article 14(2), point (a)			
195	(a) avoid the use of proprietary standards;		
Article 14(2), point (b)			
196	(b) re-use existing data formats or parts of them;		
Article 14(2), point (c)			
197	(c) use OECD or other internationally agreed formats;		
Article 14(2), point (d)			

198	(d) be coherent with other existing data formats;		
Article 14(2), point (e)			
199	(e) ensure interoperability with existing data submission approaches.		
Article 14(3)			
200	3. Those standard formats shall be interoperable with the common data platform and be user-friendly.		
Article 14(4)			
201	4. The Commission and the Agencies shall exchange data contained in the common data platform in the relevant standard format.		
Article 14(5)			
202	5. The Commission and the Agencies shall use the International Uniform Chemical Information Database format (IUCLID) for making available to the ECHA for integration in the common data platform the relevant parts of dossiers under the following Union acts:		
Article 14(5), point (a)			
203	(a) Regulation (EC) No 1831/2003 of the European Parliament and of the Council ⁵³ ; ⁵³ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268 18.20.2003, p. 29).		
Article 14(5), point (b)			
204	(b) Regulation (EC) No 1935/2004 of the European Parliament and of the Council ⁵⁴ ; ⁵⁴ Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and		

	89/109/EEC (OJ L 338 13.11.2004, p. 4).		
Article 14(5), point (c)			
205	(c) Regulation (EC) No 1331/2008 of the European Parliament and of the Council ⁵⁵ ; ⁵⁵ Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354 31.12.2008, p. 1).		
Article 14(5), point (d)			
206	(d) Regulation (EC) No 1332/2008 of the European Parliament and of the Council ⁵⁶ ; ⁵⁶ Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354 31.12.2008, p. 7).		
Article 14(5), point (e)			
207	(e) Regulation (EC) No 1333/2008 of the European Parliament and of the Council ⁵⁷ ; ⁵⁷ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354 31.12.2008, p. 16).		
Article 14(5), point (f)			
208	(f) Regulation (EC) No 1334/2008 of the European Parliament and of the Council ⁵⁸ ; ⁵⁸ Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food		

	ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354 31.12.2008, p. 34).		
Article 14(5), point (g)			
209	(g) Regulation (EC) No 1223/2009 of the European Parliament and of the Council 59; 59 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342 22.12.2009, p. 59).		
Article 14(5), point (h)			
210	(h) Commission Regulation (EU) No 234/201160; 60 Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 064 11.3.2011, p. 15).		
Article 14(5), point (i)			
211	(i) Directive 2009/48/EC of the European Parliament and of the Council.61 61 Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170 30.6.2009, p. 1).		
Article 14(6)			
212	6. The Commission and the Agencies shall cooperate when setting standard formats to ensure coherence with other formats and the interoperability of the standard formats with the common data platform and with existing data submission approaches.		

Article 14(7)			
213	7. The Commission and the Agencies shall take the necessary and appropriate measures to monitor and identify at an early stage any potential divergence between data formats that could cause interoperability problems. If a divergence is identified, the Agencies concerned shall cooperate to resolve it or, where the divergence is justified, explain the underlying reasons. Where the Agencies concerned are not able to resolve that divergence, they shall draw up a joint report and present it to the Commission. The report shall clearly outline the reasons for the divergence, clarify any underlying technical issue and make a proposal to remedy the divergence.		
Article 14(8)			
214	8. The Commission shall adopt an implementing decision to remedy the divergence.		
Article 15			
215	Article 15 Controlled vocabularies	→ PRES is seeking written comments on the remarks by DE about the difficulties related to differences in vocabularies between legislations. → PRES seeks for comments on the difficulties related to substances identification inconsistencies between regulations (see DE comment). PRES highlights that this problem is also relevant for art.22,25,26 on studies notification (a lack of correct identification might render difficult to implement them)	
Article 15(1)			
216	1. The Commission and the Agencies shall specify and regularly update controlled vocabularies within their mandate for the data referred to in Article 3(2), where relevant.		
Article 15(2)			
217	2. The Commission and the Agencies shall prioritise specifying controlled vocabularies for the identification of chemicals and the characterisation of their forms.		

Article 15(3)			
218	3. Those controlled vocabularies shall:		
Article 15(3), point (a)			
219	(a) avoid the use of proprietary controlled vocabularies to the extent possible;		
Article 15(3), point (b)			
220	(b) re-use existing substance identifiers and controlled vocabularies or parts of them to the extent possible;		
Article 15(3), point (c)			
221	(c) use OECD or other internationally agreed controlled vocabularies to the extent possible;		
Article 15(3), point (d)			
222	(d) ensure coherence with other relevant controlled vocabularies including by preparing alignment tables.		
Article 15(4)			
223	4. Those controlled vocabularies shall be interoperable with the common data platform.		
Article 15(5)			
224	5. Where controlled vocabularies are specified, the Commission and the Agencies shall:		
Article 15(5), point (a)			
225	(a) make them available free of charge through the common data		

	platform and as open datasets;		
Article 15(5), point (b)			
226	(b) integrate them in any submission software or template to be used by duty holders under the Union acts listed in Annex I and referred to in Article 3(2); and		
Article 15(5), point (c)			
227	(c) use them when exchanging data between them through the common data platform.		
Article 15(6)			
228	6. The Commission and the Agencies shall cooperate with each other in setting the controlled vocabularies.		
Article 15(7)			
229	7. The Commission and the Agencies shall take the necessary and appropriate measures to monitor and identify at an early stage any potential divergence between controlled vocabularies. If a divergence is identified, the Agencies concerned shall cooperate to resolve it or, where the divergence is justified, explain the underlying reasons. Where the Agencies concerned are not able to resolve that divergence, they shall draw up a joint report and present it to the Commission. The report shall clearly outline the reasons for the divergence, clarify any underlying technical issue and make a proposal to remedy the divergence.		
Article 15(8)			
230	8. The Commission shall adopt an implementing decision to remedy the divergence.		
Chapter IV			
231	Chapter IV	→ PRES: FR and PT comments here are to be discussed at the WP.	

	CHEMICALS DATA CONFIDENTIALITY AND USE		
Article 16			
232	Article 16 Access rights and transparency	→ PRES: SI request and DE questions (line 232 of the comments file) are to be discussed at the WP	
Article 16(1)			
233	1. The Authorities shall have access to all the chemicals data contained in the common data platform, including data which is deemed to be confidential under Article 5(2), second sentence.		
Article 16(2)			
234	2. The Authorities shall take the necessary measures to ensure that information contained in the common data platform marked as confidential in accordance with Article 5(2) is not made public.	→ PRES: ES comments and IE questions are to be discussed at the WP (line 234 of the comments file)	
Article 16(3)			
235	3. The general public shall have access to all the chemicals data contained in the common data platform and considered as available to the public in accordance with the Union act under which the data was generated or submitted.		
Article 17			
236	Article 17 Use of chemicals data contained in the common data platform	• DK comment on the meaning of “products” is addressed here in art.2 (see line 70). • PRES: Regarding the other comments: → PRES seeks written comments on IE concern on the identification in the data platform of cosmetics ingredients that may have been tested on animals. → PRES invites the COM to update MS on the possibility of an overview table on confidentiality provisions requested by DK •	
Article 17(1)			
237	1. The Authorities may use the chemicals data contained in the common data platform in the performance of any of their activities, where those activities support the development or implementation of chemicals legislation and policy.	→ PRES: DK request for amendment to explicitly allow national use of the data is set for discussion at the WP.	

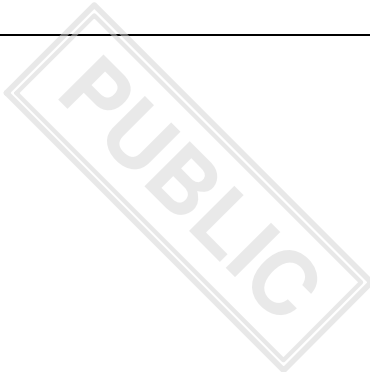
Article 17(2)			
238	2. Without prejudice to existing provisions enabling the sharing and use of chemicals data under the Union acts listed in Annexes I and II, Authorities shall not use chemicals data contained in the common data platform to fulfil any legal obligations of duty holders.	DE requested clarifications on the use of data in relation to duty holders obligations. → PRES invites for written comments on this.	
Article 17(3)			
239	3. When using chemicals data contained in the common data platform that is deemed confidential under Article 5(2), second sentence, the Authorities shall respect the confidentiality of information data as marked by the originator and shall not disclose that data to the public without the consent of the originator.		
Chapter V			
240	Chapter V MONITORING AND OUTLOOK FRAMEWORK FOR CHEMICALS		
Article 18			
241	Article 18 Framework of indicators	- DE question on MS involvement is set of discussion at the 2nd WP → PRES sets PT question on EIONET impacts for discussion at the 2 nd WP. - IE comments on cosmetics: → PRES invites for written comments on questions raised by IE on cosmetics aspects (notification of undesirable effects, link to the Communication System for Market Surveillance (ICSMS) Art 23 Reg 1223/2009, consequences on the allowance of use for critical circumstances). - PT comment on the relation to existing statistics systems → PRES invites for written comments	
Article 18(1)			
242	1. The EEA, in collaboration with the ECHA, the EFSA, the EMA, the EU-		

	OSHA and the Commission, shall establish, operate, and maintain a framework of indicators to monitor the drivers and impacts of exposure to chemicals, measure the effectiveness of chemicals legislation and measure the transition towards the production of safe and sustainable chemicals.		
Article 18(2)			
243	2. The framework of indicators referred to in paragraph 1 shall be accessible in the form of an indicator dashboard, which the EEA shall establish and which the ECHA shall make available through the common data platform.		
Article 18(3)			
243.b	3. The framework of indicators referred to in paragraph 1 shall be established, operated, and maintained by [OP: please insert date: 3 years after the end of the first calendar year after entry into force of this Regulation].	- FR expressed concerns on the timescale for establishing the framework - PRES highlights that several other articles contain indications on the timeframe → PRES submits this amendment for consideration, and set this for discussion at the 2 nd WP.	ES: We agree that a timeframe is needed.
Article 19			
244	Article 19 Early warning and action system for emerging chemical risks	→ PRES: DE question on MS experts and RAC involvement is set for discussion at 2 nd WP → PRES: PT request for clarification on implications/role of EIONET and MS is set for discussion at the 2 nd WP Regarding the other comments: → PRES seeks written comments about DE question on the relation between the indicators and the early warning system (art.18,19). → PRES invites for written comments on PT question about the level of ambition of the system in relation to complex systemic risks. → PRES invites written comment on PT proposal to include the word “prevention” in the proposal	
Article 19(1)			

245	1. The EEA shall establish, operate and maintain a Union early warning system for emerging chemical risks by [OP please insert date: one year after the date of entry into force of this Regulation].		
Article 19(2)			
246	2. For the purpose of paragraph 1, the EEA shall compile early warning signals, which shall include at least signals from:		
Article 19(2), point (a)			
247	(a) the EFSA's emerging risks exchange network;		
Article 19(2), point (b)			
248	(b) existing national early warning systems;		
Article 19(2), point (c)			
249	(c) data that the EEA holds;		
Article 19(2), point (d)			
250	(d) targeted literature searches performed by the EEA;		
Article 19(2), point (e)			
251	(e) data made available by the ECHA, the EFSA, the EU-OSHA and the EMA in accordance with paragraph 3.		
Article 19(2)			
252	The early warning signals compiled by the EEA under the first subparagraph may be based on a positive identification of an emerging risk or on an uncertainty in the data leading to a potential positive identification of an emerging risk.		
Article 19(3)			

253	3. The ECHA, the EFSA, the EU-OSHA and the EMA shall identify and gather relevant available data on early warning signals from the field falling within their mandate and provide this data to the EEA.		
Article 19(4)			
254	4. The EEA shall draw up an annual report, compiling and analysing the data on early warning signals gathered in accordance with paragraphs 2 and 3. [The first report shall be prepared by [OP: please insert date: 6 months after the end of the first calendar year after entry into force of this Regulation]. The EEA shall present this report to the Commission, relevant Union agencies and ~~Member State competent authorities for consideration of the need~~ Member State competent authorities who shall consider the need for regulatory or policy action related to the early warning signals.	FR expressed questions the request to EEA to highlight areas on which to FOCUS, in the report. PRES suppose that this may be solved by a change in the wording (mostly editorial) → PRES submits for consideration the amendment here in trackchanges	
Article 19(5)			
255	5. The EEA shall make all relevant data on early warning signals that it holds or hosts as well as the report referred to in paragraph 4 available to the ECHA for integration in the common data platform.		
Article 20			
256	Article 20 Observatory for specific chemicals with potential contribution to emerging chemical risks	→ PRES seeks written comments on DE question about the type of risks covered here, and the interplay with existing chemicals legislation.	
Article 20(1)			
257	1. The ECHA shall establish, operate and maintain an observatory for specific chemicals that the Commission considers as requiring additional scrutiny. The observatory shall include reliable information on the chemicals' properties, safety aspects, uses and market presence.		
Article 20(2)			
258	2. By [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall adopt and publish a list of the selected chemicals by means of an implementing decision. The Commission shall review the list of selected chemicals regularly and	FR highlighted that the linking word "and" is missing before the proposal "adopt any revision thereof by the same means". → PRES sees this as an editorial amendment and proposes to	ES supports this editorial amendment.

	adopt any revision thereof by the same means.	modify article 20(2) consequently (see <i>bold italic</i>). • DK request for amendments (implementing “decisions”). → PRES: questions on the meaning of “implementing”, and MS participation are set for discussion at the 2 nd WP.	
Article 20(3)			
259	3. The Commission shall select the chemicals referred to in paragraph 1 based on the scientific and technical progress and using the signals of the early warning system referred to in Article 19. The selection shall include potential contributors to new and emerging chemical risks among innovative rationally designed materials with new or enhanced properties or targeted or enhanced structural features at nanoscale.		
Article 20(4)			
260	4. For the purpose of operating the observatory referred to in paragraph 1, the ECHA shall:		
Article 20(4), point (a)			
261	(a) make use of relevant datasets integrated in the common data platform, and compile, analyse and curate further available data on selected chemicals or classes of chemicals;		
Article 20(4), point (b)			
262	(b) commission studies and, where relevant, use the data generation mechanism established under Article 21 to address knowledge gaps or significant uncertainties;		
Article 20(4), point (c)			
263	(c) make compiled data publicly available through the common data		ES: We believe it is necessary to include the following two exceptions: - active substances used in medicines (reason: misunderstanding of information



			can lead to bad decisions being made by the patient and can affect public health, e.g. misinformation on vaccines.) - data that have not been adequately evaluated and harmonized between Agencies (explanation: in the sense that there cannot be Substances that have divergent evaluations between Agencies, and as long as this divergence is not resolved by the COM, they should not be published.)

	platform or other communication and outreach tools as appropriate, to facilitate informed societal discussion and increase public awareness on the properties, use and safety aspects of specific chemicals, and regularly update that information.		
Chapter VI			
264	Chapter VI DATA GENERATION MECHANISM		
Article 21			
265	Article 21 Data generation mechanism	- IE raised the question of the promotion of animal testing in relation to article 1. PRES understands that the type of tests are prescribed in each regulation mentioned in annex I, and thus this regulation is not modifying that. However, art.21 here is new, and thus the question of the minimization of animal testing might be relevant here. DK would like to know if commissioned animal studies will be notified → PRES requests written reactions and proposals on this matter. - NL expressed the need to frame the mandate in such a way that the burden of proof on companies is preserved. ES insist also on the burden of proof on industry and highlights the need for clarify on procedures and financing. → PRES invites for written comments and amendments proposals. - Comments were received in relation to the involvement of MS, industry, stakeholders in the data generation mechanism (DE,ES). → PRES schedule a discussion on this at the 2nd WP	ES: We would like to reiterate our earlier comments in the centre column.
Article 21(1)			
266	1. Using the best independent resources available, the ECHA may commission scientific studies to support the implementation of Union acts on chemicals listed in Annex I within its mandate and to contribute to the support, evaluation or development of a Union chemicals policy.	DK requests clarity on the meaning of scientific studies, and which one will not be covered. → PRES invites for written comments on this	
Article			

21(2)			
267	2. The Commission may request the ECHA to commission the scientific studies referred to in paragraph 1.		
Article 21(3)			
268	3. The ECHA shall only commission scientific studies when results cannot be obtained through existing legal provisions or processes under Union legislation listed in Annex I. It shall not commission studies with a predominant research objective.		ES: For consistency with other articles, and the way Annex I is referred to, we propose the following wording: 3. The ECHA shall only commission scientific studies when results cannot be obtained through ~~existing legal provisions or processes under Union legislation~~ Union acts on chemicals listed in Annex I. It shall not commission studies with a predominant research objective.
Article 21(4)			
269	4. The ECHA shall seek to avoid duplication with Member State or Union research or implementation programmes.		
Article 21(5)			
270	5. The ECHA shall commission these scientific studies in an open and transparent manner.	DK suggests to amend this to introduce compulsory prior MS consultation. → PRES schedules this for discussion at the 2nd WP	
Article 21(6)			
271	6. The ECHA and the EFSA shall closely cooperate with each other on the planning and commissioning of scientific studies undertaken by the ECHA in accordance with paragraph 1 and of studies undertaken by the EFSA in accordance with Article 32 of Regulation (EC) No 178/2002.		
Article 21(7)			
272	7. The ECHA shall make the results of the scientific studies performed under this Article available through the common data platform.		
Chapter VII			

273	Chapter VII NOTIFICATION OF STUDIES	Several comments were received on this chapter: on the legal scope and definition of studies to be notified, duplications, studies conducted outside the EU, late notifications, absence of a transitional period, practical arrangements for companies, the need for early access before publication in the data platform (FR,DE,ES,AT,PT).	

		→ PRES scheduled this for discussion at the 2 nd WP	
Article 22			
274	Article 22 Notification of studies		
Article 22(1)			
275	1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, without undue delay, any studies on chemicals they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment, prior to placing on the market, under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.		
Article 22(2)			
276	2. For the purposes of paragraph 1, business operators shall notify to the Database of Study Notifications referred to in Article 9 the title, scope, laboratory, or testing facility carrying out the study, the intended starting and planned completion dates and, where relevant, whether the study is commissioned to comply with a decision of the ECHA pursuant to Articles 40, 41 or 46 of Regulation (EC) No 1907/2006.		
Article 22(3)			
277	3. Laboratories and testing facilities shall also, without undue delay, notify any study commissioned by business operators to support a regulatory dossier on which an Agency is required to provide a scientific output, including a scientific opinion, under the Union acts listed in Annex I. However, laboratories and testing facilities shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.		
Article 22(4)			
278	4. For the purposes of paragraph 3, laboratories and testing facilities		

	shall notify to the Database of Study Notifications referred to in Article 9 the title, scope, intended starting and planned completion dates of any test they carry out, as well as the name of the business operator who commissioned the test.		
Article 22(5)			
279	5. Paragraphs 3 and 4 shall apply, mutatis mutandis, to laboratories and testing facilities located in third countries insofar as set out in relevant agreements with those third countries.		
Article 22(6)			
280	6. The obligations set under this article shall apply from [OP please insert date: 24 months after the date of entry into force of this Regulation].		
Article 22(7)			
281	7. The ECHA shall lay down the practical arrangements for implementing the provisions of this Article.		
Chapter VIII			
282	Chapter VIII DELEGATED POWERS		
Article 23			
283	Article 23 Amendment of Annexes I, II and III		
Article 23(1)			
284	1. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex I in order to adjust the content of that Annex to technical and scientific progress in the field of chemicals or, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it new Union acts under which relevant chemicals data is generated or submitted.		
Article 23(2)			

285	2. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex II by adding, where relevant, new categories of data types.		
Article 23(3)			
286	3. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex III in order to adjust the content of that Annex to technical and scientific and technical progress in the field of chemicals and, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it Union acts relevant for data on new regulatory processes on chemicals.		
Article 24			
287	Article 24 Exercise of the delegation		
Article 24 (1)			
288	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.		
Article 24(2)			
289	2. The power to adopt delegated acts referred to in Article 23 shall be conferred on the Commission for a period of five years from [OP please insert: the date of the entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each five-year period.		
Article 24(3)			
290	3. The delegation of power referred to in Article 23 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the		

	decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.		
Article 24(4)			
291	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.		
Article 24(5)			
292	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.		
Article 24(6)			
293	6. A delegated act adopted pursuant to Article 23 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.		
Chapter IX			
294	Chapter IX ENFORCEMENT AND PENALTIES	PT expressed concerns on enforcement for third countries; FR questions the effectiveness of national sanctions. → PRES schedules this for discussion at the 2nd WP	
Article 25			
295	Article 25 Enforcement The Agencies shall cooperate with Member States' enforcement authorities and exchange information on the compliance, by business operators and laboratories, with the obligation to notify studies in		

	accordance with Article 22.		
Article 26			
296	Article 26 Penalties for non-compliance		
Article 26(1)			
297	1. Member States shall introduce penalties for non-compliance, by business operators and laboratories, with the obligations laid out in Article 22 and shall take all necessary measures to ensure that they are implemented. The penalties provided for shall be effective, proportionate, and dissuasive.		
Article 26(2)			
298	2. Member States shall notify the Commission of those rules and of those measures by 30 June 2025 and shall notify to the Commission without delay any subsequent amendment affecting them.		
Article 27			
299	Article 27 Entry into force and application in time This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.		
Formula			
300	This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels, For the European Parliament For the Council The President The President		

	Presidency proposals: amendments (~~deletions~~ / additions)	Presidency proposals: follow-up or proposal to work on amendments, or requests for written comments	Reactions from the Commission and MS
Annex I			
301	Annex I UNION ACTS REFERRED TO IN ARTICLES 2, 3, 8, 11, 12, 15, 17, 21, 22 AND 23 Reference to each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.		
302	1. Council Directive 91/271/EEC of 21 May 1991 concerning urban wastewater treatment (OJ L 135, 30.5.1991, p. 40)		
303	2. Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources (OJ L 375, 31.12.1991, p.1)		

304	3. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1)		
305	4. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste		
306	5. Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11)		
307	6. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50)		
308	7. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34)		
309	8. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for the Community action in the field of water policy (OJ L 327, 22.12.2000, p.1)		
310	9. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified		

	organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1)		
311	10. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p. 1)		
312	11. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10)		
313	12. Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51)		
314	13. Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1)		
315	14. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29)		
316	15. Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (OJ L 309, 26.11.2003, p. 1)		
317	16. Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying		

	down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55)		
318	17. Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1)		
319	18. Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1)		
320	19. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)		
321	20. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3)		
322	21. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 070, 16.3.2005, p. 1)		
323	22. Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register and amending Council		

	Directives 91/689/EEC and 96/61/EC (OJ L 033, 4.2.2006, p. 1)		
324	23. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19)		
325	24. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)		
326	25. Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9)		
327	26. Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26)		
328	27. Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European		

	Community (INSPIRE) (OJ L 108, 25.4.2007, p. 1)		
329	~~28. Regulation (EC) No 108/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 39, 13.2.2008, p. 11)~~	FR highlighted the fact that regulation 108/2008 is mentioned in point 28 of Annex I, whereas this regulation is already covered by regulation 1925/2006 mentioned in point 26 of Annex I. → PRES proposes to amend the text (deleting point 28).	
330	29. Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19)		
331	30. Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1)		
332	31. Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3)		
333	32. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive		

	2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84)		
334	33. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)		
335	34. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)		
336	35. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC, and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p.7)		
337	36. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16)		
338	37. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91,		

	Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34)		
339	38. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energyrelated products		
340	39. Regulation (EC) No 401/2009 of the European Parliament and of the Council of 23 April 2009 on the European Environment Agency and the European Environment Information and Observation Network (OJ L 126, 21.5.2009, p. 13)		
341	40. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3)		
342	41. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1)		
343	42. Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (OJ L 300, 14.11.2009, p. 1)		
344	43. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009		

	concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)		
345	44. Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71)		
346	45. Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28)		
347	46. Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community ecomanagement and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC (OJ L 342, 22.12.2009, p. 1)		
348	47. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)		
349	48. Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17)		

350	49. Regulation (EC) No 66/210 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel (OJ L 027, 30.1.2010, p. 1)		
351	50. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)		
352	51. Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18)		
353	52. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)		
354	53. Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.7.2012, p. 1)		
355	54. Directive 2012/19/EU of the European Parliament		

	and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38)		
356	55. Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the import and export of hazardous chemicals (OJ L 201, 27.7.2012, p. 60)		
357	56. Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35)		
358	57. Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (OJ L 96, 29.3.2014, p. 1)		
359	58. Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1)		

360	59. Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006 (OJ L 150, 20.5.2014, p. 195)		
361	60. Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1)		
362	61. Directive (EU) 2016/2284 of the European Parliament and of the Council of 14 December 2016 on the reduction of national emissions of certain atmospheric pollutants, amending Directive 2003/35/EC and repealing Directive 2001/81/EC (OJ L 344, 17.12.2016, p. 1)		
363	62. Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council		

	Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 095, 7.4.2017, p. 1)		
364	63. Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1)		
365	64. Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008 (OJ L 137, 24.5.2017, p. 1)		
366	65. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).		
367	66. Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing		

	Regulation (EC) No 2003/2003 (OJ L 170, 25.6.2019, p. 1)		
368	67. Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45)		
369	68. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435, 23.12.2020, p. 1)		
370	69. Regulation (EU) .../... of the European Parliament and of the Council on nature restoration (OJ .../ELI: ... [OP: please add number and publication reference].		
371	70. Regulation (EU) .../... of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (OJ .../ELI: ... [OP: please add number and publication reference]		
ANNEX II			
372	ANNEX II UNION ACTS REFERRED TO IN ARTICLES 2, 3, 12, 17 AND 23 AND REFERENCE VALUES REFERRED TO IN ARTICLE 8		
Part 1			
373	Part 1 - Specific data on relevant active substances to be identified in accordance with Article4(5)(b) falling under the scope of this Regulation for the purposes of		

	Article 3 for human and veterinary medicinal products		
374	1. Non-clinical safety data, including data related to environmental risk assessments, compiled pursuant to Directive 2001/83/EC of the European Parliament and of the Council¹ and Regulation (EC) No 726/2004 of the European Parliament and of the Council²; ¹ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67). ² Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).		
375	2. Data related to environmental risk assessments, compiled pursuant to Regulation (EU) 2019/6 of the European Parliament and of the Council³; and ³ Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).		
376	3. Maximum residue levels data compiled pursuant to Regulation (EC) No 470/2009 of		

	the European Parliament and of the Council⁴. ⁴ Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).		
377	These data shall be limited to data submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation. Where relevant, the data held by the EMA resulting from procedures concluded before the entry into force of this Regulation may also be considered for inclusion into the common data platform.		
Part 2			
378	Part 2 - Reference values to be included in the repository of reference values following Article 8(3)		

379	1. Predicted no effect concentrations derived as part of the environmental risk assessment under Directive 2001/83/EC of the European Parliament and of the Council, Regulation (EC) No 726/2004 of the European Parliament and of the Council and Regulation (EU) 2019/6 of the European Parliament and of the Council.		
380	These data shall be limited to data submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation. Where relevant, data held by the EMA resulting from procedures concluded before the date of entry into force of this Regulation shall also be considered for inclusion into the common data platform.		
Annex III			
381	Annex III UNION ACTS REFERRED TO IN ARTICLES 2, 10 AND 23		
382	Reference to each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.		
383	1. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1)		
384	2. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste		

385	3. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50)		
386	4. Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11)		
387	5. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34)		
388	6. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p. 1)		
389	7. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10)		
390	8. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29)		

391	9. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)		
392	10. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3)		
393	11. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1)		
394	12. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19)		
395	13. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)		

396	14. Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38)		
397	15. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84)		
398	16. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)		
399	17. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)		
380	18. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC, and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008,		

	p.7)		
381	19. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16)		
382	20. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34)		
383	~~21. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)~~	FR and AT highlighted the fact that Regulation 1331/2008 is mentioned twice: in points 17 and 21 of Annex III. → PRES proposes to amend the text (deleting this repetition).	
384	22. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3)		
385	23. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energyrelated products		
386	24. Directive 2009/48/EC of the European Parliament		

	and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1)		
387	25. Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer (OJ L 286, 31.10.2009, p. 1)		
388	26. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)		
389	27. Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28)		
390	28. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)		
391	29. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)		
392	30. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)		

393	31. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).		
394	32. Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45)		
395	33. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435, 23.12.2020, p. 1)		
396	34. Regulation (EU) .../... of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (OJ .../ELI: ... [OP: please add number and publication reference].		

PUBLIC

FRANCE

14/3/2024

Proposal for a
DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
amending Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European
Chemicals Agency
(Text with EEA relevance)



PRESIDENCY PROPOSALS for written comments by 22 March 2024 1 PM

Delegations will find attached a **revised** Presidency compromise proposal on the above-mentioned Proposal.

Changes in comparison to the previous compromise proposal, document COM(2023) 781, are marked in **red bold underline** for additions and in ~~red strikethrough~~ for deletions.

	Commission Proposal	Presidency Justification	Delegations comments
Proposal Title			
1	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL Amending Directive 2011/65/EU control of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency (Text with EEA relevance)		
Formula			
2	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,		
Citation 1			
3	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,		
Citation 2			

4	Having regard to the proposal from the European Commission,		
Citation 3			
5	After transmission of the draft legislative act to the national parliaments,		
Citation 4			
6	Having regard to the opinion of the European Economic and Social Committee ¹		
Footnote 1			
7	¹ OJ C [...], [...], p. [...].		
Citation 5			
8	After consulting the Committee of the Regions,		
Citation 6			
9	Acting in accordance with the ordinary legislative procedure,		
Formula			
10	Whereas:		
Recital 1			

11	(1) The Commission has, in its Communication 'European Green Deal'², set an objective that chemical safety assessments should move towards a process of 'one-substance, one-assessment', calling for more transparent and simpler risk assessment processes in order to reduce the burden on all stakeholders, accelerate decision-making, as well as to increase consistency and predictability of scientific decisions and opinions. The Commission, in its Communication on Chemicals Strategy for Sustainability³ concludes that, in order to achieve that objective, part of the scientific and technical work on chemicals performed at Union level in support of Union legislation needs to be reattributed to the most suitable Union agencies. This would simplify the current set-up, improve quality and coherence of safety assessments across Union legislation, and ensure more efficient use of existing resources.		
Footnote 2			
	² Communication from the Commission to the European		

12	Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal (COM (2019) 640 final of 11 December 2019).		
Footnote 3			
13	³ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment (COM (2020) 667 final of 14 October 2020).		
Recital 2			
14	(2) The reattribution of certain scientific and technical tasks to the European Chemicals Agency is necessary in order to align processes and levels of scientific scrutiny and digitalisation with current standards and processes of the European Chemicals Agency. This is also necessary in order to ensure a consistent standard of scientific quality, transparency, data searchability and interoperability, in line with		

	the 'one-substance, one-assessment' ambition.		
Recital 3			
15	(3) Directive 2011/65/EU of the European Parliament and of the Council ⁴ contains two procedures related to the assessment of chemicals: the evaluation of economic operators' applications for granting, renewing or revoking an exemption from the substance restrictions pursuant to Article 5 of that Directive and the review of substances to be added to the list of restricted substances pursuant to Article 6 of that Directive. There is a need to increase transparency by setting detailed procedural steps for the process to review substances for a potential inclusion in the list of restricted substances.		
Footnote 4			
16	⁴ Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment – OJ L 174 1.7.2011, p 88.		

Recital 4

17	(4) Data and information held by the European Chemicals Agency in the context of regulatory processes under Titles VII and VIII of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁵ can be usefully deployed for the assessment of potential substance restrictions and for assessing applications for exemption under Directive 2011/65/EU. Established structures and procedures can help to build on the existing knowledge base, maximise synergies, and make the best use of available expertise and resources.		

Footnote 5

18	⁵ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as		

	well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC - OJ L 396 30.12.2006, p. 1.		
Recital 5			
19	(5) To ensure consistency between the evaluation of economic operators' applications for granting, renewing or revoking an exemption pursuant to Article 5 of the Directive 2011/65/EU, as well as to make the best use of existing chemicals-related expertise, the technical evaluation to assess the justification of such exemption requests should be carried out by the European Chemicals Agency and its committees in close coordination with the Commission.		
Recital 6			
	(6) To ensure that the restriction process referred to Article 6 in Directive 2011/65/EU is consistent with the restriction processes under other legislation related to chemicals, in particular with the substance restriction process laid down in Articles 69		

20	to 73 of Regulation (EC) No 1907/2006, it is necessary to amend Directive 2011/65/EU to formally task the European Chemicals Agency with a role in the restriction process. In the light of experience obtained when carrying out substance reviews, it is essential for the quality of the related technical assessment, and for enabling synergies, to make use of information and tools being used in the context of assessments for chemical restrictions under Regulation (EC) No 1907/2006.		
Recital 7			
21	(7) The two procedures described under Article 5 and Article 6 are applicable at the EU level. National provisions should not deviate from these Articles set in Directive 2011/65/EU.		
Recital 8			
22	(8) For amending procedural provisions under Directive 2011/65/EU, a transitional period of 12 months is necessary to allow for appropriate resource and task allocation for the European Chemicals Agency. That timeframe is considered sufficient		

	to allow for amending procedural provisions under Directive 2011/65/EU, a transitional period of 12 months is necessary to allow for appropriate resource and task allocation for the European Chemicals Agency. That timeframe is considered sufficient to allow potential applicants or Member States to adjust to the modified procedural steps under that Directive.		
Recital 9			
23	(9) Directive 2011/65/EU should therefore be amended accordingly,		
Formula			
24	HAVE ADOPTED THIS DIRECTIVE:		
Article 1			
25	<i>Article 1</i> Amendments to Directive 2011/65/EU Directive 2011/65/EU is amended as follows:		
Article 1(1)			
26	(1)Article 5 is amended as follows:		

Article 1(1), point (a)			
27	(a) paragraphs 3 and 4 are replaced by the following		
Article 1(1), point (a), paragraph 3			
28	'3. An application for granting, renewing or revoking an exemption shall be made to the European Chemicals Agency set up pursuant to Article 75(1) of Regulation (EC) No 1907/2006 ('the Agency') in accordance with Annex V.		
Article 1(1), point (a), paragraph 4a			
29	4. The Agency shall: (a) acknowledge receipt of an application within 15 days of its receipt, stating the date of receipt of the application;		
Article 1(1), point (a), paragraph 4b			
30	(b) verify that the application contains all the elements laid out in Annex V;		
Article 1(1), point (a), paragraph 4c			
	(c) if necessary, request the applicant to complete the application <u>within 45 days of</u>	Change proposed based on the comments from two delegations.	

31	<u>receipt of the application</u>, and provide an appropriate deadline <u>of maximum 60 days</u>;	One delegation suggested replacing the word “appropriate” with a specific deadline in order to improve legal certainty for the actors concerned. They motivated that this would also ensure that current applications are published on the Agency’s website in a timely manner. Additionally, other delegation motivated that the applicant should be given a deadline within which the application should be completed, since the exemption continue to apply during the process of evaluation of the application. The 45 days and 60 days were proposed based on the deadlines given in REACH Article 69 (4) for restrictions proposals, as there are no similar deadlines under the authorisation scheme in REACH. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(1), point (a), paragraph 4d			
32	(d) make the application and any supplementary information supplied by the applicant available to Member States;		
Article 1(1), point (a), paragraph 4e			
33	(e) make a summary of the application and a non-confidential version of the application as submitted by the applicant, as well as the date when the application is		

	considered complete, available to the public on the Agency's website;		
Article 1(1), point (a), paragraph 4f			
34	(f) invite interested parties to submit information within 3 months of its publication on the Agency's website.		
Article 1(1), point (a), paragraph 4			
35	Where the applicant does not complete the application with the missing elements identified by the Agency in compliance with Annex V within the deadline provided in accordance with the first subparagraph, point (c), the Agency may reject such application. The Agency shall establish and communicate to the applicant without undue delay the date when the application is considered complete. Upon receipt of an application, the Agency shall notify the Commission of the application and keep it informed of any of the procedural steps under points (b) to (f).';		
Article 1(1), point (b)			

36	b) the following paragraph 4a is inserted after paragraph 4:		
Article 1(1), point (b), regarding inclusion of article 4a			
37	4a. The Agency shall, after verifying the completeness of the application, request the opinion of the Committee for Socio-economic Analysis, set up pursuant to Article 76(1), point (d) of Regulation (EC) No 1907/2006. It shall request the opinion of the Committee for Risk Assessment, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006, in the case of an application for a new exemption or where otherwise considered appropriate. The Committee for Socio-economic Analysis and, where relevant, the Committee for Risk Assessment:	Two delegations suggested that it needs to be clearer when RAC shall evaluate an application for exemption. Therefore, they considered that it may be good to clarify that RAC shall evaluate applications for renewal of exemptions that have previously been evaluated by external consultants or where there are amendments in the exemption that have not been evaluated before. This would have the effect of increasing consistency between the evaluations. Alternatively, other delegation proposed in their comments to rather assign the tasks to ECHA (and its Expert Groups) than directly to RAC and SEAC. Their proposal was motivated by a concern related to the capacity of SEAC and RAC to perform the tasks under Art. 5 (lack of expertise in RoHS within the Committees, insufficient staff). In their opinion, the proposed change in the text would not preclude the Executive Director from requesting the assistance of the Committees of ECHA on a case-by-case basis. PRES did not modify the proposal and welcomes delegations' views/comments.	

		Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(1), point (b), regarding inclusion of article 4a (a)			
38	(a) shall draw up draft opinions within 9 months of the date the application has been considered complete by the Agency under paragraph 4, point (b);	One delegation proposed to align the deadline for RAC and SEAC for the assessment of exemptions with the authorisation scheme and assessment of authorisation under the REACH-Regulation (Article 64 (1) of the REACH Regulation). Other delegation proposed to specify that the opinions drawn shall be scientific and technical. This proposal is a consequence of their proposal above (line 37 of this document), where it is considered that tasks should be rather assigned to ECHA (and its Expert Groups) than directly to RAC and SEAC. PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(1), point (b), regarding inclusion of article 4a (b)			
39	(b) shall assess whether the criteria in Article 5(1), point (a), are met and shall provide clear guidance to the Commission on		

	granting, renewing or revoking an exemption;		
Article 1(1), point (b), regarding inclusion of article 4a (c)			
40	(c) may request the applicant or third parties to submit, within a specified period, additional information;		
Article 1(1), point (b), regarding inclusion of article 4a (d)			
41	(d) upon adopting the draft opinions, shall communicate those draft opinions to the applicant and shall allow the applicant the opportunity to comment within 4 weeks of the communication of the draft opinions to the applicant;	One delegation proposed to specify that the opinions drawn shall be scientific and technical. This proposal is a consequence of their proposal above (line 37 of this document), where it is considered that tasks should be rather assigned to ECHA (and its Expert Groups) than directly to RAC and SEAC. PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(1), point (b), regarding inclusion of article 4a (e)			
42	(e) shall adopt their final opinions, taking into account the comments from the applicant.		
Article 1(1), point (b), regarding inclusion of article 4a			

43	Each Committee shall take into account any information submitted by third parties in accordance with the second subparagraph, point (c). The Agency shall send the final opinion(s) of the Committees to the Commission within 12 months from the date an application has been considered complete by the Agency. The Agency shall identify which parts of its opinions and of any attachments thereto should be made publicly available on its website and shall make those parts publicly available on its website. For the purpose of adopting opinions pursuant to this paragraph, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.'	One delegation proposed to align the deadline for RAC and SEAC for the assessment of exemptions with the authorisation scheme and assessment of authorisation under the REACH-Regulation. Therefore, in their view the deadline for sending the final opinion to the Commission should be set to 14 months. This will assure that ECHA will have at least the same time period as is given under Article 64 (5) in REACH, where the Committees shall adopt their final opinion within two months after receiving the comments from the applicant and send it to the Commission within 15 days after this. Additionally, other delegation proposed to specify that the opinions drawn shall be scientific and technical. This proposal is a consequence of their proposal above (line 37 of this document), where it is considered that tasks should be rather assigned to ECHA (and its Expert Groups) than directly to RAC and SEAC. PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(1), point (c)			
44	(c) paragraph 8 is replaced by the following:		

Article 1(1), point (c), paragraph 8

45	8. The Agency shall, in agreement with the Commission, provide a harmonised format for the applications referred to in paragraph 3 of this Article as well as comprehensive guidelines for such applications, taking into account the situation of SMEs. Any submission to the Agency shall be made using the format and the submission tools made available by the Agency.’;	One delegation considered that a clarification is needed in relation to third criterion in Art. 5(1)(a) of the RoHS Directive: <i>‘the total negative environmental, health and consumer protection impact as a result of the substitution is likely to be greater than the total environmental, health and consumer protection benefits thereof’</i>. In their view many exemptions are granted or renewed with reference to this criterion, not infrequently, where the other criterions do not apply i.e. where substitution is possible or reliable alternatives are available, in spite of the weight of substitution in RoHS as reflected in recital 8 <i>the most effective way of ensuring a significant reduction of risks to health and the environment relating to those substances, in order to achieve the chosen level of protection in the Union, is the substitution of those substances in EEE by safe or safer materials</i>. The criterion is often applied based on energy considerations. It is unclear if this was the intention of this criteria and, which weight to assign energy considerations compared to chemicals considerations within the frame of RoHS. In light of the experienced difficulty concerning collection of information from applicants as identified during the RoHS review process, priority should be given to clarifying the applicability of this criterion.

		Therefore, there is a need to clarify the applicability of this criteria and it is important that ECHA does so through following this re-attribution of tasks. ECHA should revise this guidance and that the guidance should be adopted by the expert committee (see proposal for reference to this committee in under article 20). PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(2)			
46	(2) in Annex V, the following paragraph is added: 'In cases referred to in the first paragraph, point (h), the applicant shall submit a non-confidential version of the application.'		
Article 1(3)			
47	(3) Article 6 is amended as follows:		
Article 1(3), point (a)			

48	(a) in paragraph 1, the first subparagraph is replaced by the following: ‘With a view to achieving the objectives set out in Article 1 and taking account of the precautionary principle, a review, based on a thorough assessment, and an amendment of the list of restricted substances in Annex II shall be considered by the Commission <u>every five years</u> ~~periodically~~ on its own initiative or following the submission of a restriction dossier prepared by a Member State containing the information referred to in paragraph 2.’;	Change proposed based on the comment from one delegation. One delegation considered that the list of substances restricted under the ROHS directive should be evaluated on a more regular basis. Here a 5-year period is suggested. It is not paramount that it should be a 5-year period, however, a timeline is needed. Staff working document p. 119 assesses the impact for ECHA. Here it says: <i>As the assessments are to be done ca. every 5 years.</i> Therefore, a time limit of 5 years is considered appropriate. eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52023SC0850 One delegation proposed also some additional changes (introduction of subparagraph 1a) as they considered that the substances restricted in the POP-regulation, and where the use in EEE is exempted, should be considered for Annex II in the RoHS-Directive. PRES did not modify the proposal and welcomes delegations’ views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(3), point (b)			

49	(b) in paragraph 1, the fourth subparagraph is deleted.		
Article 1(3), point (c)			
50	(c) paragraph 2 is replaced by the following: '2. The review and amendment of the list of restricted substances, <u>or a group of similar substances</u>, in Annex II shall be based on restriction dossiers prepared by the Agency at the request of the Commission or prepared by a Member State. The Agency or a Member State shall take into account any available information and any relevant risk assessment submitted for the purposes of other Union legislation covering the life cycle of the substance used in EEE, in particular the waste phase. To this end, other bodies established under Union law and carrying out a similar task shall, on request, provide information to the Agency or Member State concerned.	Change proposed based on the comment of one delegation. One delegation considered that the reference to the assessment of groups of substances should not be deleted as it is in the current COM's proposal. Additionally, one delegation considered that any relevant assessment, including assessments of waste handling, should be included in a restriction dossier, therefore DK proposed to delete "risk" from the text. PRES did not modify the proposal and welcomes delegations' views/comments. Change based on the proposal of the COM received prior to the 2nd Ad Hoc WP and discussed during that meeting. This proposal intended to accommodate the	

	The restriction dossier shall comply with the requirements set out in Part II, point 3, of Annex XV to Regulation (EC) No 1907/2006 <u>for those requirements that relate to the criteria set out in Article 6(1)</u> and shall, in addition, contain the following information: (a) information on the use of the substance or the group of similar substances in EEE; (b) information on detrimental effects and exposure in particular during waste EEE management operations.'	concern of one delegation regarding re-shifting of focus of assessment required under the RoHS Directive when aligning restriction procedure with the REACH restriction. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(4)			
51	(4) the following Articles 6a, 6b and 6c are inserted:		
Article 1(4), regarding insertion of Article 6a			
52	'Article 6a Initiation of procedure for review and amendment of the list of restricted substances		
Article 1(4), regarding insertion of Article 6a, point (1)			
53	1. Within 12 months of receipt of the request from the Commission referred to in Article 6(2), first subparagraph, the Agency shall prepare a restriction dossier		

	conforming to the requirements referred to in Article 6(2), third subparagraph, and suggest restrictions in order to initiate the restriction process.		
Article 1(4), regarding insertion of Article 6a, point (2)			
54	2. A Member State shall notify the Agency that it proposes to prepare a restriction dossier which conforms to the requirements referred to in Article 6(2), third subparagraph, within 12 months. If that dossier demonstrates that action on a Union-wide basis is necessary, beyond any measures already in place, the Member State shall submit it to the Agency in order to initiate the restriction process.		
Article 1(4), regarding insertion of Article 6a, point (3)			
55	3. The Agency shall publish without delay the intention of the Commission or the Member State to initiate the process to review and amend the list of restricted substances in Annex II <u>on the Agency's website</u> .	Change proposed based on the comment from one delegation and in line with the text proposed in Art. 5 (see line 28 of this document). One delegation considered that it was not clear where the intention to review and amend the list of restricted substances will be published.	FR is wondering if a reference to the common data platform is not preferable.

		Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(4), regarding insertion of Article 6a, point (4)			
56	4. The Agency shall establish and maintain a list of substances for which a restriction dossier conforming to the requirements of Article 6(2) is planned or underway by either the Agency or a Member State for the purposes of a proposed restriction.		
Article 1(4), regarding insertion of Article 6a, point (5), paragraph 1			
57	5. The Agency shall consult the Committee for Risk Assessment, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006, and the Committee for Socio-economic Analysis, set up pursuant to Article 76(1), point (d), of that Regulation. The Committees shall verify whether the restriction dossier submitted conforms to the requirements referred to in Article 6(2), third subparagraph.		
Article 1(4), regarding insertion of Article 6a, point (5), paragraph 2			
	Within 30 days of receipt of the restriction dossier, the respective		

58	Committee shall inform the Agency or the Member State proposing restrictions whether the dossier conforms to the requirements referred to in Article 6(2), third subparagraph. If the dossier does not conform to those requirements, the reasons shall be given to the Agency or the Member State in writing within 45 days of receipt of that dossier. The Agency or the Member State shall bring the dossier into conformity within 60 days of the date of receipt of the reasons from the Committees, otherwise the procedure under this Article shall be terminated.		
Article 1(4), regarding insertion of Article 6a, point (6)			
59	Where the dossier meets the requirements referred to in Article 6(2), third subparagraph, the Agency shall make it publicly available without delay, clearly indicating the date of publication. The Agency shall invite all interested parties, including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations to submit, individually or jointly, within 4 months from the date of the		

	publication of the dossier, the following:		
Article 1(4), regarding insertion of Article 6a, point (6a)			
60	(a) comments on dossiers and the suggested restrictions;		
Article 1(4), regarding insertion of Article 6a, point (6b)			
61	(b) a socio-economic analysis including an analysis of alternatives, or information which can contribute to ~~one of~~ the suggested restrictions, examining the advantages and drawbacks of the proposed restrictions.	Changes partially modified based on the comment from one delegation. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(4), regarding insertion of Article 6a			
62	The analysis referred to in the first subparagraph, point (b), shall conform to the requirements in Annex XVI to Regulation (EC) No 1907/2006.	One delegation suggested to delete this text, as they consider that the restriction process in RoHS may be too extensive compared to the restriction process in REACH. They were also concerned that having in mind future revision of the REACH Regulation, it is not clear how the restriction process will look like in the future. PRES did not modify the proposal and welcomes delegations' views/comments.	FR is also wondering how the Commission intend to deal with the restriction process under RoHS if the REACH regulation is finally revised and do not end up with a similar procedure.

		Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(4), regarding insertion of Article 6b			
63	Article 6b Opinion of the Agency's Committees		
Article 1(4), regarding insertion of Article 6b, point (1)			
64	1. Within 12 months from the date of publication referred to in Article 6a(6), the Committee for Risk Assessment shall adopt an opinion as to whether the restriction is appropriate in reducing the risk to human health or the environment, specifically <u>by reference to the risks set out in Article 6(1) for those requirements that relate to the criteria set out in Article 6(1)</u>, third subparagraph, based on its consideration of the relevant parts of the dossier. This opinion shall take account of the restriction dossier prepared by the Agency at the request of the Commission or by the Member State, and the views of interested parties referred to in Article 6a(6), point (a).	Change proposed by PRES to align the text with Article 1(3), point (c) (line 50 of this document). This proposal intended to accommodate the concern of one delegation regarding re-shifting of focus of assessment required under the RoHS Directive when aligning restriction procedure with the REACH restriction. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(4), regarding insertion of Article 6b, point (2)			

65	2. Within 15 months from the date of publication referred to in Article 6a(6), the Committee for Socio-economic Analysis, shall adopt an opinion on the proposed restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. Prior to that, it shall prepare a draft opinion on the suggested restrictions and on the related socio-economic impact, taking account any existing analysis or information according to Article 6a(6), point (b).		
Article 1(4), regarding insertion of Article 6b, point (3)			
66	3. The Agency shall publish the draft opinion of the Committee for Socio-economic Analysis on its website without delay and invite interested parties to provide their comments on the draft opinion no later than 60 days from its publication.		
Article 1(4), regarding insertion of Article 6b, point (4)			
67	4. The Committee for Socio-economic Analysis shall without delay adopt its opinion, taking into account where appropriate further comments received by		

	the deadline set in paragraph 3. This opinion shall take into account the comments of interested parties submitted under Article 6a(6), point (a), and paragraph 3 of this Article.		
Article 1(4), regarding insertion of Article 6b, point (5)			
68	5. Where the opinion of the Committee for Risk Assessment diverges significantly from the restrictions proposed, the Agency shall postpone the deadline for the opinion of the Committee responsible for Socio-economic Analysis by a maximum of 90 days.		
Article 1(4), regarding insertion of Article 6b, point (6)			
69	6. For the purpose of adopting opinions pursuant to this article, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.	One delegation proposed some additional suggestions to provide for legislative provisions for the remuneration of tasks by Rapporteurs within the OSOA Package. PRES did not modify the proposal, as this is covered by mutatis mutandis application of Art. 87 of Regulation (EC) No 1907/2006 . Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(4), regarding insertion of Article 6c			

70	<i>Article 6c</i> Submission of an opinion to the Commission		
Article 1(4), regarding insertion of Article 6c, point (1)			
71	1. The Agency shall submit to the Commission, without delay, the opinions of the Committees for Risk Assessment and Socio-economic Analysis on the restrictions suggested pursuant to Article 6b. Where the opinions of the Committees for Risk Assessment and Socio-economic Analysis diverge significantly from the restrictions suggested by the dossier, the Agency shall submit an explanatory note to the Commission providing a detailed explanation of the reasons for such differences. If one or both of the Committees do not adopt an opinion by the deadlines set in Article 6b(1) and (2) the Agency shall inform the Commission accordingly, stating the reasons.		
Article 1(4), regarding insertion of Article 6c, point (2)			

72	2. The Agency shall publish the opinions of both Committees on its website without delay.		
Article 1(4), regarding insertion of Article 6c, point (3)			
73	3. The Agency shall, on request, provide the Commission or Member State with all documents and evidence submitted to or considered by it.;		
Article 2			
74	The provisions under this Directive shall be applicable from [OJ: 12 months after the publication of this Directive].		
Article 3			
75	This Directive shall enter into force on the twentieth day following that of its publication in the <i>Official Journal of the European Union</i> .		
Article 4			

76	This Directive is addressed to the Member States. Done at Brussels, <i>For the European Parliament For the Council</i> <i>The President The President</i>		
Additional recommendations (changes proposed regarding articles that were not included in the current COM's proposal)			
Concerning amendments of Article 5(5):			
77	An application for renewal of an exemption shall be made no later than 18 months before the exemption expires.	One delegation proposed extension of the deadline to 24 months as they are concerned that by aligning the exemptions assessment process with REACH, the Commission will be phased with the issue of expediting delegated directives before the expiration of the concerned exemption. Therefore it was suggested to increase the deadline in order to leave more room for the assessment procedure. PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Concerning amendments of Article 20:			

78	Exercise of the delegation 1. The powers to adopt the delegated acts referred to in Article 4(2), Article 5(1) and Article 6 shall be conferred on the Commission for a period of 5 years from 21 July 2011. The Commission shall draw up a report in respect of delegated powers at the latest 6 months before the end of the 5-year period. The delegation of power shall be ~~automatically~~ <u>tacitly</u> extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 21. <u>1a. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of</u>	Change proposed based on the comments from one delegation. The COM agreed to the proposed changes, prior to the 2nd Ad Hoc WP. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	FR supports the provision proposed by the presidency to consult the experts from the MS before the adoption of delegated acts by the Commission.

13 April 2016 on Better Law-Making.

PUBLIC

FRANCE

14/03/2024

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals

(Text with EEA relevance)



Line nr.		Presidency proposal: amendments (~~deletions~~ /additions)	Presidency justification after WP1: follow-up or proposal to work on amendments, or requests for written comments	Delegates comments/proposals after WP2
1		THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 43, 114, 168(4)(c), 192(1) and 207 thereof, Having regard to the proposal from the European Commission, After transmission of the draft legislative act to the national parliaments, Having regard to the opinion of the European Economic and Social Committee, Having regard to the opinion of the Committee of the Regions, Acting in accordance with the ordinary legislative procedure, Whereas:		
2	Recital 1	The European Green Deal¹ sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability² ('the Strategy') is a crucial delivery of the zero-pollution ambition and introduces the 'one		

		substance, one assessment' approach, which aims to improve the efficiency, effectiveness, coherence, and transparency of safety assessments of chemicals across Union legislation. ¹Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal. COM (2019) 640 final. ²Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment. COM (2020) 667 final		
3	Recital 2	In order to achieve this objective, a part of the scientific and technical work on chemicals performed at Union level in support of Union legislation needs to be consolidated in the relevant Union agencies, while obligations on Union agencies to cooperate for the development of assessment methodologies and exchange of data and information should be introduced. This would simplify the current set-up, improve quality and coherence of safety assessments across Union legislation and ensure more efficient use of existing resources.		
4	Recital 3	The reattribution of certain existing scientific and technical tasks to the	Many concerns were raised during the commenting about:	Fully acknowledging that ECHA should have a key role in the “one substance,

		European Chemicals Agency, as well as the attribution of new tasks, were proposed as part of ongoing revisions of Union acts. This horizontal proposal aims to provide for further attribution of tasks in respect of those Union acts which are not in the process of being revised and is necessary in order to ensure that the European Chemicals Agency is involved in tasks pertaining to its expertise and developed capacities on chemicals. This is in line with the ‘one substance, one assessment’ aim to ensure that technical and scientific work is performed by the appropriate Union agency, benefiting from demonstrated experience and established tools in its field. The proposal for a Regulation is accompanied by a proposal for a Directive for the amendment of Directive 2011/65/EU of the European Parliament and of the Council³, aiming to achieve the same objectives. ³Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency	Concerns on ECHA’s capacity, budget (including budget for technical and infrastructure requirements and training), workload, committees, expertise to take on the extra tasks. This relates amongst others to the expertise of committee members (and not only the number of experts), potential establishment of technical expert groups (and how they relate to the Committees’ role), what is to be left for the founding regulation, potential targeted REACH amendments, ECHA and committees expertise in medical devices and in POP-waste. Some specific elements for discussion: One delegation proposed it would be more appropriate to assign the task(s) to prepare opinions to ECHA, and allow ECHA to best determine the most efficient and appropriate way to deliver a robust opinion. For example, ECHA’s technical experts could draft opinions and establish technical expert working groups to consult with in order for scientific opinions to be delivered. In certain cases, the Executive Director can still use their powers under REACH’s Article 77 (3) to issue a request to RAC and SEAC, thus negating the need for all tasks to have a RAC and/or SEAC opinion. This delegation also prefers that the legislative package makes provisions for	one assessment approach”, FR shares the concerns raised about ECHA’s workload, budget and expertise to address new fields of chemical safety and considers these issues have to be solved in the basic regulation to come, which FR considers therefore as an urgent need.

			ECHA to prepare opinions in some circumstances without the explicit need for those opinions to be drafted by RAC and SEAC. In addition, they explained that their concern is with the capacity of the individual members to deliver the expected workload, even if both Committees were at full capacity. Therefore, they see a need for provisions to be included to allow for amending the composition of the current ECHA's committees to cover also any ad-hoc Article 77(3) requests in light of requests from the Executive Director. Finally, the inclusion of remuneration for Committee Rapporteurs for all tasks needs to be provided for. They also recommend the OSOA legislation package amends Article 85 and 87 of REACH to provide for additional experts to cover the additional work and its associated remuneration. PRES: Discussion took place during WP2	
5	Recital 4	As part of the coordinated consolidation and attribution of tasks under the 'one substance, one assessment' approach, provisions to allocate a mandate to the European Medicines Agency to develop and cooperate on the development of assessment methodologies, standard		

		formats and controlled vocabularies and exchange of data and information on chemicals have been introduced in Article 138(1), subparagraphs (zd) and (ze), as well as new procedures for ensuring the coherence between scientific opinions in Article 139 of the proposal for a Regulation amending Union pharmaceutical legislation.⁴ ⁴Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006, COM(2023) 193 final. [OJ:Please insert correct reference once the Regulation is adopted].		
6	Recital 5	To ensure the coherence of methodologies for assessments related to chemicals at Union level, all relevant Union agencies should have an equal mandate to develop such methodologies in the areas falling within their respective missions and should be subject to the same obligations to cooperate amongst each other to develop such methodologies.		
7	Recital 6	To ensure the coherence and efficiency of assessments related to chemicals		

		across Union legislation, it is also important to enable data interoperability and easy exchange of data between the relevant Union agencies, as well as to encourage cooperation on the development of standard formats and controlled vocabularies. Thus, to facilitate data exchange between agencies, any new data formats defined by the European Food Safety Authority or by the European Environmental Agency should be set in cooperation with other relevant Union agencies working on chemicals. To this end, relevant provisions should be introduced in Regulation (EC) No 401/2009 of the European Parliament and of the Council and, in Regulation (EC) No 178/2002 of the European Parliament and of the Council, existing provisions should be strengthened and, where relevant, new ones be introduced. Similar provisions should also be considered to be proposed for a strengthened mandate of the European Chemicals Agency in its founding regulation.		
8	Recital 7	To promote the coherence and efficiency of assessments related to chemicals across Union legislation, steps should be taken by the relevant Union agencies to avoid divergent scientific opinions. Existing cases of divergent opinions have lead to increased uncertainty for operators, as well as to declined public		

		trust in the scientific robustness and coherence of scientific decision making. Proposals to address and strengthen procedures for resolving divergence of scientific opinions concerning the European Medicines Agency with other scientific bodies is proposed as part of the revision of Union pharmaceutical legislation. Similar provisions should also be considered to be proposed for a strengthened mandate of the European Chemicals Agency in its founding regulation, whilst such provisions are not relevant and applicable to the European Environmental Agency, since this agency does not issue scientific opinions on individual chemicals such as to be part in divergent outcomes.		
9	Recital 8	Correspondingly, this Regulation aims to address the eventual divergence between scientific opinions of the European Food Safety Authority and those of other Union agencies. Regulation (EC) No 178/2002 of the European Parliament and Council already contains provisions establishing a procedure to solve divergent scientific opinions. Those resolution procedures should be reinforced, in that the European Food Safety Authority and the other dissenting agency should be bound to make their best effort to resolve the divergence on general scientific issues, and only when they are not able to resolve the		

		divergence, should they refer to risk managers.		
10	Recital 9	In the more specific case of scientific divergence pertaining to the hazard identification of chemical substances, a new procedure enabling the resolution of the divergence should be established. This procedure should enable the Commission to request the European Chemicals Agency, as the Union agency most equipped with expertise and capacity in hazard assessment, as well as long-standing experience with the harmonised classification and labelling process, to develop a proposal for harmonised classification and labelling, in accordance the Regulation (EC) No 1272/2008 of the European Parliament and Council, moving closer to the ‘one substance, one assessment’ vision as regards uniformity of hazard assessments of chemicals across the Union. This possibility should be reflected in the relevant provision providing for the resolution of diverging scientific opinions laid down in Regulation (EC) No 178/2002.		
11	Recital 10	To comply with the obligation laid down in Section 10.4.3 of Annex I to Regulation (EU) 2017/745 of the European Parliament and of the Council⁵, the Commission has provided the Scientific Committee on Health,		

	Environmental and Emerging Risks ('SCHEER') with a mandate to prepare guidelines on the benefit-risk assessment of the presence of phthalates which are classified as either carcinogenic, mutagenic or toxic to reproduction category 1A or 1B, or which have endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁶. The SCHEER issued those guidelines in 2019 and the Commission has issued a mandate to the SCHEER to perform a first update of those guidelines. ⁵ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1). ⁶ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives	

		91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1–849).		
12	Recital 11	To comply with the obligation laid out in Section 10.4.4. of Annex I to Regulation (EU) 2017/745, the Commission should mandate the relevant scientific committee to prepare guidelines for substances other than phthalates and which are classified as either carcinogenic, mutagenic or toxic to reproduction category 1A or 1B, or which have endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council.		
13	Recital 12	The European Chemicals Agency already provides scientific advice on chemical substances, including on phthalates, endocrine disruptors and carcinogens, mutagens and reproductive toxicants under Regulation (EC) No 1907/2006. Several key capacities of the agency can be reused, including hazard, risk, exposure and socio-economic assessment capacities, the Committee opinion development and IT capabilities for stakeholder consultation and dissemination. To enable timely future updates on the presence of phthalates and		

		to ensure that the appropriate Union agency develops new guidelines on other substances on the basis of the latest scientific evidence, these tasks should be attributed to the European Chemicals Agency.		
14	Recital 13	Taking account of the new hazard classes and criteria for classification, labelling and packaging of substances introduced by Commission Delegated Regulation (EU) 2023/707 of 19 December 2022⁷, reference to endocrine disruptors for human health, of Category 1, should be specified in 10.4.1., point (b) of Annex I of Regulation (EU) 2017/745 in light of the relevance of that hazard class to the type of substances in medical devices. ⁷ Commission Delegated Regulation (EU) 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures (OJ L 93, 31.3.2023, p. 7–39).		
15	Recital 14	To make best use of the European Chemicals Agency's knowledge and expertise gained through its involvement in the nomination and assessment processes under the Stockholm Convention on Persistent Organic Pollutants, the European Chemicals Agency should, upon request, assist the Commission in complying with its		

		obligation to amend Annexes IV and V to Regulation (EU) 2019/1021⁸. Where the opinion of the Committee for Socio-Economic analysis is required, and in order to allow for the necessary capacity and resources for the effective functioning of that committee, Member States should be given the opportunity to cover for the specific expertise required for the effective performance of the task by nominating experts. In order to ensure that the Committee for Socio-Economic analysis benefits from sufficient resources, when the committee appoints one of their members as a rapporteur, that person, or his employer should be remunerated. ⁸ Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45).		
16	Recital 15	In order to amend certain non-essential elements of Regulation (EU) 2019/1021 of the European Parliament and of the Council, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending Annexes IV and V in order to adapt them to the changes to the list of substances set out in the Annexes to the Stockholm Convention or the Protocol or adapt them to scientific and technical progress.		

17	Recital 16	As part of their reporting obligations under the Regulation (EU) 2019/1021 of the European Parliament and of the Council, Member States must report to the European Chemicals Agency information on the presence of substances listed in Part A of Annex III in the environment. The use of the Information Platform for Chemical Monitoring ('IPCHEM') is encouraged as a means for Member States to comply with their obligations to report that chemical occurrence data and to simplify and reduce their reporting obligations. Where Member States make data available through IPCHEM, they no longer need to report it to the European Chemicals Agency, as the agency may retrieve it from the platform.		
18	Recital 17	The revision of the Directive (EU) 2020/2184 of the European Parliament and of the Council ⁹ requires Member States to share with European Environmental Agency all chemical occurrence or monitoring data in water. Additionally, the monitoring data on the presence of POPs in air are already being reported by Member States to the EEA as part of the Union air quality legislation. The proposal for a Regulation of the European Parliament and the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable,		

		accessible, interoperable, and reusable and establishing a monitoring and outlook framework for chemicals¹⁰ will require all chemical occurrence data to be held by the EEA. As a result, chemical occurrence data provided to and held in IPCHEM by the Commission will thus be collected and held by the EEA, instead of by the Commission. Therefore, it is necessary to simplify the reporting obligations for Member States to ensure that, where Member States have already submitted that information to the EEA as part of fulfilling obligations required by the provisions of other pieces of Union environmental legislation, Member States should be considered to have fulfilled their reporting obligations under Regulation (EU) 2019/1021. ⁹ Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast), (OJ L 435, 23.12.2020, p. 1–62). ¹⁰ [OJ Please insert reference once proposal is adopted]		
19	Recital 18	Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 should therefore be amended accordingly,		
20	Articles	HAVE ADOPTED THIS REGULATION:		

21	1	Amendments to Regulation (EC) No 178/2002		
22		Regulation (EC) No 178/2002 is amended as follows:		
23	(1)	in Article 23, the following point (m) is added:		
24		‘(m) to cooperate with the competent bodies in the Member States that carry out similar tasks to those of the Authority and to cooperate with other scientific bodies established under Union law, notably the European Chemicals Agency, the European Medicines Agency, and the European Environment Agency on the provision of relevant scientific opinions, on the exchange of data and information, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and on the development of scientific methodologies for the assessment of chemicals.’;		
25	(2)	Article 30 is replaced by the following:	Question were raised by a delegation on whether the EFSA procedure for risk assessment must not be changed as a result of this proposal and it must be ensured that the assessment of EFSA, and if applicable, other EU authorities are properly and appropriately taken into account by ECHA. How is this ensured by the provisions in Article 30?	

			PRES: Discussion took place during WP2	
26		‘Article 30 Diverging scientific opinions	One delegation requested an example of what could be considered diverging scientific opinions. PRES: Discussion took place during WP2.	
27		1. The Authority shall take the necessary and appropriate measures to monitor and identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks.		
28		2. Where the Authority identifies a potential source of divergence, it shall contact the body concerned in order to ensure that all relevant scientific or technical information is shared and in order to identify the potentially contentious scientific or technical issues. The Authority and the body concerned shall cooperate to resolve the divergence. If the Authority and the body concerned are not able to resolve the divergence, they shall draw up a joint report. The report shall clearly outline the contentious scientific issues and identify the relevant uncertainties in the data and be made publicly available. Where the body concerned is a Union agency or a scientific committee, the		

		Authority shall present the joint report to the Commission.		
29		3. Where relevant, and where the divergence concerns conflicting scientific opinions of the Authority and another Union body or agency on whether a substance fulfils the criteria laid out in Annex I of Regulation (EC) No 1272/2008 of the European Parliament and of the Council ¹¹ , the Commission may request the European Chemicals Agency to prepare a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof following the procedure laid out in Article 37 of Regulation (EC) No 1272/2008. The Authority and the Union body or agency concerned shall co-operate with the European Chemicals Agency in developing that proposal.’.		
30		¹¹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353 31.12.2008, p. 1 – 1355.		
31	2	Amendments to Regulation (EC) No 401/2009	One delegation asked for clarification why the EEA’s cooperation with ECHA is	

			supposed to be regulated in Article 15(5) of the EEA Regulation. Systematically, paragraph 1 with a new letter c seems closer. In addition, it would be clear that paragraph 4 also refers to this cooperation. One delegation has doubts about the impact of the Eionet Network's involvement in this cooperation. PRES: Discussion took place during WP2	
32		Regulation (EC) No 401/2009 is amended as follows:		
33	(1)	in Article 2, the following point (p) is added:		
34		‘(p) to develop assessment methodologies related to chemicals in the fields falling within its mission.’;		
35	(2)	in Article 15, the following paragraph 5 is added:		
36		‘5. The Agency shall cooperate with other scientific bodies established under Union law, notably the European Chemicals Agency, the European Food Safety Authority, and the European Medicines Agency, on the exchange of data and information on chemicals, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and on the development of		

		scientific methodologies for the assessment of chemicals.’.		
37	3	Amendments to Regulation (EU) 2017/745	One delegation questions ECHA’s expertise regarding medical devices. PRES: Discussion took place during WP2	
38		Annex I to Regulation (EU) 2017/745 is amended as follows:		
39	(1)	in Section 10.4.1, point (b) is replaced by the following:		
40		‘(b) substances which are identified as endocrine disruptors for human health, of Category 1, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ¹² and substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council or substances having endocrine disrupting properties relevant to human health identified in accordance with Regulation (EU) No 528/2012.’		
41		¹² Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending		

		Regulation (EC) No 1907/2006(OJ L 353 31.12.2008, p. 1).		
42	(2)	in Section 10.4.2, point (d) is replaced by the following:		
43		‘(d) where applicable and available, the latest relevant guidelines in accordance with Sections 10.4.3. and 10.4.4.’;		
44	(3)	Section 10.4.3 is replaced by the following:		
45		‘10.4.3. Guidelines on phthalates When deemed appropriate based on the latest scientific evidence, but at least every 5 years, the Commission shall request the European Chemicals Agency (ECHA) to update guidelines on the benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in Section 10.4.1., points (a) and (b). The benefit-risk assessment shall consider the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments When appropriate or when requested by the Commission, ECHA shall consult the Committee for Risk Assessment and the Committee for Socio-economic Analysis.’;		
46	(4)	Section 10.4.4 is replaced by the following:		
47		‘10.4.4. Guidelines on other CMR and endocrine-disrupting substances		

		The Commission shall request ECHA to prepare guidelines as referred to in Section 10.4.3. and following the process described therein also for other substances referred to in Section 10.4.1., points (a) and (b), where appropriate.’.		
48	4	Amendments to Regulation (EU) 2019/1021	A delegation proposed that Article 4 of the POP Regulation would be amended to give the Commission the possibility to request ECHA to carry out the assessment required to amend the concentration limit values in the Annexes IV and V to the POP regulation It is further proposed (article 13 paragraph 2) that this provision would also introduce the adoption of amendments to Annexes IV and V by means of delegated act. Moreover, they believe that the delegation of legislative powers to the Commission in POP-regulation Article 15 needs further consideration This delegation sees the role of the POP-CA (competent authorities) very important in preparation of the delegated acts. In case the above described amendments would be accepted, what would be the role of the POP-CA in the future? Would the Commission still consult the experts	FR supports the idea of entrusting ECHA with the task of assessing the limit values for the presence of POPs as unintentional trace contaminants (UTC), specified in Annexes I and II. UTC limit values are not determined in COP decisions, but at EU level. The EU would therefore benefit from ECHA's expertise in this task. FR would also underline the importance of the POP-CA and the consultation of the experts designated by each Member State in the preparation of the delegated acts. FR would also point out that each Member State has specific regulations for waste management given the EU regulatory framework based on the directive 2008/98/CE. FR shares the question from the delegation on ECHA and SEAC knowledge on the impact of adjusting annexes IV and V to the POP regulation.

			designated by each Member State and closely collaborate with POP-CA before adopting a delegated act? One delegation proposes that ECHA is also given the task to determine limit values and amending Annex I and not only Annexes IV and V to the POP regulation. They also ask whether ECHA will have the knowledge on the impact of adjusting Annex IV values on the waste and recycling phase, while another delegate questions the knowledge of SEAC on waste management. PRES: Discussion took place during WP2. PRES proposes amendments to be made to the proposal. Written comments are welcomed.	
49		Regulation (EU) 2019/1021 is amended as follows:		
50	(1)	Article 8(1) is amended as follows:		
51	(a)	the following point (i) is added:		
52		‘(i) upon request from the Commission, and within 12 months from that request, draw up and ~~provide~~ submit a report on the human health, environmental and socio-economic impacts of introducing or modifying concentration limit values specified in Annex IV or V.’	One delegation proposes to change ‘draw up and provide a report’ to ‘draw up and submit a report.’ PRES proposed a change to the text.	FR would like the Commission to clarify if a report will be systematically requested to ECHA for the introduction or modification of the concentration limit values specified in Annex IV or V. If not, would the Commission be able to

				clarify in which circumstances the report will not be requested.
53	(2)	Article 8(1a) is added:		
54		‘1a. The report referred to in Article 8(1), point (i), shall contain the following information:		
55		(a) as appropriate, information on human health and environmental impacts of waste consisting of, containing or contaminated with POPs, including impacts on waste management;		
56		(b) information on concentrations and mass flows of POPs in relevant waste streams and on waste treatment and treatment capacities;		
57		(c) an analysis of the impacts of the different concentration limit values considered;		
58		(d) a duly motivated proposal for concentration limit values to be introduced in Annex IV and, as appropriate, in Annex V.		
59		The Agency shall, as soon as it receives the request referred to ~~in the first subparagraph~~ Article 8(1) , point (i), publish on its website a notice that a report on a possible amendment of Annex IV or V will be prepared inviting all interested parties, including waste operators and users of recycled materials, to submit comments within 8 weeks. The	One delegation proposed to change the reference, to clarify and to use the same kind of reference as is used in the paragraph above. PRES proposed change accordingly	

		Agency shall publish those comments on its website.		
60		At the latest 9 months following the submission of the ~~at~~ report <i>referred to in Article (8(1), point (i))</i> , the Committee for Socio-economic Analysis of the Agency, set up pursuant to Article 76(1), point (d), of Regulation (EC) No 1907/2006 shall adopt an opinion on the report and on the concentration limit values proposed therein. For the purpose of adopting an opinion on the report, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.	One delegation proposed to clarify which submission it is referred to given that it is mentioned in several paragraphs earlier in the text. The proposed change would help to clarify this together with a consequential amendment in Article 8(1) point (i) to change the word 'provide' to 'submit' PRES proposed change.	
61		The Agency shall submit the report and the opinion of the Committee for the Socio-economic Analysis on the concentration limit values to the Commission without delay.';		
62	(3)	in Article 13, paragraph 2 is replaced by the following:	One delegation further proposed (Article 13 paragraph 2) that this provision would also introduce the adoption of amendments to Annexes IV and V by means of delegated acts. PRES requires further clarification (potential text proposal).	
63		'2. Where a Member State shares the information referred to in paragraph 1, point (e), with the European Environmental Agency, that Member State shall indicate that in the report and the Member State shall be considered to		

		have fulfilled its reporting obligations under that point.		
64		Where the information referred to in paragraph 1, point (e), is contained in the report of a Member State provided to the Agency, the Agency shall transmit the information to the European Environmental Agency for compiling, storing and sharing that information’;		
65	(4)	in Article 15, paragraph 2 is replaced by the following:		
66		‘2. The Commission is empowered to adopt delegated acts in accordance with Article 18, to amend Annexes IV and V to this Regulation to adapt them to the changes to the list of substances set out in the Annexes to the Convention or the Protocol or to adapt them to scientific and technical progress.’	One delegation proposed the amendment in order to clarify that the reference is to the Annexes in this Regulation. PRES changed the text. One delegation would like confirmation of the Commission’s obligation to consult MS experts before adopting delegated acts as appears to be provided in Article 18(4) of the POP Regulation. Another delegation considers it of high importance to preserve the expertise of the Meeting of the Competent Authorities for Regulation (EU) 2019/1021 on POPs and would like to know in which stage of the future amendments of the annexes the experts from the CAs will be consulted and	

			whether additional POP experts will be incorporated to SEAC and/or RAC. One delegation asked for the delegation of legislative powers to the COM in POP regulation article 15 to be further considered. They see the role of the POP-CA very important in the preparation of the delegated acts. PRES: Discussion took place during WP2. Written comments are welcome.	
67	(5)	Article 18 is amended as follows:	One delegation suggests no changes to be made to Article 18, they don't want to delegate this regulatory authority to the COM. PRES: Discussion took place during WP2. Written comments are welcome.	FR supports the empowerment of the Commission to adopt delegated acts to amend annexes IV et V of the POP regulation.
68	(a)	The first sentence of paragraph 2 is replaced by the following:		
69		'2. The power to adopt delegated acts referred to in Articles 4(3), 10(2) and 15 shall be conferred on the Commission for a period of five years from 15 July 2019.'	A delegation considers that this 5-year term is very likely to have passed before the proposed delegation of authority takes effect. Therefore, they suggest adjusting the period in order to have effect in practice. PRES: Discussion took place during WP2. Written comments are welcome.	FR considers the comment from the delegation appropriate and would also propose to adjust the period.
70	(b)	The first sentence of paragraph 3 is replaced by the following:		

71		‘3. The delegation of power referred to in Articles 4(3), 10(2) and 15 may be revoked at any time by the European Parliament or by the Council.’.		
72	(c)	Paragraph 6 is replaced by the following:		
73		‘6. A delegated act adopted pursuant to Articles 4(3), 10(2) and 15 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object.’.		
74	6	Entry into force		
		This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.		
		Done at Brussels,		
		For the European Parliament The President		
		For the Council The President		

PUBLIC

FRANCE

14/3/2024

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

establishing a common **data platform** on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

(Text with EEA relevance)



	Presidency proposals: amendments (~~deletions~~ / additions)	Presidency justification after WP1: follow-up or proposal to work on amendments, or requests for written comments	Delegates comments/proposals after WP2
Proposal Title			
1	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals)		
Formula			
2	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN		
Citation 1			
3	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114(1) thereof,		
Citation 2			
4	Having regard to the proposal from the European Commission,		
Citation 3			
5	After transmission of the draft legislative act to the national parliaments,		
Citation 4			
6	Having regard to the opinion of the European Economic and Social Committee ¹		
Citation 5			
7	Acting in accordance with the ordinary legislative procedure,		
Formula			
8	Whereas:		
Recital 1			
9	(1) The European Green Deal ³⁴ sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability ³⁵ is a crucial delivery of this zero-		

	pollution ambition and introduces the ‘one substance, one assessment’ approach, which aims to improve the efficiency, effectiveness, coherence, and transparency of safety assessments of chemicals across Union legislation. According to that Strategy, ‘safe and sustainable by design’ criteria should be developed to enable the production and use of chemicals that are safe and sustainable throughout their entire lifecycle. The Strategy also sets out that the interaction between scientific developments and policy-making should be strengthened by means of an early warning system for chemicals to ensure that Union policies address emerging chemical risks as soon as these are identified by monitoring and research, and that a framework of indicators should be developed to monitor the drivers and impacts of chemical pollution and to measure the effectiveness of chemicals legislation. This Regulation aims to implement these objectives.		
Recital 2			
10	(2) The main objective of this Regulation is to increase the level of protection of the environment and human health from the risks arising from hazardous chemicals, as well as to facilitate the functioning of the internal market for chemicals. For that purpose, this Regulation should establish a common data platform data on chemicals (‘the common data platform’), to be managed by the European Chemicals Agency (‘ECHA’). The common data platform is a digital infrastructure that brings together chemicals data and information generated under the Union chemicals acquis. This Regulation should also establish dedicated services within the common data platform and lay down rules on the accessibility and usability of the data contained in that platform. This Regulation aims to create a common knowledge base on chemicals available to authorities to enable better, complete, coherent and robust scientific assessments of chemicals and their impacts and to ensure the best use of existing information for the purpose of the implementation and the development of Union legislation on chemicals. Moreover, the Regulation aims to provide a one-stop-shop on chemicals data and information in the Union accessible to the general public and, thus, to increase the predictability and the transparency of regulatory processes on chemicals, as well as to strengthen public trust in the robustness of scientific decision-making.		

Recital 3			
11	(3) Under Decision (EU) 2022/591 of the European Parliament and of the Council ³⁶ , harnessing the potential of digital and data technologies to support environmental policy, including by delivering real-time data where possible and information on the state of ecosystems, while increasing efforts to minimise the environmental footprint of these technologies and ensuring transparency, authenticity, interoperability and public accessibility of the data and information is a long-term priority objective. Data and information on chemicals are therefore essential for the proper development and implementation of a Union environmental policy, and specifically of a chemicals policy.		
Recital 4			
12	(4) In its communication of 19 February 2020 on a European strategy for data ³⁷ , the Commission described its vision of a common European data space and highlighted the need for the development of sectoral data spaces in strategic areas, since not all sectors of the economy and society are moving at the same speed. This Regulation aims therefore to build a data space for chemicals by establishing a common data platform on chemicals ('common data platform'), which is also part of the Green Deal data space, as referred to in the European strategy for data. Furthermore, in that strategy, the Commission highlighted several issues concerning the availability of data for the public good, including data availability, data infrastructures and governance, interoperability, as well as the lack of adequate sharing of data between public authorities. This Regulation aims to increase data availability on chemicals by requiring the relevant Union agencies to make data available for integration in the common data platform on chemicals, to promote interoperability of that data by providing for the establishment of standard formats and controlled vocabularies, as well as to facilitate data exchange and use by public authorities to enable them to effectively carry out their regulatory and policy developing tasks.		
Recital 5			
13	(5) This Regulation also aims to implement into the chemicals sector the principles laid out in the proposal for an Interoperable Europe Act ³⁸ by strengthening the cross-border interoperability of network		

	and information systems used to provide or manage public services on chemicals in the Union. This Regulation will contribute to increased cross-border data flows for truly European digital services and broaden the access to publicly available chemicals data for utilisation in other sectors' applications.		
Recital 6			
14	(6) Business operators and Members States' competent authorities are required by various Union acts to submit data and information to a multitude of Union agencies, as well as to the Commission in specific cases. This generates a fragmentation of data and information on chemicals, which are held under various data sharing and use conditions and in different formats. Such fragmentation prevents public authorities, as well as the general public, from having a clear overview of what information is available on individual chemicals or groups of chemicals, of where and how information can be accessed and whether it can be used. This increases the likelihood of inconsistency between various assessments of the same chemical required by various Union acts on chemicals and of damaging the general public's trust in the scientific grounds for Union decisions on chemicals. In order to ensure that data on chemicals is easily findable, accessible, interoperable and usable, the ECHA should establish a common data platform on chemicals. The common data platform on chemicals should serve as a single point of reference and as a broadened and shared evidence base to enable the efficient delivery of coherent hazard and risk assessments of chemicals across various Union acts on chemicals, as well as to enable the timely identification of emerging chemical risks and the drivers and impact of chemical pollution.		
Recital 7			
15	The common data platform should contain chemicals-related data and information held by relevant Union agencies or the Commission generated or submitted as part of the implementation of Union chemicals legislation listed in Annex I. This includes, for instance, all regulatory dossiers or applications submitted to the relevant Union agencies, but also chemicals data on occurrence of chemicals submitted by Member States to Union agencies or the Commission in compliance with their reporting obligations. The common data		

	platform should also include chemicals data and information generated as part of Union, national or international programmes or research activities related to chemicals, where this data and information is held by the Commission or one of the relevant agencies.		
Recital 8			
16	Due to the different nature of the risk and hazard assessments performed under Union acts on medicinal products, when compared to those performed under the main Union acts on chemicals, for medicinal products, only chemicals data related to environmental risk assessments for human and veterinary medicines, non-clinical studies for human medicines and maximum residue limit values the European Medicines Agency ('EMA') holds, as well as specific reference values, should be included in the common data platform. For medicinal active substances, only data on relevant substances should be included. These concern active substances covered by the medicines legislation and also used for other applications regulated by other Union legislation identified in this Regulation, as well as other active substances with particular persistent, bio-accumulative and toxic properties or with a known high level of residues in the environment.	Some delegations expressed the need for a clarification of the scope and meaning of "relevant substances" for active substances → PRES: this is scheduled for discussion at the 2 nd WP	FR would like to clarify if medicinal products from biological origin are also taken into account in this proposal (for human and veterinary medicinal products). FR considers that other chemicals data such as clinical studies could also be useful for the risk and hazard assessments performed under other Union acts. See FR proposal in row 93.
Recital 9			
17	(9) These data should also be limited to data submitted to the EMA in the context of the relevant procedures that are finalised or submitted after the entry into force of this Regulation. At a later stage, it should also be possible to include in the common data platform, where relevant, data the EMA holds on procedures concluded before the entry into force of this Regulation.		
Recital 10			
18	(10) Due to the sensitivity of the information on the exact chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health or physical effects, submitted to the bodies appointed by the Member States under Article 45 of Regulation (EC) No 1272/2008 of the European Parliament and the Council ³⁹ , that information should not be included in the common		

	data platform. Likewise, due to the commercial sensitiveness of data and information on final cosmetic products, the information related to cosmetic products notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/200940 of the European Parliament and of the Council should not be included in the common data platform either. However, chemicals data and information on individual chemical ingredients of cosmetic products should be included in the common data platform.		
Recital 11			
19	(11) To safeguard the ability of the European Commission, of the Union agencies working on chemicals and of the competent Member State authorities (hereinafter 'the Authorities'), to carry out their tasks, documents with chemicals data relating to their internal work or decision-making should in principle not be included in the common data platform.		
Recital 12			
20	(12) In order to respond to the needs of the digital economy and to ensure a high level of protection of the environment and human health, it is necessary to lay down a harmonised framework specifying who is entitled to access and use the chemicals data contained in the common data platform, under which conditions, on what basis, and for which purposes. The Authorities that are entrusted with regulatory tasks related to chemicals should be allowed and encouraged to use the chemicals data and information contained in the common data platform to effectively fulfil their regulatory duties and tasks, in order to improve the effectiveness, efficiency, and coherence of chemicals-related assessments as well as the development of Union chemicals policies.		
Recital 13			
21	(13) Chemicals data and information generated as a result of obligations set by Union acts on chemicals may be protected by confidentiality claims on confidential business information. The public dissemination of such data may affect the commercial interest of		

	private parties. To ensure legal certainty for duty holders and to protect their legitimate expectations, as well as to ensure industry's competitiveness on the internal market, the ECHA, as a manager of the common data platform, should grant differentiated access rights to the data and information contained in the common data platform. To this end, the Authorities should have full access to all chemicals data and information contained in the common data platform, including access to confidential information, while business operators and the general public should have restricted access to that data and information, which does not include access to confidential information.		
Recital 14			
22	(14) When using data contained in the common data platform, the Authorities should respect the originator principle. Under this principle, the confidentiality marking of chemicals data as done by the originator and as correspondingly indicated by the Agency when it provides that data to the common data platform should be respected by the Authorities using that data or information to perform their regulatory functions or fulfil their tasks.		
Recital 15			
23	(15) To ensure the protection of legitimate expectations of duty holders when generating or submitting data or information under the Union acts listed in Annex I, as well as to protect the confidentiality of that information when used by the Authorities, exceptional grounds for disclosing confidential information laid down in the Union acts listed in Annex I should apply only to the disclosure of the data and information submitted or generated in compliance with those acts. For example, under Article 39(4) of Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁴¹ , where urgent action is essential to protect human health, animal health or the environment, such as in emergency situations, the European Food Safety Authority ('EFSA') may disclose information previously considered confidential under that Regulation and the EFSA is required to make public information, previously considered confidential, that forms part of conclusions of scientific outputs of the EFSA and relates to foreseeable effects on		

	human health, animal health or the environment. Likewise, Article 118 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁴² provides for the possibility for the ECHA to disclose confidential information submitted to it under that Regulation if urgent action is essential to protect human health, safety or the environment, such as in emergency situations.		
Recital 16			
24	(16) Taking into account that the Agencies would be required to store scientific data, which includes confidential and personal data, it is necessary to ensure that such storage is carried out in accordance with a high level of security of information systems and that access to confidential data is auditable.		
Recital 17			
25	(17) While the ECHA should identify and develop the technical functionalities of the common data platform in stages, certain dedicated services should be defined by this Regulation. As such, the common data platform should, in addition to providing access to chemicals-related data made available by the Agencies and the Commission, provide access to the chemicals data and information made available through its dedicated services. These dedicated services should be integrated into the common data platform and consist of the existing Information Platform for Chemical Monitoring ('IPCHEM'), a repository of reference values, a database of study notifications, a database with information on regulatory processes, a database with information on applicable legal obligations, a repository of standard formats and controlled vocabularies, a database on environmental sustainability related data, as well as a dashboard of indicators on chemicals.		
Recital 18			
26	(18) The Commission should adopt an implementation plan identifying initial datasets to be made accessible via the platform and the timeline for their integration, informed by the preparatory work of the Commission and the Agencies ⁴³ . The Commission should set up a		

	governance scheme to support and steer the common data platform's operation and evolution covering the organisation of work structures and coordination between ECHA and data providers, required rules, formats and vocabularies for data integration, and maintain a rolling implementation plan to ensure the progress in identification and integration of new datasets and services for inclusion. The governance scheme should be adopted and updated as necessary by the Commission, after consultation with a newly established platform steering committee composed of representatives from Union agencies and the Commission. In order to ensure uniform conditions for the implementation of the obligations to establish an implementation plan and a governance scheme, implementing powers should be conferred on the Commission.		
Recital 19			
27	(19) The common data platform should serve the widest possible community, with the ability to address new use cases, incorporate new relevant datasets, develop new functionalities, and respond to developing tools and applications.		
Recital 20			
28	(20) In order to bring together all relevant chemicals data and information in the common data platform, the Commission and Union agencies – notably the European Agency for Safety and Health at Work ('EU-OSHA'), the ECHA, the European Environment Agency ('EEA'), the EFSA, and the EMA ('the Agencies'), should act as data providers and make available any such relevant data they have or hold to the ECHA for integration in the common data platform. The Agencies, including the ECHA itself when making its own data available, should provide the necessary standard metadata, contextual information and relevant mapping to the platform's structure, and respect rules on standard formats and controlled vocabularies where available.		
Recital 21			
29	(21) To ensure that an adequate knowledge base on chemicals is available through the common data platform, the Commission should		

	be able to request the Agencies to host, maintain and make available, via the common data platform, data generated as part of Union, national or international programmes or research activities beyond the data already flowing to the Agencies as part of the obligations under the Union acts listed in Annex I. The Commission should make such requests to the Agencies in accordance with their mandates and allocated tasks.		
Recital 22			
30	(22) Some types of data are currently not within the mandate of any of the Agencies. In order to ensure clarity of responsibilities of the Agencies and efficient management of chemicals data, the Agencies should be required to host, maintain and provide specific data types to the common data platform. To this end, the ECHA should host and be a data provider to the common data platform for workplace monitoring data, and the EEA should host and be a data provider to the common data platform for data on indoor air quality and environment monitoring data, as well as data on concentrations of chemicals in human matrices such as blood or urine ('human biomonitoring data').		
Recital 23			
31	(23) To improve the uptake of academic data and to expand the knowledge base for chemicals safety assessments and environmental sustainability impacts of chemicals, researchers or research consortia funded by Union framework programmes should make available, in line with the 'as open as possible, as closed as necessary' principle, any human biomonitoring data they collect or generate resulting from research and development programmes to the EEA and any environmental sustainability data on chemicals or materials they collect or generate to the ECHA.		
Recital 24			
32	(24) The EEA, as the agency responsible for monitoring data and information on chemicals in the environment, should also be responsible for collecting, hosting, and maintaining human biomonitoring data. To the extent that human biomonitoring data		

	constitutes a special category of personal data, namely, health data, the EEA should process that data only where the processing is necessary for reasons of substantial public interest, as required by Article 10(2)(g) of the Regulation (EU) No 2018/1725 of the European Parliament and of the Council ⁴⁴ . This Regulation lays down the cases where there is such substantial public interest in processing human biomonitoring data: namely, where the EEA processes that data to assess the impact of chemicals on human health and the environment, to monitor time and spatial trends in exposure, to develop health risk and impact indicators, to monitor the impact of regulatory intervention, and to support regulatory risk assessments.		
Recital 25			
33	(25) In order to ensure that appropriate safeguards are in place to secure the protection of this sensitive type of personal data, the EEA should only provide anonymised human biomonitoring data to the ECHA for integration in IPCHEM and the common data platform. IPCHEM, currently operated by the Commission, gathers occurrence data on chemicals in different media, including water, soil, indoor and outdoor air, biota, food and feed, humans, and products. In order to take advantage of the integration of various information systems and to ensure that occurrence data on chemicals is made available for use together with the other chemicals data, the ECHA should take over from the Commission the operation of IPCHEM and integrate it in the common data platform as one of its main dedicated services.		
Recital 26			
34	(26) In order to prevent disruption to the existing operation and functioning of the IPCHEM, the ECHA should integrate the IPCHEM in the common data platform together with the data present in IPCHEM at the moment of integration. At the same time, in order to enable optimal hosting and management of occurrence data on chemicals, the Commission should also transfer the data present in IPCHEM to the ECHA, the EEA or the EFSA for hosting and future updating in accordance with their respective mandates. In order to ensure that the ECHA takes over from the Commission the operation of the IPCHEM,		

	integrates it into the common data platform and takes over the initial data sets and sets up adequate data flows, it is necessary to allow the ECHA an appropriate period of time to carry out these actions, of up to 3 years from the date of entry into force of this Regulation.		
Recital 27			
35	In order to promote the use and harmonisation of reference values among risk assessors and risk managers across different Union acts and to facilitate compliance with, and enforcement of, regulatory reference values, the ECHA should establish and maintain a repository of reference values established or adopted under the Union acts listed in Annexes I and II The Agencies should provide the ECHA with reference values they hold or establish as part of their activities. In addition, the ECHA should regularly screen Union acts for reference values adopted under them. To facilitate automatic access of the general public to up-to-date reference values, the ECHA should integrate the repository of reference values in the common data platform as a dedicated service, include in that repository all reference values together with the relevant context data it has received or retrieved and ensure that those values and that context data are machine readable.		
Recital 28			
36	(28) In order to increase transparency, as well as to enable Authorities to have complete prior knowledge of studies commissioned by business operators, irrespective of whether such studies are carried out by the business operator itself or are outsourced, business operators and laboratories should notify to a database of study notifications established and managed by the ECHA the studies on chemicals they commission for compliance with regulatory requirements under the Union acts listed in Annex I. For this purpose, the ECHA should establish and manage a database of study notifications, as a dedicated service of the common data platform, to store the information related to those studies. In order to allow business operators and laboratories sufficient time to prepare the notifications of studies, the obligation to notify studies should only start to apply two years after the date of entry into force of this Regulation.		

Recital 29			
37	(29) Under Regulation (EC) No 178/2002 of the European Parliament and of the Council, business operators and laboratories are obliged to notify to the database of study notifications established and managed by the EFSA the studies they commission to support an application or notification in relation to which Union law contains provisions for the EFSA to provide a scientific output. To avoid overburdening business operators and laboratories, they should therefore not be required to also notify those studies to the database of study notifications established and managed by the ECHA under this Regulation.		
Recital 30			
38	(30) To ensure the coherence between those two study notification mechanisms, as well as to ensure certainty for business operators submitting notifications, the rules on the public dissemination of study notifications should, where relevant, correspond in that the notifications should only be made available through the common data platform EN 27 EN once a corresponding registration, application, notification or other relevant regulatory dossier was submitted to the relevant Union or national institution and a decision on the confidentiality of the data contained in that regulatory dossier was taken by that Union or national institution. In addition, in order to facilitate compliance with the requirement to notify a study, the ECHA and the EFSA should cooperate to ensure a common approach for the identification of notified information in order to facilitate the traceability of studies notified to their respective databases.		
Recital 31			
39	(31) While the study notification obligation established in this Regulation should apply in the context of all the Union acts on chemicals listed in Annex I, the various relevant data collection and safety assessment processes under those acts may vary widely procedurally. The overarching aim of the database of study notifications established under this Regulation should be to bring		

	together information on studies on chemicals being commissioned by business operators, such as to enable a centralised and complete overview of the studies being performed to support regulatory compliance under Union acts on chemicals as listed in Annex I. On the basis of this objective and considering the fact that assessment procedures under Union acts on chemicals in Annex I may vary widely, it would be beyond the scope and aim of this Regulation to amend existing assessment processes set under those Union acts listed in Annex I by imposing additional conditions leading to potential market access consequences not foreseen in those Union acts. Consequently, it is not appropriate to introduce in this Regulation the consequences associated non-compliance with the study notification obligation as laid out in Article 32b of Regulation (EC) No 178/2002 of the European Parliament and of the Council.		
Recital 32			
40	(32) Nevertheless, to ensure compliance with the study notification obligation laid down in this Regulation, and to cater to the specificities of individual assessment processes, where existing, Member States should lay down rules on penalties applicable to the infringement of that obligation and take all necessary measures to ensure that those rules are complied with. Those penalties should be effective, proportionate, and dissuasive, since non-compliance with this Regulation could result in less robust chemicals risk assessments, creating potential risks and consequently adverse effects on human health and the environment.		
Recital 33			
41	(33) In order to facilitate enforcement by Member States, the Agencies responsible for assessing and providing scientific output, including scientific opinions, on regulatory dossiers containing studies subject to notification to ECHA should, where relevant, cooperate and exchange information with the Member State enforcement authorities on the compliance with the obligations laid out in Article 22.		
Recital 34			

42	(34) While Regulation (EC) No 178/2002 of the European Parliament and of the Council also requires the consultation of stakeholders and the public following the notification to the EFSA of studies commissioned for the purposes of the renewal of an authorisation or approval, a similar requirement under this Regulation would lay a disproportionate administrative burden on the ECHA, given the wide scope of the studies that is to be notified under this Regulation.		
Recital 35			
43	(35) A mechanism related to study notifications exists in Regulation (EC) No 1907/2006 of the European Parliament and of the Council. Where registrants are required to perform studies to generate data in accordance with requirements in Annexes IX and X to that Regulation, they must first submit a testing proposal to the ECHA in order to receive a decision requiring them to perform a study. Such decision may also be issued as an outcome of compliance check or substance evaluation under that Regulation. In order to facilitate the transparency, traceability, and effective monitoring of studies commissioned or carried out pursuant to a decision of the ECHA in accordance with Articles 40, 41 or 46 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council, business operators should specify in their notifications of studies under this Regulation that those studies are being commissioned or carried out in compliance with those decisions.		
Recital 36			
44	(36) To strengthen the coordination and cooperation between the different bodies performing chemicals assessments in the Union, and to promote an increased transparency of chemicals assessments, the ECHA should establish and manage a database with information on regulatory processes or activities that are planned, ongoing or completed by Member States, the Commission and Agencies referred to in the Union acts listed in Annex III to this Regulation and integrate it into the common data platform for access by the authorities. The information on such regulatory processes or activities should include at least the substance identity and the identification, status and		

	eventually the outcome of the regulatory process or activity. That information should also be made available without undue delay and kept updated through the assessment process. Once the process or activity has formally started, that information should be shared also publicly on the common data platform.		
Recital 37			
45	(37) The existing 'The EU Chemicals Legislation Finder' ⁴⁵ project managed by the ECHA makes it easier to find and identify legal obligations related to the use of a specific chemical. The project is especially helpful for small and medium sized enterprises in identifying their legal obligations. To reinforce the supportive function of the project for business operators, it should be established on a permanent basis and more Union acts should be included in its scope. For this purpose, the ECHA should collect information on the legal obligations deriving from the Union acts on chemicals listed in Annex I to this Regulation and incorporate that information into the common data platform as a dedicated service.		
Recital 38			
46	(38) In order to ensure the interoperability and comparability of chemicals data and to facilitate their automatic and electronic exchange, the Agencies and the Commission should store chemicals data in adequate and mutually coherent and interoperable formats and use mutually coherent and interoperable controlled vocabularies. Some Union acts listed in Annex I or II set procedures to establish or make available data formats, in particular for the submission of chemicals data by business operators or Member States. Where such procedures do not exist in the Union acts listed in Annex I or II, the Agencies and the Commission should, where relevant, specify appropriate formats for chemicals data they receive and store, avoiding the use of proprietary standards while, as appropriate, using OECD or other internationally agreed formats, making use of existing formats and ensuring interoperability with existing data submission approaches.		
Recital			

39			
47	(39) Likewise, the Agencies and the Commission should specify appropriate controlled vocabularies for data they receive and store and, where relevant, integrate them in submission software or formats. Moreover, in order to facilitate a smooth electronic exchange of data through the common data platform, the Agencies and the Commission should agree on the required formats and controlled vocabularies for providing data to the common data platform. Whenever the Agencies or the Commission set formats or controlled vocabularies, they should cooperate with each other to ensure their coherence, consistency and interoperability. In order to ensure uniform conditions for resolving divergences in data formats and controlled vocabularies, implementing powers should be conferred on the Commission.		
Recital 40			
48	(40) In order to promote the interoperability of database systems on chemicals beyond the common data platform, the ECHA should establish a repository of standard formats and controlled vocabularies as part of the common data platform. The Agencies and the Commission should make the formats and controlled vocabularies they set available to the repository and the ECHA should make them available free of charge in electronic formats for use by developers of database systems and the general public.		
Recital 41			
49	(41) The International Uniform Chemical Information Database ('IUCLID') is a software application designed to record, store, maintain and exchange data on chemicals. The ECHA develops and maintains the IUCLID software and the underlying format in collaboration with the Organisation for Economic Cooperation and Development ('OECD'). The IUCLID implements all OECD-harmonised templates, which are harmonised formats agreed at the OECD level to facilitate structured and consistent documentation of test outputs and similar chemicals data. Since chemicals data is being submitted to the ECHA in IUCLID under Union acts such as Regulations (EC) No 1907/2006, (EC) No 1107/200946 and (EU) No 528/201247 of the European Parliament and		

	of the Council, the ECHA is closely involved in the continued development of IUCLID, and IUCLID implements the standard formats agreed at the OECD level, it is appropriate and necessary to require the Commission and the Agencies to use IUCLID for the relevant parts of dossiers under specified Union acts listed in Annex I when they make the data contained in those dossiers available to the ECHA .		
Recital 42			
50	(42) To increase the availability and facilitate the use of information on the environmental performance of chemicals throughout their lifecycle, and to enable a comprehensive assessment of the impacts of chemicals on the environment, the Commission should identify relevant data and information related to the environmental sustainability of chemicals, including, where available, information on their impact on climate change, for integration into the common data platform. Once the Commission has identified the relevant existing datasets on environmental sustainability related data and has designed the relevant related database functionalities, the ECHA should establish a database on environmental sustainability-related data, collect the data as made available by the Commission, the Agencies and, where relevant, by the researchers and research consortia funded by Union framework programmes, and integrate the content of that database into the common data platform as a dedicated service. In order to ensure uniform conditions for the implementation of the obligation to identify relevant environmental sustainability datasets, implementing powers should be conferred on the Commission.		
Recital 43			
51	(43) To monitor the impacts on humans and the environment, including the climate, of exposure to chemicals and to establish a knowledge base to measure the effectiveness of chemicals legislation in protecting human health and the environment, the EEA and the ECHA should jointly develop and regularly, at least every two years, update a set of indicators and present it in the form of a dashboard. The EFSA, the EMA, the EU-OSHA and the Commission shall regularly provide the EEA with any available data falling within their mandate and relevant for		

	the establishment of the indicators. The EEA and the ECHA should integrate this dashboard of indicators into the common data platform.		
Recital 44			
52	(44) To enable the identification and evaluation of emerging chemical risks, the EEA should develop and compile information on early warning signals and draw up an annual summary report to inform regulatory follow-up actions. In its work, the EEA should include its own sources, targeted literature searches and make use of information from national early warning systems. It should also include relevant information made available by the related work of the ECHA, the EFSA, the EU-OSHA, the EMA and their networks, such as the EFSA's task of identifying and collecting information on emerging risks under Regulation 178/2002. The EEA should make the summary report and the underlying data available through the common data platform, ensuring public access and its use for further action on existing and emerging risks. In order to allow the EEA sufficient time to organise the collection of early warning signals and to compile and analyse the initial information the EEA should only deliver the first report six months after the end of the first calendar year after entry into force of this Regulation. This Regulation sets a deadline for the first report and associated data.		
Recital 45			
53	(45) In June 2017, at the Commission' request, the ECHA set up the European Observatory for Nanomaterials ⁴⁸ ('EUON'), which collects existing data and information from databases, registries and studies and generates new data through studies and surveys on nanomaterials on the EU market.		
Recital 46			
54	(46) The ECHA should continue operating the EUON and transform it into an observatory for specific chemicals with potential contribution to emerging chemical risks ('the observatory'), which should cover also other chemicals and innovative (rationally designed complex 'advanced') materials selected by the Commission, using, as		

	appropriate, signals from the early warning and action system. One of the criteria for selecting chemicals for the observatory should be their novelty and disruptive potential that may contribute to an emerging chemical risk. Another criterion for that selection should be the higher degree of uncertainty surrounding them and, due to less regulatory experience regarding those chemicals, the resulting need for additional scrutiny and transparency. The observatory should facilitate regulatory implementation and responsible use of these chemicals by collecting, generating, and disseminating reliable information on selected chemicals' properties, uses and market presence to the general public.		
Recital 47			
55	(47) The observatory should not be regarded as a substitute for required risk management action on any chemical in cases where a hazard or risk has been identified. In order to provide for an efficient and consistent approach for the generation and dissemination of all such additional information, the ECHA should oversee the work of the observatory and make the regularly updated data and information it collects available through the common data platform, or by means of other communication channels, as appropriate. In order to ensure uniform conditions for the implementation of the requirement to select chemicals to be included in the observatory, implementing powers should be conferred on the Commission.		
Recital 48			
56	(48) Under Regulation (EC) No 178/2002, the EFSA is able to commission, in an open and transparent manner, the scientific studies it needs to accomplish its mission, while seeking to avoid duplication with Member States or Union research programmes. The ECHA should also be able to commission studies to obtain adequate data and information on chemicals within its mission, while maintaining the principle that the burden to prove compliance with Union chemicals legislation remains on the duty holder. Furthermore, the ECHA should commission such studies out of its own initiative or at the request of the Commission, with the objective of supporting the effective and efficient implementation and evaluation of Union acts on chemicals		

	within its mandate and contributing the development of a Union chemicals policy.		
Recital 49			
57	(49) In order to adjust the contents of Annexes I and III to technical and scientific progress in the field of chemicals and to bring in the scope of this Regulation new Union acts under which relevant chemicals data and information is generated or submitted, and, where relevant, to expand the specific data types and reference values, listed in Annex II, to be made available by the EMA through the common data platform, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending Annexes I, II and III. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work in relation to the amendment of the Annexes by delegated act, including at expert level through the One-Substance One-Assessment Expert Group, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016 ⁴⁹ . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.		
Recital 50			
58	(50) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States as Member States do not hold the data within the scope of this Regulation and cannot establish a Union wide common data platform, but can rather, by reason of chemicals data and information being hosted at Union level by the Agencies, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.		

Recital 51			
59	(51) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council and delivered an opinion on [OP: Please insert the date of the opinion of the EDPS].		
Formula			
60	HAVE ADOPTED THIS REGULATION:		
Chapter I			
61	Chapter I SUBJECT MATTER, SCOPE AND DEFINITIONS		
Article 1			
62	Article 1 Subject matter and scope		
Article 1(1)			
63	1. This Regulation aims to ensure the efficient delivery of coherent hazard and risk assessments of chemicals where those assessments are required by Union legal acts, to achieve a high level of protection of human health and the environment, to enable the development and use of sustainable chemicals, to ensure the proper functioning of the single market for chemicals, and to improve the Union's citizens' trust in the scientific base for the decisions taken under Union legal acts on chemicals.	One delegation proposed to include SSBD (safe and sustainable by design) as one of the roles for the platform. → PRES propose to work on an amendment introducing explicitly the safe and sustainable by design approach as one of the aims.	
Article 1(2)			
64	2. To achieve the objectives referred to in paragraph 1, this Regulation contains measures to:		
Article 1(2), point (a)			
65	(a) bring together data and information on chemicals and ensure that data and information are easily findable, accessible, interoperable and re-usable;		
Article			

1(2), point (b)			
66	(b) keep records of studies commissioned or carried out by business operators in the context of fulfilling their obligations set under Union chemicals legislation;		
Article 1(2), point(c)			
67	(c) establish the widest possible scientific base for the implementation and development of Union legislation and policy on chemicals;		
Article 1(2), point (c)			
68	(d) establish an early warning and action system for emerging chemical risks.		
Article 1(3)			
69	The provisions laid down in this Regulation apply to chemicals data as laid out in Article 3(2).		
Article 2			
70	Article 2 Definitions	One delegation requested amending art.2 to clarify the meaning of “product” in this proposal. One delegation asked what is covered by the term “products” in art.7(1) One delegation requested examples of the meaning of “chemical products” in relation to mixtures, articles, substances. PRES highlights that the term occurs in recital (8), (10),(25),art.3(3), art.7(1), art.22(1). PRES highlights also that while some of those occurrences relates to cosmetic or medicinal products, other occurrences do not refer to a particular regulation and might have overlapping meaning with e.g. articles in REACH, or products under the ESPR. → PRES is working on an amendment proposal.	FR would also welcome a clarification of the terms “products” and “chemicals”.
Formula			

71	For the purpose of this Regulation, the following definitions shall apply:		
Article 2(1)			
72	1. 'Agencies' means the European Chemicals Agency ('ECHA'), the European Environment Agency ('EEA'), the European Food Safety Authority ('EFSA') and the European Medicines Agency ('EMA') and the European Agency for Safety and Health at Work ('EU-OSHA');		
Article 2(2)			
73	2. 'Authorities' means the European Commission, the competent authorities of the Member States as referred to in any of the Union acts listed in Annexes I and III, and the Agencies, excluding their management boards;		
Article 2(3)			
74	3. 'duty holder' means a natural or legal person responsible for meeting obligations under the Union acts listed in Annex I or II;		
Article 2(4)			
75	4. 'business operators' means duty holders which are private or public undertakings;	One delegation suggests to "use 'economic operators' instead of 'business operators' to ensure alignment with other relevant legislation". PRES highlights that the term "business operator" is used in recital (8),(13),(28),(29),(30),(31),(35),(37),(38), and articles 1(2), 22, 25, and 26. Those articles relates to studies commissioned, studies notifications, and related enforcement/penalties. PRES highlights that the term "duty holder" is defined in art. 2(3) in relation to obligations in acts mentioned in annex I or II. The terms is per se used in recital (13), (15), (48),art 2(4), 15(5), and 17(2). Those later articles relate to the use of the controlled vocabularies, as well as the prohibition for Authorities to use data from the platform to fulfil legal obligations of duty holders.	

		→ PRES seeks written comments on the following: ESPR has a definition of “economic operator”: ‘economic operator’ means the manufacturer, the authorised representative, the importer, the distributor, the dealer and the fulfilment service provider. PRES understands that in the present regulation the meaning of it is much more narrow, and relates only to duty holders that at the same time are undertakings. → PRES seeks for agreement that in consequence there is no correspondence with other EU regulations, and thus no amendment here should be done.	
Article 2(5)			
76	5. ‘human biomonitoring data’ means concentrations of chemicals measured in human matrices such as blood or urine;		
Article 2(6)			
77	6. ‘reference value’ means an estimate of a maximum exposure to or emission level of a chemical below which no or only acceptable adverse effects on human health or the environment are expected, or below which risks related to the adverse effects on human health or the environment are considered acceptable or tolerable;	One delegation commented about “acceptable or tolerable” in relation to non-threshold cancerogenic substances. PRES understands that the intention is to avoid that reference values for non-threshold substances are published without mentioning as metadata the actual statistical risk they represent. → PRES proposes to work on an amendment of art 2(6), 8 and 14 for this.	
Article 2(7)			
78	7. ‘originator’ means the Commission, Agency, or Member State competent authority responsible for confidentiality assessments under any Union act listed in Annex I or Annex II;		
Article 2(8)			
79	8. ‘originating Union act’ means the Union act under which chemicals		

	data and information were generated or submitted;		
Article 2(9)			
80	9. 'controlled vocabularies' means standardised and organised arrangements of words and phrases presented as lists of terms or as thesaurus and taxonomies with a hierarchical structure of broader and narrower terms;		
Article 2(10)			
81	10. 'chemicals data' means any representation of facts or information relating to chemicals and any compilation of such facts or information, including information on physico-chemical properties, hazard properties, use, exposure, risk, occurrence, emissions and manufacturing process of the chemicals, as well as environmental sustainability related information, including climate change related information, on those chemicals, regulatory process-related information on chemicals, standard formats, controlled vocabularies, or any information on applicable legal obligations related to chemicals;		
Article 2(11)			
82	11. 'environmental sustainability related data' means any data relevant for the environmental sustainability assessment of a chemical or material throughout its entire life cycle, including:	One delegation finds this definition vague, and proposes to add an annex (e.g. in Art. 13) which can be updated on a regular basis by means of Delegated Acts. This annex should contain the respective legal acts as well as the associated sustainability information. PRES highlights that the definition here is used in a broader sense than the information available in legal acts (e.g. research in art.5(6), art 13(3) and potentially art.13(4)). → PRES requests written comments on the necessity to add a reference to a new annex IV, containing a list legal acts relevant for environmental sustainability related data. Such a reference would be added here as a new point 2(11)(d) along with related delegated powers in Chapter VIII. → PRES would also like to have comments on the provisions of art.13(4) as this partially overlaps with the concern raised by one	FR are not in favour the proposal to add an annex to list the datasets to be included in the database on environmental sustainability related data. The datasets to be included should be identified through the implementation plan such as the others chemicals data mentioned in the proposed regulation.

		delegation (by having the COM adopting an implementing decision for data not already hosted or hold by agencies/COM or not coming from EU research). Which relevant data are generated through legal acts but are not hold or hosted by COM/agencies listed in this proposal?	
Article 2(11), point (a)			
83	(a) data on resources, including raw materials, water, energy, fossil fuels and land;		
Article 2(11), point (b)			
84	(b) data on emissions, including greenhouse gases, eutrophication-relevant substances, dust and all other polluting substances; and		
Article 2(11), point (c)			
85	(c) data on by-products originating during the chemical's life cycle that can be used as resources for other production processes, including hydrogen and carbon monoxide.		
Article 2(12)			
86	12. 'personal data' means personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679 of the European Parliament and of the Council and as defined in Article 3, ~~point (16), of Regulation (EU) 2018/175~~ point (1), of Regulation (EU) 2018/1725 of the European Parliament and of the Council;	One delegation highlighted that this definition is specified in Article 3, point (1) of Regulation 2018/1725 and not in Article 3, point (16) of Regulation 2018/175. → PRES sees this as an editorial amendment and proposes to modify Article 2 (12) consequently.	
Article 2(13)			
87	13. 'processing' means processing as defined in Article 4, point (2), of Regulation (EU) 2016/679 of the European Parliament and of the	One delegation highlighted that the reference is to Regulation 2018/1725 and not to Regulation 2018/175.	

	Council and as defined in Article 3, point (3), of ~~Regulation (EU) 2018/175~~ Regulation (EU) 2018/1725 of the European Parliament and of the Council;	→ PRES sees that this is an editorial amendment and proposes to modify Article 2 (13) consequently.	
Article 2(14)			
88	14. ‘data controller’ means controller as defined in Article 4, point (7), of Regulation (EU) 2016/679 and as defined in Article 3, point (8), of ~~Regulation (EU) 2018/175~~ Regulation (EU) 2018/1725 of the European Parliament and of the Council;	One delegation highlighted that the reference is to Regulation 2018/1725 and not to Regulation 2018/175. → PRES sees that this is an editorial amendment and proposes to modify Article 2 (14) consequently.	
Article 2(15)			
89	15. ‘interoperability’ means the ability of two or more data spaces or communication networks, systems, products, applications or components to exchange and use data in order to perform their functions.	One delegation asked if advanced programming interfaces (API) will be used. PRES highlights that API are tools that MSs may use amongst others in order to query the data platform from their own advanced knowledge management systems (i.e. machine readability) instead of relying on “manual” queries in a web interface like in ECHA web site today. PRES highlights that in the explanatory memorandum the COM mentions that “The proposal also contributes to the objectives of EU data and digital policies by promoting interoperability and machine readability ”. However only interoperability is explicitly mentioned here. → PRES requests written comments on this and on the necessity to amend the proposal to explicitly mention APIs and the conditions of their use for MS and the public.	
Chapter II			
90	Chapter II INFORMATION SYSTEMS AND PLATFORMS		

Article 3			
91	Article 3 Common Data Platform on Chemicals		
Article 3(1)			
92	1. The ECHA shall establish and manage a common data platform on chemicals ('the common data platform').		
Article 3(2)			
93	2. The common data platform shall provide access to all chemicals data:	One delegation highlights that it is difficult to assess the exhaustiveness of annexes I and III. PRES request written comments on any potentially missing relevant regulations in those annexes. One delegation questioned the differentiated approach between medicinal products and biocidal and phytopharmaceutical products. → PRES would like to receive further clarity in writing.	FR did not identify any missing relevant regulations in annexes I and III for now. Regarding annex II, FR supports to add a provision to request the Commission to prepare and submit a report evaluating the opportunity to integrate more data on medicinal products that could be useful for assessments under others Union acts. For example, FR is concerned about the exposure of workers handling medicines, we lack exposure/clinical data in those cases since medicines as such are out of the scope of the CLP regulation, even it has been recently clarified that HMPs are in the scope of

PUBLIC

			the CMRD directive (2004/37/CE). The requested report should be provided within a given timeframe (2 years for example) and should present recommendations to possibly amend annex II of the proposed regulation to integrate further datasets from medicinal regulations if considered appropriate.
Article 3(2), point (a)			
94	(a) generated or submitted as part of the implementation of the Union acts listed in Annex I to this Regulation and held by the Agencies or the Commission;		
Article 3(2), point (b)			
95	(b) generated as part of Union, national or international programmes or research activities in the sphere of chemicals and held by the ECHA, the EEA, the EFSA, the EU-OSHA or the Commission;		
Article 3(2), point (c)			
96	(c) listed in Annex II and held by the EMA;		
Article 3(3)			
97	3. The following information shall not be included in the common data platform:		
Article			

3(3), point (a)			
98	(a) the information referred to in Article 45 of Regulation (EC) No 1272/2008 ⁵⁰ ; 50 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).		
Article 3(3), point (b)			
99	(b) the information related to cosmetic products and notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/2009 ⁵¹ of the European Parliament and of the Council. 51 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November on cosmetic products (OJ L 342 22.12.2009, p. 59).		
Article 3(4)			
100	4. Documents relating to Authorities' internal work or decision-making processes need not be included in the common data platform, unless required under Article 10.		
Article 3(5)			
101	5. The common data platform shall provide the dedicated services identified in the governance scheme referred to in Article 4(3) including:		
Article 3(5), point (a)			
102	(a) the Information Platform for Chemical Monitoring ('IPCHEM') referred to in Article 7;		
Article			

3(5), point (b)			
103	(b) the repository of reference values referred to in Article 8;		
Article 3(5),point (c)			
104	(c) the database of study notifications referred to in Article 9;		
Article 3(5), point (d)			
105	(d) information on regulatory processes referred to in Article 10;		
Article 3(5), point (e)			
106	(e) information on obligations under Union chemicals legislation referred to in Article 11;		
Article 3(5), point (f)			
107	(f) the repository of standard formats and controlled vocabularies referred to in Article 12;		
Article 3(5), point (g)			
108	(g) the database on environmental sustainability-related data referred to in Article 13.		
Article 3(6)			
109	6. The Authorities and the general public shall have access to the data contained in the common data platform in accordance with Article 16.		
Article 3(7)			
110	7. The data contained in the common data platform may be used in accordance with Article 17.		
Article 3(8)			

111	8. The data contained in the common data platform shall be made available in standard formats, where developed, and through controlled vocabularies where available.		
Article 3(9)			
112	9. The data contained in the common data platform shall be electronically accessible and searchable. The ECHA shall take measures to ensure a high standard of security appropriate to the security risks at stake for the storage of chemicals data in and transmission of chemicals data to the common data platform. The ECHA shall design the common data platform in a way that guarantees that any access to confidential data is auditable.		
Article 3(10)			
113	10. The Commission or Agency under whose authority chemicals data is included in the common data platform on chemicals shall remain responsible for handling any requests for access to documents made under Regulation (EC) No 1049/2001. 52 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (. OJ L 145, 31.5.2001, p. 43).		
Article 3(11)			
114	11. The common data platform and its dedicated services shall be established by [OP: please insert date: three years after the date of entry into force of this Regulation], unless specified otherwise. The relevant datasets shall be integrated progressively into the common data platform by [OP please insert date: ten years from the date of entry into force of this Regulation] according to the implementation plan referred to in Article 4 (1), first sentence. Upon integration of those datasets in the common data platform, when the ECHA receives chemicals data in accordance with Article 5, it shall make that data available through the common data platform without undue delay.	One delegation requested clarifications on this paragraph (timing for the notification service, lack of specification of the timing for the rolling plans). This delegation proposed amendments accordingly → PRES: a more general discussion at the 2d WP took place regarding the timelines	FR thanks the Commission for the presentation of the timelines during the 2 nd WP. FR still have some questions regarding the implementation of the platform. What will be the purpose of the subsequent rolling implementation plans mentioned in article 4(1) ? Will new datasets be

			identified to be included in the platform in that rolling plans ? If so, does the COM consider that this datasets will not integrate the platform by the ten years of implementation ? It is not clear why we refer only to the first implementation plan in article 3(11).
Article 4			
115	Article 4 Implementation plan and governance of the common data platform	One delegation proposed to include new provisions 5a,5b,5c in art.4., requesting that the COM prepares and presents a recommendation on “how to amend legislation listed in the Annexes to this regulation”. → PRES would like to receive written comments on this as it is not clear for us if this means amending the annexes of the data platform proposal, or if the delegation meant to amend the listed regulations. One delegation raised concerns about the wording “implementing” appearing at several places and which is seen as “misleading” with respect to the legal definition of “implementing acts”. → PRES seeks legal advice on this. The Council legal services provided an opinion on this at the 2nd WP.	FR supports the proposal made by DK to request the Commission to prepare and present a recommendation on how to amend the Union acts listed in the annexes in order to allow a better reuse of data across the different regulations. This proposal aims at going further in the implementation of the OSOA approach. Indeed more regulation amendments will probably be needed to reach the objectives of the approach in particular to improve assessments of chemicals. The implementation of a data platform is only a first step and we should anticipate further

			developments.
Article 4(1)			
116	1. By [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall adopt and publish an implementation plan identifying datasets for inclusion in the common data platform together with a timeline for their inclusion by means of an implementing decision. Subsequent rolling implementation plans shall be adopted in line with the governance scheme referred to in paragraph 3.	One delegation questioned the procedure for adopting the plan, the consultation procedures and MS involvement. → PRES: WP2 discussion on the desired level of and procedures for MS participation took place.	FR would welcome a clarification in the text that the experts of the MS will be consulted on the draft implementation plan.
Article 4(2)			
117	2. The Commission shall, by means of an implementing decision, establish and manage a platform steering committee, which shall include one representative from the ECHA, one representative from the EEA, one representative from the EFSA, one representative from the EMA, one representative from the EU-OSHA and five representatives from the Commission.		
Article 4(3)			
118	3. The platform steering committee shall advise the Commission in the preparation of the common data platform's governance scheme.		
Article 4(4)			
119	4. The Commission shall adopt and publish the governance scheme referred to in paragraph 3 and any revision thereof by means of an implementing decision		
Article 4(5)			
120	5. That governance scheme shall describe:		
Article 4(5), point (a)			
121	(a) the organisation of the main work structures supporting the development and implementation of the common data platform;		

Article 4(5), point (b)			
122	(b) the preparation and adoption of rolling implementation plans for the common data platform;		
Article 4(5), point (c)			
123	(c) the principles on data governance and the required standard formats, controlled vocabularies and further conditions for the provision of information and context data to the common data platform;		
Article 4(5), point (d)			
124	(d) the decision-making procedures for the development of new dedicated services and the inclusion of new functionalities of the platform;		
Article 4(5), point(e)			
125	(e) any other rules or requirements necessary for the operation of the common data platform such as the data update, archiving and deletion policy;		
Article 4(5), point (f)			
126	(f) the operation of the steering committee itself.		
Article 5			
127	Article 5 Data Flows for the purpose of the common data platform		
Article 5(1)			
128	1. At the Commission's request, the Agencies shall host and maintain chemicals data generated as part of Union, national or international legislation, programmes or research activities, corresponding to their		

	mandate and the type of data they already hold.		
Article 5(2)			
129	2. Where the Commission or the Agencies hold data or information referred to in Article 3(2), they shall make that data available to the ECHA, in a standard format, where available, together with the relevant context data as ~~referred to in Article 4(4), point (c).~~ referred to in Article 4(5), point (c). The Commission and the Agencies shall indicate whether that data or information is made available to the public under the originating Union act.	One delegation highlighted that the reference should be to Article 4(5), point (c) and not Article 4(4), point (c). → PRES sees this as an editorial amendment and proposes to modify Article 5(2) consequently.	
Article 5(3)			
130	3. The ECHA shall host and maintain occurrence data related to workplace monitoring.		FR is wondering why occurrence data related to workplace monitoring are hosted by ECHA whereas human biomonitoring data including occupational biomonitoring data are hosted by EEA. Correlation between these datasets is important. FR suggests therefore to request ECHA to host occupational biomonitoring data instead of EEA. Indeed there is a link between atmospheric concentrations and information provided by occupational biomonitoring (for example for cadmium in the CMRD directive (2004/37/CE)).
Article			

5(4)			
131	4. The EEA shall host and maintain human biomonitoring data, occurrence data for the environment and occurrence data related to indoor air quality.	One delegation asked if Commission pursues plans for systematic or regular surveys of indoor air quality data → PRES is requesting written comments on this.	
Article 5(5)			
132	5. Researchers or research consortia funded by Union framework programmes shall make available to the EEA any human biomonitoring data they collect or generate from [OP please insert: date of the entry into force of this Regulation].		
Article 5(6)			
133	6. Researchers or research consortia funded by Union framework programmes shall make available to the ECHA any environmental sustainability data on chemicals or materials they collect or generate from [OP please insert: date of the entry into force of this Regulation].		
Article 5(7)			
134	7. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of the chemicals data provided in accordance with paragraph 2 in the common data platform as well as its publication through that platform.		
Article 5(8)			
135	8. For the purpose of paragraph 2, the Commission and the Agencies shall make chemicals data available to the ECHA without undue delay after collection or receipt of the data, after performance of validity and confidentiality assessments in accordance with applicable rules and once the corresponding dataset has been integrated in the common data platform.		
Article 5(9)			
136	9. The Commission and the Agencies shall ensure that data made available to the ECHA shall be downloadable, machine readable and interoperable. They shall appropriately curate and validate the data before providing them to the ECHA.		

Article 6			
137	Article 6 Human biomonitoring data	→ PRES: given the numerous comments, questions and clarification requests received, PRES set this as a discussion point at the 2 nd WP (8/3), and invites MS and the COM to react to the EDPS recommendations.	FR is under scrutiny reservation regarding the recommendations of the EDPS. FR would welcome a clarification from the Commission on the scope of Article 6. More precisely, FR would like the confirmation that human biomonitoring data includes occupational biomonitoring data.
Article 6(1)			
138	1. The EEA shall collect, host, and maintain human biomonitoring data generated within the territory of the EEA's member and cooperating countries.		
Article 6(2)			
139	2. At the latest by [OP please insert date: 3 years after entry into force of this Regulation] the Commission shall transfer any human biomonitoring data it holds to the EEA.		
Article 6(3)			
140	3. The EEA may process human biomonitoring data constituting personal data to support the Commission in its policy making or to support the Agencies in fulfilling their missions.		
Article 6(4)			
141	4. Human biomonitoring data constituting personal data may be processed by the EEA for the following purposes:		
Article 6(4),			

point (a)			
142	(a) assessing the impact of chemicals on human health and the environment;		
Article 6(4), point (b)			
143	(b) monitoring time and spatial trends in exposure;		
Article 6(4), point (c)			
144	(c) developing health risk and impact indicators;		
Article 6(4), point (d)			
145	(d) monitoring the impact of regulatory intervention;		
Article 6(4), point (e)			
146	(e) supporting regulatory risk assessments.		
146.a	(f) supporting regulatory risk management	One delegation proposed to add this amendment. PRES understands that HBM data are indeed useful for risk management, e.g. trend analysis will give an idea if policy actions are having an impact or not on reducing exposure → PRES proposes thus to add this paragraph (f)	
Article 6(5)			
147	5. The EEA shall make human biomonitoring data they hold or host publicly available in anonymised form through the Information Platform for Chemical Monitoring.		
Article 6(6)			
148	6. The EEA shall act as data controller for the human biomonitoring personal data it holds or hosts and processes for the purposes referred to	Some delegations highlighted that the reference should be to para. 4. → PRES sees this as an editorial amendment and proposes to modify	

	~~in paragraph 2.~~ in paragraph 4.	art.6(6) in consequence. One delegation proposed to add an additional reference to art.3 and 5 here. → PRES, up to his knowledge, understands that from the definition of a data controller this is logical, but seeks for written opinions on this and will request a legal advice. Discussions at the 2nd WP on the EDPS recommendations might also contribute clarifications on this proposal. One delegation suggested to “include the same reference to Articles 6(3) and 6(4)” → PRES is keen to receive a written rationale for this as it seems to introduce a circular reference in the text.	
Article 7			
149	Article 7 Information Platform for Chemical Monitoring		
Article 7(1)			
150	1. The ECHA shall operate and maintain the Information Platform for Chemical Monitoring containing occurrence data on chemicals across different media, including water, soil, indoor air, outdoor air, biota, food and feed, humans, and products as part of the common data platform.	→ PRES: regarding the meaning of “products”, cfr art.2 (here in line 70).	
Article 7(2)			
151	2. At the latest by [OP please insert date: 3 years after the date of entry into force of this Regulation], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring at that moment to the ECHA for integration in the common data platform.		
Article 7(3)			
152	3. At the latest by [OP please insert date: 3 years after entry into force of this Regulation], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring to the ECHA, the EEA or the EFSA for hosting in accordance with the		

	respective agencies' mandate and in accordance with Article 5.		
Article 7(4)			
153	4. After the completion of the transfer referred to in paragraph 3, where the Commission or the Agencies host or hold occurrence data on chemicals and related chemicals data, they shall make that data available to the ECHA without undue delay for integration in the Information Platform for Chemical Monitoring.		
Article 7(5)			
154	5. The Commission and Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration and publication of occurrence data and related chemicals data they host or hold through the common data platform.		
Article 7(6)			
155	6. The ECHA shall ensure that the data contained in the Information Platform for Chemical Monitoring is machine readable and downloadable.		
Article 8			
156	Article 8 Repository of reference values	One delegation requested a amendment about the statistical (cancer) risk associated with some reference values. → PRES: see our proposal in art 2(6) here line 77	
Article 8(1)			
157	1. The ECHA shall establish and manage a repository of reference values as part of the common data platform.		
Article 8(2)			
158	2. The ECHA shall include any reference value adopted under Union acts listed in Annex I or Annex II, Part 1, in the repository of reference values without undue delay.		
Article 8(3)			
159	3. For reference values not falling under paragraph 2, the Agencies holding or establishing reference values as part of their activities under		

	Union acts listed in Annex I, or the reference values referred to in Annex II, Part 2, shall make those reference values available to the ECHA, in the standard formats provided for in Article 14, where developed, and without undue delay, for integration in the repository of reference values.		
Article 8(4)			
160	4. For the purpose of paragraph 3, where reference values are included in a regulatory dossier submitted to the Agencies, the Agencies shall share those reference values in the standard formats with ECHA without undue delay and once relevant validity and confidentiality assessments have been completed by the originator in accordance with applicable rules.		
Article 8(5)			
161	5. The ECHA shall ensure that the data contained in the repository of reference values is machine readable.		
Article 9			
162	Article 9 Database of Study Notifications		FR would like the text to clarify that the MS authorities will have access to the database of study notifications. FR is wondering what will be the rules if there is a request from a third party for an access to document on this specific database. Although FR welcomes the insertion of this database, it would like to ask the Commission if studies made on military related uses substances registered

			in REACH will fall under the scope of this Article.
Article 9(1)			
163	1. The ECHA shall establish and operate a Database of Study Notifications by [OP please insert date: two years after the date of entry into force of this Regulation].		
Article 9(2)			
164	2. The ECHA shall store in the Database of Study Notifications the data notified to it in accordance with Article 22.		
Article 9(3)			
165	3. The ECHA shall integrate the data contained in the Database of Study Notifications in the common data platform once a corresponding registration, application, notification or other relevant regulatory dossier was submitted to the relevant Union or national institution, agency, or body in accordance with corresponding Union law and after a decision was taken by that Union or national institution, agency, or body on the disclosure of the accompanying studies in accordance with the applicable rules on confidentiality.	One delegation considers that this deserves clarification as it seems to prevent Member States authorities from getting relevant information on notified studies in time. PRES notes that this might be related to enforcement. → PRES seeks further written comments on this → PRES is working on an amendment proposal	
Article 9(4)			
166	4. The EFSA shall make the data contained in the database referred to in Article 32b of Regulation (EC) No 178/2002 available to the ECHA for integration in the common data platform once it has received a corresponding application and after it has decided on the disclosure of the accompanying studies in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002.		
Article 9(5)			
167	5. The ECHA and the EFSA shall cooperate to ensure a common approach for the identification of information notified to them in accordance with Article 22 of this Regulation and Article 32b of Regulation (EC) No 178/2002, respectively and facilitate the traceability		

	of the studies notified to their respective databases.		
Article 10			
168	Article 10 Information on regulatory processes on chemicals	→ PRES is seeking written comments on one delegation's question about already existing communication channels in certain regulations, related to the stage of evaluation, and the potential need to modify those regulations. → PRES highlights that this might be the case for TRIS notifications.	
Article 10(1)			
169	1. The ECHA shall establish and manage, as part of the common data platform, a new database containing information on regulatory processes on individual substances or groups of substances that are planned, ongoing or have been completed since the entry into force of this Regulation by the Member States or the Union institutions, agencies or committees referred to in the Union acts listed in Annex III.	→ PRES is seeking for written comments on one delegation's comment that it is not clear whether the scope of art 10(1) includes national regulations processes.	
Article 10(2)			
170	2. Where Member State competent authorities as referred to in any of the Union acts listed in Annex III hold the information referred to in paragraph 1, they shall make that information available to the Union agency responsible under the respective Union act listed in Annex III without undue delay.	→ PRES is seeking for written comments on one delegation's request to clarify the COM reference (during the 1 st WP) to voluntary notifications, including examples.	
Article 10(3)			
171	3. Where the ECHA, EEA, EFSA, EU-OSHA or the Commission hold the information referred to in paragraph 1, they shall make that information available to the ECHA for integration in the common data platform in the standard formats provided for in Article 14 without undue delay and, where relevant, once the responsible agency or the Commission has performed the validity assessment. For each regulatory process or activity, at least the following information shall be included:	→ PRES is seeking written comments on one delegation's question about which information EEA might have to make available to ECHA in this context, as EEA has no competences about chemical products.	
Article 10(3), point (a)			

172	(a) substance identity;		
Article 10(3), point (b)			
173	(b) the Union act and the regulatory process under which the activity takes place;		
Article 10(3), point (c)			
174	(c) submitter or actor responsible for the regulatory process or activity;		
Article 10(3), point (d)			
175	(d) status of the regulatory process or activity;		
Article 10(3), point (e)			
176	(e) where applicable , outcome of the regulatory process or activity ~~including, where applicable, and~~ reports or opinions adopted;	PRES understand from one delegation's comment that it is not always possible to indicate the (future) outcome, so this provision is not always applicable. → PRES propose to amend art 10(3) by inserting "where applicable" as we see it more precise than "where appropriate"	
Article 10(3), point (f)			
177	(f) where applicable, date of intention to start the regulatory process or activity, completion and latest update.		
Article 10(4)			
178	4. The information referred to in paragraph 3, points (a) to (f), on a specific regulatory process or activity shall be made available to the public once that process or activity has formally started.		
Article 11			
179	Article 11 Information on the obligations under Union acts on chemicals	PRES notes one delegation's comment on the potentiality of IA in this context.	
Article			

11(1)			
180	1. The ECHA shall establish and manage, as part of the common data platform, a database with information on the provisions and legal obligations applicable to chemicals under the Union acts listed in Annex I.		
Article 11(2)			
181	2. The ECHA shall update the information in the database on a regular basis and in accordance with the governance scheme referred to in Article 4(3).		
Article 12			
182	Article 12 Repository of standards formats and controlled vocabularies		
Article 12(1)			
183	1. The ECHA shall establish and manage as part of the common data platform a repository of standard formats and controlled vocabularies.		
Article 12(2)			
184	2. Where standard data formats are established under the Union acts listed in Annexes I and II, the ECHA shall include them in the common data platform.		
Article 12(3)			
185	3. Where the Commission or the Agencies specify a standard format or controlled vocabulary in accordance with Articles 14 or 15, the Commission or the Agency shall make it available to the ECHA without undue delay for integration in the common data platform.		
Article 13			
186	Article 13 Database on environmental sustainability related data	One delegation requested for a new annex on relevant legal acts, see discussion of Article 2(11) → PRES: see line 82 here above About the role of EIONET in this → PRES included this in the discussion at the WP2 (effort needed by MS)	

Article 13(1)			
187	1. At the latest within three years after the publication of the decision referred to in paragraph 4, the ECHA shall establish and manage, as part of the common data platform, a database containing environmental sustainability related data.		
Article 13(2)			
188	2. Where the Commission or the Agencies host or hold environmental sustainability related data in addition to the chemicals data already available in the common data platform, they shall make that data available to the ECHA without undue delay once the Commission or the Agency hosting or holding that data has completed, where relevant, validity and confidentiality assessments. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of environmental sustainability related data in the database on environmental sustainability related data.		
Article 13(3)			
189	3. Where researchers or research consortia funded by Union framework programmes make available to the ECHA, under Article 5(6), any environmental sustainability data on chemicals or materials they collect or generate, the ECHA shall integrate the relevant data in the database on environmental sustainability related data.		
Article 13(4)			
190	4. By [OP please insert date: three years after the date of entry into force of this Regulation], the Commission shall adopt an implementing decision identifying existing datasets on environmental sustainability related data, other than those referred to in paragraph 2, for inclusion in the common data platform and shall design relevant related database functionalities.	→ PRES is seeking legal advice about the wording “implementing decision” (cfr delegation comment). Council legal services provided an opinion on this at the 2 nd WP.	FR would welcome a clarification in the text that the experts of the MS will be consulted on the draft implementing decision.
Chapter III			
191	Chapter III DATA FORMATS AND CONTROLLED VOCABULARIES	→ PRES seeks written comments on one delegation’s request to eventually have study reports and raw data provided	

		→ PRES seek written comments on the request by one delegation to investigate that there is no impact on the use of INCI names for cosmetics regulation, and no impact on substance identification and product labelling in that regulation.	
Article 14			
192	Article 14 Standard formats	One delegation amendment proposal on statistical risk: → PRES: see here Article 2(6) line 77	
Article 14(1)			
193	1. Without prejudice to Union provisions providing for the development or making available of data formats, the Commission and the Agencies shall specify, where relevant, for the data referred to in Article 3 (2) and falling within their mandate, standard formats and software packages and make them available free of charge through the common data platform.		
Article 14(2)			
194	2. The standard formats referred to in paragraph 1 shall, to the extent possible:		
Article 14(2), point (a)			
195	(a) avoid the use of proprietary standards;		
Article 14(2), point (b)			
196	(b) re-use existing data formats or parts of them;		
Article 14(2), point (c)			
197	(c) use OECD or other internationally agreed formats;		
Article 14(2), point (d)			
198	(d) be coherent with other existing data formats;		
Article			

14(2), point (e)			
199	(e) ensure interoperability with existing data submission approaches.		
Article 14(3)			
200	3. Those standard formats shall be interoperable with the common data platform and be user-friendly.		
Article 14(4)			
201	4. The Commission and the Agencies shall exchange data contained in the common data platform in the relevant standard format.		
Article 14(5)			
202	5. The Commission and the Agencies shall use the International Uniform Chemical Information Database format (IUCLID) for making available to the ECHA for integration in the common data platform the relevant parts of dossiers under the following Union acts:		
Article 14(5), point (a)			
203	(a) Regulation (EC) No 1831/2003 of the European Parliament and of the Council ⁵³ ; ⁵³ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268 18.20.2003, p. 29).		
Article 14(5), point (b)			
204	(b) Regulation (EC) No 1935/2004 of the European Parliament and of the Council ⁵⁴ ; ⁵⁴ Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338 13.11.2004, p. 4).		
Article			

14(5), point (c)			
205	(c) Regulation (EC) No 1331/2008 of the European Parliament and of the Council ⁵⁵ ; ⁵⁵ Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354 31.12.2008. p. 1).		
Article 14(5), point (d)			
206	(d) Regulation (EC) No 1332/2008 of the European Parliament and of the Council ⁵⁶ ; ⁵⁶ Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354 31.12.2008, p. 7).		
Article 14(5), point (e)			
207	(e) Regulation (EC) No 1333/2008 of the European Parliament and of the Council ⁵⁷ ; ⁵⁷ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354 31.12.2008, p. 16).		
Article 14(5), point (f)			
208	(f) Regulation (EC) No 1334/2008 of the European Parliament and of the Council ⁵⁸ ; ⁵⁸ Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No		

	2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354 31.12.2008, p. 34).		
Article 14(5), point (g)			
209	(g) Regulation (EC) No 1223/2009 of the European Parliament and of the Council 59; 59 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342 22.12.2009, p. 59).		
Article 14(5), point (h)			
210	(h) Commission Regulation (EU) No 234/201160; 60 Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 064 11.3.2011, p. 15).		
Article 14(5), point (i)			
211	(i) Directive 2009/48/EC of the European Parliament and of the Council.61 61 Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170 30.6.2009, p. 1).		
Article 14(6)			
212	6. The Commission and the Agencies shall cooperate when setting standard formats to ensure coherence with other formats and the interoperability of the standard formats with the common data platform and with existing data submission approaches.		
Article 14(7)			

213	7. The Commission and the Agencies shall take the necessary and appropriate measures to monitor and identify at an early stage any potential divergence between data formats that could cause interoperability problems. If a divergence is identified, the Agencies concerned shall cooperate to resolve it or, where the divergence is justified, explain the underlying reasons. Where the Agencies concerned are not able to resolve that divergence, they shall draw up a joint report and present it to the Commission. The report shall clearly outline the reasons for the divergence, clarify any underlying technical issue and make a proposal to remedy the divergence.		
Article 14(8)			
214	8. The Commission shall adopt an implementing decision to remedy the divergence.		
Article 15			
215	Article 15 Controlled vocabularies	→ PRES is seeking written comments on the remarks by one delegation about the difficulties related to differences in vocabularies between legislations. → PRES seeks for comments on the difficulties related to substances identification inconsistencies between regulations (see delegation comment). PRES highlights that this problem is also relevant for art.22,25,26 on studies notification (a lack of correct identification might render difficult to implement them)	
Article 15(1)			
216	1. The Commission and the Agencies shall specify and regularly update controlled vocabularies within their mandate for the data referred to in Article 3(2), where relevant.		
Article 15(2)			
217	2. The Commission and the Agencies shall prioritise specifying controlled vocabularies for the identification of chemicals and the characterisation of their forms.		
Article 15(3)			

218	3. Those controlled vocabularies shall:		
Article 15(3), point (a)			
219	(a) avoid the use of proprietary controlled vocabularies to the extent possible;		
Article 15(3), point (b)			
220	(b) re-use existing substance identifiers and controlled vocabularies or parts of them to the extent possible;		
Article 15(3), point (c)			
221	(c) use OECD or other internationally agreed controlled vocabularies to the extent possible;		
Article 15(3), point (d)			
222	(d) ensure coherence with other relevant controlled vocabularies including by preparing alignment tables.		
Article 15(4)			
223	4. Those controlled vocabularies shall be interoperable with the common data platform.		
Article 15(5)			
224	5. Where controlled vocabularies are specified, the Commission and the Agencies shall:		
Article 15(5), point (a)			
225	(a) make them available free of charge through the common data platform and as open datasets;		
Article			

15(5), point (b)			
226	(b) integrate them in any submission software or template to be used by duty holders under the Union acts listed in Annex I and referred to in Article 3(2); and		
Article 15(5), point (c)			
227	(c) use them when exchanging data between them through the common data platform.		
Article 15(6)			
228	6. The Commission and the Agencies shall cooperate with each other in setting the controlled vocabularies.		
Article 15(7)			
229	7. The Commission and the Agencies shall take the necessary and appropriate measures to monitor and identify at an early stage any potential divergence between controlled vocabularies. If a divergence is identified, the Agencies concerned shall cooperate to resolve it or, where the divergence is justified, explain the underlying reasons. Where the Agencies concerned are not able to resolve that divergence, they shall draw up a joint report and present it to the Commission. The report shall clearly outline the reasons for the divergence, clarify any underlying technical issue and make a proposal to remedy the divergence.		
Article 15(8)			
230	8. The Commission shall adopt an implementing decision to remedy the divergence.		
Chapter IV			
231	Chapter IV CHEMICALS DATA CONFIDENTIALITY AND USE	→ PRES: some delegation's comments here were discussed at the WP2.	
Article 16			

232	Article 16 Access rights and transparency	→ PRES: One delegation request and questions (line 232 of the comments file) were discussed at the WP2.	
Article 16(1)			
233	1. The Authorities shall have access to all the chemicals data contained in the common data platform, including data which is deemed to be confidential under Article 5(2), second sentence.		
Article 16(2)			
234	2. The Authorities shall take the necessary measures to ensure that information contained in the common data platform marked as confidential in accordance with Article 5(2) is not made public.	→ PRES: One delegation comment and questions were discussed at the WP2 (line 234 of the comments file)	
Article 16(3)			
235	3. The general public shall have access to all the chemicals data contained in the common data platform and considered as available to the public in accordance with the Union act under which the data was generated or submitted.		
Article 17			
236	Article 17 Use of chemicals data contained in the common data platform	One delegation comment on the meaning of “products” is addressed here in art.2 (see line 70). PRES: Regarding the other comments: → PRES seeks written comments on one delegation’s concern on the identification in the data platform of cosmetics ingredients that may have been tested on animals. → PRES invites the COM to update MS on the possibility of an overview table on confidentiality provisions requested by one delegation.	
Article 17(1)			
237	1. The Authorities may use the chemicals data contained in the common data platform in the performance of any of their activities, where those activities support the development or implementation of chemicals legislation and policy.	→ PRES: one delegation requested for amendment to explicitly allow national use of the data was set for discussion at WP2.	
Article			

17(2)			
238	2. Without prejudice to existing provisions enabling the sharing and use of chemicals data under the Union acts listed in Annexes I and II, Authorities shall not use chemicals data contained in the common data platform to fulfil any legal obligations of duty holders.	One delegation requested clarifications on the use of data in relation to duty holders obligations. → PRES invites for written comments on this.	
Article 17(3)			
239	3. When using chemicals data contained in the common data platform that is deemed confidential under Article 5(2), second sentence, the Authorities shall respect the confidentiality of information data as marked by the originator and shall not disclose that data to the public without the consent of the originator.		
Chapter V			
240	Chapter V MONITORING AND OUTLOOK FRAMEWORK FOR CHEMICALS		
Article 18			
241	Article 18 Framework of indicators	One delegation questioning the MS involvement was set for discussion at the 2nd WP → PRES put the question on EIONET impacts for discussion at the 2nd WP. One delegation comments on cosmetics: → PRES invites for written comments on questions raised by one delegation on cosmetics aspects (notification of undesirable effects, link to the Communication System for Market Surveillance (ICSMS) Art 23 Reg 1223/2009, consequences on the allowance of use for critical circumstances). One delegation comment on the relation to existing statistics systems → PRES invites for written comments	
Article 18(1)			
242	1. The EEA, in collaboration with the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission, shall establish, operate, and maintain a		

	framework of indicators to monitor the drivers and impacts of exposure to chemicals, measure the effectiveness of chemicals legislation and measure the transition towards the production of safe and sustainable chemicals.		
Article 18(2)			
243	2. The framework of indicators referred to in paragraph 1 shall be accessible in the form of an indicator dashboard, which the EEA shall establish and which the ECHA shall make available through the common data platform.		
Article 18(3)			
243.b	3. The framework of indicators referred to in paragraph 1 shall be established, operated, and maintained by [OP: please insert date: 3 years after the end of the first calendar year after entry into force of this Regulation].	One delegation expressed concerns on the timescale for establishing the framework PRES highlights that several other articles contain indications on the timeframe → PRES submits this amendment for consideration, and discussion took place at the 2nd WP.	FR supports this additional provision from the Presidency but questions the implementation period of 3 years considering that the framework will be soon available (April 2024).
Article 19			
244	Article 19 Early warning and action system for emerging chemical risks	→ PRES: One delegation's question on MS experts and RAC involvement was set for discussion at 2nd WP → PRES: One delegation's request for clarification on implications/role of EIONET and MS was set for discussion at the 2nd WP Regarding the other comments: → PRES seeks written comments about one delegation's question on the relation between the indicators and the early warning system (art.18,19). → PRES invites for written comments on the question regarding the level of ambition of the system in relation to complex systemic risks. → PRES invites written comment on the proposal to include the word "prevention" in the proposal	FR considers that the level of ambition of the early warning and action system proposed is rather low. The purpose of the system is to identify emerging risks and to take the necessary action to solve the issue. The action part is only covered by a report from the EEA where the authorities "shall consider the need for regulatory or policy action". FR would

			welcome stronger provisions to respond to the emerging risks identified by the system (see row 254).
Article 19(1)			
245	1. The EEA shall establish, operate and maintain a Union early warning system for emerging chemical risks by [OP please insert date: one year after the date of entry into force of this Regulation].		
Article 19(2)			
246	2. For the purpose of paragraph 1, the EEA shall compile early warning signals, which shall include at least signals from:		
Article 19(2), point (a)			
247	(a) the EFSA's emerging risks exchange network;		
Article 19(2), point (b)			
248	(b) existing national early warning systems;		
Article 19(2), point (c)			
249	(c) data that the EEA holds;		
Article 19(2), point (d)			
250	(d) targeted literature searches performed by the EEA;		
Article 19(2), point (e)			
251	(e) data made available by the ECHA, the EFSA, the EU-OSHA and the EMA in accordance with paragraph 3.		
Article			

19(2)			
252	The early warning signals compiled by the EEA under the first subparagraph may be based on a positive identification of an emerging risk or on an uncertainty in the data leading to a potential positive identification of an emerging risk.		
Article 19(3)			
253	3. The ECHA, the EFSA, the EU-OSHA and the EMA shall identify and gather relevant available data on early warning signals from the field falling within their mandate and provide this data to the EEA.		
Article 19(4)			
254	4. The EEA shall draw up an annual report, compiling and analysing the data on early warning signals gathered in accordance with paragraphs 2 and 3. [The first report shall be prepared by [OP: please insert date: 6 months after the end of the first calendar year after entry into force of this Regulation]. The EEA shall present this report to the Commission, relevant Union agencies and ~~Member State competent authorities for consideration of the need~~ Member State competent authorities who shall consider the need for regulatory or policy action related to the early warning signals.	One delegation expressed questions the request to EEA to highlight areas on which to FOCUS, in the report. PRES suppose that this may be solved by a change in the wording (mostly editorial) → PRES proposes for consideration a proposed amendment to the text.	FR thanks the PRES for this redrafting proposal. However in consistency with its previous comment, FR would like to strengthen the provision as follows: “The EEA shall present this report to the Commission, relevant Union agencies and Member State competent authorities who shall undertake regulatory or policy actions accordingly or justify if they decide not to proceed with any action.”
Article 19(5)			
255	5. The EEA shall make all relevant data on early warning signals that it holds or hosts as well as the report referred to in paragraph 4 available to the ECHA for integration in the common data platform.		
Article 20			
256	Article 20	PRES seeks written comments on one delegation’s question about	

	Observatory for specific chemicals with potential contribution to emerging chemical risks	the type of risks covered here, and the interplay with existing chemicals legislation.	
Article 20(1)			
257	1. The ECHA shall establish, operate and maintain an observatory for specific chemicals that the Commission considers as requiring additional scrutiny. The observatory shall include reliable information on the chemicals' properties, safety aspects, uses and market presence.		
Article 20(2)			
258	2. By [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall adopt and publish a list of the selected chemicals by means of an implementing decision. The Commission shall review the list of selected chemicals regularly and adopt any revision thereof by the same means.	One delegation highlighted that the linking word "and" is missing before the proposal "adopt any revision thereof by the same means". à PRES sees this as an editorial amendment and proposes to modify article 20(2) consequently (see <i>bold italic</i>). One delegation requested for amendments (implementing "decisions"). → PRES: questions on the meaning of "implementing", and MS participation were discussed at the 2nd WP.	FR would welcome a clarification in the text that the experts of the MS will be consulted on the draft implementing decision.
Article 20(3)			
259	3. The Commission shall select the chemicals referred to in paragraph 1 based on the scientific and technical progress and using the signals of the early warning system referred to in Article 19. The selection shall include potential contributors to new and emerging chemical risks among innovative rationally designed materials with new or enhanced properties or targeted or enhanced structural features at nanoscale.		
Article 20(4)			
260	4. For the purpose of operating the observatory referred to in paragraph 1, the ECHA shall:		
Article 20(4), point (a)			

261	(a) make use of relevant datasets integrated in the common data platform, and compile, analyse and curate further available data on selected chemicals or classes of chemicals;		
Article 20(4), point (b)			
262	(b) commission studies and, where relevant, use the data generation mechanism established under Article 21 to address knowledge gaps or significant uncertainties;		
Article 20(4), point (c)			
263	(c) make compiled data publicly available through the common data platform or other communication and outreach tools as appropriate, to facilitate informed societal discussion and increase public awareness on the properties, use and safety aspects of specific chemicals, and regularly update that information.		
Chapter VI			
264	Chapter VI DATA GENERATION MECHANISM		
Article 21			
265	Article 21 Data generation mechanism	One delegation raised the question of the promotion of animal testing in relation to article 1. PRES understands that the type of tests are prescribed in each regulation mentioned in annex I, and thus this regulation is not modifying that. However, art.21 here is new, and thus the question of the minimization of animal testing might be relevant here. One delegation would like to know if commissioned animal studies will be notified → PRES requests written reactions and proposals on this matter. One delegation expressed the need to frame the mandate in such a way that the burden of proof on companies is preserved. One delegation insisted also on the burden of proof on industry and highlights the need for clarity on procedures and financing.	FR acknowledge that the question of animal testing is relevant here. A proposal could be to take inspiration from REACH article 13 and add a sentence (see row 270).

		→ PRES invites for written comments and amendments proposals. Some Comments were received in relation to the involvement of MS, industry, stakeholders in the data generation mechanism. → PRES: discussion during the 2nd WP	
Article 21(1)			
266	1. Using the best independent resources available, the ECHA may commission scientific studies to support the implementation of Union acts on chemicals listed in Annex I within its mandate and to contribute to the support, evaluation or development of a Union chemicals policy.	One delegation requested clarity on the meaning of scientific studies, and which ones will not be covered. → PRES invites for written comments on this	
Article 21(2)			
267	2. The Commission may request the ECHA to commission the scientific studies referred to in paragraph 1.		
Article 21(3)			
268	3. The ECHA shall only commission scientific studies when results cannot be obtained through existing legal provisions or processes under Union legislation listed in Annex I. It shall not commission studies with a predominant research objective.		
Article 21(4)			
269	4. The ECHA shall seek to avoid duplication with Member State or Union research or implementation programmes.		
Article 21(5)			
270	5. The ECHA shall commission these scientific studies in an open and transparent manner.	One delegation suggested to amend this to introduce compulsory prior MS consultation. → PRES scheduled this for discussion at the 2nd WP	Proposal for addition: "Moreover, in particular for human toxicity, information shall be generated whenever possible by means other than vertebrate animal tests, through the use of alternative methods, for

			example, in vitro methods or qualitative or quantitative structure-activity relationship models or from information from structurally related substances (grouping or read-across).”
Article 21(6)			
271	6. The ECHA and the EFSA shall closely cooperate with each other on the planning and commissioning of scientific studies undertaken by the ECHA in accordance with paragraph 1 and of studies undertaken by the EFSA in accordance with Article 32 of Regulation (EC) No 178/2002.		
Article 21(7)			
272	7. The ECHA shall make the results of the scientific studies performed under this Article available through the common data platform.		
Chapter VII			
273	Chapter VII NOTIFICATION OF STUDIES	Several comments were received on this chapter: on the legal scope and definition of studies to be notified, duplications, studies conducted outside the EU, late notifications, absence of a transitional period, practical arrangements for companies, the need for early access before publication in the data platform. → PRES scheduled this for discussion at the 2 nd WP	
Article 22			
274	Article 22 Notification of studies		
Article 22(1)			
275	1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, without undue delay, any studies on chemicals they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on		

	chemicals on their own or in products they commission as part of a risk or safety assessment , prior to placing on the market, under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.		
Article 22(2)			
276	2. For the purposes of paragraph 1, business operators shall notify to the Database of Study Notifications referred to in Article 9 the title, scope, laboratory, or testing facility carrying out the study, the intended starting and planned completion dates and, where relevant, whether the study is commissioned to comply with a decision of the ECHA pursuant to Articles 40, 41 or 46 of Regulation (EC) No 1907/2006.		
Article 22(3)			
277	3. Laboratories and testing facilities shall also, without undue delay, notify any study commissioned by business operators to support a regulatory dossier on which an Agency is required to provide a scientific output, including a scientific opinion, under the Union acts listed in Annex I. However, laboratories and testing facilities shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.		
Article 22(4)			
278	4. For the purposes of paragraph 3, laboratories and testing facilities shall notify to the Database of Study Notifications referred to in Article 9 the title, scope, intended starting and planned completion dates of any test they carry out, as well as the name of the business operator who commissioned the test.		
Article 22(5)			
279	5. Paragraphs 3 and 4 shall apply, mutatis mutandis, to laboratories and testing facilities located in third countries insofar as set out in relevant agreements with those third countries.		
Article			

22(6)			
280	6. The obligations set under this article shall apply from [OP please insert date: 24 months after the date of entry into force of this Regulation].		
Article 22(7)			
281	7. The ECHA shall lay down the practical arrangements for implementing the provisions of this Article.		
Chapter VIII			
282	Chapter VIII DELEGATED POWERS		
Article 23			
283	Article 23 Amendment of Annexes I, II and III		
Article 23(1)			
284	1. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex I in order to adjust the content of that Annex to technical and scientific progress in the field of chemicals or, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it new Union acts under which relevant chemicals data is generated or submitted.		
Article 23(2)			
285	2. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex II by adding, where relevant, new categories of data types.		
Article 23(3)			
286	3. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex III in order to adjust the content of that Annex to technical and scientific and technical progress in the field of chemicals and, where the development of Union chemicals legislation so requires, to supplement that Annex by adding		

	to it Union acts relevant for data on new regulatory processes on chemicals.		
Article 24			
287	Article 24 Exercise of the delegation		
Article 24 (1)			
288	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.		
Article 24(2)			
289	2. The power to adopt delegated acts referred to in Article 23 shall be conferred on the Commission for a period of five years from [OP please insert: the date of the entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each five-year period.		
Article 24(3)			
290	3. The delegation of power referred to in Article 23 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.		
Article 24(4)			
291	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.		
Article			

24(5)			
292	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.		
Article 24(6)			
293	6. A delegated act adopted pursuant to Article 23 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.		
Chapter IX			
294	Chapter IX ENFORCEMENT AND PENALTIES	One delegation expressed concerns on enforcement for third countries; one delegation questioned the effectiveness of national sanctions. → PRES scheduled this for discussion at the 2 nd WP	
Article 25			
295	Article 25 Enforcement The Agencies shall cooperate with Member States' enforcement authorities and exchange information on the compliance, by business operators and laboratories, with the obligation to notify studies in accordance with Article 22.		
Article 26			
296	Article 26 Penalties for non-compliance		
Article 26(1)			
297	1. Member States shall introduce penalties for non-compliance, by business operators and laboratories, with the obligations laid out in		

	Article 22 and shall take all necessary measures to ensure that they are implemented. The penalties provided for shall be effective, proportionate, and dissuasive.		
Article 26(2)			
298	2. Member States shall notify the Commission of those rules and of those measures by 30 June 2025 and shall notify to the Commission without delay any subsequent amendment affecting them.		
Article 27			
299	Article 27 Entry into force and application in time This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.		
Formula			
300	This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels, For the European Parliament For the Council The President The President		

	Presidency proposals: amendments (~~deletions~~ / additions)	Presidency proposals: follow-up or proposal to work on amendments, or requests for written comments	Reactions from the Commission and MS
Annex I			
301	Annex I UNION ACTS REFERRED TO IN ARTICLES 2, 3, 8, 11, 12, 15, 17, 21, 22 AND 23 Reference to each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.		
302	1. Council Directive 91/271/EEC of 21 May 1991 concerning urban wastewater treatment (OJ L 135, 30.5.1991, p. 40)		
303	2. Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources (OJ L 375, 31.12.1991, p.1)		
304	3. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1)		
305	4. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste		
306	5. Council Directive 98/24/EC of 7 April 1998 on the		

	protection of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11)		
307	6. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50)		
308	7. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34)		
309	8. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for the Community action in the field of water policy (OJ L 327, 22.12.2000, p.1)		
310	9. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1)		
311	10. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p. 1)		

312	11. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10)		
313	12. Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51)		
314	13. Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1)		
315	14. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29)		
316	15. Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (OJ L 309, 26.11.2003, p. 1)		
317	16. Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55)		
318	17. Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1)		
319	18. Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1)		

320	19. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)		
321	20. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3)		
322	21. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 070, 16.3.2005, p. 1)		
323	22. Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC (OJ L 033, 4.2.2006, p. 1)		
324	23. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19)		
325	24. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation		

	and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)		
326	25. Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9)		
327	26. Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26)		
328	27. Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE) (OJ L 108, 25.4.2007, p. 1)		
329	~~28. Regulation (EC) No 108/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 39, 13.2.2008, p. 11)~~	One delegation highlighted the fact that regulation 108/2008 is mentioned in point 28 of Annex I, whereas this regulation is already covered by regulation 1925/2006 mentioned in point 26 of Annex I. → PRES proposes to amend the text (deleting point 28).	

330	29. Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19)		
331	30. Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1)		
332	31. Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3)		
333	32. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84)		
334	33. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)		
335	34. Regulation (EC) No 1331/2008 of the European		

	Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)		
336	35. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC, and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p.7)		
337	36. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16)		
338	37. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34)		
339	38. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energyrelated products		
340	39. Regulation (EC) No 401/2009 of the European Parliament and of the Council of 23 April 2009 on the European Environment Agency and the European Environment Information and Observation Network		

	(OJ L 126, 21.5.2009, p. 13)		
341	40. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3)		
342	41. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1)		
343	42. Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (OJ L 300, 14.11.2009, p. 1)		
344	43. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)		
345	44. Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71)		
346	45. Directive 2009/148/EC of the European Parliament		

	and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28)		
347	46. Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community ecomanagement and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC (OJ L 342, 22.12.2009, p. 1)		
348	47. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)		
349	48. Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17)		
350	49. Regulation (EC) No 66/210 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel (OJ L 027, 30.1.2010, p. 1)		
351	50. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)		
352	51. Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers,		

	amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18)		
353	52. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)		
354	53. Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.7.2012, p. 1)		
355	54. Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38)		
356	55. Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the import and export of hazardous chemicals (OJ L 201, 27.7.2012, p. 60)		
357	56. Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for		

	special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35)		
358	57. Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (OJ L 96, 29.3.2014, p. 1)		
359	58. Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1)		
360	59. Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006 (OJ L 150, 20.5.2014, p. 195)		
361	60. Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of		

	the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1)		
362	61. Directive (EU) 2016/2284 of the European Parliament and of the Council of 14 December 2016 on the reduction of national emissions of certain atmospheric pollutants, amending Directive 2003/35/EC and repealing Directive 2001/81/EC (OJ L 344, 17.12.2016, p. 1)		
363	62. Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 095, 7.4.2017, p. 1)		
364	63. Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices,		

	amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1)		
365	64. Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008 (OJ L 137, 24.5.2017, p. 1)		
366	65. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).		
367	66. Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (OJ L 170, 25.6.2019, p. 1)		
368	67. Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45)		
369	68. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human		

	consumption (OJ L 435, 23.12.2020, p. 1)		
370	69. Regulation (EU) .../... of the European Parliament and of the Council on nature restoration (OJ .../ELI: ... [OP: please add number and publication reference].		
371	70. Regulation (EU) .../... of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (OJ .../ELI: ... [OP: please add number and publication reference]		
ANNEX II			
372	ANNEX II UNION ACTS REFERRED TO IN ARTICLES 2, 3, 12, 17 AND 23 AND REFERENCE VALUES REFERRED TO IN ARTICLE 8		
Part 1			
373	Part 1 - Specific data on relevant active substances to be identified in accordance with Article 4(5)(b) falling under the scope of this Regulation for the purposes of Article 3 for human and veterinary medicinal products		
374	1. Non-clinical safety data, including data related to environmental risk assessments, compiled pursuant to Directive 2001/83/EC of the European Parliament and of the Council ¹ and Regulation (EC) No 726/2004 of the European Parliament and of the Council ² ;		



	¹ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67). ² Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).		
375	2. Data related to environmental risk assessments, compiled pursuant to Regulation (EU) 2019/6 of the European Parliament and of the Council³; and ³ Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).		
376	3. Maximum residue levels data compiled pursuant to Regulation (EC) No 470/2009 of the European Parliament and of the Council⁴. ⁴ Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the		

	European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).		
377	These data shall be limited to data submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation. Where relevant, the data held by the EMA resulting from procedures concluded before the entry into force of this Regulation may also be considered for inclusion into the common data platform.		
Part 2			
378	Part 2 - Reference values to be included in the repository of reference values following Article 8(3)		
379	1. Predicted no effect concentrations derived as part of the environmental risk assessment under Directive 2001/83/EC of the European Parliament and of the Council, Regulation (EC) No 726/2004 of the European Parliament and of the Council and Regulation (EU) 2019/6 of the European Parliament and of the Council.		
380	These data shall be limited to data submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this		

	Regulation. Where relevant, data held by the EMA resulting from procedures concluded before the date of entry into force of this Regulation shall also be considered for inclusion into the common data platform.		
Annex III			
381	Annex III UNION ACTS REFERRED TO IN ARTICLES 2, 10 AND 23		
382	Reference to each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.		
383	1. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1)		
384	2. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste		
385	3. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50)		
386	4. Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work (fourteenth individual		

	Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11)		
387	5. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34)		
388	6. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p. 1)		
389	7. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10)		
390	8. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29)		
391	9. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)		
392	10. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3)		

393	11. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1)		
394	12. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19)		
395	13. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)		
396	14. Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38)		
397	15. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive		

	2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84)		
398	16. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)		
399	17. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)		
380	18. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC, and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p.7)		
381	19. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16)		
382	20. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91,		

	Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34)		
383	~~21. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)~~	Some delegations highlighted the fact that Regulation 1331/2008 is mentioned twice: in points 17 and 21 of Annex III. → PRES proposes to amend the text (deleting this repetition).	
384	22. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3)		
385	23. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energyrelated products		
386	24. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1)		
387	25. Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer (OJ L 286, 31.10.2009, p. 1)		
388	26. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on		

	the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)		
389	27. Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28)		
390	28. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)		
391	29. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)		
392	30. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)		
393	31. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).		
394	32. Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on		

	persistent organic pollutants (OJ L 169, 25.6.2019, p. 45)		
395	33. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435, 23.12.2020, p. 1)		
396	34. Regulation (EU) .../... of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (OJ .../ELI: ... [OP: please add number and publication reference].		

PUBLIC

ITALY

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

establishing a common **data platform** on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

(Text with EEA relevance)



	Presidency proposals: amendments (~~deletions~~ / additions)	Presidency justification after WP1: follow-up or proposal to work on amendments, or requests for written comments	Delegates comments/proposals after WP2
Proposal Title			
1	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals)		
Formula			
2	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN		
Citation 1			
3	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114(1) thereof,		
Citation 2			
4	Having regard to the proposal from the European Commission,		
Citation 3			
5	After transmission of the draft legislative act to the national parliaments,		
Citation 4			
6	Having regard to the opinion of the European Economic and Social Committee ¹		
Citation 5			
7	Acting in accordance with the ordinary legislative procedure,		
Formula			
8	Whereas:		
Recital 1			
9	(1) The European Green Deal ³⁴ sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability ³⁵ is a crucial delivery of this zero-		

	pollution ambition and introduces the ‘one substance, one assessment’ approach, which aims to improve the efficiency, effectiveness, coherence, and transparency of safety assessments of chemicals across Union legislation. According to that Strategy, ‘safe and sustainable by design’ criteria should be developed to enable the production and use of chemicals that are safe and sustainable throughout their entire lifecycle. The Strategy also sets out that the interaction between scientific developments and policy-making should be strengthened by means of an early warning system for chemicals to ensure that Union policies address emerging chemical risks as soon as these are identified by monitoring and research, and that a framework of indicators should be developed to monitor the drivers and impacts of chemical pollution and to measure the effectiveness of chemicals legislation. This Regulation aims to implement these objectives.		
Recital 2			
10	(2) The main objective of this Regulation is to increase the level of protection of the environment and human health from the risks arising from hazardous chemicals, as well as to facilitate the functioning of the internal market for chemicals. For that purpose, this Regulation should establish a common data platform data on chemicals (‘the common data platform’), to be managed by the European Chemicals Agency (‘ECHA’). The common data platform is a digital infrastructure that brings together chemicals data and information generated under the Union chemicals acquis. This Regulation should also establish dedicated services within the common data platform and lay down rules on the accessibility and usability of the data contained in that platform. This Regulation aims to create a common knowledge base on chemicals available to authorities to enable better, complete, coherent and robust scientific assessments of chemicals and their impacts and to ensure the best use of existing information for the purpose of the implementation and the development of Union legislation on chemicals. Moreover, the Regulation aims to provide a one-stop-shop on chemicals data and information in the Union accessible to the general public and, thus, to increase the predictability and the transparency of regulatory processes on chemicals, as well as to strengthen public trust in the robustness of scientific decision-making.		

Recital 3			
11	(3) Under Decision (EU) 2022/591 of the European Parliament and of the Council ³⁶ , harnessing the potential of digital and data technologies to support environmental policy, including by delivering real-time data where possible and information on the state of ecosystems, while increasing efforts to minimise the environmental footprint of these technologies and ensuring transparency, authenticity, interoperability and public accessibility of the data and information is a long-term priority objective. Data and information on chemicals are therefore essential for the proper development and implementation of a Union environmental policy, and specifically of a chemicals policy.		
Recital 4			
12	(4) In its communication of 19 February 2020 on a European strategy for data ³⁷ , the Commission described its vision of a common European data space and highlighted the need for the development of sectoral data spaces in strategic areas, since not all sectors of the economy and society are moving at the same speed. This Regulation aims therefore to build a data space for chemicals by establishing a common data platform on chemicals ('common data platform'), which is also part of the Green Deal data space, as referred to in the European strategy for data. Furthermore, in that strategy, the Commission highlighted several issues concerning the availability of data for the public good, including data availability, data infrastructures and governance, interoperability, as well as the lack of adequate sharing of data between public authorities. This Regulation aims to increase data availability on chemicals by requiring the relevant Union agencies to make data available for integration in the common data platform on chemicals, to promote interoperability of that data by providing for the establishment of standard formats and controlled vocabularies, as well as to facilitate data exchange and use by public authorities to enable them to effectively carry out their regulatory and policy developing tasks.		
Recital 5			
13	(5) This Regulation also aims to implement into the chemicals sector the principles laid out in the proposal for an Interoperable Europe Act ³⁸ by strengthening the cross-border interoperability of network		

	and information systems used to provide or manage public services on chemicals in the Union. This Regulation will contribute to increased cross-border data flows for truly European digital services and broaden the access to publicly available chemicals data for utilisation in other sectors' applications.		
Recital 6			
14	(6) Business operators and Members States' competent authorities are required by various Union acts to submit data and information to a multitude of Union agencies, as well as to the Commission in specific cases. This generates a fragmentation of data and information on chemicals, which are held under various data sharing and use conditions and in different formats. Such fragmentation prevents public authorities, as well as the general public, from having a clear overview of what information is available on individual chemicals or groups of chemicals, of where and how information can be accessed and whether it can be used. This increases the likelihood of inconsistency between various assessments of the same chemical required by various Union acts on chemicals and of damaging the general public's trust in the scientific grounds for Union decisions on chemicals. In order to ensure that data on chemicals is easily findable, accessible, interoperable and usable, the ECHA should establish a common data platform on chemicals. The common data platform on chemicals should serve as a single point of reference and as a broadened and shared evidence base to enable the efficient delivery of coherent hazard and risk assessments of chemicals across various Union acts on chemicals, as well as to enable the timely identification of emerging chemical risks and the drivers and impact of chemical pollution.		
Recital 7			
15	The common data platform should contain chemicals-related data and information held by relevant Union agencies or the Commission generated or submitted as part of the implementation of Union chemicals legislation listed in Annex I. This includes, for instance, all regulatory dossiers or applications submitted to the relevant Union agencies, but also chemicals data on occurrence of chemicals submitted by Member States to Union agencies or the Commission in compliance with their reporting obligations. The common data		

	platform should also include chemicals data and information generated as part of Union, national or international programmes or research activities related to chemicals, where this data and information is held by the Commission or one of the relevant agencies.		
Recital 8			
16	Due to the different nature of the risk and hazard assessments performed under Union acts on medicinal products, when compared to those performed under the main Union acts on chemicals, for medicinal products, only chemicals data related to environmental risk assessments for human and veterinary medicines, non-clinical studies for human medicines and maximum residue limit values the European Medicines Agency ('EMA') holds, as well as specific reference values, should be included in the common data platform. For medicinal active substances, only data on relevant substances should be included. These concern active substances covered by the medicines legislation and also used for other applications regulated by other Union legislation identified in this Regulation, as well as other active substances with particular persistent, bio-accumulative and toxic properties or with a known high level of residues in the environment.	Some delegations expressed the need for a clarification of the scope and meaning of "relevant substances" for active substances → PRES: this is scheduled for discussion at the 2 nd WP	In our view it is important to clarify the meaning of "relevant substances" also taking into account that other substances used in the manufacture of medicines to define their pharmaceutical form have an environmental impact but which cannot be defined as active because they do not have pharmacological activity in humans. It could be useful to consider also a data sharing with the active substance monographs which would also provides for an update of the environmental risk.
Recital 9			
17	(9) These data should also be limited to data submitted to the EMA in the context of the relevant procedures that are finalised or submitted after the entry into force of this Regulation. At a later stage, it should also be possible to include in the common data platform, where relevant, data the EMA holds on procedures concluded before the entry into force of this Regulation.		
Recital 10			
18	(10) Due to the sensitivity of the information on the exact chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health or physical effects, submitted to the bodies appointed by the Member States under Article 45 of Regulation (EC) No 1272/2008 of the European Parliament and the Council ³⁹ , that information should not be included in the common data platform. Likewise, due to the commercial sensitiveness of data and information on final cosmetic products, the information related to		

	cosmetic products notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/200940 of the European Parliament and of the Council should not be included in the common data platform either. However, chemicals data and information on individual chemical ingredients of cosmetic products should be included in the common data platform.		
Recital 11			
19	(11) To safeguard the ability of the European Commission, of the Union agencies working on chemicals and of the competent Member State authorities (hereinafter ‘the Authorities’), to carry out their tasks, documents with chemicals data relating to their internal work or decision-making should in principle not be included in the common data platform.		
Recital 12			
20	(12) In order to respond to the needs of the digital economy and to ensure a high level of protection of the environment and human health, it is necessary to lay down a harmonised framework specifying who is entitled to access and use the chemicals data contained in the common data platform, under which conditions, on what basis, and for which purposes. The Authorities that are entrusted with regulatory tasks related to chemicals should be allowed and encouraged to use the chemicals data and information contained in the common data platform to effectively fulfil their regulatory duties and tasks, in order to improve the effectiveness, efficiency, and coherence of chemicals-related assessments as well as the development of Union chemicals policies.		
Recital 13			
21	(13) Chemicals data and information generated as a result of obligations set by Union acts on chemicals may be protected by confidentiality claims on confidential business information. The public dissemination of such data may affect the commercial interest of private parties. To ensure legal certainty for duty holders and to protect their legitimate expectations, as well as to ensure industry’s		

	competitiveness on the internal market, the ECHA, as a manager of the common data platform, should grant differentiated access rights to the data and information contained in the common data platform. To this end, the Authorities should have full access to all chemicals data and information contained in the common data platform, including access to confidential information, while business operators and the general public should have restricted access to that data and information, which does not include access to confidential information.		
Recital 14			
22	(14) When using data contained in the common data platform, the Authorities should respect the originator principle. Under this principle, the confidentiality marking of chemicals data as done by the originator and as correspondingly indicated by the Agency when it provides that data to the common data platform should be respected by the Authorities using that data or information to perform their regulatory functions or fulfil their tasks.		
Recital 15			
23	(15) To ensure the protection of legitimate expectations of duty holders when generating or submitting data or information under the Union acts listed in Annex I, as well as to protect the confidentiality of that information when used by the Authorities, exceptional grounds for disclosing confidential information laid down in the Union acts listed in Annex I should apply only to the disclosure of the data and information submitted or generated in compliance with those acts. For example, under Article 39(4) of Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁴¹ , where urgent action is essential to protect human health, animal health or the environment, such as in emergency situations, the European Food Safety Authority ('EFSA') may disclose information previously considered confidential under that Regulation and the EFSA is required to make public information, previously considered confidential, that forms part of conclusions of scientific outputs of the EFSA and relates to foreseeable effects on human health, animal health or the environment. Likewise, Article 118 of Regulation (EC) No 1907/2006 of the European Parliament and of		

	the Council ⁴² provides for the possibility for the ECHA to disclose confidential information submitted to it under that Regulation if urgent action is essential to protect human health, safety or the environment, such as in emergency situations.		
Recital 16			
24	(16) Taking into account that the Agencies would be required to store scientific data, which includes confidential and personal data, it is necessary to ensure that such storage is carried out in accordance with a high level of security of information systems and that access to confidential data is auditable.		
Recital 17			
25	(17) While the ECHA should identify and develop the technical functionalities of the common data platform in stages, certain dedicated services should be defined by this Regulation. As such, the common data platform should, in addition to providing access to chemicals-related data made available by the Agencies and the Commission, provide access to the chemicals data and information made available through its dedicated services. These dedicated services should be integrated into the common data platform and consist of the existing Information Platform for Chemical Monitoring ('IPCHEM'), a repository of reference values, a database of study notifications, a database with information on regulatory processes, a database with information on applicable legal obligations, a repository of standard formats and controlled vocabularies, a database on environmental sustainability related data, as well as a dashboard of indicators on chemicals.		
Recital 18			
26	(18) The Commission should adopt an implementation plan identifying initial datasets to be made accessible via the platform and the timeline for their integration, informed by the preparatory work of the Commission and the Agencies ⁴³ . The Commission should set up a governance scheme to support and steer the common data platform's operation and evolution covering the organisation of work structures		

	and coordination between ECHA and data providers, required rules, formats and vocabularies for data integration, and maintain a rolling implementation plan to ensure the progress in identification and integration of new datasets and services for inclusion. The governance scheme should be adopted and updated as necessary by the Commission, after consultation with a newly established platform steering committee composed of representatives from Union agencies and the Commission. In order to ensure uniform conditions for the implementation of the obligations to establish an implementation plan and a governance scheme, implementing powers should be conferred on the Commission.		
Recital 19			
27	(19) The common data platform should serve the widest possible community, with the ability to address new use cases, incorporate new relevant datasets, develop new functionalities, and respond to developing tools and applications.		
Recital 20			
28	(20) In order to bring together all relevant chemicals data and information in the common data platform, the Commission and Union agencies – notably the European Agency for Safety and Health at Work ('EU-OSHA'), the ECHA, the European Environment Agency ('EEA'), the EFSA, and the EMA ('the Agencies'), should act as data providers and make available any such relevant data they have or hold to the ECHA for integration in the common data platform. The Agencies, including the ECHA itself when making its own data available, should provide the necessary standard metadata, contextual information and relevant mapping to the platform's structure, and respect rules on standard formats and controlled vocabularies where available.		
Recital 21			
29	(21) To ensure that an adequate knowledge base on chemicals is available through the common data platform, the Commission should be able to request the Agencies to host, maintain and make available, via the common data platform, data generated as part of Union,		

	national or international programmes or research activities beyond the data already flowing to the Agencies as part of the obligations under the Union acts listed in Annex I. The Commission should make such requests to the Agencies in accordance with their mandates and allocated tasks.		
Recital 22			
30	(22) Some types of data are currently not within the mandate of any of the Agencies. In order to ensure clarity of responsibilities of the Agencies and efficient management of chemicals data, the Agencies should be required to host, maintain and provide specific data types to the common data platform. To this end, the ECHA should host and be a data provider to the common data platform for workplace monitoring data, and the EEA should host and be a data provider to the common data platform for data on indoor air quality and environment monitoring data, as well as data on concentrations of chemicals in human matrices such as blood or urine ('human biomonitoring data').		
Recital 23			
31	(23) To improve the uptake of academic data and to expand the knowledge base for chemicals safety assessments and environmental sustainability impacts of chemicals, researchers or research consortia funded by Union framework programmes should make available, in line with the 'as open as possible, as closed as necessary' principle, any human biomonitoring data they collect or generate resulting from research and development programmes to the EEA and any environmental sustainability data on chemicals or materials they collect or generate to the ECHA.		
Recital 24			
32	(24) The EEA, as the agency responsible for monitoring data and information on chemicals in the environment, should also be responsible for collecting, hosting, and maintaining human biomonitoring data. To the extent that human biomonitoring data constitutes a special category of personal data, namely, health data, the EEA should process that data only where the processing is		

	necessary for reasons of substantial public interest, as required by Article 10(2)(g) of the Regulation (EU) No 2018/1725 of the European Parliament and of the Council ⁴⁴ . This Regulation lays down the cases where there is such substantial public interest in processing human biomonitoring data: namely, where the EEA processes that data to assess the impact of chemicals on human health and the environment, to monitor time and spatial trends in exposure, to develop health risk and impact indicators, to monitor the impact of regulatory intervention, and to support regulatory risk assessments.		
Recital 25			
33	(25) In order to ensure that appropriate safeguards are in place to secure the protection of this sensitive type of personal data, the EEA should only provide anonymised human biomonitoring data to the ECHA for integration in IPCHEM and the common data platform. IPCHEM, currently operated by the Commission, gathers occurrence data on chemicals in different media, including water, soil, indoor and outdoor air, biota, food and feed, humans, and products. In order to take advantage of the integration of various information systems and to ensure that occurrence data on chemicals is made available for use together with the other chemicals data, the ECHA should take over from the Commission the operation of IPCHEM and integrate it in the common data platform as one of its main dedicated services.		
Recital 26			
34	(26) In order to prevent disruption to the existing operation and functioning of the IPCHEM, the ECHA should integrate the IPCHEM in the common data platform together with the data present in IPCHEM at the moment of integration. At the same time, in order to enable optimal hosting and management of occurrence data on chemicals, the Commission should also transfer the data present in IPCHEM to the ECHA, the EEA or the EFSA for hosting and future updating in accordance with their respective mandates. In order to ensure that the ECHA takes over from the Commission the operation of the IPCHEM, integrates it into the common data platform and takes over the initial data sets and sets up adequate data flows, it is necessary to allow the		

	ECHA an appropriate period of time to carry out these actions, of up to 3 years from the date of entry into force of this Regulation.		
Recital 27			
35	In order to promote the use and harmonisation of reference values among risk assessors and risk managers across different Union acts and to facilitate compliance with, and enforcement of, regulatory reference values, the ECHA should establish and maintain a repository of reference values established or adopted under the Union acts listed in Annexes I and II The Agencies should provide the ECHA with reference values they hold or establish as part of their activities. In addition, the ECHA should regularly screen Union acts for reference values adopted under them. To facilitate automatic access of the general public to up-to-date reference values, the ECHA should integrate the repository of reference values in the common data platform as a dedicated service, include in that repository all reference values together with the relevant context data it has received or retrieved and ensure that those values and that context data are machine readable.		
Recital 28			
36	(28) In order to increase transparency, as well as to enable Authorities to have complete prior knowledge of studies commissioned by business operators, irrespective of whether such studies are carried out by the business operator itself or are outsourced, business operators and laboratories should notify to a database of study notifications established and managed by the ECHA the studies on chemicals they commission for compliance with regulatory requirements under the Union acts listed in Annex I. For this purpose, the ECHA should establish and manage a database of study notifications, as a dedicated service of the common data platform, to store the information related to those studies. In order to allow business operators and laboratories sufficient time to prepare the notifications of studies, the obligation to notify studies should only start to apply two years after the date of entry into force of this Regulation.		
Recital 29			

37	(29) Under Regulation (EC) No 178/2002 of the European Parliament and of the Council, business operators and laboratories are obliged to notify to the database of study notifications established and managed by the EFSA the studies they commission to support an application or notification in relation to which Union law contains provisions for the EFSA to provide a scientific output. To avoid overburdening business operators and laboratories, they should therefore not be required to also notify those studies to the database of study notifications established and managed by the ECHA under this Regulation.		
Recital 30			
38	(30) To ensure the coherence between those two study notification mechanisms, as well as to ensure certainty for business operators submitting notifications, the rules on the public dissemination of study notifications should, where relevant, correspond in that the notifications should only be made available through the common data platform EN 27 EN once a corresponding registration, application, notification or other relevant regulatory dossier was submitted to the relevant Union or national institution and a decision on the confidentiality of the data contained in that regulatory dossier was taken by that Union or national institution. In addition, in order to facilitate compliance with the requirement to notify a study, the ECHA and the EFSA should cooperate to ensure a common approach for the identification of notified information in order to facilitate the traceability of studies notified to their respective databases.		
Recital 31			
39	(31) While the study notification obligation established in this Regulation should apply in the context of all the Union acts on chemicals listed in Annex I, the various relevant data collection and safety assessment processes under those acts may vary widely procedurally. The overarching aim of the database of study notifications established under this Regulation should be to bring together information on studies on chemicals being commissioned by business operators, such as to enable a centralised and complete		

	overview of the studies being performed to support regulatory compliance under Union acts on chemicals as listed in Annex I. On the basis of this objective and considering the fact that assessment procedures under Union acts on chemicals in Annex I may vary widely, it would be beyond the scope and aim of this Regulation to amend existing assessment processes set under those Union acts listed in Annex I by imposing additional conditions leading to potential market access consequences not foreseen in those Union acts. Consequently, it is not appropriate to introduce in this Regulation the consequences associated non-compliance with the study notification obligation as laid out in Article 32b of Regulation (EC) No 178/2002 of the European Parliament and of the Council.		
Recital 32			
40	(32) Nevertheless, to ensure compliance with the study notification obligation laid down in this Regulation, and to cater to the specificities of individual assessment processes, where existing, Member States should lay down rules on penalties applicable to the infringement of that obligation and take all necessary measures to ensure that those rules are complied with. Those penalties should be effective, proportionate, and dissuasive, since non-compliance with this Regulation could result in less robust chemicals risk assessments, creating potential risks and consequently adverse effects on human health and the environment.		
Recital 33			
41	(33) In order to facilitate enforcement by Member States, the Agencies responsible for assessing and providing scientific output, including scientific opinions, on regulatory dossiers containing studies subject to notification to ECHA should, where relevant, cooperate and exchange information with the Member State enforcement authorities on the compliance with the obligations laid out in Article 22.		
Recital 34			
42	(34) While Regulation (EC) No 178/2002 of the European Parliament and of the Council also requires the consultation of stakeholders and		

	the public following the notification to the EFSA of studies commissioned for the purposes of the renewal of an authorisation or approval, a similar requirement under this Regulation would lay a disproportionate administrative burden on the ECHA, given the wide scope of the studies that is to be notified under this Regulation.		
Recital 35			
43	(35) A mechanism related to study notifications exists in Regulation (EC) No 1907/2006 of the European Parliament and of the Council. Where registrants are required to perform studies to generate data in accordance with requirements in Annexes IX and X to that Regulation, they must first submit a testing proposal to the ECHA in order to receive a decision requiring them to perform a study. Such decision may also be issued as an outcome of compliance check or substance evaluation under that Regulation. In order to facilitate the transparency, traceability, and effective monitoring of studies commissioned or carried out pursuant to a decision of the ECHA in accordance with Articles 40, 41 or 46 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council, business operators should specify in their notifications of studies under this Regulation that those studies are being commissioned or carried out in compliance with those decisions.		
Recital 36			
44	(36) To strengthen the coordination and cooperation between the different bodies performing chemicals assessments in the Union, and to promote an increased transparency of chemicals assessments, the ECHA should establish and manage a database with information on regulatory processes or activities that are planned, ongoing or completed by Member States, the Commission and Agencies referred to in the Union acts listed in Annex III to this Regulation and integrate it into the common data platform for access by the authorities. The information on such regulatory processes or activities should include at least the substance identity and the identification, status and eventually the outcome of the regulatory process or activity. That information should also be made available without undue delay and		

	kept updated through the assessment process. Once the process or activity has formally started, that information should be shared also publicly on the common data platform.		
Recital 37			
45	(37) The existing 'The EU Chemicals Legislation Finder' ⁴⁵ project managed by the ECHA makes it easier to find and identify legal obligations related to the use of a specific chemical. The project is especially helpful for small and medium sized enterprises in identifying their legal obligations. To reinforce the supportive function of the project for business operators, it should be established on a permanent basis and more Union acts should be included in its scope. For this purpose, the ECHA should collect information on the legal obligations deriving from the Union acts on chemicals listed in Annex I to this Regulation and incorporate that information into the common data platform as a dedicated service.		
Recital 38			
46	(38) In order to ensure the interoperability and comparability of chemicals data and to facilitate their automatic and electronic exchange, the Agencies and the Commission should store chemicals data in adequate and mutually coherent and interoperable formats and use mutually coherent and interoperable controlled vocabularies. Some Union acts listed in Annex I or II set procedures to establish or make available data formats, in particular for the submission of chemicals data by business operators or Member States. Where such procedures do not exist in the Union acts listed in Annex I or II, the Agencies and the Commission should, where relevant, specify appropriate formats for chemicals data they receive and store, avoiding the use of proprietary standards while, as appropriate, using OECD or other internationally agreed formats, making use of existing formats and ensuring interoperability with existing data submission approaches.		
Recital 39			
47	(39) Likewise, the Agencies and the Commission should specify		

	appropriate controlled vocabularies for data they receive and store and, where relevant, integrate them in submission software or formats. Moreover, in order to facilitate a smooth electronic exchange of data through the common data platform, the Agencies and the Commission should agree on the required formats and controlled vocabularies for providing data to the common data platform. Whenever the Agencies or the Commission set formats or controlled vocabularies, they should cooperate with each other to ensure their coherence, consistency and interoperability. In order to ensure uniform conditions for resolving divergences in data formats and controlled vocabularies, implementing powers should be conferred on the Commission.		
Recital 40			
48	(40) In order to promote the interoperability of database systems on chemicals beyond the common data platform, the ECHA should establish a repository of standard formats and controlled vocabularies as part of the common data platform. The Agencies and the Commission should make the formats and controlled vocabularies they set available to the repository and the ECHA should make them available free of charge in electronic formats for use by developers of database systems and the general public.		
Recital 41			
49	(41) The International Uniform Chemical Information Database ('IUCLID') is a software application designed to record, store, maintain and exchange data on chemicals. The ECHA develops and maintains the IUCLID software and the underlying format in collaboration with the Organisation for Economic Cooperation and Development ('OECD'). The IUCLID implements all OECD-harmonised templates, which are harmonised formats agreed at the OECD level to facilitate structured and consistent documentation of test outputs and similar chemicals data. Since chemicals data is being submitted to the ECHA in IUCLID under Union acts such as Regulations (EC) No 1907/2006, (EC) No 1107/200946 and (EU) No 528/201247 of the European Parliament and of the Council, the ECHA is closely involved in the continued development of IUCLID, and IUCLID implements the standard formats		

	agreed at the OECD level, it is appropriate and necessary to require the Commission and the Agencies to use IUCLID for the relevant parts of dossiers under specified Union acts listed in Annex I when they make the data contained in those dossiers available to the ECHA .		
Recital 42			
50	(42) To increase the availability and facilitate the use of information on the environmental performance of chemicals throughout their lifecycle, and to enable a comprehensive assessment of the impacts of chemicals on the environment, the Commission should identify relevant data and information related to the environmental sustainability of chemicals, including, where available, information on their impact on climate change, for integration into the common data platform. Once the Commission has identified the relevant existing datasets on environmental sustainability related data and has designed the relevant related database functionalities, the ECHA should establish a database on environmental sustainability-related data, collect the data as made available by the Commission, the Agencies and, where relevant, by the researchers and research consortia funded by Union framework programmes, and integrate the content of that database into the common data platform as a dedicated service. In order to ensure uniform conditions for the implementation of the obligation to identify relevant environmental sustainability datasets, implementing powers should be conferred on the Commission.		
Recital 43			
51	(43) To monitor the impacts on humans and the environment, including the climate, of exposure to chemicals and to establish a knowledge base to measure the effectiveness of chemicals legislation in protecting human health and the environment, the EEA and the ECHA should jointly develop and regularly, at least every two years, update a set of indicators and present it in the form of a dashboard. The EFSA, the EMA, the EU-OSHA and the Commission shall regularly provide the EEA with any available data falling within their mandate and relevant for the establishment of the indicators. The EEA and the ECHA should integrate this dashboard of indicators into the common data platform.		

Recital 44			
52	(44) To enable the identification and evaluation of emerging chemical risks, the EEA should develop and compile information on early warning signals and draw up an annual summary report to inform regulatory follow-up actions. In its work, the EEA should include its own sources, targeted literature searches and make use of information from national early warning systems. It should also include relevant information made available by the related work of the ECHA, the EFSA, the EU-OSHA, the EMA and their networks, such as the EFSA's task of identifying and collecting information on emerging risks under Regulation 178/2002. The EEA should make the summary report and the underlying data available through the common data platform, ensuring public access and its use for further action on existing and emerging risks. In order to allow the EEA sufficient time to organise the collection of early warning signals and to compile and analyse the initial information the EEA should only deliver the first report six months after the end of the first calendar year after entry into force of this Regulation. This Regulation sets a deadline for the first report and associated data.		
Recital 45			
53	(45) In June 2017, at the Commission' request, the ECHA set up the European Observatory for Nanomaterials⁴⁸ ('EUON'), which collects existing data and information from databases, registries and studies and generates new data through studies and surveys on nanomaterials on the EU market.		
Recital 46			
54	(46) The ECHA should continue operating the EUON and transform it into an observatory for specific chemicals with potential contribution to emerging chemical risks ('the observatory'), which should cover also other chemicals and innovative (rationally designed complex 'advanced') materials selected by the Commission, using, as appropriate, signals from the early warning and action system. One of the criteria for selecting chemicals for the observatory should be their		

	novelty and disruptive potential that may contribute to an emerging chemical risk. Another criterion for that selection should be the higher degree of uncertainty surrounding them and, due to less regulatory experience regarding those chemicals, the resulting need for additional scrutiny and transparency. The observatory should facilitate regulatory implementation and responsible use of these chemicals by collecting, generating, and disseminating reliable information on selected chemicals' properties, uses and market presence to the general public.		
Recital 47			
55	(47) The observatory should not be regarded as a substitute for required risk management action on any chemical in cases where a hazard or risk has been identified. In order to provide for an efficient and consistent approach for the generation and dissemination of all such additional information, the ECHA should oversee the work of the observatory and make the regularly updated data and information it collects available through the common data platform, or by means of other communication channels, as appropriate. In order to ensure uniform conditions for the implementation of the requirement to select chemicals to be included in the observatory, implementing powers should be conferred on the Commission.		
Recital 48			
56	(48) Under Regulation (EC) No 178/2002, the EFSA is able to commission, in an open and transparent manner, the scientific studies it needs to accomplish its mission, while seeking to avoid duplication with Member States or Union research programmes. The ECHA should also be able to commission studies to obtain adequate data and information on chemicals within its mission, while maintaining the principle that the burden to prove compliance with Union chemicals legislation remains on the duty holder. Furthermore, the ECHA should commission such studies out of its own initiative or at the request of the Commission, with the objective of supporting the effective and efficient implementation and evaluation of Union acts on chemicals within its mandate and contributing the development of a Union chemicals policy.		

Recital 49			
57	(49) In order to adjust the contents of Annexes I and III to technical and scientific progress in the field of chemicals and to bring in the scope of this Regulation new Union acts under which relevant chemicals data and information is generated or submitted, and, where relevant, to expand the specific data types and reference values, listed in Annex II, to be made available by the EMA through the common data platform, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending Annexes I, II and III. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work in relation to the amendment of the Annexes by delegated act, including at expert level through the One-Substance One-Assessment Expert Group, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016⁴⁹. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.		
Recital 50			
58	(50) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States as Member States do not hold the data within the scope of this Regulation and cannot establish a Union wide common data platform, but can rather, by reason of chemicals data and information being hosted at Union level by the Agencies, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.		
Recital 51			

59	(51) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council and delivered an opinion on [OP: Please insert the date of the opinion of the EDPS].		
Formula			
60	HAVE ADOPTED THIS REGULATION:		
Chapter I			
61	Chapter I SUBJECT MATTER, SCOPE AND DEFINITIONS		
Article 1			
62	Article 1 Subject matter and scope		
Article 1(1)			
63	1. This Regulation aims to ensure the efficient delivery of coherent hazard and risk assessments of chemicals where those assessments are required by Union legal acts, to achieve a high level of protection of human health and the environment, to enable the development and use of sustainable chemicals, to ensure the proper functioning of the single market for chemicals, and to improve the Union's citizens' trust in the scientific base for the decisions taken under Union legal acts on chemicals.	One delegation proposed to include SSBD (safe and sustainable by design) as one of the roles for the platform. → PRES propose to work on an amendment introducing explicitly the safe and sustainable by design approach as one of the aims.	
Article 1(2)			
64	2. To achieve the objectives referred to in paragraph 1, this Regulation contains measures to:		
Article 1(2), point (a)			
65	(a) bring together data and information on chemicals and ensure that data and information are easily findable, accessible, interoperable and re-usable;		
Article 1(2), point (b)			

66	(b) keep records of studies commissioned or carried out by business operators in the context of fulfilling their obligations set under Union chemicals legislation;		
Article 1(2), point(c)			
67	(c) establish the widest possible scientific base for the implementation and development of Union legislation and policy on chemicals;		
Article 1(2), point (c)			
68	(d) establish an early warning and action system for emerging chemical risks.		
Article 1(3)			
69	The provisions laid down in this Regulation apply to chemicals data as laid out in Article 3(2).		
Article 2			
70	Article 2 Definitions	One delegation requested amending art.2 to clarify the meaning of “product” in this proposal. One delegation asked what is covered by the term “products” in art.7(1) One delegation requested examples of the meaning of “chemical products” in relation to mixtures, articles, substances. PRES highlights that the term occurs in recital (8), (10),(25),art.3(3), art.7(1), art.22(1). PRES highlights also that while some of those occurrences relates to cosmetic or medicinal products, other occurrences do not refer to a particular regulation and might have overlapping meaning with e.g. articles in REACH, or products under the ESPR. → PRES is working on an amendment proposal.	
Formula			
71	For the purpose of this Regulation, the following definitions shall apply:		
Article			

2(1)			
72	1. 'Agencies' means the European Chemicals Agency ('ECHA'), the European Environment Agency ('EEA'), the European Food Safety Authority ('EFSA') and the European Medicines Agency ('EMA') and the European Agency for Safety and Health at Work ('EU-OSHA');		
Article 2(2)			
73	2. 'Authorities' means the European Commission, the competent authorities of the Member States as referred to in any of the Union acts listed in Annexes I and III, and the Agencies, excluding their management boards;		
Article 2(3)			
74	3. 'duty holder' means a natural or legal person responsible for meeting obligations under the Union acts listed in Annex I or II;		
Article 2(4)			
75	4. 'business operators' means duty holders which are private or public undertakings;	One delegation suggests to “use ‘economic operators’ instead of ‘business operators’ to ensure alignment with other relevant legislation”. PRES highlights that the term “business operator” is used in recital (8),(13),(28),(29),(30),(31),(35),(37),(38), and articles 1(2), 22, 25, and 26. Those articles relates to studies commissioned, studies notifications, and related enforcement/penalties. PRES highlights that the term “duty holder” is defined in art. 2(3) in relation to obligations in acts mentioned in annex I or II. The terms is per se used in recital (13), (15), (48), art 2(4), 15(5), and 17(2). Those later articles relate to the use of the controlled vocabularies, as well as the prohibition for Authorities to use data from the platform to fulfil legal obligations of duty holders. → PRES seeks written comments on the following: ESPR has a definition of “economic operator”: ‘economic operator’	

		means the manufacturer, the authorised representative, the importer, the distributor, the dealer and the fulfilment service provider. PRES understands that in the present regulation the meaning of it is much more narrow, and relates only to duty holders that at the same time are undertakings. → PRES seeks for agreement that in consequence there is no correspondence with other EU regulations, and thus no amendment here should be done.	
Article 2(5)			
76	5. 'human biomonitoring data' means concentrations of chemicals measured in human matrices such as blood or urine;		
Article 2(6)			
77	6. 'reference value' means an estimate of a maximum exposure to or emission level of a chemical below which no or only acceptable adverse effects on human health or the environment are expected, or below which risks related to the adverse effects on human health or the environment are considered acceptable or tolerable;	One delegation commented about "acceptable or tolerable" in relation to non-threshold cancerogenic substances. PRES understands that the intention is to avoid that reference values for non-threshold substances are published without mentioning as metadata the actual statistical risk they represent. → PRES proposes to work on an amendment of art 2(6), 8 and 14 for this.	
Article 2(7)			
78	7. 'originator' means the Commission, Agency, or Member State competent authority responsible for confidentiality assessments under any Union act listed in Annex I or Annex II;		
Article 2(8)			
79	8. 'originating Union act' means the Union act under which chemicals data and information were generated or submitted;		
Article 2(9)			

80	9. 'controlled vocabularies' means standardised and organised arrangements of words and phrases presented as lists of terms or as thesaurus and taxonomies with a hierarchical structure of broader and narrower terms;		
Article 2(10)			
81	10. 'chemicals data' means any representation of facts or information relating to chemicals and any compilation of such facts or information, including information on physico-chemical properties, hazard properties, use, exposure, risk, occurrence, emissions and manufacturing process of the chemicals, as well as environmental sustainability related information, including climate change related information, on those chemicals, regulatory process-related information on chemicals, standard formats, controlled vocabularies, or any information on applicable legal obligations related to chemicals;		
Article 2(11)			
82	11. 'environmental sustainability related data' means any data relevant for the environmental sustainability assessment of a chemical or material throughout its entire life cycle, including:	One delegation finds this definition vague, and proposes to add an annex (e.g. in Art. 13) which can be updated on a regular basis by means of Delegated Acts. This annex should contain the respective legal acts as well as the associated sustainability information. PRES highlights that the definition here is used in a broader sense than the information available in legal acts (e.g. research in art.5(6), art 13(3) and potentially art.13(4)). → PRES requests written comments on the necessity to add a reference to a new annex IV, containing a list legal acts relevant for environmental sustainability related data. Such a reference would be added here as a new point 2(11)(d) along with related delegated powers in Chapter VIII. → PRES would also like to have comments on the provisions of art.13(4) as this partially overlaps with the concern raised by one delegation (by having the COM adopting an implementing decision for data not already hosted or hold by agencies/COM or not coming from EU research). Which relevant data are generated through legal	

		acts but are not hold or hosted by COM/agencies listed in this proposal?	
Article 2(11), point (a)			
83	(a) data on resources, including raw materials, water, energy, fossil fuels and land;		
Article 2(11), point (b)			
84	(b) data on emissions, including greenhouse gases, eutrophication-relevant substances, dust and all other polluting substances; and		
Article 2(11), point (c)			
85	(c) data on by-products originating during the chemical's life cycle that can be used as resources for other production processes, including hydrogen and carbon monoxide.		
Article 2(12)			
86	12. 'personal data' means personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679 of the European Parliament and of the Council and as defined in Article 3, ~~point (16), of Regulation (EU) 2018/175~~ point (1), of Regulation (EU) 2018/1725 of the European Parliament and of the Council;	One delegation highlighted that this definition is specified in Article 3, point (1) of Regulation 2018/1725 and not in Article 3, point (16) of Regulation 2018/175. → PRES sees this as an editorial amendment and proposes to modify Article 2 (12) consequently.	
Article 2(13)			
87	13. 'processing' means processing as defined in Article 4, point (2), of Regulation (EU) 2016/679 of the European Parliament and of the Council and as defined in Article 3, point (3), of ~~Regulation (EU) 2018/175~~ Regulation (EU) 2018/1725	One delegation highlighted that the reference is to Regulation 2018/1725 and not to Regulation 2018/175. → PRES sees that this is an editorial amendment and proposes to modify Article 2 (13) consequently.	

	of the European Parliament and of the Council;		
Article 2(14)			
88	14. 'data controller' means controller as defined in Article 4, point (7), of Regulation (EU) 2016/679 and as defined in Article 3, point (8), of ~~Regulation (EU) 2018/175~~ Regulation (EU) 2018/1725 of the European Parliament and of the Council;	One delegation highlighted that the reference is to Regulation 2018/1725 and not to Regulation 2018/175. → PRES sees that this is an editorial amendment and proposes to modify Article 2 (14) consequently.	
Article 2(15)			
89	15. 'interoperability' means the ability of two or more data spaces or communication networks, systems, products, applications or components to exchange and use data in order to perform their functions.	One delegation asked if advanced programming interfaces (API) will be used. PRES highlights that API are tools that MSs may use amongst others in order to query the data platform from their own advanced knowledge management systems (i.e. machine readability) instead of relying on "manual" queries in a web interface like in ECHA web site today. PRES highlights that in the explanatory memorandum the COM mentions that "The proposal also contributes to the objectives of EU data and digital policies by promoting interoperability and machine readability ". However only interoperability is explicitly mentioned here. → PRES requests written comments on this and on the necessity to amend the proposal to explicitly mention APIs and the conditions of their use for MS and the public.	
Chapter II			
90	Chapter II INFORMATION SYSTEMS AND PLATFORMS		
Article 3			
91	Article 3 Common Data Platform on Chemicals		

Article 3(1)			
92	1. The ECHA shall establish and manage a common data platform on chemicals ('the common data platform').		
Article 3(2)			
93	2. The common data platform shall provide access to all chemicals data:	One delegation highlights that it is difficult to assess the exhaustiveness of annexes I and III. PRES request written comments on any potentially missing relevant regulations in those annexes. One delegation questioned the differentiated approach between medicinal products and biocidal and phytopharmaceutical products. → PRES would like to receive further clarity in writing.	
Article 3(2), point (a)			
94	(a) generated or submitted as part of the implementation of the Union acts listed in Annex I to this Regulation and held by the Agencies or the Commission;		
Article 3(2), point (b)			
95	(b) generated as part of Union, national or international programmes or research activities in the sphere of chemicals and held by the ECHA, the EEA, the EFSA, the EU-OSHA or the Commission;		
Article 3(2), point (c)			
96	(c) listed in Annex II and held by the EMA;		
Article 3(3)			

97	3. The following information shall not be included in the common data platform:		We agree to exclude the information on the composition of mixtures
Article 3(3), point (a)			communicated in the context of Art. 45 CLP and in the context of the Cosmetics Regulation but we consider it appropriate, as already pointed out by France, that some form of correlation/communication
98	(a) the information referred to in Article 45 of Regulation (EC) No 1272/2008 ⁵⁰ ; 50 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).		is made between these notifications and the common platform on chemicals referred to in the proposed Regulation. Therefore, we believe that whether a substance is contained in a mixture or mixtures for certain uses, this information could be extrapolated from the database referred to in Article 45CLP and database referred to the Cosmetics Regulation, and converged to the common database. This would
Article 3(3), point (b)			undoubtedly promote awareness in risk assessments of the possible uses of a given substance, and this would also appear not to be in dissonance with Article 45(2)(b), rather it would
99	(b) the information related to cosmetic products and notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/2009 ⁵¹ of the European Parliament and of the Council. 51 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November on cosmetic products (OJ L 342 22.12.2009, p. 59).		substantiate the action referred to of improving risk management measures. We propose to add the following sentence to Article 3(3) after point (b): "Nevertheless, information on a substance linked to a use as recalled in the European Product Categorisation System (EuPCS) can be extrapolated from the above platforms in an aggregated form".
Article 3(4)			
100	4. Documents relating to Authorities' internal work or decision-making processes need not be included in the common data platform, unless required under Article 10.		
Article 3(5)			
101	5. The common data platform shall provide the dedicated services identified in the governance scheme referred to in Article 4(3) including:		
Article 3(5), point (a)			
102	(a) the Information Platform for Chemical Monitoring ('IPCHEM')		

	referred to in Article 7;		
Article 3(5), point (b)			
103	(b) the repository of reference values referred to in Article 8;		
Article 3(5), point (c)			
104	(c) the database of study notifications referred to in Article 9;		
Article 3(5), point (d)			
105	(d) information on regulatory processes referred to in Article 10;		
Article 3(5), point (e)			
106	(e) information on obligations under Union chemicals legislation referred to in Article 11;		
Article 3(5), point (f)			
107	(f) the repository of standard formats and controlled vocabularies referred to in Article 12;		
Article 3(5), point (g)			
108	(g) the database on environmental sustainability-related data referred to in Article 13.		
Article 3(6)			
109	6. The Authorities and the general public shall have access to the data contained in the common data platform in accordance with Article 16.		We suggest the following integration in row 109: "6. The Authorities and the general public shall have access to the data contained in the common data platform in accordance with Article 16.
Article 3(7)			The data assessed by authorities or agencies should prevail or be more visible"
110	7. The data contained in the common data platform may be used in		

	accordance with Article 17.		
Article 3(8)			
111	8. The data contained in the common data platform shall be made available in standard formats, where developed, and through controlled vocabularies where available.		
Article 3(9)			
112	9. The data contained in the common data platform shall be electronically accessible and searchable. The ECHA shall take measures to ensure a high standard of security appropriate to the security risks at stake for the storage of chemicals data in and transmission of chemicals data to the common data platform. The ECHA shall design the common data platform in a way that guarantees that any access to confidential data is auditable.		
Article 3(10)			
113	10. The Commission or Agency under whose authority chemicals data is included in the common data platform on chemicals shall remain responsible for handling any requests for access to documents made under Regulation (EC) No 1049/200152. 52 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (. OJ L 145, 31.5.2001, p. 43).		
Article 3(11)			
114	11. The common data platform and its dedicated services shall be established by [OP: please insert date: three years after the date of entry into force of this Regulation], unless specified otherwise. The relevant datasets shall be integrated progressively into the common data platform by [OP please insert date: ten years from the date of entry into force of this Regulation] according to the implementation plan referred to in Article 4 (1), first sentence. Upon integration of those datasets in the common data platform, when the ECHA receives	One delegation requested clarifications on this paragraph (timing for the notification service, lack of specification of the timing for the rolling plans). This delegation proposed amendments accordingly → PRES: a more general discussion at the 2d WP took place regarding the timelines	

	chemicals data in accordance with Article 5, it shall make that data available through the common data platform without undue delay.		
Article 4			
115	Article 4 Implementation plan and governance of the common data platform	One delegation proposed to include new provisions 5a,5b,5c in art.4., requesting that the COM prepares and presents a recommendation on “how to amend legislation listed in the Annexes to this regulation”. → PRES would like to receive written comments on this as it is not clear for us if this means amending the annexes of the data platform proposal, or if the delegation meant to amend the listed regulations. One delegation raised concerns about the wording “implementing” appearing at several places and which is seen as “misleading” with respect to the legal definition of “implementing acts”. → PRES seeks legal advice on this. The Council legal services provided an opinion on this at the 2nd WP.	
Article 4(1)			
116	1. By [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall adopt and publish an implementation plan identifying datasets for inclusion in the common data platform together with a timeline for their inclusion by means of an implementing decision. Subsequent rolling implementation plans shall be adopted in line with the governance scheme referred to in paragraph 3.	One delegation questioned the procedure for adopting the plan, the consultation procedures and MS involvement. → PRES: WP2 discussion on the desired level of and procedures for MS participation took place.	
Article 4(2)			
117	2. The Commission shall, by means of an implementing decision, establish and manage a platform steering committee, which shall include one representative from the ECHA, one representative from the EEA, one representative from the EFSA, one representative from the EMA, one representative from the EU-OSHA and five representatives from the Commission.		
Article 4(3)			
118	3. The platform steering committee shall advise the Commission in the		

	preparation of the common data platform's governance scheme.		
Article 4(4)			
119	4. The Commission shall adopt and publish the governance scheme referred to in paragraph 3 and any revision thereof by means of an implementing decision		
Article 4(5)			
120	5. That governance scheme shall describe:		
Article 4(5), point (a)			
121	(a) the organisation of the main work structures supporting the development and implementation of the common data platform;		
Article 4(5), point (b)			
122	(b) the preparation and adoption of rolling implementation plans for the common data platform;		
Article 4(5), point (c)			
123	(c) the principles on data governance and the required standard formats, controlled vocabularies and further conditions for the provision of information and context data to the common data platform;		
Article 4(5), point (d)			
124	(d) the decision-making procedures for the development of new dedicated services and the inclusion of new functionalities of the platform;		
Article 4(5), point(e)			

125	(e) any other rules or requirements necessary for the operation of the common data platform such as the data update, archiving and deletion policy;		
Article 4(5), point (f)			
126	(f) the operation of the steering committee itself.		
Article 5			
127	Article 5 Data Flows for the purpose of the common data platform		
Article 5(1)			
128	1. At the Commission's request, the Agencies shall host and maintain chemicals data generated as part of Union, national or international legislation, programmes or research activities, corresponding to their mandate and the type of data they already hold.		
Article 5(2)			
129	2. Where the Commission or the Agencies hold data or information referred to in Article 3(2), they shall make that data available to the ECHA, in a standard format, where available, together with the relevant context data as ~~referred to in Article 4(4), point (c).~~ referred to in Article 4(5), point (c). The Commission and the Agencies shall indicate whether that data or information is made available to the public under the originating Union act.	One delegation highlighted that the reference should be to Article 4(5), point (c) and not Article 4(4), point (c). → PRES sees this as an editorial amendment and proposes to modify Article 5(2) consequently.	
Article 5(3)			
130	3. The ECHA shall host and maintain occurrence data related to workplace monitoring.		
Article 5(4)			
131	4. The EEA shall host and maintain human biomonitoring data, occurrence data for the environment and occurrence data related to indoor air quality.	One delegation asked if Commission pursues plans for systematic or regular surveys of indoor air quality data → PRES is requesting written comments on this.	
Article			

5(5)			
132	5. Researchers or research consortia funded by Union framework programmes shall make available to the EEA any human biomonitoring data they collect or generate from [OP please insert: date of the entry into force of this Regulation].		
Article 5(6)			
133	6. Researchers or research consortia funded by Union framework programmes shall make available to the ECHA any environmental sustainability data on chemicals or materials they collect or generate from [OP please insert: date of the entry into force of this Regulation].		
Article 5(7)			
134	7. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of the chemicals data provided in accordance with paragraph 2 in the common data platform as well as its publication through that platform.		
Article 5(8)			
135	8. For the purpose of paragraph 2, the Commission and the Agencies shall make chemicals data available to the ECHA without undue delay after collection or receipt of the data, after performance of validity and confidentiality assessments in accordance with applicable rules and once the corresponding dataset has been integrated in the common data platform.		
Article 5(9)			
136	9. The Commission and the Agencies shall ensure that data made available to the ECHA shall be downloadable, machine readable and interoperable. They shall appropriately curate and validate the data before providing them to the ECHA.		
Article 6			
137	Article 6 Human biomonitoring data	→ PRES: given the numerous comments, questions and clarification requests received, PRES set this as a discussion point at the 2 nd WP (8/3), and invites MS and the COM to react to the EDPS recommendations.	Concerning human biomonitoring data, we ask for clarity on whether MS (authorities, research organisations, etc.) implementing e.g. workplace legislation etc. will be obliged to send the data collected in their territories and how consent for their use by trial participants can be obtained.

It could be useful to include a reference in an appropriate recital if the EDPS recommendations are relevant to the scope of this Regulation.

Article 6(1)			
138	1. The EEA shall collect, host, and maintain human biomonitoring data generated within the territory of the EEA's member and cooperating countries.		
Article 6(2)			
139	2. At the latest by [OP please insert date: 3 years after entry into force of this Regulation] the Commission shall transfer any human biomonitoring data it holds to the EEA.		
Article 6(3)			
140	3. The EEA may process human biomonitoring data constituting personal data to support the Commission in its policy making or to support the Agencies in fulfilling their missions.		
Article 6(4)			
141	4. Human biomonitoring data constituting personal data may be processed by the EEA for the following purposes:		
Article 6(4), point (a)			
142	(a) assessing the impact of chemicals on human health and the environment;		
Article 6(4), point (b)			
143	(b) monitoring time and spatial trends in exposure;		
Article 6(4), point (c)			
144	(c) developing health risk and impact indicators;		
Article 6(4), point (d)			
145	(d) monitoring the impact of regulatory intervention;		

Article 6(4), point (e)			
146	(e) supporting regulatory risk assessments.		
146.a	(f) supporting regulatory risk management	One delegation proposed to add this amendment. PRES understands that HBM data are indeed useful for risk management, e.g. trend analysis will give an idea if policy actions are having an impact or not on reducing exposure → PRES proposes thus to add this paragraph (f)	agree
Article 6(5)			
147	5. The EEA shall make human biomonitoring data they hold or host publicly available in anonymised form through the Information Platform for Chemical Monitoring.		
Article 6(6)			
148	6. The EEA shall act as data controller for the human biomonitoring personal data it holds or hosts and processes for the purposes referred to ~~in paragraph 2.~~ in paragraph 4.	Some delegations highlighted that the reference should be to para. 4. → PRES sees this as an editorial amendment and proposes to modify art.6(6) in consequence. One delegation proposed to add an additional reference to art.3 and 5 here. → PRES, up to his knowledge, understands that from the definition of a data controller this is logical, but seeks for written opinions on this and will request a legal advice. Discussions at the 2nd WP on the EDPS recommendations might also contribute clarifications on this proposal. One delegation suggested to “include the same reference to Articles 6(3) and 6(4)” → PRES is keen to receive a written rationale for this as it seems to introduce a circular reference in the text.	
Article 7			

149	Article 7 Information Platform for Chemical Monitoring		
Article 7(1)			
150	1. The ECHA shall operate and maintain the Information Platform for Chemical Monitoring containing occurrence data on chemicals across different media, including water, soil, indoor air, outdoor air, biota, food and feed, humans, and products as part of the common data platform.	→ PRES: regarding the meaning of “products”, cfr art.2 (here in line 70).	
Article 7(2)			
151	2. At the latest by [OP please insert date: 3 years after the date of entry into force of this Regulation], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring at that moment to the ECHA for integration in the common data platform.		
Article 7(3)			
152	3. At the latest by [OP please insert date: 3 years after entry into force of this Regulation], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring to the ECHA, the EEA or the EFSA for hosting in accordance with the respective agencies’ mandate and in accordance with Article 5.		
Article 7(4)			
153	4. After the completion of the transfer referred to in paragraph 3, where the Commission or the Agencies host or hold occurrence data on chemicals and related chemicals data, they shall make that data available to the ECHA without undue delay for integration in the Information Platform for Chemical Monitoring.		
Article 7(5)			
154	5. The Commission and Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration and publication of occurrence data and related chemicals data they host or hold through the common data platform.		
Article			

7(6)			
155	6. The ECHA shall ensure that the data contained in the Information Platform for Chemical Monitoring is machine readable and downloadable.		
Article 8			
156	Article 8 Repository of reference values	One delegation requested a amendment about the statistical (cancer) risk associated with some reference values. → PRES: see our proposal in art 2(6) here line 77	
Article 8(1)			
157	1. The ECHA shall establish and manage a repository of reference values as part of the common data platform.		
Article 8(2)			
158	2. The ECHA shall include any reference value adopted under Union acts listed in Annex I or Annex II, Part 1, in the repository of reference values without undue delay.		
Article 8(3)			
159	3. For reference values not falling under paragraph 2, the Agencies holding or establishing reference values as part of their activities under Union acts listed in Annex I, or the reference values referred to in Annex II, Part 2, shall make those reference values available to the ECHA, in the standard formats provided for in Article 14, where developed, and without undue delay, for integration in the repository of reference values.		
Article 8(4)			
160	4. For the purpose of paragraph 3, where reference values are included in a regulatory dossier submitted to the Agencies, the Agencies shall share those reference values in the standard formats with ECHA without undue delay and once relevant validity and confidentiality assessments have been completed by the originator in accordance with applicable rules.		
Article 8(5)			

161	5. The ECHA shall ensure that the data contained in the repository of reference values is machine readable.		
Article 9			
162	Article 9 Database of Study Notifications		
Article 9(1)			
163	1. The ECHA shall establish and operate a Database of Study Notifications by [OP please insert date: two years after the date of entry into force of this Regulation].		
Article 9(2)			
164	2. The ECHA shall store in the Database of Study Notifications the data notified to it in accordance with Article 22.		
Article 9(3)			
165	3. The ECHA shall integrate the data contained in the Database of Study Notifications in the common data platform once a corresponding registration, application, notification or other relevant regulatory dossier was submitted to the relevant Union or national institution, agency, or body in accordance with corresponding Union law and after a decision was taken by that Union or national institution, agency, or body on the disclosure of the accompanying studies in accordance with the applicable rules on confidentiality.	One delegation considers that this deserves clarification as it seems to prevent Member States authorities from getting relevant information on notified studies in time. PRES notes that this might be related to enforcement. → PRES seeks further written comments on this → PRES is working on an amendment proposal	
Article 9(4)			
166	4. The EFSA shall make the data contained in the database referred to in Article 32b of Regulation (EC) No 178/2002 available to the ECHA for integration in the common data platform once it has received a corresponding application and after it has decided on the disclosure of the accompanying studies in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002.		
Article 9(5)			
167	5. The ECHA and the EFSA shall cooperate to ensure a common approach for the identification of information notified to them in		

	accordance with Article 22 of this Regulation and Article 32b of Regulation (EC) No 178/2002, respectively and facilitate the traceability of the studies notified to their respective databases.		
Article 10			
168	Article 10 Information on regulatory processes on chemicals	→ PRES is seeking written comments on one delegation's question about already existing communication channels in certain regulations, related to the stage of evaluation, and the potential need to modify those regulations. → PRES highlights that this might be the case for TRIS notifications.	
Article 10(1)			
169	1. The ECHA shall establish and manage, as part of the common data platform, a new database containing information on regulatory processes on individual substances or groups of substances that are planned, ongoing or have been completed since the entry into force of this Regulation by the Member States or the Union institutions, agencies or committees referred to in the Union acts listed in Annex III.	→ PRES is seeking for written comments on one delegation's comment that it is not clear whether the scope of art 10(1) includes national regulations processes.	
Article 10(2)			
170	2. Where Member State competent authorities as referred to in any of the Union acts listed in Annex III hold the information referred to in paragraph 1, they shall make that information available to the Union agency responsible under the respective Union act listed in Annex III without undue delay.	→ PRES is seeking for written comments on one delegation's request to clarify the COM reference (during the 1 st WP) to voluntary notifications, including examples.	
Article 10(3)			
171	3. Where the ECHA, EEA, EFSA, EU-OSHA or the Commission hold the information referred to in paragraph 1, they shall make that information available to the ECHA for integration in the common data platform in the standard formats provided for in Article 14 without undue delay and, where relevant, once the responsible agency or the Commission has performed the validity assessment. For each regulatory process or activity, at least the following information shall be included:	→ PRES is seeking written comments on one delegation's question about which information EEA might have to make available to ECHA in this context, as EEA has no competences about chemical products.	
Article			

10(3), point (a)			
172	(a) substance identity;		
Article 10(3), point (b)			
173	(b) the Union act and the regulatory process under which the activity takes place;		
Article 10(3), point (c)			
174	(c) submitter or actor responsible for the regulatory process or activity;		
Article 10(3), point (d)			
175	(d) status of the regulatory process or activity;		
Article 10(3), point (e)			
176	(e) where applicable , outcome of the regulatory process or activity ~~, including, where applicable, and~~ reports or opinions adopted;	PRES understand from one delegation's comment that it is not always possible to indicate the (future) outcome, so this provision is not always applicable. → PRES propose to amend art 10(3) by inserting "where applicable" as we see it more precise than "where appropriate"	
Article 10(3), point (f)			
177	(f) where applicable, date of intention to start the regulatory process or activity, completion and latest update.		
Article 10(4)			
178	4. The information referred to in paragraph 3, points (a) to (f), on a specific regulatory process or activity shall be made available to the public once that process or activity has formally started.		
Article 11			
179	Article 11	PRES notes one delegation's comment on the potentiality of	

	Information on the obligations under Union acts on chemicals	IA in this context.	
Article 11(1)			
180	1. The ECHA shall establish and manage, as part of the common data platform, a database with information on the provisions and legal obligations applicable to chemicals under the Union acts listed in Annex I.		
Article 11(2)			
181	2. The ECHA shall update the information in the database on a regular basis and in accordance with the governance scheme referred to in Article 4(3).		
Article 12			
182	Article 12 Repository of standards formats and controlled vocabularies		
Article 12(1)			
183	1. The ECHA shall establish and manage as part of the common data platform a repository of standard formats and controlled vocabularies.		
Article 12(2)			
184	2. Where standard data formats are established under the Union acts listed in Annexes I and II, the ECHA shall include them in the common data platform.		
Article 12(3)			
185	3. Where the Commission or the Agencies specify a standard format or controlled vocabulary in accordance with Articles 14 or 15, the Commission or the Agency shall make it available to the ECHA without undue delay for integration in the common data platform.		
Article 13			
186	Article 13 Database on environmental sustainability related data	One delegation requested for a new annex on relevant legal acts, see discussion of Article 2(11) → PRES: see line 82 here above About the role of EIONET in this	

		→ PRES included this in the discussion at the WP2 (effort needed by MS)	
Article 13(1)			
187	1. At the latest within three years after the publication of the decision referred to in paragraph 4, the ECHA shall establish and manage, as part of the common data platform, a database containing environmental sustainability related data.		
Article 13(2)			
188	2. Where the Commission or the Agencies host or hold environmental sustainability related data in addition to the chemicals data already available in the common data platform, they shall make that data available to the ECHA without undue delay once the Commission or the Agency hosting or holding that data has completed, where relevant, validity and confidentiality assessments. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of environmental sustainability related data in the database on environmental sustainability related data.		
Article 13(3)			
189	3. Where researchers or research consortia funded by Union framework programmes make available to the ECHA, under Article 5(6), any environmental sustainability data on chemicals or materials they collect or generate, the ECHA shall integrate the relevant data in the database on environmental sustainability related data.		
Article 13(4)			
190	4. By [OP please insert date: three years after the date of entry into force of this Regulation], the Commission shall adopt an implementing decision identifying existing datasets on environmental sustainability related data, other than those referred to in paragraph 2, for inclusion in the common data platform and shall design relevant related database functionalities.	→ PRES is seeking legal advice about the wording “implementing decision” (cfr delegation comment). Council legal services provided an opinion on this at the 2 nd WP.	
Chapter III			

191	Chapter III DATA FORMATS AND CONTROLLED VOCABULARIES	→ PRES seeks written comments on one delegation's request to eventually have study reports and raw data provided → PRES seek written comments on the request by one delegation to investigate that there is no impact on the use of INCI names for cosmetics regulation, and no impact on substance identification and product labelling in that regulation.	
Article 14			
192	Article 14 Standard formats	One delegation amendment proposal on statistical risk: → PRES: see here Article 2(6) line 77	
Article 14(1)			
193	1. Without prejudice to Union provisions providing for the development or making available of data formats, the Commission and the Agencies shall specify, where relevant, for the data referred to in Article 3 (2) and falling within their mandate, standard formats and software packages and make them available free of charge through the common data platform.		
Article 14(2)			
194	2. The standard formats referred to in paragraph 1 shall, to the extent possible:		
Article 14(2), point (a)			
195	(a) avoid the use of proprietary standards;		
Article 14(2), point (b)			
196	(b) re-use existing data formats or parts of them;		
Article 14(2), point (c)			
197	(c) use OECD or other internationally agreed formats;		
Article 14(2), point (d)			

198	(d) be coherent with other existing data formats;		
Article 14(2), point (e)			
199	(e) ensure interoperability with existing data submission approaches.		
Article 14(3)			
200	3. Those standard formats shall be interoperable with the common data platform and be user-friendly.		
Article 14(4)			
201	4. The Commission and the Agencies shall exchange data contained in the common data platform in the relevant standard format.		
Article 14(5)			
202	5. The Commission and the Agencies shall use the International Uniform Chemical Information Database format (IUCLID) for making available to the ECHA for integration in the common data platform the relevant parts of dossiers under the following Union acts:		
Article 14(5), point (a)			
203	(a) Regulation (EC) No 1831/2003 of the European Parliament and of the Council ⁵³ ; ⁵³ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268 18.20.2003, p. 29).		
Article 14(5), point (b)			
204	(b) Regulation (EC) No 1935/2004 of the European Parliament and of the Council ⁵⁴ ; ⁵⁴ Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and		

	89/109/EEC (OJ L 338 13.11.2004, p. 4).		
Article 14(5), point (c)			
205	(c) Regulation (EC) No 1331/2008 of the European Parliament and of the Council ⁵⁵ ; ⁵⁵ Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354 31.12.2008, p. 1).		
Article 14(5), point (d)			
206	(d) Regulation (EC) No 1332/2008 of the European Parliament and of the Council ⁵⁶ ; ⁵⁶ Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354 31.12.2008, p. 7).		
Article 14(5), point (e)			
207	(e) Regulation (EC) No 1333/2008 of the European Parliament and of the Council ⁵⁷ ; ⁵⁷ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354 31.12.2008, p. 16).		
Article 14(5), point (f)			
208	(f) Regulation (EC) No 1334/2008 of the European Parliament and of the Council ⁵⁸ ; ⁵⁸ Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food		

	ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354 31.12.2008, p. 34).		
Article 14(5), point (g)			
209	(g) Regulation (EC) No 1223/2009 of the European Parliament and of the Council 59; 59 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342 22.12.2009, p. 59).		
Article 14(5), point (h)			
210	(h) Commission Regulation (EU) No 234/201160; 60 Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 064 11.3.2011, p. 15).		
Article 14(5), point (i)			
211	(i) Directive 2009/48/EC of the European Parliament and of the Council.61 61 Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170 30.6.2009, p. 1).		
Article 14(6)			
212	6. The Commission and the Agencies shall cooperate when setting standard formats to ensure coherence with other formats and the interoperability of the standard formats with the common data platform and with existing data submission approaches.		

Article 14(7)			
213	7. The Commission and the Agencies shall take the necessary and appropriate measures to monitor and identify at an early stage any potential divergence between data formats that could cause interoperability problems. If a divergence is identified, the Agencies concerned shall cooperate to resolve it or, where the divergence is justified, explain the underlying reasons. Where the Agencies concerned are not able to resolve that divergence, they shall draw up a joint report and present it to the Commission. The report shall clearly outline the reasons for the divergence, clarify any underlying technical issue and make a proposal to remedy the divergence.		
Article 14(8)			
214	8. The Commission shall adopt an implementing decision to remedy the divergence.		
Article 15			
215	Article 15 Controlled vocabularies	→ PRES is seeking written comments on the remarks by one delegation about the difficulties related to differences in vocabularies between legislations. → PRES seeks for comments on the difficulties related to substances identification inconsistencies between regulations (see delegation comment). PRES highlights that this problem is also relevant for art.22,25,26 on studies notification (a lack of correct identification might render difficult to implement them)	
Article 15(1)			
216	1. The Commission and the Agencies shall specify and regularly update controlled vocabularies within their mandate for the data referred to in Article 3(2), where relevant.		
Article 15(2)			
217	2. The Commission and the Agencies shall prioritise specifying controlled vocabularies for the identification of chemicals and the characterisation of their forms.		

Article 15(3)			
218	3. Those controlled vocabularies shall:		
Article 15(3), point (a)			
219	(a) avoid the use of proprietary controlled vocabularies to the extent possible;		
Article 15(3), point (b)			
220	(b) re-use existing substance identifiers and controlled vocabularies or parts of them to the extent possible;		
Article 15(3), point (c)			
221	(c) use OECD or other internationally agreed controlled vocabularies to the extent possible;		
Article 15(3), point (d)			
222	(d) ensure coherence with other relevant controlled vocabularies including by preparing alignment tables.		
Article 15(4)			
223	4. Those controlled vocabularies shall be interoperable with the common data platform.		
Article 15(5)			
224	5. Where controlled vocabularies are specified, the Commission and the Agencies shall:		
Article 15(5), point (a)			
225	(a) make them available free of charge through the common data		

	platform and as open datasets;		
Article 15(5), point (b)			
226	(b) integrate them in any submission software or template to be used by duty holders under the Union acts listed in Annex I and referred to in Article 3(2); and		
Article 15(5), point (c)			
227	(c) use them when exchanging data between them through the common data platform.		
Article 15(6)			
228	6. The Commission and the Agencies shall cooperate with each other in setting the controlled vocabularies.		
Article 15(7)			
229	7. The Commission and the Agencies shall take the necessary and appropriate measures to monitor and identify at an early stage any potential divergence between controlled vocabularies. If a divergence is identified, the Agencies concerned shall cooperate to resolve it or, where the divergence is justified, explain the underlying reasons. Where the Agencies concerned are not able to resolve that divergence, they shall draw up a joint report and present it to the Commission. The report shall clearly outline the reasons for the divergence, clarify any underlying technical issue and make a proposal to remedy the divergence.		
Article 15(8)			
230	8. The Commission shall adopt an implementing decision to remedy the divergence.		
Chapter IV			
231	Chapter IV	→ PRES: some delegation's comments here were discussed at the	

	CHEMICALS DATA CONFIDENTIALITY AND USE	WP2.	
Article 16			
232	Article 16 Access rights and transparency	→ PRES: One delegation request and questions (line 232 of the comments file) were discussed at the WP2.	
Article 16(1)			
233	1. The Authorities shall have access to all the chemicals data contained in the common data platform, including data which is deemed to be confidential under Article 5(2), second sentence.		
Article 16(2)			
234	2. The Authorities shall take the necessary measures to ensure that information contained in the common data platform marked as confidential in accordance with Article 5(2) is not made public.	→ PRES: One delegation comment and questions were discussed at the WP2 (line 234 of the comments file)	
Article 16(3)			
235	3. The general public shall have access to all the chemicals data contained in the common data platform and considered as available to the public in accordance with the Union act under which the data was generated or submitted.		we are concerned that providing data to the public could be misinterpreted or difficult to understand. We therefore suggest the following addition to the text, in the row 235 after the word "submitted." : "To facilitate the comprehension of the public some key reading should be provided".
Article 17			
236	Article 17 Use of chemicals data contained in the common data platform	One delegation comment on the meaning of "products" is addressed here in art.2 (see line 70). PRES: Regarding the other comments: → PRES seeks written comments on one delegation's concern on the identification in the data platform of cosmetics ingredients that may have been tested on animals. → PRES invites the COM to update MS on the possibility of an overview table on confidentiality provisions requested by one delegation.	
Article 17(1)			
237	1. The Authorities may use the chemicals data contained in the common data platform in the performance of any of their activities, where those activities support the development or implementation of	→ PRES: one delegation requested for amendment to explicitly allow national use of the data was set for discussion at WP2.	

	chemicals legislation and policy.		
Article 17(2)			
238	2. Without prejudice to existing provisions enabling the sharing and use of chemicals data under the Union acts listed in Annexes I and II, Authorities shall not use chemicals data contained in the common data platform to fulfil any legal obligations of duty holders.	One delegation requested clarifications on the use of data in relation to duty holders obligations. → PRES invites for written comments on this.	ROW 238. We thanks the Presidency to clarify that the "duty holders" and "business operator" are terms limited to studies commissioned, studies notifications but also it includes the enforcement activity. We would like to underline that this last one is an institutional task. So, we would like to distinguish the situation where the Authorities shall not use chemicals data to favour business operators for their own duties and the situation where the Authorities could use the chemicals data of the platform for its own duties. Consequently we would like to propose this following modification: "Without prejudice to existing provisions enabling the sharing and use of chemicals data under the Union acts listed in Annexes I and II, Authorities shall not use chemicals data contained in the common data platform to fulfil any legal obligation of duty holders and business operators"
Article 17(3)			
239	3. When using chemicals data contained in the common data platform that is deemed confidential under Article 5(2), second sentence, the Authorities shall respect the confidentiality of information data as marked by the originator and shall not disclose that data to the public without the consent of the originator.		
Chapter V			
240	Chapter V MONITORING AND OUTLOOK FRAMEWORK FOR CHEMICALS		
Article 18			
241	Article 18 Framework of indicators	One delegation questioning the MS involvement was set for discussion at the 2 nd WP → PRES put the question on EIONET impacts for discussion at the 2 nd WP. One delegation comments on cosmetics: → PRES invites for written comments on questions raised by one delegation on cosmetics aspects (notification of undesirable effects, link to the Communication System for Market Surveillance (ICSMS) Art 23 Reg 1223/2009, consequences on the allowance of use for critical circumstances). One delegation comment on the relation to existing statistics systems → PRES invites for written comments	
Article 18(1)			

242	1. The EEA, in collaboration with the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission, shall establish, operate, and maintain a framework of indicators to monitor the drivers and impacts of exposure to chemicals, measure the effectiveness of chemicals legislation and measure the transition towards the production of safe and sustainable chemicals.		
Article 18(2)			
243	2. The framework of indicators referred to in paragraph 1 shall be accessible in the form of an indicator dashboard, which the EEA shall establish and which the ECHA shall make available through the common data platform.		
Article 18(3)			
243.b	3. The framework of indicators referred to in paragraph 1 shall be established, operated, and maintained by [OP: please insert date: 3 years after the end of the first calendar year after entry into force of this Regulation].	One delegation expressed concerns on the timescale for establishing the framework PRES highlights that several other articles contain indications on the timeframe → PRES submits this amendment for consideration, and discussion took place at the 2nd WP.	
Article 19			
244	Article 19 Early warning and action system for emerging chemical risks	→ PRES: One delegation's question on MS experts and RAC involvement was set for discussion at 2nd WP → PRES: One delegation's request for clarification on implications/role of EIONET and MS was set for discussion at the 2nd WP Regarding the other comments: → PRES seeks written comments about one delegation's question on the relation between the indicators and the early warning system (art.18,19). → PRES invites for written comments on the question regarding the level of ambition of the system in relation to complex systemic risks.	

		→ PRES invites written comment on the proposal to include the word “prevention” in the proposal	
Article 19(1)			
245	1. The EEA shall establish, operate and maintain a Union early warning system for emerging chemical risks by [OP please insert date: one year after the date of entry into force of this Regulation].		
Article 19(2)			
246	2. For the purpose of paragraph 1, the EEA shall compile early warning signals, which shall include at least signals from:		
Article 19(2), point (a)			
247	(a) the EFSA’s emerging risks exchange network;		
Article 19(2), point (b)			
248	(b) existing national early warning systems;		
Article 19(2), point (c)			
249	(c) data that the EEA holds;		
Article 19(2), point (d)			
250	(d) targeted literature searches performed by the EEA;		
Article 19(2), point (e)			
251	(e) data made available by the ECHA, the EFSA, the EU-OSHA and the EMA in accordance with paragraph 3.		
Article 19(2)			
252	The early warning signals compiled by the EEA under the first		

	subparagraph may be based on a positive identification of an emerging risk or on an uncertainty in the data leading to a potential positive identification of an emerging risk.		
Article 19(3)			
253	3. The ECHA, the EFSA, the EU-OSHA and the EMA shall identify and gather relevant available data on early warning signals from the field falling within their mandate and provide this data to the EEA.		
Article 19(4)			
254	4. The EEA shall draw up an annual report, compiling and analysing the data on early warning signals gathered in accordance with paragraphs 2 and 3. [The first report shall be prepared by [OP: please insert date: 6 months after the end of the first calendar year after entry into force of this Regulation]. The EEA shall present this report to the Commission, relevant Union agencies and ~~Member State competent authorities for consideration of the need~~ Member State competent authorities who shall consider the need for regulatory or policy action related to the early warning signals.	One delegation expressed questions the request to EEA to highlight areas on which to FOCUS, in the report. PRES suppose that this may be solved by a change in the wording (mostly editorial) → PRES proposes for consideration a proposed amendment to the text.	
Article 19(5)			
255	5. The EEA shall make all relevant data on early warning signals that it holds or hosts as well as the report referred to in paragraph 4 available to the ECHA for integration in the common data platform.		
Article 20			
256	Article 20 Observatory for specific chemicals with potential contribution to emerging chemical risks	PRES seeks written comments on one delegation's question about the type of risks covered here, and the interplay with existing chemicals legislation.	
Article 20(1)			
257	1. The ECHA shall establish, operate and maintain an observatory for specific chemicals that the Commission considers as requiring additional scrutiny. The observatory shall include reliable information on the chemicals' properties, safety aspects, uses and market presence.		
Article			

20(2)			
258	2. By [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall adopt and publish a list of the selected chemicals by means of an implementing decision. The Commission shall review the list of selected chemicals regularly and adopt any revision thereof by the same means.	One delegation highlighted that the linking word "and" is missing before the proposal "adopt any revision thereof by the same means". à PRES sees this as an editorial amendment and proposes to modify article 20(2) consequently (see <i>bold italic</i>). One delegation requested for amendments (implementing "decisions"). → PRES: questions on the meaning of "implementing", and MS participation were discussed at the 2nd WP.	
Article 20(3)			
259	3. The Commission shall select the chemicals referred to in paragraph 1 based on the scientific and technical progress and using the signals of the early warning system referred to in Article 19. The selection shall include potential contributors to new and emerging chemical risks among innovative rationally designed materials with new or enhanced properties or targeted or enhanced structural features at nanoscale.		
Article 20(4)			
260	4. For the purpose of operating the observatory referred to in paragraph 1, the ECHA shall:		
Article 20(4), point (a)			
261	(a) make use of relevant datasets integrated in the common data platform, and compile, analyse and curate further available data on selected chemicals or classes of chemicals;		
Article 20(4), point (b)			
262	(b) commission studies and, where relevant, use the data generation mechanism established under Article 21 to address knowledge gaps or significant uncertainties;		
Article			

20(4), point (c)			
263	(c) make compiled data publicly available through the common data platform or other communication and outreach tools as appropriate, to facilitate informed societal discussion and increase public awareness on the properties, use and safety aspects of specific chemicals, and regularly update that information.		
Chapter VI			
264	Chapter VI DATA GENERATION MECHANISM		
Article 21			
265	Article 21 Data generation mechanism	One delegation raised the question of the promotion of animal testing in relation to article 1. PRES understands that the type of tests are prescribed in each regulation mentioned in annex I, and thus this regulation is not modifying that. However, art.21 here is new, and thus the question of the minimization of animal testing might be relevant here. One delegation would like to know if commissioned animal studies will be notified → PRES requests written reactions and proposals on this matter. One delegation expressed the need to frame the mandate in such a way that the burden of proof on companies is preserved. One delegation insisted also on the burden of proof on industry and highlights the need for clarity on procedures and financing. → PRES invites for written comments and amendments proposals. Some Comments were received in relation to the involvement of MS, industry, stakeholders in the data generation mechanism. → PRES: discussion during the 2nd WP	
Article 21(1)			
266	1. Using the best independent resources available, the ECHA may commission scientific studies to support the implementation of Union acts on chemicals listed in Annex I within its mandate and to contribute	One delegation requested clarity on the meaning of scientific studies, and which ones will not be covered. → PRES invites for written comments on this	

	to the support, evaluation or development of a Union chemicals policy.		
Article 21(2)			
267	2. The Commission may request the ECHA to commission the scientific studies referred to in paragraph 1.		
Article 21(3)			
268	3. The ECHA shall only commission scientific studies when results cannot be obtained through existing legal provisions or processes under Union legislation listed in Annex I. It shall not commission studies with a predominant research objective.		
Article 21(4)			
269	4. The ECHA shall seek to avoid duplication with Member State or Union research or implementation programmes.		
Article 21(5)			
270	5. The ECHA shall commission these scientific studies in an open and transparent manner.	One delegation suggested to amend this to introduce compulsory prior MS consultation. → PRES scheduled this for discussion at the 2 nd WP	
Article 21(6)			
271	6. The ECHA and the EFSA shall closely cooperate with each other on the planning and commissioning of scientific studies undertaken by the ECHA in accordance with paragraph 1 and of studies undertaken by the EFSA in accordance with Article 32 of Regulation (EC) No 178/2002.		
Article 21(7)			
272	7. The ECHA shall make the results of the scientific studies performed under this Article available through the common data platform.		
Chapter VII			
273	Chapter VII NOTIFICATION OF STUDIES	Several comments were received on this chapter: on the legal scope and definition of studies to be notified, duplications, studies conducted outside the EU, late notifications, absence of a transitional period, practical arrangements for companies, the need	

		for early access before publication in the data platform. → PRES scheduled this for discussion at the 2 nd WP	
Article 22			
274	Article 22 Notification of studies		
Article 22(1)			
275	1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, without undue delay, any studies on chemicals they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment, prior to placing on the market, under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.		
Article 22(2)			
276	2. For the purposes of paragraph 1, business operators shall notify to the Database of Study Notifications referred to in Article 9 the title, scope, laboratory, or testing facility carrying out the study, the intended starting and planned completion dates and, where relevant, whether the study is commissioned to comply with a decision of the ECHA pursuant to Articles 40, 41 or 46 of Regulation (EC) No 1907/2006.		
Article 22(3)			
277	3. Laboratories and testing facilities shall also, without undue delay, notify any study commissioned by business operators to support a regulatory dossier on which an Agency is required to provide a scientific output, including a scientific opinion, under the Union acts listed in Annex I. However, laboratories and testing facilities shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.		
Article 22(4)			

278	4. For the purposes of paragraph 3, laboratories and testing facilities shall notify to the Database of Study Notifications referred to in Article 9 the title, scope, intended starting and planned completion dates of any test they carry out, as well as the name of the business operator who commissioned the test.		
Article 22(5)			
279	5. Paragraphs 3 and 4 shall apply, mutatis mutandis, to laboratories and testing facilities located in third countries insofar as set out in relevant agreements with those third countries.		
Article 22(6)			
280	6. The obligations set under this article shall apply from [OP please insert date: 24 months after the date of entry into force of this Regulation].		
Article 22(7)			
281	7. The ECHA shall lay down the practical arrangements for implementing the provisions of this Article.		
Chapter VIII			
282	Chapter VIII DELEGATED POWERS		
Article 23			
283	Article 23 Amendment of Annexes I, II and III		
Article 23(1)			
284	1. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex I in order to adjust the content of that Annex to technical and scientific progress in the field of chemicals or, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it new Union acts under which relevant chemicals data is generated or submitted.		
Article			

23(2)			
285	2. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex II by adding, where relevant, new categories of data types.		
Article 23(3)			
286	3. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex III in order to adjust the content of that Annex to technical and scientific and technical progress in the field of chemicals and, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it Union acts relevant for data on new regulatory processes on chemicals.		
Article 24			
287	Article 24 Exercise of the delegation		
Article 24 (1)			
288	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.		
Article 24(2)			
289	2. The power to adopt delegated acts referred to in Article 23 shall be conferred on the Commission for a period of five years from [OP please insert: the date of the entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each five-year period.		
Article 24(3)			
290	3. The delegation of power referred to in Article 23 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that		

	decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.		
Article 24(4)			
291	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.		
Article 24(5)			
292	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.		
Article 24(6)			
293	6. A delegated act adopted pursuant to Article 23 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.		
Chapter IX			
294	Chapter IX ENFORCEMENT AND PENALTIES	One delegation expressed concerns on enforcement for third countries; one delegation questioned the effectiveness of national sanctions. → PRES scheduled this for discussion at the 2 nd WP	
Article 25			
295	Article 25 Enforcement The Agencies shall cooperate with Member States' enforcement		

	authorities and exchange information on the compliance, by business operators and laboratories, with the obligation to notify studies in accordance with Article 22.		
Article 26			
296	Article 26 Penalties for non-compliance		
Article 26(1)			
297	1. Member States shall introduce penalties for non-compliance, by business operators and laboratories, with the obligations laid out in Article 22 and shall take all necessary measures to ensure that they are implemented. The penalties provided for shall be effective, proportionate, and dissuasive.		
Article 26(2)			
298	2. Member States shall notify the Commission of those rules and of those measures by 30 June 2025 and shall notify to the Commission without delay any subsequent amendment affecting them.		
Article 27			
299	Article 27 Entry into force and application in time This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.		
Formula			
300	This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels, For the European Parliament For the Council The President The President		

	Presidency proposals: amendments (~~deletions~~ / additions)	Presidency proposals: follow-up or proposal to work on amendments, or requests for written comments	Reactions from the Commission and MS
Annex I			
301	Annex I UNION ACTS REFERRED TO IN ARTICLES 2, 3, 8, 11, 12, 15, 17, 21, 22 AND 23 Reference to each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.		
302	1. Council Directive 91/271/EEC of 21 May 1991 concerning urban wastewater treatment (OJ L 135, 30.5.1991, p. 40)		
303	2. Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources (OJ L 375,		

	31.12.1991, p.1)		
304	3. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1)		
305	4. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste		
306	5. Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11)		
307	6. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50)		
308	7. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34)		
309	8. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for the Community action in the field of water policy (OJ L 327, 22.12.2000, p.1)		
310	9. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate		

	release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1)		
311	10. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p. 1)		
312	11. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10)		
313	12. Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51)		
314	13. Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1)		
315	14. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29)		
316	15. Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (OJ L 309, 26.11.2003, p. 1)		
317	16. Regulation (EC) No 853/2004 of the European		

	Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55)		
318	17. Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1)		
319	18. Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1)		
320	19. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)		
321	20. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3)		
322	21. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 070, 16.3.2005, p. 1)		
323	22. Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant		

	Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC (OJ L 033, 4.2.2006, p. 1)		
324	23. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19)		
325	24. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)		
326	25. Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9)		
327	26. Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26)		
328	27. Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an		

	Infrastructure for Spatial Information in the European Community (INSPIRE) (OJ L 108, 25.4.2007, p. 1)		
329	~~28. Regulation (EC) No 108/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 39, 13.2.2008, p. 11)~~	One delegation highlighted the fact that regulation 108/2008 is mentioned in point 28 of Annex I, whereas this regulation is already covered by regulation 1925/2006 mentioned in point 26 of Annex I. →PRES proposes to amend the text (deleting point 28).	
330	29. Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19)		
331	30. Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1)		
332	31. Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3)		
333	32. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive		

	2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84)		
334	33. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)		
335	34. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)		
336	35. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC, and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p.7)		
337	36. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16)		
338	37. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91,		

	Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34)		
339	38. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energyrelated products		
340	39. Regulation (EC) No 401/2009 of the European Parliament and of the Council of 23 April 2009 on the European Environment Agency and the European Environment Information and Observation Network (OJ L 126, 21.5.2009, p. 13)		
341	40. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3)		
342	41. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1)		
343	42. Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (OJ L 300, 14.11.2009, p. 1)		
344	43. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009		

	concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)		
345	44. Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71)		
346	45. Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28)		
347	46. Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community ecomanagement and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC (OJ L 342, 22.12.2009, p. 1)		
348	47. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)		
349	48. Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17)		

350	49. Regulation (EC) No 66/210 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel (OJ L 027, 30.1.2010, p. 1)		
351	50. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)		
352	51. Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18)		
353	52. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)		
354	53. Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.7.2012, p. 1)		
355	54. Directive 2012/19/EU of the European Parliament		

	and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38)		
356	55. Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the import and export of hazardous chemicals (OJ L 201, 27.7.2012, p. 60)		
357	56. Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35)		
358	57. Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (OJ L 96, 29.3.2014, p. 1)		
359	58. Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1)		

360	59. Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006 (OJ L 150, 20.5.2014, p. 195)		
361	60. Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1)		
362	61. Directive (EU) 2016/2284 of the European Parliament and of the Council of 14 December 2016 on the reduction of national emissions of certain atmospheric pollutants, amending Directive 2003/35/EC and repealing Directive 2001/81/EC (OJ L 344, 17.12.2016, p. 1)		
363	62. Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council		



	Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 095, 7.4.2017, p. 1)		
364	63. Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1)		
365	64. Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008 (OJ L 137, 24.5.2017, p. 1)		
366	65. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).		
367	66. Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing		

	Regulation (EC) No 2003/2003 (OJ L 170, 25.6.2019, p. 1)		
368	67. Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45)		
369	68. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435, 23.12.2020, p. 1)		
370	69. Regulation (EU) .../... of the European Parliament and of the Council on nature restoration (OJ .../ELI: ... [OP: please add number and publication reference].		
371	70. Regulation (EU) .../... of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (OJ .../ELI: ... [OP: please add number and publication reference]		
ANNEX II			
372	ANNEX II UNION ACTS REFERRED TO IN ARTICLES 2, 3, 12, 17 AND 23 AND REFERENCE VALUES REFERRED TO IN ARTICLE 8		
Part 1			
373	Part 1 - Specific data on relevant active substances to be identified in accordance with Article4(5)(b) falling under the scope of this Regulation for the purposes of		

	Article 3 for human and veterinary medicinal products		
374	1. Non-clinical safety data, including data related to environmental risk assessments, compiled pursuant to Directive 2001/83/EC of the European Parliament and of the Council¹ and Regulation (EC) No 726/2004 of the European Parliament and of the Council²; ¹ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67). ² Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).		
375	2. Data related to environmental risk assessments, compiled pursuant to Regulation (EU) 2019/6 of the European Parliament and of the Council³; and ³ Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).		
376	3. Maximum residue levels data compiled pursuant to Regulation (EC) No 470/2009 of		



	the European Parliament and of the Council⁴. ⁴ Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).		
377	These data shall be limited to data submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation. Where relevant, the data held by the EMA resulting from procedures concluded before the entry into force of this Regulation may also be considered for inclusion into the common data platform.		
Part 2			
378	Part 2 - Reference values to be included in the repository of reference values following Article 8(3)		

379	1. Predicted no effect concentrations derived as part of the environmental risk assessment under Directive 2001/83/EC of the European Parliament and of the Council, Regulation (EC) No 726/2004 of the European Parliament and of the Council and Regulation (EU) 2019/6 of the European Parliament and of the Council.		
380	These data shall be limited to data submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation. Where relevant, data held by the EMA resulting from procedures concluded before the date of entry into force of this Regulation shall also be considered for inclusion into the common data platform.		
Annex III			
381	Annex III UNION ACTS REFERRED TO IN ARTICLES 2, 10 AND 23		
382	Reference to each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.		
383	1. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1)		
384	2. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste		

385	3. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50)		
386	4. Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11)		
387	5. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34)		
388	6. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p. 1)		
389	7. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10)		
390	8. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29)		

391	9. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)		
392	10. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3)		
393	11. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1)		
394	12. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19)		
395	13. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)		

396	14. Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38)		
397	15. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84)		
398	16. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)		
399	17. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)		
380	18. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC, and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008,		

	p.7)		
381	19. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16)		
382	20. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34)		
383	~~21. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)~~	Some delegations highlighted the fact that Regulation 1331/2008 is mentioned twice: in points 17 and 21 of Annex III. → PRES proposes to amend the text (deleting this repetition).	
384	22. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3)		
385	23. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energyrelated products		
386	24. Directive 2009/48/EC of the European Parliament		

	and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1)		
387	25. Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer (OJ L 286, 31.10.2009, p. 1)		
388	26. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)		
389	27. Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28)		
390	28. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)		
391	29. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)		
392	30. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)		

393	31. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).		
394	32. Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45)		
395	33. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435, 23.12.2020, p. 1)		
396	34. Regulation (EU) .../... of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (OJ .../ELI: ... [OP: please add number and publication reference].		

PUBLIC

14/03/2024

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the **re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals**

(Text with EEA relevance)



Line nr.		Presidency proposal: amendments (~~deletions~~ /additions)	Presidency justification after WP1: follow-up or proposal to work on amendments, or requests for written comments	Delegates comments/proposals after WP2
1		THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 43, 114, 168(4)(c), 192(1) and 207 thereof, Having regard to the proposal from the European Commission, After transmission of the draft legislative act to the national parliaments, Having regard to the opinion of the European Economic and Social Committee, Having regard to the opinion of the Committee of the Regions, Acting in accordance with the ordinary legislative procedure, Whereas:		
2	Recital 1	The European Green Deal¹ sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability² ('the Strategy') is a crucial delivery of the zero-pollution ambition and introduces the 'one		

		substance, one assessment' approach, which aims to improve the efficiency, effectiveness, coherence, and transparency of safety assessments of chemicals across Union legislation. ¹Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal. COM (2019) 640 final. ²Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment. COM (2020) 667 final		
3	Recital 2	In order to achieve this objective, a part of the scientific and technical work on chemicals performed at Union level in support of Union legislation needs to be consolidated in the relevant Union agencies, while obligations on Union agencies to cooperate for the development of assessment methodologies and exchange of data and information should be introduced. This would simplify the current set-up, improve quality and coherence of safety assessments across Union legislation and ensure more efficient use of existing resources.		
4	Recital 3	The reattribution of certain existing scientific and technical tasks to the	Many concerns were raised during the commenting about:	

		European Chemicals Agency, as well as the attribution of new tasks, were proposed as part of ongoing revisions of Union acts. This horizontal proposal aims to provide for further attribution of tasks in respect of those Union acts which are not in the process of being revised and is necessary in order to ensure that the European Chemicals Agency is involved in tasks pertaining to its expertise and developed capacities on chemicals. This is in line with the ‘one substance, one assessment’ aim to ensure that technical and scientific work is performed by the appropriate Union agency, benefiting from demonstrated experience and established tools in its field. The proposal for a Regulation is accompanied by a proposal for a Directive for the amendment of Directive 2011/65/EU of the European Parliament and of the Council³, aiming to achieve the same objectives. ³Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency	Concerns on ECHA’s capacity, budget (including budget for technical and infrastructure requirements and training), workload, committees, expertise to take on the extra tasks. This relates amongst others to the expertise of committee members (and not only the number of experts), potential establishment of technical expert groups (and how they relate to the Committees’ role), what is to be left for the founding regulation, potential targeted REACH amendments, ECHA and committees expertise in medical devices and in POP-waste. Some specific elements for discussion: One delegation proposed it would be more appropriate to assign the task(s) to prepare opinions to ECHA, and allow ECHA to best determine the most efficient and appropriate way to deliver a robust opinion. For example, ECHA’s technical experts could draft opinions and establish technical expert working groups to consult with in order for scientific opinions to be delivered. In certain cases, the Executive Director can still use their powers under REACH’s Article 77 (3) to issue a request to RAC and SEAC, thus negating the need for all tasks to have a RAC and/or SEAC opinion. This delegation also prefers that the legislative package makes provisions for	

			ECHA to prepare opinions in some circumstances without the explicit need for those opinions to be drafted by RAC and SEAC. In addition, they explained that their concern is with the capacity of the individual members to deliver the expected workload, even if both Committees were at full capacity. Therefore, they see a need for provisions to be included to allow for amending the composition of the current ECHA's committees to cover also any ad-hoc Article 77(3) requests in light of requests from the Executive Director. Finally, the inclusion of remuneration for Committee Rapporteurs for all tasks needs to be provided for. They also recommend the OSOA legislation package amends Article 85 and 87 of REACH to provide for additional experts to cover the additional work and its associated remuneration. PRES: Discussion took place during WP2	
5	Recital 4	As part of the coordinated consolidation and attribution of tasks under the 'one substance, one assessment' approach, provisions to allocate a mandate to the European Medicines Agency to develop and cooperate on the development of assessment methodologies, standard		

		formats and controlled vocabularies and exchange of data and information on chemicals have been introduced in Article 138(1), subparagraphs (zd) and (ze), as well as new procedures for ensuring the coherence between scientific opinions in Article 139 of the proposal for a Regulation amending Union pharmaceutical legislation.⁴ ⁴Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006, COM(2023) 193 final. [OJ: <i>Please insert correct reference once the Regulation is adopted</i>].		
6	Recital 5	To ensure the coherence of methodologies for assessments related to chemicals at Union level, all relevant Union agencies should have an equal mandate to develop such methodologies in the areas falling within their respective missions and should be subject to the same obligations to cooperate amongst each other to develop such methodologies.		
7	Recital 6	To ensure the coherence and efficiency of assessments related to chemicals		

		across Union legislation, it is also important to enable data interoperability and easy exchange of data between the relevant Union agencies, as well as to encourage cooperation on the development of standard formats and controlled vocabularies. Thus, to facilitate data exchange between agencies, any new data formats defined by the European Food Safety Authority or by the European Environmental Agency should be set in cooperation with other relevant Union agencies working on chemicals. To this end, relevant provisions should be introduced in Regulation (EC) No 401/2009 of the European Parliament and of the Council and, in Regulation (EC) No 178/2002 of the European Parliament and of the Council, existing provisions should be strengthened and, where relevant, new ones be introduced. Similar provisions should also be considered to be proposed for a strengthened mandate of the European Chemicals Agency in its founding regulation.		
8	Recital 7	To promote the coherence and efficiency of assessments related to chemicals across Union legislation, steps should be taken by the relevant Union agencies to avoid divergent scientific opinions. Existing cases of divergent opinions have lead to increased uncertainty for operators, as well as to declined public		

		trust in the scientific robustness and coherence of scientific decision making. Proposals to address and strengthen procedures for resolving divergence of scientific opinions concerning the European Medicines Agency with other scientific bodies is proposed as part of the revision of Union pharmaceutical legislation. Similar provisions should also be considered to be proposed for a strengthened mandate of the European Chemicals Agency in its founding regulation, whilst such provisions are not relevant and applicable to the European Environmental Agency, since this agency does not issue scientific opinions on individual chemicals such as to be part in divergent outcomes.		
9	Recital 8	Correspondingly, this Regulation aims to address the eventual divergence between scientific opinions of the European Food Safety Authority and those of other Union agencies. Regulation (EC) No 178/2002 of the European Parliament and Council already contains provisions establishing a procedure to solve divergent scientific opinions. Those resolution procedures should be reinforced, in that the European Food Safety Authority and the other dissenting agency should be bound to make their best effort to resolve the divergence on general scientific issues, and only when they are not able to resolve the		

		divergence, should they refer to risk managers.		
10	Recital 9	In the more specific case of scientific divergence pertaining to the hazard identification of chemical substances, a new procedure enabling the resolution of the divergence should be established. This procedure should enable the Commission to request the European Chemicals Agency, as the Union agency most equipped with expertise and capacity in hazard assessment, as well as long-standing experience with the harmonised classification and labelling process, to develop a proposal for harmonised classification and labelling, in accordance the Regulation (EC) No 1272/2008 of the European Parliament and Council, moving closer to the ‘one substance, one assessment’ vision as regards uniformity of hazard assessments of chemicals across the Union. This possibility should be reflected in the relevant provision providing for the resolution of diverging scientific opinions laid down in Regulation (EC) No 178/2002.		
11	Recital 10	To comply with the obligation laid down in Section 10.4.3 of Annex I to Regulation (EU) 2017/745 of the European Parliament and of the Council ⁵ , the Commission has provided the Scientific Committee on Health,		

		Environmental and Emerging Risks ('SCHEER') with a mandate to prepare guidelines on the benefit-risk assessment of the presence of phthalates which are classified as either carcinogenic, mutagenic or toxic to reproduction category 1A or 1B, or which have endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁶. The SCHEER issued those guidelines in 2019 and the Commission has issued a mandate to the SCHEER to perform a first update of those guidelines. ⁵ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1). ⁶ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives	

		91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1–849).		
12	Recital 11	To comply with the obligation laid out in Section 10.4.4. of Annex I to Regulation (EU) 2017/745, the Commission should mandate the relevant scientific committee to prepare guidelines for substances other than phthalates and which are classified as either carcinogenic, mutagenic or toxic to reproduction category 1A or 1B, or which have endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council.		
13	Recital 12	The European Chemicals Agency already provides scientific advice on chemical substances, including on phthalates, endocrine disruptors and carcinogens, mutagens and reproductive toxicants under Regulation (EC) No 1907/2006. Several key capacities of the agency can be reused, including hazard, risk, exposure and socio-economic assessment capacities, the Committee opinion development and IT capabilities for stakeholder consultation and dissemination. To enable timely future updates on the presence of phthalates and		

		to ensure that the appropriate Union agency develops new guidelines on other substances on the basis of the latest scientific evidence, these tasks should be attributed to the European Chemicals Agency.		
14	Recital 13	Taking account of the new hazard classes and criteria for classification, labelling and packaging of substances introduced by Commission Delegated Regulation (EU) 2023/707 of 19 December 2022⁷, reference to endocrine disruptors for human health, of Category 1, should be specified in 10.4.1., point (b) of Annex I of Regulation (EU) 2017/745 in light of the relevance of that hazard class to the type of substances in medical devices. ⁷ Commission Delegated Regulation (EU) 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures (OJ L 93, 31.3.2023, p. 7–39).		
15	Recital 14	To make best use of the European Chemicals Agency's knowledge and expertise gained through its involvement in the nomination and assessment processes under the Stockholm Convention on Persistent Organic Pollutants, the European Chemicals Agency should, upon request, assist the Commission in complying with its		

		obligation to amend Annexes IV and V to Regulation (EU) 2019/1021⁸. Where the opinion of the Committee for Socio-Economic analysis is required, and in order to allow for the necessary capacity and resources for the effective functioning of that committee, Member States should be given the opportunity to cover for the specific expertise required for the effective performance of the task by nominating experts. In order to ensure that the Committee for Socio-Economic analysis benefits from sufficient resources, when the committee appoints one of their members as a rapporteur, that person, or his employer should be remunerated. ⁸ Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45).		
16	Recital 15	In order to amend certain non-essential elements of Regulation (EU) 2019/1021 of the European Parliament and of the Council, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending Annexes IV and V in order to adapt them to the changes to the list of substances set out in the Annexes to the Stockholm Convention or the Protocol or adapt them to scientific and technical progress.		

17	Recital 16	As part of their reporting obligations under the Regulation (EU) 2019/1021 of the European Parliament and of the Council, Member States must report to the European Chemicals Agency information on the presence of substances listed in Part A of Annex III in the environment. The use of the Information Platform for Chemical Monitoring ('IPCHEM') is encouraged as a means for Member States to comply with their obligations to report that chemical occurrence data and to simplify and reduce their reporting obligations. Where Member States make data available through IPCHEM, they no longer need to report it to the European Chemicals Agency, as the agency may retrieve it from the platform.		
18	Recital 17	The revision of the Directive (EU) 2020/2184 of the European Parliament and of the Council⁹ requires Member States to share with European Environmental Agency all chemical occurrence or monitoring data in water. Additionally, the monitoring data on the presence of POPs in air are already being reported by Member States to the EEA as part of the Union air quality legislation. The proposal for a Regulation of the European Parliament and the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable,		

		accessible, interoperable, and reusable and establishing a monitoring and outlook framework for chemicals¹⁰ will require all chemical occurrence data to be held by the EEA. As a result, chemical occurrence data provided to and held in IPCHEM by the Commission will thus be collected and held by the EEA, instead of by the Commission. Therefore, it is necessary to simplify the reporting obligations for Member States to ensure that, where Member States have already submitted that information to the EEA as part of fulfilling obligations required by the provisions of other pieces of Union environmental legislation, Member States should be considered to have fulfilled their reporting obligations under Regulation (EU) 2019/1021. ⁹ Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast), (OJ L 435, 23.12.2020, p. 1–62). ¹⁰ [OJ Please insert reference once proposal is adopted]		
19	Recital 18	Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 should therefore be amended accordingly,		
20	Articles	HAVE ADOPTED THIS REGULATION:		

21	1	Amendments to Regulation (EC) No 178/2002		
22		Regulation (EC) No 178/2002 is amended as follows:		
23	(1)	in Article 23, the following point (m) is added:		
24		‘(m) to cooperate with the competent bodies in the Member States that carry out similar tasks to those of the Authority and to cooperate with other scientific bodies established under Union law, notably the European Chemicals Agency, the European Medicines Agency, and the European Environment Agency on the provision of relevant scientific opinions, on the exchange of data and information, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and on the development of scientific methodologies for the assessment of chemicals.’;		
25	(2)	Article 30 is replaced by the following:	Question were raised by a delegation on whether the EFSA procedure for risk assessment must not be changed as a result of this proposal and it must be ensured that the assessment of EFSA, and if applicable, other EU authorities are properly and appropriately taken into account by ECHA. How is this ensured by the provisions in Article 30?	

			PRES: Discussion took place during WP2	
26		‘Article 30 Diverging scientific opinions	One delegation requested an example of what could be considered diverging scientific opinions. PRES: Discussion took place during WP2.	
27		1. The Authority shall take the necessary and appropriate measures to monitor and identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks.		
28		2. Where the Authority identifies a potential source of divergence, it shall contact the body concerned in order to ensure that all relevant scientific or technical information is shared and in order to identify the potentially contentious scientific or technical issues. The Authority and the body concerned shall cooperate to resolve the divergence. If the Authority and the body concerned are not able to resolve the divergence, they shall draw up a joint report. The report shall clearly outline the contentious scientific issues and identify the relevant uncertainties in the data and be made publicly available. Where the body concerned is a Union agency or a scientific committee, the		

		Authority shall present the joint report to the Commission.		
29		3. Where relevant, and where the divergence concerns conflicting scientific opinions of the Authority and another Union body or agency on whether a substance fulfils the criteria laid out in Annex I of Regulation (EC) No 1272/2008 of the European Parliament and of the Council ¹¹ , the Commission may request the European Chemicals Agency to prepare a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof following the procedure laid out in Article 37 of Regulation (EC) No 1272/2008. The Authority and the Union body or agency concerned shall co-operate with the European Chemicals Agency in developing that proposal.’.		
30		¹¹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353 31.12.2008, p. 1 – 1355.		
31	2	Amendments to Regulation (EC) No 401/2009	One delegation asked for clarification why the EEA’s cooperation with ECHA is	

			supposed to be regulated in Article 15(5) of the EEA Regulation. Systematically, paragraph 1 with a new letter c seems closer. In addition, it would be clear that paragraph 4 also refers to this cooperation. One delegation has doubts about the impact of the Eionet Network's involvement in this cooperation. PRES: Discussion took place during WP2	
32		Regulation (EC) No 401/2009 is amended as follows:		
33	(1)	in Article 2, the following point (p) is added:		
34		‘(p) to develop assessment methodologies related to chemicals in the fields falling within its mission.’;		
35	(2)	in Article 15, the following paragraph 5 is added:		
36		‘5. The Agency shall cooperate with other scientific bodies established under Union law, notably the European Chemicals Agency, the European Food Safety Authority, and the European Medicines Agency, on the exchange of data and information on chemicals, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and on the development of		

		scientific methodologies for the assessment of chemicals.’.		
37	3	Amendments to Regulation (EU) 2017/745	One delegation questions ECHA’s expertise regarding medical devices. PRES: Discussion took place during WP2	
38		Annex I to Regulation (EU) 2017/745 is amended as follows:		
39	(1)	in Section 10.4.1, point (b) is replaced by the following:		
40		‘(b) substances which are identified as endocrine disruptors for human health, of Category 1, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ¹² and substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council or substances having endocrine disrupting properties relevant to human health identified in accordance with Regulation (EU) No 528/2012.’		
41		¹² Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending		

		Regulation (EC) No 1907/2006(OJ L 353 31.12.2008, p. 1).		
42	(2)	in Section 10.4.2, point (d) is replaced by the following:		
43		‘(d) where applicable and available, the latest relevant guidelines in accordance with Sections 10.4.3. and 10.4.4.’;		
44	(3)	Section 10.4.3 is replaced by the following:		
45		‘10.4.3. Guidelines on phthalates When deemed appropriate based on the latest scientific evidence, but at least every 5 years, the Commission shall request the European Chemicals Agency (ECHA) to update guidelines on the benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in Section 10.4.1., points (a) and (b). The benefit-risk assessment shall consider the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments When appropriate or when requested by the Commission, ECHA shall consult the Committee for Risk Assessment and the Committee for Socio-economic Analysis.’;		
46	(4)	Section 10.4.4 is replaced by the following:		
47		‘10.4.4. Guidelines on other CMR and endocrine-disrupting substances		

		The Commission shall request ECHA to prepare guidelines as referred to in Section 10.4.3. and following the process described therein also for other substances referred to in Section 10.4.1., points (a) and (b), where appropriate.’		
48	4	Amendments to Regulation (EU) 2019/1021	A delegation proposed that Article 4 of the POP Regulation would be amended to give the Commission the possibility to request ECHA to carry out the assessment required to amend the concentration limit values in the Annexes IV and V to the POP regulation It is further proposed (article 13 paragraph 2) that this provision would also introduce the adoption of amendments to Annexes IV and V by means of delegated act. Moreover, they believe that the delegation of legislative powers to the Commission in POP-regulation Article 15 needs further consideration This delegation sees the role of the POP-CA (competent authorities) very important in preparation of the delegated acts. In case the above described amendments would be accepted, what would be the role of the POP-CA in the future? Would the Commission still consult the experts	

			designated by each Member State and closely collaborate with POP-CA before adopting a delegated act? One delegation proposes that ECHA is also given the task to determine limit values and amending Annex I and not only Annexes IV and V to the POP regulation. They also ask whether ECHA will have the knowledge on the impact of adjusting Annex IV values on the waste and recycling phase, while another delegate questions the knowledge of SEAC on waste management. PRES: Discussion took place during WP2. PRES proposes amendments to be made to the proposal. Written comments are welcomed.	
49		Regulation (EU) 2019/1021 is amended as follows:		
50	(1)	Article 8(1) is amended as follows:		
51	(a)	the following point (i) is added:		
52		‘(i) upon request from the Commission, and within 12 months from that request, draw up and ~~provide-submit~~ a report on the human health, environmental and socio-economic impacts of introducing or modifying concentration limit values specified in Annex IV or V.’	One delegation proposes to change ‘draw up and provide a report’ to ‘draw up and submit a report.’ PRES proposed a change to the text.	

53	(2)	Article 8(1a) is added:		
54		‘1a. The report referred to in Article 8(1), point (i), shall contain the following information:		
55		(a) as appropriate, information on human health and environmental impacts of waste consisting of, containing or contaminated with POPs, including impacts on waste management;		
56		(b) information on concentrations and mass flows of POPs in relevant waste streams and on waste treatment and treatment capacities;		
57		(c) an analysis of the impacts of the different concentration limit values considered;		
58		(d) a duly motivated proposal for concentration limit values to be introduced in Annex IV and, as appropriate, in Annex V.		
59		The Agency shall, as soon as it receives the request referred to ~~in the first subparagraph~~ Article 8(1) , point (i), publish on its website a notice that a report on a possible amendment of Annex IV or V will be prepared inviting all interested parties, including waste operators and users of recycled materials, to submit comments within 8 weeks. The Agency shall publish those comments on its website.	One delegation proposed to change the reference, to clarify and to use the same kind of reference as is used in the paragraph above. PRES proposed change accordingly	

60		At the latest 9 months following the submission of the ~~at~~ report <i>referred to in Article (8(1), point (i))</i> , the Committee for Socio-economic Analysis of the Agency, set up pursuant to Article 76(1), point (d), of Regulation (EC) No 1907/2006 shall adopt an opinion on the report and on the concentration limit values proposed therein. For the purpose of adopting an opinion on the report, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.	One delegation proposed to clarify which submission it is referred to given that it is mentioned in several paragraphs earlier in the text. The proposed change would help to clarify this together with a consequential amendment in Article 8(1) point (i) to change the word 'provide' to 'submit' PRES proposed change.	
61		The Agency shall submit the report and the opinion of the Committee for the Socio-economic Analysis on the concentration limit values to the Commission without delay.';		
62	(3)	in Article 13, paragraph 2 is replaced by the following:	One delegation further proposed (Article 13 paragraph 2) that this provision would also introduce the adoption of amendments to Annexes IV and V by means of delegated acts. PRES requires further clarification (potential text proposal).	
63		'2. Where a Member State shares the information referred to in paragraph 1, point (e), with the European Environmental Agency, that Member State shall indicate that in the report and the Member State shall be considered to have fulfilled its reporting obligations under that point.		

64		Where the information referred to in paragraph 1, point (e), is contained in the report of a Member State provided to the Agency, the Agency shall transmit the information to the European Environmental Agency for compiling, storing and sharing that information’;		
65	(4)	in Article 15, paragraph 2 is replaced by the following:		
66		‘2. The Commission is empowered to adopt delegated acts in accordance with Article 18, to amend Annexes IV and V to this Regulation to adapt them to the changes to the list of substances set out in the Annexes to the Convention or the Protocol or to adapt them to scientific and technical progress.’	One delegation proposed the amendment in order to clarify that the reference is to the Annexes in this Regulation. PRES changed the text. One delegation would like confirmation of the Commission’s obligation to consult MS experts before adopting delegated acts as appears to be provided in Article 18(4) of the POP Regulation. Another delegation considers it of high importance to preserve the expertise of the Meeting of the Competent Authorities for Regulation (EU) 2019/1021 on POPs and would like to know in which stage of the future amendments of the annexes the experts from the CAs will be consulted and whether additional POP experts will be incorporated to SEAC and/or RAC.	

			One delegation asked for the delegation of legislative powers to the COM in POP regulation article 15 to be further considered. They see the role of the POP-CA very important in the preparation of the delegated acts. PRES: Discussion took place during WP2. Written comments are welcome.	
67	(5)	Article 18 is amended as follows:	One delegation suggests no changes to be made to Article 18, they don't want to delegate this regulatory authority to the COM. PRES: Discussion took place during WP2. Written comments are welcome.	
68	(a)	The first sentence of paragraph 2 is replaced by the following:		
69		'2. The power to adopt delegated acts referred to in Articles 4(3), 10(2) and 15 shall be conferred on the Commission for a period of five years from 15 July 2019.'	A delegation considers that this 5-year term is very likely to have passed before the proposed delegation of authority takes effect. Therefore, they suggest adjusting the period in order to have effect in practice. PRES: Discussion took place during WP2. Written comments are welcome.	
70	(b)	The first sentence of paragraph 3 is replaced by the following:		
71		'3. The delegation of power referred to in Articles 4(3), 10(2) and 15 may be		

		revoked at any time by the European Parliament or by the Council.’.		
72	(c)	Paragraph 6 is replaced by the following:		
73		‘6. A delegated act adopted pursuant to Articles 4(3), 10(2) and 15 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object.’.		
74	6	Entry into force		
		This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.		
		Done at Brussels,		
		For the European Parliament The President		
		For the Council The President		

PUBLIC

14/3/2024

Proposal for a
DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
amending Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European
Chemicals Agency
(Text with EEA relevance)



PRESIDENCY PROPOSALS for written comments by 22 March 2024 1 PM

Delegations will find attached a **revised** Presidency compromise proposal on the above-mentioned Proposal.

Changes in comparison to the previous compromise proposal, document COM(2023) 781, are marked in **red bold underline** for additions and in ~~red strikethrough~~ for deletions.

	Commission Proposal	Presidency Justification	Delegations comments
Proposal Title			
1	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL Amending Directive 2011/65/EU control of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency (Text with EEA relevance)		
Formula			
2	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,		
Citation 1			
3	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,		
Citation 2			

4	Having regard to the proposal from the European Commission,		
Citation 3			
5	After transmission of the draft legislative act to the national parliaments,		
Citation 4			
6	Having regard to the opinion of the European Economic and Social Committee ¹		
Footnote 1			
7	¹ OJ C [...], [...], p. [...].		
Citation 5			
8	After consulting the Committee of the Regions,		
Citation 6			
9	Acting in accordance with the ordinary legislative procedure,		
Formula			
10	Whereas:		
Recital 1			

11	(1) The Commission has, in its Communication 'European Green Deal'², set an objective that chemical safety assessments should move towards a process of 'one-substance, one-assessment', calling for more transparent and simpler risk assessment processes in order to reduce the burden on all stakeholders, accelerate decision-making, as well as to increase consistency and predictability of scientific decisions and opinions. The Commission, in its Communication on Chemicals Strategy for Sustainability³ concludes that, in order to achieve that objective, part of the scientific and technical work on chemicals performed at Union level in support of Union legislation needs to be reattributed to the most suitable Union agencies. This would simplify the current set-up, improve quality and coherence of safety assessments across Union legislation, and ensure more efficient use of existing resources.		
Footnote 2			
	² Communication from the Commission to the European		

12	Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal (COM (2019) 640 final of 11 December 2019).		
Footnote 3			
13	³ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment (COM (2020) 667 final of 14 October 2020).		
Recital 2			
14	(2) The reattribution of certain scientific and technical tasks to the European Chemicals Agency is necessary in order to align processes and levels of scientific scrutiny and digitalisation with current standards and processes of the European Chemicals Agency. This is also necessary in order to ensure a consistent standard of scientific quality, transparency, data searchability and interoperability, in line with		

	the 'one-substance, one-assessment' ambition.		
Recital 3			
15	(3) Directive 2011/65/EU of the European Parliament and of the Council ⁴ contains two procedures related to the assessment of chemicals: the evaluation of economic operators' applications for granting, renewing or revoking an exemption from the substance restrictions pursuant to Article 5 of that Directive and the review of substances to be added to the list of restricted substances pursuant to Article 6 of that Directive. There is a need to increase transparency by setting detailed procedural steps for the process to review substances for a potential inclusion in the list of restricted substances.		
Footnote 4			
16	⁴ Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment – OJ L 174 1.7.2011, p 88.		

Recital 4

17	(4) Data and information held by the European Chemicals Agency in the context of regulatory processes under Titles VII and VIII of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁵ can be usefully deployed for the assessment of potential substance restrictions and for assessing applications for exemption under Directive 2011/65/EU. Established structures and procedures can help to build on the existing knowledge base, maximise synergies, and make the best use of available expertise and resources.		

Footnote 5

18	⁵ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as		

	well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC - OJ L 396 30.12.2006, p. 1.		
Recital 5			
19	(5) To ensure consistency between the evaluation of economic operators' applications for granting, renewing or revoking an exemption pursuant to Article 5 of the Directive 2011/65/EU, as well as to make the best use of existing chemicals-related expertise, the technical evaluation to assess the justification of such exemption requests should be carried out by the European Chemicals Agency and its committees in close coordination with the Commission.		
Recital 6			
	(6) To ensure that the restriction process referred to Article 6 in Directive 2011/65/EU is consistent with the restriction processes under other legislation related to chemicals, in particular with the substance restriction process laid down in Articles 69		

20	to 73 of Regulation (EC) No 1907/2006, it is necessary to amend Directive 2011/65/EU to formally task the European Chemicals Agency with a role in the restriction process. In the light of experience obtained when carrying out substance reviews, it is essential for the quality of the related technical assessment, and for enabling synergies, to make use of information and tools being used in the context of assessments for chemical restrictions under Regulation (EC) No 1907/2006.		
Recital 7			
21	(7) The two procedures described under Article 5 and Article 6 are applicable at the EU level. National provisions should not deviate from these Articles set in Directive 2011/65/EU.		
Recital 8			
22	(8) For amending procedural provisions under Directive 2011/65/EU, a transitional period of 12 months is necessary to allow for appropriate resource and task allocation for the European Chemicals Agency. That timeframe is considered sufficient		

	to allow for amending procedural provisions under Directive 2011/65/EU, a transitional period of 12 months is necessary to allow for appropriate resource and task allocation for the European Chemicals Agency. That timeframe is considered sufficient to allow potential applicants or Member States to adjust to the modified procedural steps under that Directive.		
Recital 9			
23	(9) Directive 2011/65/EU should therefore be amended accordingly,		
Formula			
24	HAVE ADOPTED THIS DIRECTIVE:		
Article 1			
25	<i>Article 1</i> Amendments to Directive 2011/65/EU Directive 2011/65/EU is amended as follows:		
Article 1(1)			
26	(1)Article 5 is amended as follows:		

Article 1(1), point (a)			
27	(a) paragraphs 3 and 4 are replaced by the following		
Article 1(1), point (a), paragraph 3			
28	'3. An application for granting, renewing or revoking an exemption shall be made to the European Chemicals Agency set up pursuant to Article 75(1) of Regulation (EC) No 1907/2006 ('the Agency') in accordance with Annex V.		
Article 1(1), point (a), paragraph 4a			
29	4. The Agency shall: (a) acknowledge receipt of an application within 15 days of its receipt, stating the date of receipt of the application;		
Article 1(1), point (a), paragraph 4b			
30	(b) verify that the application contains all the elements laid out in Annex V;		
Article 1(1), point (a), paragraph 4c			
	(c) if necessary, request the applicant to complete the application <u>within 45 days of</u>	Change proposed based on the comments from two delegations.	

31	<u>receipt of the application</u>, and provide an appropriate deadline <u>of maximum 60 days</u>;	One delegation suggested replacing the word “appropriate” with a specific deadline in order to improve legal certainty for the actors concerned. They motivated that this would also ensure that current applications are published on the Agency’s website in a timely manner. Additionally, other delegation motivated that the applicant should be given a deadline within which the application should be completed, since the exemption continue to apply during the process of evaluation of the application. The 45 days and 60 days were proposed based on the deadlines given in REACH Article 69 (4) for restrictions proposals, as there are no similar deadlines under the authorisation scheme in REACH. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(1), point (a), paragraph 4d			
32	(d) make the application and any supplementary information supplied by the applicant available to Member States;		
Article 1(1), point (a), paragraph 4e			
33	(e) make a summary of the application and a non-confidential version of the application as submitted by the applicant, as well as the date when the application is		

	considered complete, available to the public on the Agency's website;		
Article 1(1), point (a), paragraph 4f			
34	(f) invite interested parties to submit information within 3 months of its publication on the Agency's website.		
Article 1(1), point (a), paragraph 4			
35	Where the applicant does not complete the application with the missing elements identified by the Agency in compliance with Annex V within the deadline provided in accordance with the first subparagraph, point (c), the Agency may reject such application. The Agency shall establish and communicate to the applicant without undue delay the date when the application is considered complete. Upon receipt of an application, the Agency shall notify the Commission of the application and keep it informed of any of the procedural steps under points (b) to (f).';		
Article 1(1), point (b)			

36	b) the following paragraph 4a is inserted after paragraph 4:		
Article 1(1), point (b), regarding inclusion of article 4a			
37	4a. The Agency shall, after verifying the completeness of the application, request the opinion of the Committee for Socio-economic Analysis, set up pursuant to Article 76(1), point (d) of Regulation (EC) No 1907/2006. It shall request the opinion of the Committee for Risk Assessment, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006, in the case of an application for a new exemption or where otherwise considered appropriate. The Committee for Socio-economic Analysis and, where relevant, the Committee for Risk Assessment:	Two delegations suggested that it needs to be clearer when RAC shall evaluate an application for exemption. Therefore, they considered that it may be good to clarify that RAC shall evaluate applications for renewal of exemptions that have previously been evaluated by external consultants or where there are amendments in the exemption that have not been evaluated before. This would have the effect of increasing consistency between the evaluations. Alternatively, other delegation proposed in their comments to rather assign the tasks to ECHA (and its Expert Groups) than directly to RAC and SEAC. Their proposal was motivated by a concern related to the capacity of SEAC and RAC to perform the tasks under Art. 5 (lack of expertise in RoHS within the Committees, insufficient staff). In their opinion, the proposed change in the text would not preclude the Executive Director from requesting the assistance of the Committees of ECHA on a case-by-case basis. PRES did not modify the proposal and welcomes delegations' views/comments.	

		Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(1), point (b), regarding inclusion of article 4a (a)			
38	(a) shall draw up draft opinions within 9 months of the date the application has been considered complete by the Agency under paragraph 4, point (b);	One delegation proposed to align the deadline for RAC and SEAC for the assessment of exemptions with the authorisation scheme and assessment of authorisation under the REACH-Regulation (Article 64 (1) of the REACH Regulation). Other delegation proposed to specify that the opinions drawn shall be scientific and technical. This proposal is a consequence of their proposal above (line 37 of this document), where it is considered that tasks should be rather assigned to ECHA (and its Expert Groups) than directly to RAC and SEAC. PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(1), point (b), regarding inclusion of article 4a (b)			
39	(b) shall assess whether the criteria in Article 5(1), point (a), are met and shall provide clear guidance to the Commission on		

	granting, renewing or revoking an exemption;		
Article 1(1), point (b), regarding inclusion of article 4a (c)			
40	(c) may request the applicant or third parties to submit, within a specified period, additional information;		
Article 1(1), point (b), regarding inclusion of article 4a (d)			
41	(d) upon adopting the draft opinions, shall communicate those draft opinions to the applicant and shall allow the applicant the opportunity to comment within 4 weeks of the communication of the draft opinions to the applicant;	One delegation proposed to specify that the opinions drawn shall be scientific and technical. This proposal is a consequence of their proposal above (line 37 of this document), where it is considered that tasks should be rather assigned to ECHA (and its Expert Groups) than directly to RAC and SEAC. PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(1), point (b), regarding inclusion of article 4a (e)			
42	(e) shall adopt their final opinions, taking into account the comments from the applicant.		
Article 1(1), point (b), regarding inclusion of article 4a			

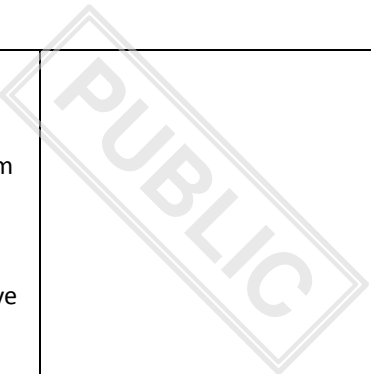
43	Each Committee shall take into account any information submitted by third parties in accordance with the second subparagraph, point (c). The Agency shall send the final opinion(s) of the Committees to the Commission within 12 months from the date an application has been considered complete by the Agency. The Agency shall identify which parts of its opinions and of any attachments thereto should be made publicly available on its website and shall make those parts publicly available on its website. For the purpose of adopting opinions pursuant to this paragraph, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.'	One delegation proposed to align the deadline for RAC and SEAC for the assessment of exemptions with the authorisation scheme and assessment of authorisation under the REACH-Regulation. Therefore, in their view the deadline for sending the final opinion to the Commission should be set to 14 months. This will assure that ECHA will have at least the same time period as is given under Article 64 (5) in REACH, where the Committees shall adopt their final opinion within two months after receiving the comments from the applicant and send it to the Commission within 15 days after this. Additionally, other delegation proposed to specify that the opinions drawn shall be scientific and technical. This proposal is a consequence of their proposal above (line 37 of this document), where it is considered that tasks should be rather assigned to ECHA (and its Expert Groups) than directly to RAC and SEAC. PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(1), point (c)			
44	(c) paragraph 8 is replaced by the following:		

Article 1(1), point (c), paragraph 8

45	8. The Agency shall, in agreement with the Commission, provide a harmonised format for the applications referred to in paragraph 3 of this Article as well as comprehensive guidelines for such applications, taking into account the situation of SMEs. Any submission to the Agency shall be made using the format and the submission tools made available by the Agency.’;	One delegation considered that a clarification is needed in relation to third criterion in Art. 5(1)(a) of the RoHS Directive: <i>‘the total negative environmental, health and consumer protection impact as a result of the substitution is likely to be greater than the total environmental, health and consumer protection benefits thereof’</i>. In their view many exemptions are granted or renewed with reference to this criterion, not infrequently, where the other criteria do not apply i.e. where substitution is possible or reliable alternatives are available, in spite of the weight of substitution in RoHS as reflected in recital 8 <i>the most effective way of ensuring a significant reduction of risks to health and the environment relating to those substances, in order to achieve the chosen level of protection in the Union, is the substitution of those substances in EEE by safe or safer materials</i>. The criterion is often applied based on energy considerations. It is unclear if this was the intention of this criteria and, which weight to assign energy considerations compared to chemicals considerations within the frame of RoHS. In light of the experienced difficulty concerning collection of information from applicants as identified during the RoHS review process, priority should be given to clarifying the applicability of this criterion.	

PUBLIC

		Therefore, there is a need to clarify the applicability of this criteria and it is important that ECHA does so through following this re-attribution of tasks. ECHA should revise this guidance and that the guidance should be adopted by the expert committee (see proposal for reference to this committee in under article 20). PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(2)			
46	(2) in Annex V, the following paragraph is added: 'In cases referred to in the first paragraph, point (h), the applicant shall submit a non-confidential version of the application.'		
Article 1(3)			
47	(3) Article 6 is amended as follows:		
Article 1(3), point (a)			

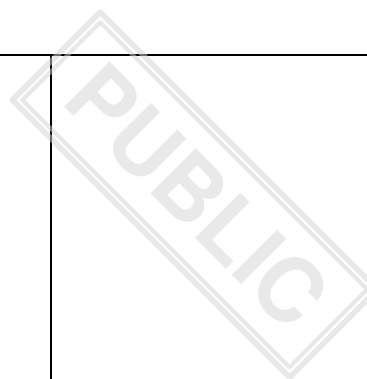
48	(a) in paragraph 1, the first subparagraph is replaced by the following: ‘With a view to achieving the objectives set out in Article 1 and taking account of the precautionary principle, a review, based on a thorough assessment, and an amendment of the list of restricted substances in Annex II shall be considered by the Commission <u>every five years</u> ~~periodically~~ on its own initiative or following the submission of a restriction dossier prepared by a Member State containing the information referred to in paragraph 2.’;	Change proposed based on the comment from one delegation. One delegation considered that the list of substances restricted under the ROHS directive should be evaluated on a more regular basis. Here a 5-year period is suggested. It is not paramount that it should be a 5-year period, however, a timeline is needed. Staff working document p. 119 assesses the impact for ECHA. Here it says: <i>As the assessments are to be done ca. every 5 years.</i> Therefore, a time limit of 5 years is considered appropriate. eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52023SC0850 One delegation proposed also some additional changes (introduction of subparagraph 1a) as they considered that the substances restricted in the POP-regulation, and where the use in EEE is exempted, should be considered for Annex II in the RoHS-Directive. PRES did not modify the proposal and welcomes delegations’ views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(3), point (b)			

49	(b) in paragraph 1, the fourth subparagraph is deleted.		
Article 1(3), point (c)			
50	(c) paragraph 2 is replaced by the following: '2. The review and amendment of the list of restricted substances, <u>or a group of similar substances</u>, in Annex II shall be based on restriction dossiers prepared by the Agency at the request of the Commission or prepared by a Member State. The Agency or a Member State shall take into account any available information and any relevant risk assessment submitted for the purposes of other Union legislation covering the life cycle of the substance used in EEE, in particular the waste phase. To this end, other bodies established under Union law and carrying out a similar task shall, on request, provide information to the Agency or Member State concerned.	Change proposed based on the comment of one delegation. One delegation considered that the reference to the assessment of groups of substances should not be deleted as it is in the current COM's proposal. Additionally, one delegation considered that any relevant assessment, including assessments of waste handling, should be included in a restriction dossier, therefore DK proposed to delete "risk" from the text. PRES did not modify the proposal and welcomes delegations' views/comments. Change based on the proposal of the COM received prior to the 2nd Ad Hoc WP and discussed during that meeting. This proposal intended to accommodate the	

	The restriction dossier shall comply with the requirements set out in Part II, point 3, of Annex XV to Regulation (EC) No 1907/2006 for those requirements that relate to the criteria set out in Article 6(1) and shall, in addition, contain the following information: (a) information on the use of the substance or the group of similar substances in EEE; (b) information on detrimental effects and exposure in particular during waste EEE management operations.'	concern of one delegation regarding re-shifting of focus of assessment required under the RoHS Directive when aligning restriction procedure with the REACH restriction. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(4)			
51	(4) the following Articles 6a, 6b and 6c are inserted:		
Article 1(4), regarding insertion of Article 6a			
52	'Article 6a Initiation of procedure for review and amendment of the list of restricted substances		
Article 1(4), regarding insertion of Article 6a, point (1)			
53	1. Within 12 months of receipt of the request from the Commission referred to in Article 6(2), first subparagraph, the Agency shall prepare a restriction dossier		

	conforming to the requirements referred to in Article 6(2), third subparagraph, and suggest restrictions in order to initiate the restriction process.		
Article 1(4), regarding insertion of Article 6a, point (2)			
54	2. A Member State shall notify the Agency that it proposes to prepare a restriction dossier which conforms to the requirements referred to in Article 6(2), third subparagraph, within 12 months. If that dossier demonstrates that action on a Union-wide basis is necessary, beyond any measures already in place, the Member State shall submit it to the Agency in order to initiate the restriction process.		
Article 1(4), regarding insertion of Article 6a, point (3)			
55	3. The Agency shall publish without delay the intention of the Commission or the Member State to initiate the process to review and amend the list of restricted substances in Annex II <u>on the Agency's website</u> .	Change proposed based on the comment from one delegation and in line with the text proposed in Art. 5 (see line 28 of this document). One delegation considered that it was not clear where the intention to review and amend the list of restricted substances will be published.	

		Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(4), regarding insertion of Article 6a, point (4)			
56	4. The Agency shall establish and maintain a list of substances for which a restriction dossier conforming to the requirements of Article 6(2) is planned or underway by either the Agency or a Member State for the purposes of a proposed restriction.		
Article 1(4), regarding insertion of Article 6a, point (5), paragraph 1			
57	5. The Agency shall consult the Committee for Risk Assessment, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006, and the Committee for Socio-economic Analysis, set up pursuant to Article 76(1), point (d), of that Regulation. The Committees shall verify whether the restriction dossier submitted conforms to the requirements referred to in Article 6(2), third subparagraph.		
Article 1(4), regarding insertion of Article 6a, point (5), paragraph 2			
	Within 30 days of receipt of the restriction dossier, the respective		



58	Committee shall inform the Agency or the Member State proposing restrictions whether the dossier conforms to the requirements referred to in Article 6(2), third subparagraph. If the dossier does not conform to those requirements, the reasons shall be given to the Agency or the Member State in writing within 45 days of receipt of that dossier. The Agency or the Member State shall bring the dossier into conformity within 60 days of the date of receipt of the reasons from the Committees, otherwise the procedure under this Article shall be terminated.		
Article 1(4), regarding insertion of Article 6a, point (6)			
59	Where the dossier meets the requirements referred to in Article 6(2), third subparagraph, the Agency shall make it publicly available without delay, clearly indicating the date of publication. The Agency shall invite all interested parties, including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations to submit, individually or jointly, within 4 months from the date of the		

	publication of the dossier, the following:		
Article 1(4), regarding insertion of Article 6a, point (6a)			
60	(a) comments on dossiers and the suggested restrictions;		
Article 1(4), regarding insertion of Article 6a, point (6b)			
61	(b) a socio-economic analysis including an analysis of alternatives, or information which can contribute to ~~one of~~ the suggested restrictions, examining the advantages and drawbacks of the proposed restrictions.	Changes partially modified based on the comment from one delegation. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(4), regarding insertion of Article 6a			
62	The analysis referred to in the first subparagraph, point (b), shall conform to the requirements in Annex XVI to Regulation (EC) No 1907/2006.	One delegation suggested to delete this text, as they consider that the restriction process in RoHS may be too extensive compared to the restriction process in REACH. They were also concerned that having in mind future revision of the REACH Regulation, it is not clear how the restriction process will look like in the future. PRES did not modify the proposal and welcomes delegations' views/comments.	

		Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(4), regarding insertion of Article 6b			
63	Article 6b Opinion of the Agency's Committees		
Article 1(4), regarding insertion of Article 6b, point (1)			
64	1. Within 12 months from the date of publication referred to in Article 6a(6), the Committee for Risk Assessment shall adopt an opinion as to whether the restriction is appropriate in reducing the risk to human health or the environment, specifically <u>by reference to the risks set out in Article 6(1) for those requirements that relate to the criteria set out in Article 6(1)</u>, third subparagraph, based on its consideration of the relevant parts of the dossier. This opinion shall take account of the restriction dossier prepared by the Agency at the request of the Commission or by the Member State, and the views of interested parties referred to in Article 6a(6), point (a).	Change proposed by PRES to align the text with Article 1(3), point (c) (line 50 of this document). This proposal intended to accommodate the concern of one delegation regarding re-shifting of focus of assessment required under the RoHS Directive when aligning restriction procedure with the REACH restriction. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(4), regarding insertion of Article 6b, point (2)			

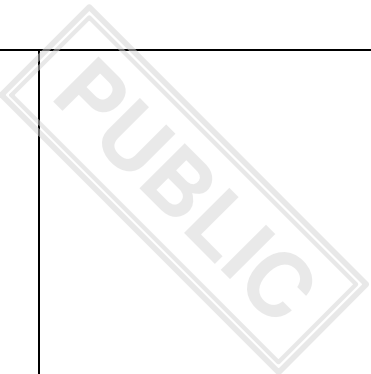
65	2. Within 15 months from the date of publication referred to in Article 6a(6), the Committee for Socio-economic Analysis, shall adopt an opinion on the proposed restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. Prior to that, it shall prepare a draft opinion on the suggested restrictions and on the related socio-economic impact, taking account any existing analysis or information according to Article 6a(6), point (b).		
Article 1(4), regarding insertion of Article 6b, point (3)			
66	3. The Agency shall publish the draft opinion of the Committee for Socio-economic Analysis on its website without delay and invite interested parties to provide their comments on the draft opinion no later than 60 days from its publication.		
Article 1(4), regarding insertion of Article 6b, point (4)			
67	4. The Committee for Socio-economic Analysis shall without delay adopt its opinion, taking into account where appropriate further comments received by		

	the deadline set in paragraph 3. This opinion shall take into account the comments of interested parties submitted under Article 6a(6), point (a), and paragraph 3 of this Article.		
Article 1(4), regarding insertion of Article 6b, point (5)			
68	5. Where the opinion of the Committee for Risk Assessment diverges significantly from the restrictions proposed, the Agency shall postpone the deadline for the opinion of the Committee responsible for Socio-economic Analysis by a maximum of 90 days.		
Article 1(4), regarding insertion of Article 6b, point (6)			
69	6. For the purpose of adopting opinions pursuant to this article, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.	One delegation proposed some additional suggestions to provide for legislative provisions for the remuneration of tasks by Rapporteurs within the OSOA Package. PRES did not modify the proposal, as this is covered by mutatis mutandis application of Art. 87 of Regulation (EC) No 1907/2006 . Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(4), regarding insertion of Article 6c			

70	<i>Article 6c</i> Submission of an opinion to the Commission		
Article 1(4), regarding insertion of Article 6c, point (1)			
71	1. The Agency shall submit to the Commission, without delay, the opinions of the Committees for Risk Assessment and Socio-economic Analysis on the restrictions suggested pursuant to Article 6b. Where the opinions of the Committees for Risk Assessment and Socio-economic Analysis diverge significantly from the restrictions suggested by the dossier, the Agency shall submit an explanatory note to the Commission providing a detailed explanation of the reasons for such differences. If one or both of the Committees do not adopt an opinion by the deadlines set in Article 6b(1) and (2) the Agency shall inform the Commission accordingly, stating the reasons.		
Article 1(4), regarding insertion of Article 6c, point (2)			

72	2. The Agency shall publish the opinions of both Committees on its website without delay.		
Article 1(4), regarding insertion of Article 6c, point (3)			
73	3. The Agency shall, on request, provide the Commission or Member State with all documents and evidence submitted to or considered by it.';		
Article 2			
74	The provisions under this Directive shall be applicable from [OJ: 12 months after the publication of this Directive].		
Article 3			
75	This Directive shall enter into force on the twentieth day following that of its publication in the <i>Official Journal of the European Union</i> .		
Article 4			

76	This Directive is addressed to the Member States. Done at Brussels, <i>For the European Parliament For the Council</i> <i>The President The President</i>		
Additional recommendations (changes proposed regarding articles that were not included in the current COM's proposal)			
Concerning amendments of Article 5(5):			
77	An application for renewal of an exemption shall be made no later than 18 months before the exemption expires.	One delegation proposed extension of the deadline to 24 months as they are concerned that by aligning the exemptions assessment process with REACH, the Commission will be phased with the issue of expediting delegated directives before the expiration of the concerned exemption. Therefore it was suggested to increase the deadline in order to leave more room for the assessment procedure. PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Concerning amendments of Article 20:			

78	Exercise of the delegation 1. The powers to adopt the delegated acts referred to in Article 4(2), Article 5(1) and Article 6 shall be conferred on the Commission for a period of 5 years from 21 July 2011. The Commission shall draw up a report in respect of delegated powers at the latest 6 months before the end of the 5-year period. The delegation of power shall be ~~automatically~~ <u>tacitly</u> extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 21. <u>1a. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of</u>	Change proposed based on the comments from one delegation. The COM agreed to the proposed changes, prior to the 2nd Ad Hoc WP. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	

13 April 2016 on Better Law-Making.

PUBLIC

CYPRUS

Comments on the OSOA legislative package

Cyprus welcomes the three proposals by Commission under the package “One Substance One Assessment”. Cyprus is positive and supportive on the undertaken effort for legislations promoting the green transition, via the creation of central databases and through strengthening the role and the functioning of the European Chemicals Agency (ECHA). The coherence of all the European databases for chemicals will enhance the transparency of this information and ease the access to it. ECHA has correctly been chosen to act as the central European body for gathering and disseminating these data. At the same time, Cyprus resonates with the concerns expressed by other Member States regarding the imperative need to assure ECHA’s efficacy in fulfilling its expanded mandate, through a robust framework of competencies, staffing and financial support. Cyprus is also concerned about the increase on the number of opinions expected to be delivered from the RAC and SEAC committees, especially considering the already extremely high workload of those committees at present.

AUSTRIA

14/03/2024

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the **re-attribution** of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals

(Text with EEA relevance)



Line nr.		Presidency proposal: amendments (~~deletions~~ /additions)	Presidency justification after WP1: follow-up or proposal to work on amendments, or requests for written comments	Delegates comments/proposals after WP2
1		THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 43, 114, 168(4)(c), 192(1) and 207 thereof, Having regard to the proposal from the European Commission, After transmission of the draft legislative act to the national parliaments, Having regard to the opinion of the European Economic and Social Committee, Having regard to the opinion of the Committee of the Regions, Acting in accordance with the ordinary legislative procedure, Whereas:		AT thinks that it is important to clarify the question, why the COM did decide to exclude the veterinary medicinal products Regulation (EU) 2019/6 from the scope of OSOA and how will the legislative gaps be addressed? Veterinary medicinal products are included in the scope of the common data platform, in many instances. However, a revision of the veterinary medicinal products Regulation (EU) 2019/6 is excluded from the scope of the OSOA-approach, although deemed necessary.
2	Recital 1	The European Green Deal¹ sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability² ('the Strategy') is a crucial delivery of the zero-pollution ambition and introduces the 'one		

		substance, one assessment' approach, which aims to improve the efficiency, effectiveness, coherence, and transparency of safety assessments of chemicals across Union legislation. ¹Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal. COM (2019) 640 final. ²Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment. COM (2020) 667 final		
3	Recital 2	In order to achieve this objective, a part of the scientific and technical work on chemicals performed at Union level in support of Union legislation needs to be consolidated in the relevant Union agencies, while obligations on Union agencies to cooperate for the development of assessment methodologies and exchange of data and information should be introduced. This would simplify the current set-up, improve quality and coherence of safety assessments across Union legislation and ensure more efficient use of existing resources.		
4	Recital 3	The reattribution of certain existing scientific and technical tasks to the	Many concerns were raised during the commenting about:	

		European Chemicals Agency, as well as the attribution of new tasks, were proposed as part of ongoing revisions of Union acts. This horizontal proposal aims to provide for further attribution of tasks in respect of those Union acts which are not in the process of being revised and is necessary in order to ensure that the European Chemicals Agency is involved in tasks pertaining to its expertise and developed capacities on chemicals. This is in line with the ‘one substance, one assessment’ aim to ensure that technical and scientific work is performed by the appropriate Union agency, benefiting from demonstrated experience and established tools in its field. The proposal for a Regulation is accompanied by a proposal for a Directive for the amendment of Directive 2011/65/EU of the European Parliament and of the Council³, aiming to achieve the same objectives. ³Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency	Concerns on ECHA’s capacity, budget (including budget for technical and infrastructure requirements and training), workload, committees, expertise to take on the extra tasks. This relates amongst others to the expertise of committee members (and not only the number of experts), potential establishment of technical expert groups (and how they relate to the Committees’ role), what is to be left for the founding regulation, potential targeted REACH amendments, ECHA and committees expertise in medical devices and in POP-waste. Some specific elements for discussion: One delegation proposed it would be more appropriate to assign the task(s) to prepare opinions to ECHA, and allow ECHA to best determine the most efficient and appropriate way to deliver a robust opinion. For example, ECHA’s technical experts could draft opinions and establish technical expert working groups to consult with in order for scientific opinions to be delivered. In certain cases, the Executive Director can still use their powers under REACH’s Article 77 (3) to issue a request to RAC and SEAC, thus negating the need for all tasks to have a RAC and/or SEAC opinion. This delegation also prefers that the legislative package makes provisions for	

			ECHA to prepare opinions in some circumstances without the explicit need for those opinions to be drafted by RAC and SEAC. In addition, they explained that their concern is with the capacity of the individual members to deliver the expected workload, even if both Committees were at full capacity. Therefore, they see a need for provisions to be included to allow for amending the composition of the current ECHA's committees to cover also any ad-hoc Article 77(3) requests in light of requests from the Executive Director. Finally, the inclusion of remuneration for Committee Rapporteurs for all tasks needs to be provided for. They also recommend the OSOA legislation package amends Article 85 and 87 of REACH to provide for additional experts to cover the additional work and its associated remuneration. PRES: Discussion took place during WP2	
5	Recital 4	As part of the coordinated consolidation and attribution of tasks under the 'one substance, one assessment' approach, provisions to allocate a mandate to the European Medicines Agency to develop and cooperate on the development of assessment methodologies, standard		

		formats and controlled vocabularies and exchange of data and information on chemicals have been introduced in Article 138(1), subparagraphs (zd) and (ze), as well as new procedures for ensuring the coherence between scientific opinions in Article 139 of the proposal for a Regulation amending Union pharmaceutical legislation.⁴ ⁴Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006, COM(2023) 193 final. [OJ:Please insert correct reference once the Regulation is adopted].		
6	Recital 5	To ensure the coherence of methodologies for assessments related to chemicals at Union level, all relevant Union agencies should have an equal mandate to develop such methodologies in the areas falling within their respective missions and should be subject to the same obligations to cooperate amongst each other to develop such methodologies.		
7	Recital 6	To ensure the coherence and efficiency of assessments related to chemicals		

		across Union legislation, it is also important to enable data interoperability and easy exchange of data between the relevant Union agencies, as well as to encourage cooperation on the development of standard formats and controlled vocabularies. Thus, to facilitate data exchange between agencies, any new data formats defined by the European Food Safety Authority or by the European Environmental Agency should be set in cooperation with other relevant Union agencies working on chemicals. To this end, relevant provisions should be introduced in Regulation (EC) No 401/2009 of the European Parliament and of the Council and, in Regulation (EC) No 178/2002 of the European Parliament and of the Council, existing provisions should be strengthened and, where relevant, new ones be introduced. Similar provisions should also be considered to be proposed for a strengthened mandate of the European Chemicals Agency in its founding regulation.		
8	Recital 7	To promote the coherence and efficiency of assessments related to chemicals across Union legislation, steps should be taken by the relevant Union agencies to avoid divergent scientific opinions. Existing cases of divergent opinions have lead to increased uncertainty for operators, as well as to declined public		

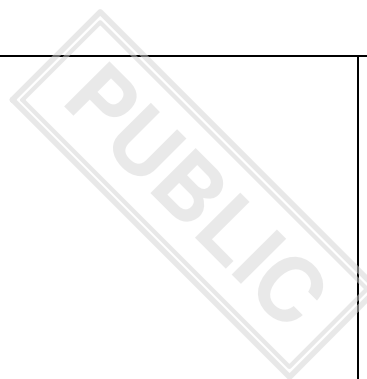
		trust in the scientific robustness and coherence of scientific decision making. Proposals to address and strengthen procedures for resolving divergence of scientific opinions concerning the European Medicines Agency with other scientific bodies is proposed as part of the revision of Union pharmaceutical legislation. Similar provisions should also be considered to be proposed for a strengthened mandate of the European Chemicals Agency in its founding regulation, whilst such provisions are not relevant and applicable to the European Environmental Agency, since this agency does not issue scientific opinions on individual chemicals such as to be part in divergent outcomes.		
9	Recital 8	Correspondingly, this Regulation aims to address the eventual divergence between scientific opinions of the European Food Safety Authority and those of other Union agencies. Regulation (EC) No 178/2002 of the European Parliament and Council already contains provisions establishing a procedure to solve divergent scientific opinions. Those resolution procedures should be reinforced, in that the European Food Safety Authority and the other dissenting agency should be bound to make their best effort to resolve the divergence on general scientific issues, and only when they are not able to resolve the		

		divergence, should they refer to risk managers.		
10	Recital 9	In the more specific case of scientific divergence pertaining to the hazard identification of chemical substances, a new procedure enabling the resolution of the divergence should be established. This procedure should enable the Commission to request the European Chemicals Agency, as the Union agency most equipped with expertise and capacity in hazard assessment, as well as long-standing experience with the harmonised classification and labelling process, to develop a proposal for harmonised classification and labelling, in accordance the Regulation (EC) No 1272/2008 of the European Parliament and Council, moving closer to the ‘one substance, one assessment’ vision as regards uniformity of hazard assessments of chemicals across the Union. This possibility should be reflected in the relevant provision providing for the resolution of diverging scientific opinions laid down in Regulation (EC) No 178/2002.		
11	Recital 10	To comply with the obligation laid down in Section 10.4.3 of Annex I to Regulation (EU) 2017/745 of the European Parliament and of the Council⁵, the Commission has provided the Scientific Committee on Health,		

	Environmental and Emerging Risks ('SCHEER') with a mandate to prepare guidelines on the benefit-risk assessment of the presence of phthalates which are classified as either carcinogenic, mutagenic or toxic to reproduction category 1A or 1B, or which have endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁶. The SCHEER issued those guidelines in 2019 and the Commission has issued a mandate to the SCHEER to perform a first update of those guidelines. ⁵ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1). ⁶ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives	

		91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1–849).		
12	Recital 11	To comply with the obligation laid out in Section 10.4.4. of Annex I to Regulation (EU) 2017/745, the Commission should mandate the relevant scientific committee to prepare guidelines for substances other than phthalates and which are classified as either carcinogenic, mutagenic or toxic to reproduction category 1A or 1B, or which have endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council.		
13	Recital 12	The European Chemicals Agency already provides scientific advice on chemical substances, including on phthalates, endocrine disruptors and carcinogens, mutagens and reproductive toxicants under Regulation (EC) No 1907/2006. Several key capacities of the agency can be reused, including hazard, risk, exposure and socio-economic assessment capacities, the Committee opinion development and IT capabilities for stakeholder consultation and dissemination. To enable timely future updates on the presence of phthalates and		

		to ensure that the appropriate Union agency develops new guidelines on other substances on the basis of the latest scientific evidence, these tasks should be attributed to the European Chemicals Agency.		
14	Recital 13	Taking account of the new hazard classes and criteria for classification, labelling and packaging of substances introduced by Commission Delegated Regulation (EU) 2023/707 of 19 December 2022⁷, reference to endocrine disruptors for human health, of Category 1, should be specified in 10.4.1., point (b) of Annex I of Regulation (EU) 2017/745 in light of the relevance of that hazard class to the type of substances in medical devices. ⁷ Commission Delegated Regulation (EU) 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures (OJ L 93, 31.3.2023, p. 7–39).		
15	Recital 14	To make best use of the European Chemicals Agency's knowledge and expertise gained through its involvement in the nomination and assessment processes under the Stockholm Convention on Persistent Organic Pollutants, the European Chemicals Agency should, upon request, assist the Commission in complying with its		



		obligation to amend Annexes IV and V to Regulation (EU) 2019/1021⁸. Where the opinion of the Committee for Socio-Economic analysis is required, and in order to allow for the necessary capacity and resources for the effective functioning of that committee, Member States should be given the opportunity to cover for the specific expertise required for the effective performance of the task by nominating experts. In order to ensure that the Committee for Socio-Economic analysis benefits from sufficient resources, when the committee appoints one of their members as a rapporteur, that person, or his employer should be remunerated. ⁸ Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45).		
16	Recital 15	In order to amend certain non-essential elements of Regulation (EU) 2019/1021 of the European Parliament and of the Council, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending Annexes IV and V in order to adapt them to the changes to the list of substances set out in the Annexes to the Stockholm Convention or the Protocol or adapt them to scientific and technical progress.		

17	Recital 16	As part of their reporting obligations under the Regulation (EU) 2019/1021 of the European Parliament and of the Council, Member States must report to the European Chemicals Agency information on the presence of substances listed in Part A of Annex III in the environment. The use of the Information Platform for Chemical Monitoring ('IPCHEM') is encouraged as a means for Member States to comply with their obligations to report that chemical occurrence data and to simplify and reduce their reporting obligations. Where Member States make data available through IPCHEM, they no longer need to report it to the European Chemicals Agency, as the agency may retrieve it from the platform.		
18	Recital 17	The revision of the Directive (EU) 2020/2184 of the European Parliament and of the Council⁹ requires Member States to share with European Environmental Agency all chemical occurrence or monitoring data in water. Additionally, the monitoring data on the presence of POPs in air are already being reported by Member States to the EEA as part of the Union air quality legislation. The proposal for a Regulation of the European Parliament and the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable,		

		accessible, interoperable, and reusable and establishing a monitoring and outlook framework for chemicals¹⁰ will require all chemical occurrence data to be held by the EEA. As a result, chemical occurrence data provided to and held in IPCHEM by the Commission will thus be collected and held by the EEA, instead of by the Commission. Therefore, it is necessary to simplify the reporting obligations for Member States to ensure that, where Member States have already submitted that information to the EEA as part of fulfilling obligations required by the provisions of other pieces of Union environmental legislation, Member States should be considered to have fulfilled their reporting obligations under Regulation (EU) 2019/1021. ⁹ Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast), (OJ L 435, 23.12.2020, p. 1–62). ¹⁰ [OJ Please insert reference once proposal is adopted]		
19	Recital 18	Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 should therefore be amended accordingly,		
20	Articles	HAVE ADOPTED THIS REGULATION:		

21	1	Amendments to Regulation (EC) No 178/2002		
22		Regulation (EC) No 178/2002 is amended as follows:		
23	(1)	in Article 23, the following point (m) is added:		
24		‘(m) to cooperate with the competent bodies in the Member States that carry out similar tasks to those of the Authority and to cooperate with other scientific bodies established under Union law, notably the European Chemicals Agency, the European Medicines Agency, and the European Environment Agency on the provision of relevant scientific opinions, on the exchange of data and information, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and on the development of scientific methodologies for the assessment of chemicals.’;		
25	(2)	Article 30 is replaced by the following:	Question were raised by a delegation on whether the EFSA procedure for risk assessment must not be changed as a result of this proposal and it must be ensured that the assessment of EFSA, and if applicable, other EU authorities are properly and appropriately taken into account by ECHA. How is this ensured by the provisions in Article 30?	

			PRES: Discussion took place during WP2	
26		‘Article 30 Diverging scientific opinions	One delegation requested an example of what could be considered diverging scientific opinions. PRES: Discussion took place during WP2.	
27		1. The Authority shall take the necessary and appropriate measures to monitor and identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks.		
28		2. Where the Authority identifies a potential source of divergence, it shall contact the body concerned in order to ensure that all relevant scientific or technical information is shared and in order to identify the potentially contentious scientific or technical issues. The Authority and the body concerned shall cooperate to resolve the divergence. If the Authority and the body concerned are not able to resolve the divergence, they shall draw up a joint report. The report shall clearly outline the contentious scientific issues and identify the relevant uncertainties in the data and be made publicly available. Where the body concerned is a Union agency or a scientific committee, the		

		Authority shall present the joint report to the Commission.		
29		3. Where relevant, and where the divergence concerns conflicting scientific opinions of the Authority and another Union body or agency on whether a substance fulfils the criteria laid out in Annex I of Regulation (EC) No 1272/2008 of the European Parliament and of the Council ¹¹ , the Commission may request the European Chemicals Agency to prepare a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof following the procedure laid out in Article 37 of Regulation (EC) No 1272/2008. The Authority and the Union body or agency concerned shall co-operate with the European Chemicals Agency in developing that proposal.’.		
30		¹¹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353 31.12.2008, p. 1 – 1355.		
31	2	Amendments to Regulation (EC) No 401/2009	One delegation asked for clarification why the EEA’s cooperation with ECHA is	

			supposed to be regulated in Article 15(5) of the EEA Regulation. Systematically, paragraph 1 with a new letter c seems closer. In addition, it would be clear that paragraph 4 also refers to this cooperation. One delegation has doubts about the impact of the Eionet Network's involvement in this cooperation. PRES: Discussion took place during WP2	
32		Regulation (EC) No 401/2009 is amended as follows:		
33	(1)	in Article 2, the following point (p) is added:		
34		‘(p) to develop assessment methodologies related to chemicals in the fields falling within its mission.’;		
35	(2)	in Article 15, the following paragraph 5 is added:		
36		‘5. The Agency shall cooperate with other scientific bodies established under Union law, notably the European Chemicals Agency, the European Food Safety Authority, and the European Medicines Agency, on the exchange of data and information on chemicals, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and on the development of		

		scientific methodologies for the assessment of chemicals.’.		
37	3	Amendments to Regulation (EU) 2017/745	One delegation questions ECHA’s expertise regarding medical devices. PRES: Discussion took place during WP2	
38		Annex I to Regulation (EU) 2017/745 is amended as follows:		
39	(1)	in Section 10.4.1, point (b) is replaced by the following:		
40		‘(b) substances which are identified as endocrine disruptors for human health, of Category 1, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ¹² and substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council or substances having endocrine disrupting properties relevant to human health identified in accordance with Regulation (EU) No 528/2012.’		
41		¹² Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending		

		Regulation (EC) No 1907/2006(OJ L 353 31.12.2008, p. 1).		
42	(2)	in Section 10.4.2, point (d) is replaced by the following:		
43		‘(d) where applicable and available, the latest relevant guidelines in accordance with Sections 10.4.3. and 10.4.4.’;		
44	(3)	Section 10.4.3 is replaced by the following:		
45		‘10.4.3. Guidelines on phthalates When deemed appropriate based on the latest scientific evidence, but at least every 5 years, the Commission shall request the European Chemicals Agency (ECHA) to update guidelines on the benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in Section 10.4.1., points (a) and (b). The benefit-risk assessment shall consider the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments When appropriate or when requested by the Commission, ECHA shall consult the Committee for Risk Assessment and the Committee for Socio-economic Analysis.’;		
46	(4)	Section 10.4.4 is replaced by the following:		
47		‘10.4.4. Guidelines on other CMR and endocrine-disrupting substances		

		The Commission shall request ECHA to prepare guidelines as referred to in Section 10.4.3. and following the process described therein also for other substances referred to in Section 10.4.1., points (a) and (b), where appropriate.’		
48	4	Amendments to Regulation (EU) 2019/1021	A delegation proposed that Article 4 of the POP Regulation would be amended to give the Commission the possibility to request ECHA to carry out the assessment required to amend the concentration limit values in the Annexes IV and V to the POP regulation It is further proposed (article 13 paragraph 2) that this provision would also introduce the adoption of amendments to Annexes IV and V by means of delegated act. Moreover, they believe that the delegation of legislative powers to the Commission in POP-regulation Article 15 needs further consideration This delegation sees the role of the POP-CA (competent authorities) very important in preparation of the delegated acts. In case the above described amendments would be accepted, what would be the role of the POP-CA in the future? Would the Commission still consult the experts	

			designated by each Member State and closely collaborate with POP-CA before adopting a delegated act? One delegation proposes that ECHA is also given the task to determine limit values and amending Annex I and not only Annexes IV and V to the POP regulation. They also ask whether ECHA will have the knowledge on the impact of adjusting Annex IV values on the waste and recycling phase, while another delegate questions the knowledge of SEAC on waste management. PRES: Discussion took place during WP2. PRES proposes amendments to be made to the proposal. Written comments are welcomed.	
49		Regulation (EU) 2019/1021 is amended as follows:		
50	(1)	Article 8(1) is amended as follows:		
51	(a)	the following point (i) is added:		
52		‘(i) upon request from the Commission, and within 12 months from that request, draw up and ~~provide~~ submit a report on the human health, environmental and socio-economic impacts of introducing or modifying concentration limit values specified in Annex IV or V.’	One delegation proposes to change ‘draw up and provide a report’ to ‘draw up and submit a report.’ PRES proposed a change to the text.	

53	(2)	Article 8(1a) is added:		
54		‘1a. The report referred to in Article 8(1), point (i), shall contain the following information:		
55		(a) as appropriate, information on human health and environmental impacts of waste consisting of, containing or contaminated with POPs, including impacts on waste management;		
56		(b) information on concentrations and mass flows of POPs in relevant waste streams and on waste treatment and treatment capacities;		
57		(c) an analysis of the impacts of the different concentration limit values considered;		
58		(d) a duly motivated proposal for concentration limit values to be introduced in Annex IV and, as appropriate, in Annex V.		
59		The Agency shall, as soon as it receives the request referred to ~~in the first subparagraph~~ Article 8(1) , point (i), publish on its website a notice that a report on a possible amendment of Annex IV or V will be prepared inviting all interested parties, including waste operators and users of recycled materials, to submit comments within 8 weeks. The Agency shall publish those comments on its website.	One delegation proposed to change the reference, to clarify and to use the same kind of reference as is used in the paragraph above. PRES proposed change accordingly	AT thinks that term "<i>users of recycled materials</i>" is unclear. We question the necessity of adding this term and ask for clarification as to who is encompassed by it. Additionally, AT believes that a deadline for ECHA to publish the comments of all interested parties on its website should be added.

60		At the latest 9 months following the submission of ~~the~~ report <i>referred to in Article (8(1), point (i))</i> , the Committee for Socio-economic Analysis of the Agency, set up pursuant to Article 76(1), point (d), of Regulation (EC) No 1907/2006 shall adopt an opinion on the report and on the concentration limit values proposed therein. For the purpose of adopting an opinion on the report, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.	One delegation proposed to clarify which submission it is referred to given that it is mentioned in several paragraphs earlier in the text. The proposed change would help to clarify this together with a consequential amendment in Article 8(1) point (i) to change the word 'provide' to 'submit' PRES proposed change.	
61		The Agency shall submit the report and the opinion of the Committee for the Socio-economic Analysis on the concentration limit values to the Commission without delay.';		
62	(3)	in Article 13, paragraph 2 is replaced by the following:	One delegation further proposed (Article 13 paragraph 2) that this provision would also introduce the adoption of amendments to Annexes IV and V by means of delegated acts. PRES requires further clarification (potential text proposal).	
63		'2. Where a Member State shares the information referred to in paragraph 1, point (e), with the European Environmental Agency, that Member State shall indicate that in the report and the Member State shall be considered to have fulfilled its reporting obligations under that point.		

64		Where the information referred to in paragraph 1, point (e), is contained in the report of a Member State provided to the Agency, the Agency shall transmit the information to the European Environmental Agency for compiling, storing and sharing that information’;		
65	(4)	in Article 15, paragraph 2 is replaced by the following:		
66		‘2. The Commission is empowered to adopt delegated acts in accordance with Article 18, to amend Annexes IV and V to this Regulation to adapt them to the changes to the list of substances set out in the Annexes to the Convention or the Protocol or to adapt them to scientific and technical progress.’	One delegation proposed the amendment in order to clarify that the reference is to the Annexes in this Regulation. PRES changed the text. One delegation would like confirmation of the Commission’s obligation to consult MS experts before adopting delegated acts as appears to be provided in Article 18(4) of the POP Regulation. Another delegation considers it of high importance to preserve the expertise of the Meeting of the Competent Authorities for Regulation (EU) 2019/1021 on POPs and would like to know in which stage of the future amendments of the annexes the experts from the CAs will be consulted and whether additional POP experts will be incorporated to SEAC and/or RAC.	AT does not support the proposed amendment to empower the Commission to adopt delegated acts to amend Annexes IV and V of the POPs Regulation. We would prefer instead, the ordinary legislative procedure for amending these Annexes to be retained and the wording to remain unchanged. The possible effects of changes made to Annexes IV and V are so far-reaching that severe impacts on the national waste management systems could be expected. Therefore, a thorough involvement of the Member States would be necessary for a smooth application of the regulation at a national level. If an agreement in favour of the ordinary legislative procedure cannot be attained, a delegated act would be acceptable under certain conditions. Like FR, we would like the Commission to confirm that an impact assessment or an analysis of the effects for each amendment to Annexes IV and V will be submitted to ensure the smooth application of the regulation at a national level through these means. This would ensure a solid knowledge base to inform the transitional provisions, which we also consider necessary to assure sufficient treatment of additional POP-waste is possible. This should prevent generators of POP-waste from being forced into illegality due to a lack of waste infrastructure. To ensure this, we propose the following wording for paragraph 4 in the event that an agreement on the ordinary legislative procedure cannot be reached. <i>(4) in Article 15, paragraph 2 is replaced by the following:</i> ‘2. the Commission is empowered to adopt delegated acts in accordance with Article 18, to amend Annexes IV

			One delegation asked for the delegation of legislative powers to the COM in POP regulation article 15 to be further considered. They see the role of the POP-CA very important in the preparation of the delegated acts. PRES: Discussion took place during WP2. Written comments are welcome.	<i>and V to adapt them to the changes to the list of substances set out in the Annexes to the Convention or the Protocol or to adapt them to scientific and technical progress. <u>Before adopting such delegated acts, the Commission shall provide an impact assessment analysing the effects expected due to amendments to Annexes IV and V. The delegated acts shall foresee a sufficiently long transitional period to allow Member States to ensure adequate waste management infrastructure is in place.</u></i>
67	(5)	Article 18 is amended as follows:	One delegation suggests no changes to be made to Article 18, they don't want to delegate this regulatory authority to the COM. PRES: Discussion took place during WP2. Written comments are welcome.	
68	(a)	The first sentence of paragraph 2 is replaced by the following:		
69		'2. The power to adopt delegated acts referred to in Articles 4(3), 10(2) and 15 shall be conferred on the Commission for a period of five years from 15 July 2019.'	A delegation considers that this 5-year term is very likely to have passed before the proposed delegation of authority takes effect. Therefore, they suggest adjusting the period in order to have effect in practice. PRES: Discussion took place during WP2. Written comments are welcome.	
70	(b)	The first sentence of paragraph 3 is replaced by the following:		
71		'3. The delegation of power referred to in Articles 4(3), 10(2) and 15 may be		

		revoked at any time by the European Parliament or by the Council.’.		
72	(c)	Paragraph 6 is replaced by the following:		
73		‘6. A delegated act adopted pursuant to Articles 4(3), 10(2) and 15 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object.’.		
74	6	Entry into force		
		This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.		
		Done at Brussels,		
		For the European Parliament The President		
		For the Council The President		

[illegible]

AUSTRIA

14/3/2024

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

(Text with EEA relevance)



	Presidency proposals: amendments (~~deletions~~ / additions)	Presidency justification after WP1: follow-up or proposal to work on amendments, or requests for written comments	Delegates comments/proposals after WP2
Proposal Title			
1	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals)		General comment by AT: We think that the regulation on the common data platform should in principle ensure that the general public has access to relevant information on the effects of chemicals on health and the environment, while at the same time safeguarding intellectual property rights and protecting the sensitive data of the companies concerned.
Formula			
2	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN		
Citation 1			
3	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114(1) thereof,		
Citation 2			
4	Having regard to the proposal from the European Commission,		
Citation 3			
5	After transmission of the draft legislative act to the national parliaments,		
Citation 4			
6	Having regard to the opinion of the European Economic and Social Committee ¹		
Citation 5			
7	Acting in accordance with the ordinary legislative procedure,		
Formula			
8	Whereas:		

Recital 1			
9	(1) The European Green Deal³⁴ sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability³⁵ is a crucial delivery of this zero-pollution ambition and introduces the 'one substance, one assessment' approach, which aims to improve the efficiency, effectiveness, coherence, and transparency of safety assessments of chemicals across Union legislation. According to that Strategy, 'safe and sustainable by design' criteria should be developed to enable the production and use of chemicals that are safe and sustainable throughout their entire lifecycle. The Strategy also sets out that the interaction between scientific developments and policy-making should be strengthened by means of an early warning system for chemicals to ensure that Union policies address emerging chemical risks as soon as these are identified by monitoring and research, and that a framework of indicators should be developed to monitor the drivers and impacts of chemical pollution and to measure the effectiveness of chemicals legislation. This Regulation aims to implement these objectives.		
Recital 2			
10	(2) The main objective of this Regulation is to increase the level of protection of the environment and human health from the risks arising from hazardous chemicals, as well as to facilitate the functioning of the internal market for chemicals. For that purpose, this Regulation should establish a common data platform data on chemicals ('the common data platform'), to be managed by the European Chemicals Agency ('ECHA'). The common data platform is a digital infrastructure that brings together chemicals data and information generated under the Union chemicals acquis. This Regulation should also establish dedicated services within the common data platform and lay down rules on the accessibility and usability of the data contained in that platform. This Regulation aims to create a common knowledge base on chemicals available to authorities to enable better, complete, coherent and robust scientific assessments of chemicals and their impacts and to ensure the best use of existing information for the purpose of the implementation and the development of Union legislation on chemicals. Moreover, the Regulation aims to provide a one-stop-shop on chemicals data and		

	information in the Union accessible to the general public and, thus, to increase the predictability and the transparency of regulatory processes on chemicals, as well as to strengthen public trust in the robustness of scientific decision-making.		
Recital 3			
11	(3) Under Decision (EU) 2022/591 of the European Parliament and of the Council ³⁶ , harnessing the potential of digital and data technologies to support environmental policy, including by delivering real-time data where possible and information on the state of ecosystems, while increasing efforts to minimise the environmental footprint of these technologies and ensuring transparency, authenticity, interoperability and public accessibility of the data and information is a long-term priority objective. Data and information on chemicals are therefore essential for the proper development and implementation of a Union environmental policy, and specifically of a chemicals policy.		
Recital 4			
12	(4) In its communication of 19 February 2020 on a European strategy for data ³⁷ , the Commission described its vision of a common European data space and highlighted the need for the development of sectoral data spaces in strategic areas, since not all sectors of the economy and society are moving at the same speed. This Regulation aims therefore to build a data space for chemicals by establishing a common data platform on chemicals ('common data platform'), which is also part of the Green Deal data space, as referred to in the European strategy for data. Furthermore, in that strategy, the Commission highlighted several issues concerning the availability of data for the public good, including data availability, data infrastructures and governance, interoperability, as well as the lack of adequate sharing of data between public authorities. This Regulation aims to increase data availability on chemicals by requiring the relevant Union agencies to make data available for integration in the common data platform on chemicals, to promote interoperability of that data by providing for the establishment of standard formats and controlled vocabularies, as well as to facilitate data exchange and use by public authorities to enable them to effectively carry out their regulatory and policy developing tasks.		

Recital 5			
13	(5) This Regulation also aims to implement into the chemicals sector the principles laid out in the proposal for an Interoperable Europe Act ³⁸ by strengthening the cross-border interoperability of network and information systems used to provide or manage public services on chemicals in the Union. This Regulation will contribute to increased cross-border data flows for truly European digital services and broaden the access to publicly available chemicals data for utilisation in other sectors' applications.		
Recital 6			
14	(6) Business operators and Member States' competent authorities are required by various Union acts to submit data and information to a multitude of Union agencies, as well as to the Commission in specific cases. This generates a fragmentation of data and information on chemicals, which are held under various data sharing and use conditions and in different formats. Such fragmentation prevents public authorities, as well as the general public, from having a clear overview of what information is available on individual chemicals or groups of chemicals, of where and how information can be accessed and whether it can be used. This increases the likelihood of inconsistency between various assessments of the same chemical required by various Union acts on chemicals and of damaging the general public's trust in the scientific grounds for Union decisions on chemicals. In order to ensure that data on chemicals is easily findable, accessible, interoperable and usable, the ECHA should establish a common data platform on chemicals. The common data platform on chemicals should serve as a single point of reference and as a broadened and shared evidence base to enable the efficient delivery of coherent hazard and risk assessments of chemicals across various Union acts on chemicals, as well as to enable the timely identification of emerging chemical risks and the drivers and impact of chemical pollution.		
Recital 7			
15	The common data platform should contain chemicals-related data and information held by relevant Union agencies or the Commission generated or submitted as part of the implementation of Union chemicals legislation listed in Annex I. This includes, for instance, all		

	regulatory dossiers or applications submitted to the relevant Union agencies, but also chemicals data on occurrence of chemicals submitted by Member States to Union agencies or the Commission in compliance with their reporting obligations. The common data platform should also include chemicals data and information generated as part of Union, national or international programmes or research activities related to chemicals, where this data and information is held by the Commission or one of the relevant agencies.		
Recital 8			
16	Due to the different nature of the risk and hazard assessments performed under Union acts on medicinal products, when compared to those performed under the main Union acts on chemicals, for medicinal products, only chemicals data related to environmental risk assessments for human and veterinary medicines, non-clinical studies for human medicines and maximum residue limit values the European Medicines Agency ('EMA') holds, as well as specific reference values, should be included in the common data platform. For medicinal active substances, only data on relevant substances should be included. These concern active substances covered by the medicines legislation and also used for other applications regulated by other Union legislation identified in this Regulation, as well as other active substances with particular persistent, bio-accumulative and toxic properties or with a known high level of residues in the environment.	Some delegations expressed the need for a clarification of the scope and meaning of "relevant substances" for active substances → PRES: this is scheduled for discussion at the 2 nd WP	
Recital 9			
17	(9) These data should also be limited to data submitted to the EMA in the context of the relevant procedures that are finalised or submitted after the entry into force of this Regulation. At a later stage, it should also be possible to include in the common data platform, where relevant, data the EMA holds on procedures concluded before the entry into force of this Regulation.		
Recital 10			
18	(10) Due to the sensitivity of the information on the exact chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health or physical effects, submitted to the bodies appointed by the Member States under Article 45 of		

	Regulation (EC) No 1272/2008 of the European Parliament and the Council ³⁹ , that information should not be included in the common data platform. Likewise, due to the commercial sensitiveness of data and information on final cosmetic products, the information related to cosmetic products notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/2009 ⁴⁰ of the European Parliament and of the Council should not be included in the common data platform either. However, chemicals data and information on individual chemical ingredients of cosmetic products should be included in the common data platform.		
Recital 11			
19	(11) To safeguard the ability of the European Commission, of the Union agencies working on chemicals and of the competent Member State authorities (hereinafter 'the Authorities'), to carry out their tasks, documents with chemicals data relating to their internal work or decision-making should in principle not be included in the common data platform.		
Recital 12			
20	(12) In order to respond to the needs of the digital economy and to ensure a high level of protection of the environment and human health, it is necessary to lay down a harmonised framework specifying who is entitled to access and use the chemicals data contained in the common data platform, under which conditions, on what basis, and for which purposes. The Authorities that are entrusted with regulatory tasks related to chemicals should be allowed and encouraged to use the chemicals data and information contained in the common data platform to effectively fulfil their regulatory duties and tasks, in order to improve the effectiveness, efficiency, and coherence of chemicals-related assessments as well as the development of Union chemicals policies.		
Recital 13			
21	(13) Chemicals data and information generated as a result of obligations set by Union acts on chemicals may be protected by		

	confidentiality claims on confidential business information. The public dissemination of such data may affect the commercial interest of private parties. To ensure legal certainty for duty holders and to protect their legitimate expectations, as well as to ensure industry's competitiveness on the internal market, the ECHA, as a manager of the common data platform, should grant differentiated access rights to the data and information contained in the common data platform. To this end, the Authorities should have full access to all chemicals data and information contained in the common data platform, including access to confidential information, while business operators and the general public should have restricted access to that data and information, which does not include access to confidential information.		
Recital 14			
22	(14) When using data contained in the common data platform, the Authorities should respect the originator principle. Under this principle, the confidentiality marking of chemicals data as done by the originator and as correspondingly indicated by the Agency when it provides that data to the common data platform should be respected by the Authorities using that data or information to perform their regulatory functions or fulfil their tasks.		
Recital 15			
23	(15) To ensure the protection of legitimate expectations of duty holders when generating or submitting data or information under the Union acts listed in Annex I, as well as to protect the confidentiality of that information when used by the Authorities, exceptional grounds for disclosing confidential information laid down in the Union acts listed in Annex I should apply only to the disclosure of the data and information submitted or generated in compliance with those acts. For example, under Article 39(4) of Regulation (EC) No 178/2002 of the European Parliament and of the Council⁴¹, where urgent action is essential to protect human health, animal health or the environment, such as in emergency situations, the European Food Safety Authority ('EFSA') may disclose information previously considered confidential under that Regulation and the EFSA is required to make public information,		

	previously considered confidential, that forms part of conclusions of scientific outputs of the EFSA and relates to foreseeable effects on human health, animal health or the environment. Likewise, Article 118 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁴² provides for the possibility for the ECHA to disclose confidential information submitted to it under that Regulation if urgent action is essential to protect human health, safety or the environment, such as in emergency situations.		
Recital 16			
24	(16) Taking into account that the Agencies would be required to store scientific data, which includes confidential and personal data, it is necessary to ensure that such storage is carried out in accordance with a high level of security of information systems and that access to confidential data is auditable.		
Recital 17			
25	(17) While the ECHA should identify and develop the technical functionalities of the common data platform in stages, certain dedicated services should be defined by this Regulation. As such, the common data platform should, in addition to providing access to chemicals-related data made available by the Agencies and the Commission, provide access to the chemicals data and information made available through its dedicated services. These dedicated services should be integrated into the common data platform and consist of the existing Information Platform for Chemical Monitoring ('IPCHEM'), a repository of reference values, a database of study notifications, a database with information on regulatory processes, a database with information on applicable legal obligations, a repository of standard formats and controlled vocabularies, a database on environmental sustainability related data, as well as a dashboard of indicators on chemicals.		
Recital 18			
26	(18) The Commission should adopt an implementation plan identifying initial datasets to be made accessible via the platform and the timeline		

	for their integration, informed by the preparatory work of the Commission and the Agencies ⁴³ . The Commission should set up a governance scheme to support and steer the common data platform's operation and evolution covering the organisation of work structures and coordination between ECHA and data providers, required rules, formats and vocabularies for data integration, and maintain a rolling implementation plan to ensure the progress in identification and integration of new datasets and services for inclusion. The governance scheme should be adopted and updated as necessary by the Commission, after consultation with a newly established platform steering committee composed of representatives from Union agencies and the Commission. In order to ensure uniform conditions for the implementation of the obligations to establish an implementation plan and a governance scheme, implementing powers should be conferred on the Commission.		
Recital 19			
27	(19) The common data platform should serve the widest possible community, with the ability to address new use cases, incorporate new relevant datasets, develop new functionalities, and respond to developing tools and applications.		
Recital 20			
28	(20) In order to bring together all relevant chemicals data and information in the common data platform, the Commission and Union agencies – notably the European Agency for Safety and Health at Work ('EU-OSHA'), the ECHA, the European Environment Agency ('EEA'), the EFSA, and the EMA ('the Agencies'), should act as data providers and make available any such relevant data they have or hold to the ECHA for integration in the common data platform. The Agencies, including the ECHA itself when making its own data available, should provide the necessary standard metadata, contextual information and relevant mapping to the platform's structure, and respect rules on standard formats and controlled vocabularies where available.		
Recital 21			

29	(21) To ensure that an adequate knowledge base on chemicals is available through the common data platform, the Commission should be able to request the Agencies to host, maintain and make available, via the common data platform, data generated as part of Union, national or international programmes or research activities beyond the data already flowing to the Agencies as part of the obligations under the Union acts listed in Annex I. The Commission should make such requests to the Agencies in accordance with their mandates and allocated tasks.		
Recital 22			
30	(22) Some types of data are currently not within the mandate of any of the Agencies. In order to ensure clarity of responsibilities of the Agencies and efficient management of chemicals data, the Agencies should be required to host, maintain and provide specific data types to the common data platform. To this end, the ECHA should host and be a data provider to the common data platform for workplace monitoring data, and the EEA should host and be a data provider to the common data platform for data on indoor air quality and environment monitoring data, as well as data on concentrations of chemicals in human matrices such as blood or urine ('human biomonitoring data').		
Recital 23			
31	(23) To improve the uptake of academic data and to expand the knowledge base for chemicals safety assessments and environmental sustainability impacts of chemicals, researchers or research consortia funded by Union framework programmes should make available, in line with the 'as open as possible, as closed as necessary' principle, any human biomonitoring data they collect or generate resulting from research and development programmes to the EEA and any environmental sustainability data on chemicals or materials they collect or generate to the ECHA.		
Recital 24			
32	(24) The EEA, as the agency responsible for monitoring data and information on chemicals in the environment, should also be		

	responsible for collecting, hosting, and maintaining human biomonitoring data. To the extent that human biomonitoring data constitutes a special category of personal data, namely, health data, the EEA should process that data only where the processing is necessary for reasons of substantial public interest, as required by Article 10(2)(g) of the Regulation (EU) No 2018/1725 of the European Parliament and of the Council ⁴⁴ . This Regulation lays down the cases where there is such substantial public interest in processing human biomonitoring data: namely, where the EEA processes that data to assess the impact of chemicals on human health and the environment, to monitor time and spatial trends in exposure, to develop health risk and impact indicators, to monitor the impact of regulatory intervention, and to support regulatory risk assessments.		
Recital 25			
33	(25) In order to ensure that appropriate safeguards are in place to secure the protection of this sensitive type of personal data, the EEA should only provide anonymised human biomonitoring data to the ECHA for integration in IPCHEM and the common data platform. IPCHEM, currently operated by the Commission, gathers occurrence data on chemicals in different media, including water, soil, indoor and outdoor air, biota, food and feed, humans, and products. In order to take advantage of the integration of various information systems and to ensure that occurrence data on chemicals is made available for use together with the other chemicals data, the ECHA should take over from the Commission the operation of IPCHEM and integrate it in the common data platform as one of its main dedicated services.		
Recital 26			
34	(26) In order to prevent disruption to the existing operation and functioning of the IPCHEM, the ECHA should integrate the IPCHEM in the common data platform together with the data present in IPCHEM at the moment of integration. At the same time, in order to enable optimal hosting and management of occurrence data on chemicals, the Commission should also transfer the data present in IPCHEM to the ECHA, the EEA or the EFSA for hosting and future updating in		

	accordance with their respective mandates. In order to ensure that the ECHA takes over from the Commission the operation of the IPCHEM, integrates it into the common data platform and takes over the initial data sets and sets up adequate data flows, it is necessary to allow the ECHA an appropriate period of time to carry out these actions, of up to 3 years from the date of entry into force of this Regulation.		
Recital 27			
35	In order to promote the use and harmonisation of reference values among risk assessors and risk managers across different Union acts and to facilitate compliance with, and enforcement of, regulatory reference values, the ECHA should establish and maintain a repository of reference values established or adopted under the Union acts listed in Annexes I and II The Agencies should provide the ECHA with reference values they hold or establish as part of their activities. In addition, the ECHA should regularly screen Union acts for reference values adopted under them. To facilitate automatic access of the general public to up-to-date reference values, the ECHA should integrate the repository of reference values in the common data platform as a dedicated service, include in that repository all reference values together with the relevant context data it has received or retrieved and ensure that those values and that context data are machine readable.		
Recital 28			
36	(28) In order to increase transparency, as well as to enable Authorities to have complete prior knowledge of studies commissioned by business operators, irrespective of whether such studies are carried out by the business operator itself or are outsourced, business operators and laboratories should notify to a database of study notifications established and managed by the ECHA the studies on chemicals they commission for compliance with regulatory requirements under the Union acts listed in Annex I. For this purpose, the ECHA should establish and manage a database of study notifications, as a dedicated service of the common data platform, to store the information related to those studies. In order to allow business operators and laboratories sufficient time to prepare the notifications of studies, the obligation to		

	notify studies should only start to apply two years after the date of entry into force of this Regulation.		
Recital 29			
37	(29) Under Regulation (EC) No 178/2002 of the European Parliament and of the Council, business operators and laboratories are obliged to notify to the database of study notifications established and managed by the EFSA the studies they commission to support an application or notification in relation to which Union law contains provisions for the EFSA to provide a scientific output. To avoid overburdening business operators and laboratories, they should therefore not be required to also notify those studies to the database of study notifications established and managed by the ECHA under this Regulation.		
Recital 30			
38	(30) To ensure the coherence between those two study notification mechanisms, as well as to ensure certainty for business operators submitting notifications, the rules on the public dissemination of study notifications should, where relevant, correspond in that the notifications should only be made available through the common data platform EN 27 EN once a corresponding registration, application, notification or other relevant regulatory dossier was submitted to the relevant Union or national institution and a decision on the confidentiality of the data contained in that regulatory dossier was taken by that Union or national institution. In addition, in order to facilitate compliance with the requirement to notify a study, the ECHA and the EFSA should cooperate to ensure a common approach for the identification of notified information in order to facilitate the traceability of studies notified to their respective databases.		
Recital 31			
39	(31) While the study notification obligation established in this Regulation should apply in the context of all the Union acts on chemicals listed in Annex I, the various relevant data collection and safety assessment processes under those acts may vary widely		

	procedurally. The overarching aim of the database of study notifications established under this Regulation should be to bring together information on studies on chemicals being commissioned by business operators, such as to enable a centralised and complete overview of the studies being performed to support regulatory compliance under Union acts on chemicals as listed in Annex I. On the basis of this objective and considering the fact that assessment procedures under Union acts on chemicals in Annex I may vary widely, it would be beyond the scope and aim of this Regulation to amend existing assessment processes set under those Union acts listed in Annex I by imposing additional conditions leading to potential market access consequences not foreseen in those Union acts. Consequently, it is not appropriate to introduce in this Regulation the consequences associated non-compliance with the study notification obligation as laid out in Article 32b of Regulation (EC) No 178/2002 of the European Parliament and of the Council.		
Recital 32			
40	(32) Nevertheless, to ensure compliance with the study notification obligation laid down in this Regulation, and to cater to the specificities of individual assessment processes, where existing, Member States should lay down rules on penalties applicable to the infringement of that obligation and take all necessary measures to ensure that those rules are complied with. Those penalties should be effective, proportionate, and dissuasive, since non-compliance with this Regulation could result in less robust chemicals risk assessments, creating potential risks and consequently adverse effects on human health and the environment.		
Recital 33			
41	(33) In order to facilitate enforcement by Member States, the Agencies responsible for assessing and providing scientific output, including scientific opinions, on regulatory dossiers containing studies subject to notification to ECHA should, where relevant, cooperate and exchange information with the Member State enforcement authorities on the compliance with the obligations laid out in Article 22.		

Recital 34			
42	(34) While Regulation (EC) No 178/2002 of the European Parliament and of the Council also requires the consultation of stakeholders and the public following the notification to the EFSA of studies commissioned for the purposes of the renewal of an authorisation or approval, a similar requirement under this Regulation would lay a disproportionate administrative burden on the ECHA, given the wide scope of the studies that is to be notified under this Regulation.		
Recital 35			
43	(35) A mechanism related to study notifications exists in Regulation (EC) No 1907/2006 of the European Parliament and of the Council. Where registrants are required to perform studies to generate data in accordance with requirements in Annexes IX and X to that Regulation, they must first submit a testing proposal to the ECHA in order to receive a decision requiring them to perform a study. Such decision may also be issued as an outcome of compliance check or substance evaluation under that Regulation. In order to facilitate the transparency, traceability, and effective monitoring of studies commissioned or carried out pursuant to a decision of the ECHA in accordance with Articles 40, 41 or 46 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council, business operators should specify in their notifications of studies under this Regulation that those studies are being commissioned or carried out in compliance with those decisions.		
Recital 36			
44	(36) To strengthen the coordination and cooperation between the different bodies performing chemicals assessments in the Union, and to promote an increased transparency of chemicals assessments, the ECHA should establish and manage a database with information on regulatory processes or activities that are planned, ongoing or completed by Member States, the Commission and Agencies referred to in the Union acts listed in Annex III to this Regulation and integrate it into the common data platform for access by the authorities. The		

	information on such regulatory processes or activities should include at least the substance identity and the identification, status and eventually the outcome of the regulatory process or activity. That information should also be made available without undue delay and kept updated through the assessment process. Once the process or activity has formally started, that information should be shared also publicly on the common data platform.		
Recital 37			
45	(37) The existing 'The EU Chemicals Legislation Finder' ⁴⁵ project managed by the ECHA makes it easier to find and identify legal obligations related to the use of a specific chemical. The project is especially helpful for small and medium sized enterprises in identifying their legal obligations. To reinforce the supportive function of the project for business operators, it should be established on a permanent basis and more Union acts should be included in its scope. For this purpose, the ECHA should collect information on the legal obligations deriving from the Union acts on chemicals listed in Annex I to this Regulation and incorporate that information into the common data platform as a dedicated service.		
Recital 38			
46	(38) In order to ensure the interoperability and comparability of chemicals data and to facilitate their automatic and electronic exchange, the Agencies and the Commission should store chemicals data in adequate and mutually coherent and interoperable formats and use mutually coherent and interoperable controlled vocabularies. Some Union acts listed in Annex I or II set procedures to establish or make available data formats, in particular for the submission of chemicals data by business operators or Member States. Where such procedures do not exist in the Union acts listed in Annex I or II, the Agencies and the Commission should, where relevant, specify appropriate formats for chemicals data they receive and store, avoiding the use of proprietary standards while, as appropriate, using OECD or other internationally agreed formats, making use of existing formats and ensuring interoperability with existing data submission		

	approaches.		
Recital 39			
47	(39) Likewise, the Agencies and the Commission should specify appropriate controlled vocabularies for data they receive and store and, where relevant, integrate them in submission software or formats. Moreover, in order to facilitate a smooth electronic exchange of data through the common data platform, the Agencies and the Commission should agree on the required formats and controlled vocabularies for providing data to the common data platform. Whenever the Agencies or the Commission set formats or controlled vocabularies, they should cooperate with each other to ensure their coherence, consistency and interoperability. In order to ensure uniform conditions for resolving divergences in data formats and controlled vocabularies, implementing powers should be conferred on the Commission.		
Recital 40			
48	(40) In order to promote the interoperability of database systems on chemicals beyond the common data platform, the ECHA should establish a repository of standard formats and controlled vocabularies as part of the common data platform. The Agencies and the Commission should make the formats and controlled vocabularies they set available to the repository and the ECHA should make them available free of charge in electronic formats for use by developers of database systems and the general public.		
Recital 41			
49	(41) The International Uniform Chemical Information Database ('IUCLID') is a software application designed to record, store, maintain and exchange data on chemicals. The ECHA develops and maintains the IUCLID software and the underlying format in collaboration with the Organisation for Economic Cooperation and Development ('OECD'). The IUCLID implements all OECD-harmonised templates, which are harmonised formats agreed at the OECD level to facilitate structured and consistent documentation of test outputs and similar chemicals data. Since chemicals data is being submitted to the ECHA in IUCLID		

	under Union acts such as Regulations (EC) No 1907/2006, (EC) No 1107/200946 and (EU) No 528/201247 of the European Parliament and of the Council, the ECHA is closely involved in the continued development of IUCLID, and IUCLID implements the standard formats agreed at the OECD level, it is appropriate and necessary to require the Commission and the Agencies to use IUCLID for the relevant parts of dossiers under specified Union acts listed in Annex I when they make the data contained in those dossiers available to the ECHA .		
Recital 42			
50	(42) To increase the availability and facilitate the use of information on the environmental performance of chemicals throughout their lifecycle, and to enable a comprehensive assessment of the impacts of chemicals on the environment, the Commission should identify relevant data and information related to the environmental sustainability of chemicals, including, where available, information on their impact on climate change, for integration into the common data platform. Once the Commission has identified the relevant existing datasets on environmental sustainability related data and has designed the relevant related database functionalities, the ECHA should establish a database on environmental sustainability-related data, collect the data as made available by the Commission, the Agencies and, where relevant, by the researchers and research consortia funded by Union framework programmes, and integrate the content of that database into the common data platform as a dedicated service. In order to ensure uniform conditions for the implementation of the obligation to identify relevant environmental sustainability datasets, implementing powers should be conferred on the Commission.		
Recital 43			
51	(43) To monitor the impacts on humans and the environment, including the climate, of exposure to chemicals and to establish a knowledge base to measure the effectiveness of chemicals legislation in protecting human health and the environment, the EEA and the ECHA should jointly develop and regularly, at least every two years, update a set of indicators and present it in the form of a dashboard. The EFSA, the		

	EMA, the EU-OSHA and the Commission shall regularly provide the EEA with any available data falling within their mandate and relevant for the establishment of the indicators. The EEA and the ECHA should integrate this dashboard of indicators into the common data platform.		
Recital 44			
52	(44) To enable the identification and evaluation of emerging chemical risks, the EEA should develop and compile information on early warning signals and draw up an annual summary report to inform regulatory follow-up actions. In its work, the EEA should include its own sources, targeted literature searches and make use of information from national early warning systems. It should also include relevant information made available by the related work of the ECHA, the EFSA, the EU-OSHA, the EMA and their networks, such as the EFSA's task of identifying and collecting information on emerging risks under Regulation 178/2002. The EEA should make the summary report and the underlying data available through the common data platform, ensuring public access and its use for further action on existing and emerging risks. In order to allow the EEA sufficient time to organise the collection of early warning signals and to compile and analyse the initial information the EEA should only deliver the first report six months after the end of the first calendar year after entry into force of this Regulation. This Regulation sets a deadline for the first report and associated data.		
Recital 45			
53	(45) In June 2017, at the Commission' request, the ECHA set up the European Observatory for Nanomaterials ⁴⁸ ('EUON'), which collects existing data and information from databases, registries and studies and generates new data through studies and surveys on nanomaterials on the EU market.		
Recital 46			
54	(46) The ECHA should continue operating the EUON and transform it into an observatory for specific chemicals with potential contribution to emerging chemical risks ('the observatory'), which should cover also		

	other chemicals and innovative (rationally designed complex 'advanced') materials selected by the Commission, using, as appropriate, signals from the early warning and action system. One of the criteria for selecting chemicals for the observatory should be their novelty and disruptive potential that may contribute to an emerging chemical risk. Another criterion for that selection should be the higher degree of uncertainty surrounding them and, due to less regulatory experience regarding those chemicals, the resulting need for additional scrutiny and transparency. The observatory should facilitate regulatory implementation and responsible use of these chemicals by collecting, generating, and disseminating reliable information on selected chemicals' properties, uses and market presence to the general public.		
Recital 47			
55	(47) The observatory should not be regarded as a substitute for required risk management action on any chemical in cases where a hazard or risk has been identified. In order to provide for an efficient and consistent approach for the generation and dissemination of all such additional information, the ECHA should oversee the work of the observatory and make the regularly updated data and information it collects available through the common data platform, or by means of other communication channels, as appropriate. In order to ensure uniform conditions for the implementation of the requirement to select chemicals to be included in the observatory, implementing powers should be conferred on the Commission.		
Recital 48			
56	(48) Under Regulation (EC) No 178/2002, the EFSA is able to commission, in an open and transparent manner, the scientific studies it needs to accomplish its mission, while seeking to avoid duplication with Member States or Union research programmes. The ECHA should also be able to commission studies to obtain adequate data and information on chemicals within its mission, while maintaining the principle that the burden to prove compliance with Union chemicals legislation remains on the duty holder. Furthermore, the ECHA should commission such studies out of its own initiative or at the request of		

	the Commission, with the objective of supporting the effective and efficient implementation and evaluation of Union acts on chemicals within its mandate and contributing the development of a Union chemicals policy.		
Recital 49			
57	(49) In order to adjust the contents of Annexes I and III to technical and scientific progress in the field of chemicals and to bring in the scope of this Regulation new Union acts under which relevant chemicals data and information is generated or submitted, and, where relevant, to expand the specific data types and reference values, listed in Annex II, to be made available by the EMA through the common data platform, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending Annexes I, II and III. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work in relation to the amendment of the Annexes by delegated act, including at expert level through the One-Substance One-Assessment Expert Group, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016 ⁴⁹ . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.		
Recital 50			
58	(50) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States as Member States do not hold the data within the scope of this Regulation and cannot establish a Union wide common data platform, but can rather, by reason of chemicals data and information being hosted at Union level by the Agencies, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as		

	set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.		
Recital 51			
59	(51) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council and delivered an opinion on [OP: Please insert the date of the opinion of the EDPS].		
Formula			
60	HAVE ADOPTED THIS REGULATION:		
Chapter I			
61	Chapter I SUBJECT MATTER, SCOPE AND DEFINITIONS		
Article 1			
62	Article 1 Subject matter and scope		
Article 1(1)			
63	1. This Regulation aims to ensure the efficient delivery of coherent hazard and risk assessments of chemicals where those assessments are required by Union legal acts, to achieve a high level of protection of human health and the environment, to enable the development and use of sustainable chemicals, to ensure the proper functioning of the single market for chemicals, and to improve the Union's citizens' trust in the scientific base for the decisions taken under Union legal acts on chemicals.	One delegation proposed to include SSBD (safe and sustainable by design) as one of the roles for the platform. → PRES propose to work on an amendment introducing explicitly the safe and sustainable by design approach as one of the aims.	
Article 1(2)			
64	2. To achieve the objectives referred to in paragraph 1, this Regulation contains measures to:		
Article 1(2), point (a)			
65	(a) bring together data and information on chemicals and ensure that data and information are easily findable, accessible, interoperable and		

	re-usable;		
Article 1(2), point (b)			
66	(b) keep records of studies commissioned or carried out by business operators in the context of fulfilling their obligations set under Union chemicals legislation;		
Article 1(2), point(c)			
67	(c) establish the widest possible scientific base for the implementation and development of Union legislation and policy on chemicals;		
Article 1(2), point (c)			
68	(d) establish an early warning and action system for emerging chemical risks.		
Article 1(3)			
69	The provisions laid down in this Regulation apply to chemicals data as laid out in Article 3(2).		
Article 2			
70	Article 2 Definitions	One delegation requested amending art.2 to clarify the meaning of “product” in this proposal. One delegation asked what is covered by the term “products” in art.7(1) One delegation requested examples of the meaning of “chemical products” in relation to mixtures, articles, substances. PRES highlights that the term occurs in recital (8), (10),(25),art.3(3), art.7(1), art.22(1). PRES highlights also that while some of those occurrences relates to cosmetic or medicinal products, other occurrences do not refer to a particular regulation and might have overlapping meaning with e.g. articles in REACH, or products under the ESPR. → PRES is working on an amendment proposal.	

Formula			
71	For the purpose of this Regulation, the following definitions shall apply:		
Article 2(1)			
72	1. 'Agencies' means the European Chemicals Agency ('ECHA'), the European Environment Agency ('EEA'), the European Food Safety Authority ('EFSA') and the European Medicines Agency ('EMA') and the European Agency for Safety and Health at Work ('EU-OSHA');		
Article 2(2)			
73	2. 'Authorities' means the European Commission, the competent authorities of the Member States as referred to in any of the Union acts listed in Annexes I and III, and the Agencies, excluding their management boards;		
Article 2(3)			
74	3. 'duty holder' means a natural or legal person responsible for meeting obligations under the Union acts listed in Annex I or II;		
Article 2(4)			
75	4. 'business operators' means duty holders which are private or public undertakings;	One delegation suggests to "use 'economic operators' instead of 'business operators' to ensure alignment with other relevant legislation". PRES highlights that the term "business operator" is used in recital (8),(13),(28),(29),(30),(31),(35),(37),(38), and articles 1(2), 22, 25, and 26. Those articles relates to studies commissioned, studies notifications, and related enforcement/penalties. PRES highlights that the term "duty holder" is defined in art. 2(3) in relation to obligations in acts mentioned in annex I or II. The terms is per se used in recital (13), (15), (48), art 2(4), 15(5), and 17(2). Those later articles relate to the use of the controlled vocabularies, as well as the prohibition for Authorities to use data from the platform to	

		fulfil legal obligations of duty holders. → PRES seeks written comments on the following: ESPR has a definition of “economic operator”: ‘economic operator’ means the manufacturer, the authorised representative, the importer, the distributor, the dealer and the fulfilment service provider. PRES understands that in the present regulation the meaning of it is much more narrow, and relates only to duty holders that at the same time are undertakings. → PRES seeks for agreement that in consequence there is no correspondence with other EU regulations, and thus no amendment here should be done.	
Article 2(5)			
76	5. ‘human biomonitoring data’ means concentrations of chemicals measured in human matrices such as blood or urine;		
Article 2(6)			
77	6. ‘reference value’ means an estimate of a maximum exposure to or emission level of a chemical below which no or only acceptable adverse effects on human health or the environment are expected, or below which risks related to the adverse effects on human health or the environment are considered acceptable or tolerable;	One delegation commented about “acceptable or tolerable” in relation to non-threshold cancerogenic substances. PRES understands that the intention is to avoid that reference values for non-threshold substances are published without mentioning as metadata the actual statistical risk they represent. → PRES proposes to work on an amendment of art 2(6), 8 and 14 for this.	
Article 2(7)			
78	7. ‘originator’ means the Commission, Agency, or Member State competent authority responsible for confidentiality assessments under any Union act listed in Annex I or Annex II;		
Article 2(8)			

79	8. 'originating Union act' means the Union act under which chemicals data and information were generated or submitted;		
Article 2(9)			
80	9. 'controlled vocabularies' means standardised and organised arrangements of words and phrases presented as lists of terms or as thesaurus and taxonomies with a hierarchical structure of broader and narrower terms;		
Article 2(10)			
81	10. 'chemicals data' means any representation of facts or information relating to chemicals and any compilation of such facts or information, including information on physico-chemical properties, hazard properties, use, exposure, risk, occurrence, emissions and manufacturing process of the chemicals, as well as environmental sustainability related information, including climate change related information, on those chemicals, regulatory process-related information on chemicals, standard formats, controlled vocabularies, or any information on applicable legal obligations related to chemicals;		
Article 2(11)			
82	11. 'environmental sustainability related data' means any data relevant for the environmental sustainability assessment of a chemical or material throughout its entire life cycle, including:	One delegation finds this definition vague, and proposes to add an annex (e.g. in Art. 13) which can be updated on a regular basis by means of Delegated Acts. This annex should contain the respective legal acts as well as the associated sustainability information. PRES highlights that the definition here is used in a broader sense than the information available in legal acts (e.g. research in art.5(6), art 13(3) and potentially art.13(4)). → PRES requests written comments on the necessity to add a reference to a new annex IV, containing a list legal acts relevant for environmental sustainability related data. Such a reference would be added here as a new point 2(11)(d) along with related delegated powers in Chapter VIII. → PRES would also like to have comments on the provisions of	AT thanks COM for providing a reply regarding environmental sustainability data. However, we maintain our view, that it is important that the term environmental sustainability data should be well clarified and concretised e.g. also regarding waste. <i>[Previous AT comment: The term "environmental sustainability related data" is very vague and comprehensive. We believe that this term should be clarified and concretised, since the concrete data content will only be defined at EU level in the coming years (e.g. via "eco-design</i>

		art.13(4) as this partially overlaps with the concern raised by one delegation (by having the COM adopting an implementing decision for data not already hosted or hold by agencies/COM or not coming from EU research). Which relevant data are generated through legal acts but are not hold or hosted by COM/agencies listed in this proposal?	<i>requirements" as part of the Eco-design Regulation). Therefore, we suggest adding a reference to an Annex (e.g. in Art. 13) which can be updated on a regular basis by means of Delegated Acts. This annex should contain the respective legal acts as well as the associated sustainability information.</i>
Article 2(11), point (a)			
83	(a) data on resources, including raw materials, water, energy, fossil fuels and land;		
Article 2(11), point (b)			
84	(b) data on emissions, including greenhouse gases, eutrophication-relevant substances, dust and all other polluting substances; and		
Article 2(11), point (c)			
85	(c) data on by-products originating during the chemical's life cycle that can be used as resources for other production processes, including hydrogen and carbon monoxide.		
Article 2(12)			
86	12. 'personal data' means personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679 of the European Parliament and of the Council and as defined in Article 3, ~~point (16), of Regulation (EU) 2018/175~~ point (1), of Regulation (EU) 2018/1725 of the European Parliament and of the Council;	One delegation highlighted that this definition is specified in Article 3, point (1) of Regulation 2018/1725 and not in Article 3, point (16) of Regulation 2018/175. → PRES sees this as an editorial amendment and proposes to modify Article 2 (12) consequently.	
Article			

2(13)			
87	13. 'processing' means processing as defined in Article 4, point (2), of Regulation (EU) 2016/679 of the European Parliament and of the Council and as defined in Article 3, point (3), of ~~Regulation (EU) 2018/175~~ Regulation (EU) 2018/1725 of the European Parliament and of the Council;	One delegation highlighted that the reference is to Regulation 2018/1725 and not to Regulation 2018/175. → PRES sees that this is an editorial amendment and proposes to modify Article 2 (13) consequently.	
Article 2(14)			
88	14. 'data controller' means controller as defined in Article 4, point (7), of Regulation (EU) 2016/679 and as defined in Article 3, point (8), of ~~Regulation (EU) 2018/175~~ Regulation (EU) 2018/1725 of the European Parliament and of the Council;	One delegation highlighted that the reference is to Regulation 2018/1725 and not to Regulation 2018/175. → PRES sees that this is an editorial amendment and proposes to modify Article 2 (14) consequently.	
Article 2(15)			
89	15. 'interoperability' means the ability of two or more data spaces or communication networks, systems, products, applications or components to exchange and use data in order to perform their functions.	One delegation asked if advanced programming interfaces (API) will be used. PRES highlights that API are tools that MSs may use amongst others in order to query the data platform from their own advanced knowledge management systems (i.e. machine readability) instead of relying on "manual" queries in a web interface like in ECHA web site today. PRES highlights that in the explanatory memorandum the COM mentions that "The proposal also contributes to the objectives of EU data and digital policies by promoting interoperability and machine readability ". However only interoperability is explicitly mentioned here. → PRES requests written comments on this and on the necessity to amend the proposal to explicitly mention APIs and the conditions of their use for MS and the public.	
Chapter			

II			
90	Chapter II INFORMATION SYSTEMS AND PLATFORMS		
Article 3			
91	Article 3 Common Data Platform on Chemicals		
Article 3(1)			
92	1. The ECHA shall establish and manage a common data platform on chemicals ('the common data platform').		
Article 3(2)			
93	2. The common data platform shall provide access to all chemicals data:	One delegation highlights that it is difficult to assess the exhaustiveness of annexes I and III. PRES request written comments on any potentially missing relevant regulations in those annexes. One delegation questioned the differentiated approach between medicinal products and biocidal and phytopharmaceutical products. → PRES would like to receive further clarity in writing.	
Article 3(2), point (a)			
94	(a) generated or submitted as part of the implementation of the Union acts listed in Annex I to this Regulation and held by the Agencies or the Commission;		
Article 3(2), point (b)			
95	(b) generated as part of Union, national or international programmes or research activities in the sphere of chemicals and held by the ECHA, the EEA, the EFSA, the EU-OSHA or the Commission;		

Article 3(2), point (c)			
96	(c) listed in Annex II and held by the EMA;		
Article 3(3)			
97	3. The following information shall not be included in the common data platform:		
Article 3(3), point (a)			
98	(a) the information referred to in Article 45 of Regulation (EC) No 1272/2008 ⁵⁰ , 50 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).		
Article 3(3), point (b)			
99	(b) the information related to cosmetic products and notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/2009 ⁵¹ of the European Parliament and of the Council. 51 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November on cosmetic products (OJ L 342 22.12.2009, p. 59).		
Article 3(4)			
100	4. Documents relating to Authorities' internal work or decision-making processes need not be included in the common data platform, unless required under Article 10.		
Article 3(5)			

101	5. The common data platform shall provide the dedicated services identified in the governance scheme referred to in Article 4(3) including:		
Article 3(5), point (a)			
102	(a) the Information Platform for Chemical Monitoring ('IPCHEM') referred to in Article 7;		
Article 3(5), point (b)			
103	(b) the repository of reference values referred to in Article 8;		
Article 3(5), point (c)			
104	(c) the database of study notifications referred to in Article 9;		
Article 3(5), point (d)			
105	(d) information on regulatory processes referred to in Article 10;		
Article 3(5), point (e)			
106	(e) information on obligations under Union chemicals legislation referred to in Article 11;		
Article 3(5), point (f)			
107	(f) the repository of standard formats and controlled vocabularies referred to in Article 12;		
Article 3(5), point (g)			
108	(g) the database on environmental sustainability-related data referred to in Article 13.		

Article 3(6)			
109	6. The Authorities and the general public shall have access to the data contained in the common data platform in accordance with Article 16.		
Article 3(7)			
110	7. The data contained in the common data platform may be used in accordance with Article 17.		
Article 3(8)			
111	8. The data contained in the common data platform shall be made available in standard formats, where developed, and through controlled vocabularies where available.		
Article 3(9)			
112	9. The data contained in the common data platform shall be electronically accessible and searchable. The ECHA shall take measures to ensure a high standard of security appropriate to the security risks at stake for the storage of chemicals data in and transmission of chemicals data to the common data platform. The ECHA shall design the common data platform in a way that guarantees that any access to confidential data is auditable.		
Article 3(10)			
113	10. The Commission or Agency under whose authority chemicals data is included in the common data platform on chemicals shall remain responsible for handling any requests for access to documents made under Regulation (EC) No 1049/2001. 52 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (. OJ L 145, 31.5.2001, p. 43).		
Article 3(11)			
114	11. The common data platform and its dedicated services shall be	One delegation requested clarifications on this paragraph (timing for	

	established by [OP: please insert date: three years after the date of entry into force of this Regulation], unless specified otherwise. The relevant datasets shall be integrated progressively into the common data platform by [OP please insert date: ten years from the date of entry into force of this Regulation] according to the implementation plan referred to in Article 4 (1), first sentence. Upon integration of those datasets in the common data platform, when the ECHA receives chemicals data in accordance with Article 5, it shall make that data available through the common data platform without undue delay.	the notification service, lack of specification of the timing for the rolling plans). This delegation proposed amendments accordingly → PRES: a more general discussion at the 2d WP took place regarding the timelines	
Article 4			
115	Article 4 Implementation plan and governance of the common data platform	One delegation proposed to include new provisions 5a,5b,5c in art.4., requesting that the COM prepares and presents a recommendation on “how to amend legislation listed in the Annexes to this regulation”. → PRES would like to receive written comments on this as it is not clear for us if this means amending the annexes of the data platform proposal, or if the delegation meant to amend the listed regulations. One delegation raised concerns about the wording “implementing” appearing at several places and which is seen as “misleading” with respect to the legal definition of “implementing acts”. → PRES seeks legal advice on this. The Council legal services provided an opinion on this at the 2 nd WP.	
Article 4(1)			
116	1. By [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall adopt and publish an implementation plan identifying datasets for inclusion in the common data platform together with a timeline for their inclusion by means of an implementing decision. Subsequent rolling implementation plans shall be adopted in line with the governance scheme referred to in paragraph 3.	One delegation questioned the procedure for adopting the plan, the consultation procedures and MS involvement. → PRES: WP2 discussion on the desired level of and procedures for MS participation took place.	
Article 4(2)			
117	2. The Commission shall, by means of an implementing decision, establish and manage a platform steering committee, which shall		

	include one representative from the ECHA, one representative from the EEA, one representative from the EFSA, one representative from the EMA, one representative from the EU-OSHA and five representatives from the Commission.		
Article 4(3)			
118	3. The platform steering committee shall advise the Commission in the preparation of the common data platform's governance scheme.		
Article 4(4)			
119	4. The Commission shall adopt and publish the governance scheme referred to in paragraph 3 and any revision thereof by means of an implementing decision		
Article 4(5)			
120	5. That governance scheme shall describe:		
Article 4(5), point (a)			
121	(a) the organisation of the main work structures supporting the development and implementation of the common data platform;		
Article 4(5), point (b)			
122	(b) the preparation and adoption of rolling implementation plans for the common data platform;		
Article 4(5), point (c)			
123	(c) the principles on data governance and the required standard formats, controlled vocabularies and further conditions for the provision of information and context data to the common data platform;		
Article 4(5)			

point (d)			
124	(d) the decision-making procedures for the development of new dedicated services and the inclusion of new functionalities of the platform;		
Article 4(5), point(e)			
125	(e) any other rules or requirements necessary for the operation of the common data platform such as the data update, archiving and deletion policy;		
Article 4(5), point (f)			
126	(f) the operation of the steering committee itself.		
Article 5			
127	Article 5 Data Flows for the purpose of the common data platform		
Article 5(1)			
128	1. At the Commission's request, the Agencies shall host and maintain chemicals data generated as part of Union, national or international legislation, programmes or research activities, corresponding to their mandate and the type of data they already hold.		
Article 5(2)			
129	2. Where the Commission or the Agencies hold data or information referred to in Article 3(2), they shall make that data available to the ECHA, in a standard format, where available, together with the relevant context data as ~~referred to in Article 4(4), point (c).~~ referred to in Article 4(5), point (c). The Commission and the Agencies shall indicate whether that data or information is made available to the public under the originating Union act.	One delegation highlighted that the reference should be to Article 4(5), point (c) and not Article 4(4), point (c). → PRES sees this as an editorial amendment and proposes to modify Article 5(2) consequently.	
Article 5(3)			
130	3. The ECHA shall host and maintain occurrence data related to		

	workplace monitoring.		
Article 5(4)			
131	4. The EEA shall host and maintain human biomonitoring data, occurrence data for the environment and occurrence data related to indoor air quality.	One delegation asked if Commission pursues plans for systematic or regular surveys of indoor air quality data → PRES is requesting written comments on this.	
Article 5(5)			
132	5. Researchers or research consortia funded by Union framework programmes shall make available to the EEA any human biomonitoring data they collect or generate from [OP please insert: date of the entry into force of this Regulation].		
Article 5(6)			
133	6. Researchers or research consortia funded by Union framework programmes shall make available to the ECHA any environmental sustainability data on chemicals or materials they collect or generate from [OP please insert: date of the entry into force of this Regulation].		
Article 5(7)			
134	7. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of the chemicals data provided in accordance with paragraph 2 in the common data platform as well as its publication through that platform.		
Article 5(8)			
135	8. For the purpose of paragraph 2, the Commission and the Agencies shall make chemicals data available to the ECHA without undue delay after collection or receipt of the data, after performance of validity and confidentiality assessments in accordance with applicable rules and once the corresponding dataset has been integrated in the common data platform.		
Article 5(9)			
136	9. The Commission and the Agencies shall ensure that data made available to the ECHA shall be downloadable, machine readable and		

	interoperable. They shall appropriately curate and validate the data before providing them to the ECHA.		
Article 6			
137	Article 6 Human biomonitoring data	→ PRES: given the numerous comments, questions and clarification requests received, PRES set this as a discussion point at the 2 nd WP (8/3), and invites MS and the COM to react to the EDPS recommendations.	
Article 6(1)			
138	1. The EEA shall collect, host, and maintain human biomonitoring data generated within the territory of the EEA's member and cooperating countries.		
Article 6(2)			
139	2. At the latest by [OP please insert date: 3 years after entry into force of this Regulation] the Commission shall transfer any human biomonitoring data it holds to the EEA.		
Article 6(3)			
140	3. The EEA may process human biomonitoring data constituting personal data to support the Commission in its policy making or to support the Agencies in fulfilling their missions.		
Article 6(4)			
141	4. Human biomonitoring data constituting personal data may be processed by the EEA for the following purposes:		
Article 6(4), point (a)			
142	(a) assessing the impact of chemicals on human health and the environment;		
Article 6(4), point (b)			
143	(b) monitoring time and spatial trends in exposure;		
Article			

6(4), point (c)			
144	(c) developing health risk and impact indicators;		
Article 6(4), point (d)			
145	(d) monitoring the impact of regulatory intervention;		
Article 6(4), point (e)			
146	(e) supporting regulatory risk assessments.		
146.a	(f) supporting regulatory risk management	One delegation proposed to add this amendment. PRES understands that HBM data are indeed useful for risk management, e.g. trend analysis will give an idea if policy actions are having an impact or not on reducing exposure → PRES proposes thus to add this paragraph (f)	
Article 6(5)			
147	5. The EEA shall make human biomonitoring data they hold or host publicly available in anonymised form through the Information Platform for Chemical Monitoring.		
Article 6(6)			
148	6. The EEA shall act as data controller for the human biomonitoring personal data it holds or hosts and processes for the purposes referred to ~~in paragraph 2.~~ in paragraph 4.	Some delegations highlighted that the reference should be to para. 4. → PRES sees this as an editorial amendment and proposes to modify art.6(6) in consequence. One delegation proposed to add an additional reference to art.3 and 5 here. → PRES, up to his knowledge, understands that from the definition of a data controller this is logical, but seeks for written opinions on this and will request a legal advice. Discussions at the 2nd WP on the EDPS recommendations might also contribute clarifications on this	

		proposal. One delegation suggested to “include the same reference to Articles 6(3) and 6(4)” → PRES is keen to receive a written rationale for this as it seems to introduce a circular reference in the text.	
Article 7			
149	Article 7 Information Platform for Chemical Monitoring		
Article 7(1)			
150	1. The ECHA shall operate and maintain the Information Platform for Chemical Monitoring containing occurrence data on chemicals across different media, including water, soil, indoor air, outdoor air, biota, food and feed, humans, and products as part of the common data platform.	→ PRES: regarding the meaning of “products”, cfr art.2 (here in line 70).	
Article 7(2)			
151	2. At the latest by [OP please insert date: 3 years after the date of entry into force of this Regulation], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring at that moment to the ECHA for integration in the common data platform.		
Article 7(3)			
152	3. At the latest by [OP please insert date: 3 years after entry into force of this Regulation], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring to the ECHA, the EEA or the EFSA for hosting in accordance with the respective agencies’ mandate and in accordance with Article 5.		
Article 7(4)			
153	4. After the completion of the transfer referred to in paragraph 3, where the Commission or the Agencies host or hold occurrence data on chemicals and related chemicals data, they shall make that data available to the ECHA without undue delay for integration in the Information Platform for Chemical Monitoring.		

Article 7(5)			
154	5. The Commission and Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration and publication of occurrence data and related chemicals data they host or hold through the common data platform.		
Article 7(6)			
155	6. The ECHA shall ensure that the data contained in the Information Platform for Chemical Monitoring is machine readable and downloadable.		
Article 8			
156	Article 8 Repository of reference values	One delegation requested a amendment about the statistical (cancer) risk associated with some reference values. → PRES: see our proposal in art 2(6) here line 77	
Article 8(1)			
157	1. The ECHA shall establish and manage a repository of reference values as part of the common data platform.		
Article 8(2)			
158	2. The ECHA shall include any reference value adopted under Union acts listed in Annex I or Annex II, Part 1, in the repository of reference values without undue delay.		
Article 8(3)			
159	3. For reference values not falling under paragraph 2, the Agencies holding or establishing reference values as part of their activities under Union acts listed in Annex I, or the reference values referred to in Annex II, Part 2, shall make those reference values available to the ECHA, in the standard formats provided for in Article 14, where developed, and without undue delay, for integration in the repository of reference values.		
Article 8(4)			
160	4. For the purpose of paragraph 3, where reference values are included		

	in a regulatory dossier submitted to the Agencies, the Agencies shall share those reference values in the standard formats with ECHA without undue delay and once relevant validity and confidentiality assessments have been completed by the originator in accordance with applicable rules.		
Article 8(5)			
161	5. The ECHA shall ensure that the data contained in the repository of reference values is machine readable.		
Article 9			
162	Article 9 Database of Study Notifications		
Article 9(1)			
163	1. The ECHA shall establish and operate a Database of Study Notifications by [OP please insert date: two years after the date of entry into force of this Regulation].		
Article 9(2)			
164	2. The ECHA shall store in the Database of Study Notifications the data notified to it in accordance with Article 22.		
Article 9(3)			
165	3. The ECHA shall integrate the data contained in the Database of Study Notifications in the common data platform once a corresponding registration, application, notification or other relevant regulatory dossier was submitted to the relevant Union or national institution, agency, or body in accordance with corresponding Union law and after a decision was taken by that Union or national institution, agency, or body on the disclosure of the accompanying studies in accordance with the applicable rules on confidentiality.	One delegation considers that this deserves clarification as it seems to prevent Member States authorities from getting relevant information on notified studies in time. PRES notes that this might be related to enforcement. → PRES seeks further written comments on this → PRES is working on an amendment proposal	AT thanks the COM for clarifying that MS will have access to the database on study notifications, already before a corresponding regulatory dossier is submitted. However, for the sake of clarity, AT would like to ask the COM to explicitly state in Article 9 that Member States have immediate access to the data base of study notifications. <i>[Previous comment: AT considers that the concept of Article 9 (3) needs further discussion, as it seems to prevent Member States</i>

			<i>authorities from getting relevant information on notified studies in time.</i> <i>COM to AT's comments:</i> <i>MS will have access to the database on study notifications, already before a corresponding regulatory dossier is submitted. ECHA will only disseminate (make public to other users than MS through its inclusion in the platform) the information once a regulatory dossier is submitted.]</i>
Article 9(4)			
166	4. The EFSA shall make the data contained in the database referred to in Article 32b of Regulation (EC) No 178/2002 available to the ECHA for integration in the common data platform once it has received a corresponding application and after it has decided on the disclosure of the accompanying studies in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002.		
Article 9(5)			
167	5. The ECHA and the EFSA shall cooperate to ensure a common approach for the identification of information notified to them in accordance with Article 22 of this Regulation and Article 32b of Regulation (EC) No 178/2002, respectively and facilitate the traceability of the studies notified to their respective databases.		
Article 10			
168	Article 10 Information on regulatory processes on chemicals	→ PRES is seeking written comments on one delegation's question about already existing communication channels in certain regulations, related to the stage of evaluation, and the potential need to modify those regulations. → PRES highlights that this might be the case for TRIS notifications.	
Article 10(1)			
169	1. The ECHA shall establish and manage, as part of the common data platform, a new database containing information on regulatory	→ PRES is seeking for written comments on one delegation's comment that it is not clear whether the scope of art 10(1) includes	

	processes on individual substances or groups of substances that are planned, ongoing or have been completed since the entry into force of this Regulation by the Member States or the Union institutions, agencies or committees referred to in the Union acts listed in Annex III.	national regulations processes.	
Article 10(2)			
170	2. Where Member State competent authorities as referred to in any of the Union acts listed in Annex III hold the information referred to in paragraph 1, they shall make that information available to the Union agency responsible under the respective Union act listed in Annex III without undue delay.	→ PRES is seeking for written comments on one delegation's request to clarify the COM reference (during the 1 st WP) to voluntary notifications, including examples.	
Article 10(3)			
171	3. Where the ECHA, EEA, EFSA, EU-OSHA or the Commission hold the information referred to in paragraph 1, they shall make that information available to the ECHA for integration in the common data platform in the standard formats provided for in Article 14 without undue delay and, where relevant, once the responsible agency or the Commission has performed the validity assessment. For each regulatory process or activity, at least the following information shall be included:	→ PRES is seeking written comments on one delegation's question about which information EEA might have to make available to ECHA in this context, as EEA has no competences about chemical products.	
Article 10(3), point (a)			
172	(a) substance identity;		
Article 10(3), point (b)			
173	(b) the Union act and the regulatory process under which the activity takes place;		
Article 10(3), point (c)			
174	(c) submitter or actor responsible for the regulatory process or activity;		
Article			

10(3), point (d)			
175	(d) status of the regulatory process or activity;		
Article 10(3), point (e)			
176	(e) where applicable , outcome of the regulatory process or activity ~~, including, where applicable, and~~ reports or opinions adopted;	PRES understand from one delegation's comment that it is not always possible to indicate the (future) outcome, so this provision is not always applicable. → PRES propose to amend art 10(3) by inserting "where applicable" as we see it more precise than "where appropriate"	
Article 10(3), point (f)			
177	(f) where applicable, date of intention to start the regulatory process or activity, completion and latest update.		
Article 10(4)			
178	4. The information referred to in paragraph 3, points (a) to (f), on a specific regulatory process or activity shall be made available to the public once that process or activity has formally started.		
Article 11			
179	Article 11 Information on the obligations under Union acts on chemicals	PRES notes one delegation's comment on the potentiality of IA in this context.	
Article 11(1)			
180	1. The ECHA shall establish and manage, as part of the common data platform, a database with information on the provisions and legal obligations applicable to chemicals under the Union acts listed in Annex I.		
Article 11(2)			
181	2. The ECHA shall update the information in the database on a regular basis and in accordance with the governance scheme referred to in Article 4(3).		
Article 12			

182	Article 12 Repository of standards formats and controlled vocabularies		
Article 12(1)			
183	1. The ECHA shall establish and manage as part of the common data platform a repository of standard formats and controlled vocabularies.		
Article 12(2)			
184	2. Where standard data formats are established under the Union acts listed in Annexes I and II, the ECHA shall include them in the common data platform.		
Article 12(3)			
185	3. Where the Commission or the Agencies specify a standard format or controlled vocabulary in accordance with Articles 14 or 15, the Commission or the Agency shall make it available to the ECHA without undue delay for integration in the common data platform.		
Article 13			
186	Article 13 Database on environmental sustainability related data	One delegation requested for a new annex on relevant legal acts, see discussion of Article 2(11) → PRES: see line 82 here above About the role of EIONET in this → PRES included this in the discussion at the WP2 (effort needed by MS)	See AT comments for Art. 2 (11)
Article 13(1)			
187	1. At the latest within three years after the publication of the decision referred to in paragraph 4, the ECHA shall establish and manage, as part of the common data platform, a database containing environmental sustainability related data.		
Article 13(2)			
188	2. Where the Commission or the Agencies host or hold environmental sustainability related data in addition to the chemicals data already available in the common data platform, they shall make that data		

	available to the ECHA without undue delay once the Commission or the Agency hosting or holding that data has completed, where relevant, validity and confidentiality assessments. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of environmental sustainability related data in the database on environmental sustainability related data.		
Article 13(3)			
189	3. Where researchers or research consortia funded by Union framework programmes make available to the ECHA, under Article 5(6), any environmental sustainability data on chemicals or materials they collect or generate, the ECHA shall integrate the relevant data in the database on environmental sustainability related data.		
Article 13(4)			
190	4. By [OP please insert date: three years after the date of entry into force of this Regulation], the Commission shall adopt an implementing decision identifying existing datasets on environmental sustainability related data, other than those referred to in paragraph 2, for inclusion in the common data platform and shall design relevant related database functionalities.	→ PRES is seeking legal advice about the wording “implementing decision” (cfr delegation comment). Council legal services provided an opinion on this at the 2 nd WP.	
Chapter III			
191	Chapter III DATA FORMATS AND CONTROLLED VOCABULARIES	→ PRES seeks written comments on one delegation’s request to eventually have study reports and raw data provided → PRES seek written comments on the request by one delegation to investigate that there is no impact on the use of INCI names for cosmetics regulation, and no impact on substance identification and product labelling in that regulation.	AT thinks that it would be beneficial to give all concerned stakeholders, in particular industry, the opportunity to contribute to the development of standard data formats and controlled vocabularies
Article 14			
192	Article 14 Standard formats	One delegation amendment proposal on statistical risk: → PRES: see here Article 2(6) line 77	
Article 14(1)			

193	1. Without prejudice to Union provisions providing for the development or making available of data formats, the Commission and the Agencies shall specify, where relevant, for the data referred to in Article 3 (2) and falling within their mandate, standard formats and software packages and make them available free of charge through the common data platform.		
Article 14(2)			
194	2. The standard formats referred to in paragraph 1 shall, to the extent possible:		
Article 14(2), point (a)			
195	(a) avoid the use of proprietary standards;		
Article 14(2), point (b)			
196	(b) re-use existing data formats or parts of them;		
Article 14(2), point (c)			
197	(c) use OECD or other internationally agreed formats;		
Article 14(2), point (d)			
198	(d) be coherent with other existing data formats;		
Article 14(2), point (e)			
199	(e) ensure interoperability with existing data submission approaches.		
Article 14(3)			
200	3. Those standard formats shall be interoperable with the common data platform and be user-friendly.		
Article 14(4)			

201	4. The Commission and the Agencies shall exchange data contained in the common data platform in the relevant standard format.		
Article 14(5)			
202	5. The Commission and the Agencies shall use the International Uniform Chemical Information Database format (IUCLID) for making available to the ECHA for integration in the common data platform the relevant parts of dossiers under the following Union acts:		
Article 14(5), point (a)			
203	(a) Regulation (EC) No 1831/2003 of the European Parliament and of the Council ⁵³ ; ⁵³ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268 18.10.2003, p. 29).		
Article 14(5), point (b)			
204	(b) Regulation (EC) No 1935/2004 of the European Parliament and of the Council ⁵⁴ ; ⁵⁴ Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338 13.11.2004, p. 4).		
Article 14(5), point (c)			
205	(c) Regulation (EC) No 1331/2008 of the European Parliament and of the Council ⁵⁵ ; ⁵⁵ Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354 31.12.2008, p. 1).		
Article			

14(5), point (d)			
206	(d) Regulation (EC) No 1332/2008 of the European Parliament and of the Council⁵⁶; ⁵⁶ Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354 31.12.2008, p. 7).		
Article 14(5), point (e)			
207	(e) Regulation (EC) No 1333/2008 of the European Parliament and of the Council⁵⁷; ⁵⁷ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354 31.12.2008, p. 16).		
Article 14(5), point (f)			
208	(f) Regulation (EC) No 1334/2008 of the European Parliament and of the Council⁵⁸; ⁵⁸ Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354 31.12.2008, p. 34).		
Article 14(5), point (g)			
209	(g) Regulation (EC) No 1223/2009 of the European Parliament and of the Council ⁵⁹; ⁵⁹ Regulation (EC) No 1223/2009 of the European Parliament and of the		

	Council of 30 November 2009 on cosmetic products (OJ L 342 22.12.2009. p, 59).		
Article 14(5), point (h)			
210	(h) Commission Regulation (EU) No 234/2011 ⁶⁰ ; ⁶⁰ Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 064 11.3.2011, p. 15).		
Article 14(5), point (i)			
211	(i) Directive 2009/48/EC of the European Parliament and of the Council. ⁶¹ ⁶¹ Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170 30.6.2009, p. 1).		
Article 14(6)			
212	6. The Commission and the Agencies shall cooperate when setting standard formats to ensure coherence with other formats and the interoperability of the standard formats with the common data platform and with existing data submission approaches.		
Article 14(7)			
213	7. The Commission and the Agencies shall take the necessary and appropriate measures to monitor and identify at an early stage any potential divergence between data formats that could cause interoperability problems. If a divergence is identified, the Agencies concerned shall cooperate to resolve it or, where the divergence is justified, explain the underlying reasons. Where the Agencies concerned are not able to resolve that divergence, they shall draw up a joint report and present it to the Commission. The report shall clearly outline the reasons for the divergence, clarify any underlying technical		

	issue and make a proposal to remedy the divergence.		
Article 14(8)			
214	8. The Commission shall adopt an implementing decision to remedy the divergence.		
Article 15			
215	Article 15 Controlled vocabularies	→ PRES is seeking written comments on the remarks by one delegation about the difficulties related to differences in vocabularies between legislations. → PRES seeks for comments on the difficulties related to substances identification inconsistencies between regulations (see delegation comment). PRES highlights that this problem is also relevant for art.22,25,26 on studies notification (a lack of correct identification might render difficult to implement them)	AT thinks that it would be beneficial to give all concerned stakeholders, in particular industry, the opportunity to contribute to the development of standard data formats and controlled vocabularies.
Article 15(1)			
216	1. The Commission and the Agencies shall specify and regularly update controlled vocabularies within their mandate for the data referred to in Article 3(2), where relevant.		
Article 15(2)			
217	2. The Commission and the Agencies shall prioritise specifying controlled vocabularies for the identification of chemicals and the characterisation of their forms.		
Article 15(3)			
218	3. Those controlled vocabularies shall:		
Article 15(3), point (a)			
219	(a) avoid the use of proprietary controlled vocabularies to the extent possible;		
Article			

15(3), point (b)			
220	(b) re-use existing substance identifiers and controlled vocabularies or parts of them to the extent possible;		
Article 15(3), point (c)			
221	(c) use OECD or other internationally agreed controlled vocabularies to the extent possible;		
Article 15(3), point (d)			
222	(d) ensure coherence with other relevant controlled vocabularies including by preparing alignment tables.		
Article 15(4)			
223	4. Those controlled vocabularies shall be interoperable with the common data platform.		
Article 15(5)			
224	5. Where controlled vocabularies are specified, the Commission and the Agencies shall:		
Article 15(5), point (a)			
225	(a) make them available free of charge through the common data platform and as open datasets;		
Article 15(5), point (b)			
226	(b) integrate them in any submission software or template to be used by duty holders under the Union acts listed in Annex I and referred to in Article 3(2); and		
Article 15(5),			

point (c)			
227	(c) use them when exchanging data between them through the common data platform.		
Article 15(6)			
228	6. The Commission and the Agencies shall cooperate with each other in setting the controlled vocabularies.		
Article 15(7)			
229	7. The Commission and the Agencies shall take the necessary and appropriate measures to monitor and identify at an early stage any potential divergence between controlled vocabularies. If a divergence is identified, the Agencies concerned shall cooperate to resolve it or, where the divergence is justified, explain the underlying reasons. Where the Agencies concerned are not able to resolve that divergence, they shall draw up a joint report and present it to the Commission. The report shall clearly outline the reasons for the divergence, clarify any underlying technical issue and make a proposal to remedy the divergence.		
Article 15(8)			
230	8. The Commission shall adopt an implementing decision to remedy the divergence.		
Chapter IV			
231	Chapter IV CHEMICALS DATA CONFIDENTIALITY AND USE	→ PRES: some delegation's comments here were discussed at the WP2.	
Article 16			
232	Article 16 Access rights and transparency	→ PRES: One delegation request and questions (line 232 of the comments file) were discussed at the WP2.	
Article 16(1)			
233	1. The Authorities shall have access to all the chemicals data contained in the common data platform, including data which is deemed to be confidential under Article 5(2), second sentence.		

Article 16(2)			
234	2. The Authorities shall take the necessary measures to ensure that information contained in the common data platform marked as confidential in accordance with Article 5(2) is not made public.	→ PRES: One delegation comment and questions were discussed at the WP2 (line 234 of the comments file)	
Article 16(3)			
235	3. The general public shall have access to all the chemicals data contained in the common data platform and considered as available to the public in accordance with the Union act under which the data was generated or submitted.		
Article 17			
236	Article 17 Use of chemicals data contained in the common data platform	One delegation comment on the meaning of “products” is addressed here in art.2 (see line 70). PRES: Regarding the other comments: → PRES seeks written comments on one delegation’s concern on the identification in the data platform of cosmetics ingredients that may have been tested on animals. → PRES invites the COM to update MS on the possibility of an overview table on confidentiality provisions requested by one delegation.	
Article 17(1)			
237	1. The Authorities may use the chemicals data contained in the common data platform in the performance of any of their activities, where those activities support the development or implementation of chemicals legislation and policy.	→ PRES: one delegation requested for amendment to explicitly allow national use of the data was set for discussion at WP2.	
Article 17(2)			
238	2. Without prejudice to existing provisions enabling the sharing and use of chemicals data under the Union acts listed in Annexes I and II, Authorities shall not use chemicals data contained in the common data platform to fulfil any legal obligations of duty holders.	One delegation requested clarifications on the use of data in relation to duty holders obligations. → PRES invites for written comments on this.	
Article 17(3)			

239	3. When using chemicals data contained in the common data platform that is deemed confidential under Article 5(2), second sentence, the Authorities shall respect the confidentiality of information data as marked by the originator and shall not disclose that data to the public without the consent of the originator.		
Chapter V			
240	Chapter V MONITORING AND OUTLOOK FRAMEWORK FOR CHEMICALS		
Article 18			
241	Article 18 Framework of indicators	One delegation questioning the MS involvement was set for discussion at the 2nd WP → PRES put the question on EIONET impacts for discussion at the 2nd WP. One delegation comments on cosmetics: → PRES invites for written comments on questions raised by one delegation on cosmetics aspects (notification of undesirable effects, link to the Communication System for Market Surveillance (ICSMS) Art 23 Reg 1223/2009, consequences on the allowance of use for critical circumstances). One delegation comment on the relation to existing statistics systems → PRES invites for written comments	
Article 18(1)			
242	1. The EEA, in collaboration with the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission, shall establish, operate, and maintain a framework of indicators to monitor the drivers and impacts of exposure to chemicals, measure the effectiveness of chemicals legislation and measure the transition towards the production of safe and sustainable chemicals.		
Article 18(2)			
243	2. The framework of indicators referred to in paragraph 1 shall be		

	accessible in the form of an indicator dashboard, which the EEA shall establish and which the ECHA shall make available through the common data platform.		
Article 18(3)			
243.b	3. The framework of indicators referred to in paragraph 1 shall be established, operated, and maintained by [OP: please insert date: 3 years after the end of the first calendar year after entry into force of this Regulation].	One delegation expressed concerns on the timescale for establishing the framework PRES highlights that several other articles contain indications on the timeframe → PRES submits this amendment for consideration, and discussion took place at the 2nd WP.	
Article 19			
244	Article 19 Early warning and action system for emerging chemical risks	→ PRES: One delegation's question on MS experts and RAC involvement was set for discussion at 2nd WP → PRES: One delegation's request for clarification on implications/role of EIONET and MS was set for discussion at the 2nd WP Regarding the other comments: → PRES seeks written comments about one delegation's question on the relation between the indicators and the early warning system (art.18,19). → PRES invites for written comments on the question regarding the level of ambition of the system in relation to complex systemic risks. → PRES invites written comment on the proposal to include the word "prevention" in the proposal	
Article 19(1)			
245	1. The EEA shall establish, operate and maintain a Union early warning system for emerging chemical risks by [OP please insert date: one year after the date of entry into force of this Regulation].		
Article			

19(2)			
246	2. For the purpose of paragraph 1, the EEA shall compile early warning signals, which shall include at least signals from:		
Article 19(2), point (a)			
247	(a) the EFSA's emerging risks exchange network;		
Article 19(2), point (b)			
248	(b) existing national early warning systems;		
Article 19(2), point (c)			
249	(c) data that the EEA holds;		
Article 19(2), point (d)			
250	(d) targeted literature searches performed by the EEA;		
Article 19(2), point (e)			
251	(e) data made available by the ECHA, the EFSA, the EU-OSHA and the EMA in accordance with paragraph 3.		
Article 19(2)			
252	The early warning signals compiled by the EEA under the first subparagraph may be based on a positive identification of an emerging risk or on an uncertainty in the data leading to a potential positive identification of an emerging risk.		
Article 19(3)			
253	3. The ECHA, the EFSA, the EU-OSHA and the EMA shall identify and gather relevant available data on early warning signals from the field falling within their mandate and provide this data to the EEA.		
Article			

19(4)			
254	4. The EEA shall draw up an annual report, compiling and analysing the data on early warning signals gathered in accordance with paragraphs 2 and 3. [The first report shall be prepared by [OP: please insert date: 6 months after the end of the first calendar year after entry into force of this Regulation]. The EEA shall present this report to the Commission, relevant Union agencies and ~~Member State competent authorities for consideration of the need~~ Member State competent authorities who shall consider the need for regulatory or policy action related to the early warning signals.	One delegation expressed questions the request to EEA to highlight areas on which to FOCUS, in the report. PRES suppose that this may be solved by a change in the wording (mostly editorial) → PRES proposes for consideration a proposed amendment to the text.	
Article 19(5)			
255	5. The EEA shall make all relevant data on early warning signals that it holds or hosts as well as the report referred to in paragraph 4 available to the ECHA for integration in the common data platform.		
Article 20			
256	Article 20 Observatory for specific chemicals with potential contribution to emerging chemical risks	PRES seeks written comments on one delegation's question about the type of risks covered here, and the interplay with existing chemicals legislation.	
Article 20(1)			
257	1. The ECHA shall establish, operate and maintain an observatory for specific chemicals that the Commission considers as requiring additional scrutiny. The observatory shall include reliable information on the chemicals' properties, safety aspects, uses and market presence.		
Article 20(2)			
258	2. By [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall adopt and publish a list of the selected chemicals by means of an implementing decision. The Commission shall review the list of selected chemicals regularly and adopt any revision thereof by the same means.	One delegation highlighted that the linking word "and" is missing before the proposal "adopt any revision thereof by the same means". à PRES sees this as an editorial amendment and proposes to modify article 20(2) consequently (see bold italic). One delegation requested for amendments (implementing "decisions"). → PRES: questions on the meaning of "implementing", and MS	

		participation were discussed at the 2 nd WP.	
Article 20(3)			
259	3. The Commission shall select the chemicals referred to in paragraph 1 based on the scientific and technical progress and using the signals of the early warning system referred to in Article 19. The selection shall include potential contributors to new and emerging chemical risks among innovative rationally designed materials with new or enhanced properties or targeted or enhanced structural features at nanoscale.		
Article 20(4)			
260	4. For the purpose of operating the observatory referred to in paragraph 1, the ECHA shall:		
Article 20(4), point (a)			
261	(a) make use of relevant datasets integrated in the common data platform, and compile, analyse and curate further available data on selected chemicals or classes of chemicals;		
Article 20(4), point (b)			
262	(b) commission studies and, where relevant, use the data generation mechanism established under Article 21 to address knowledge gaps or significant uncertainties;		
Article 20(4), point (c)			
263	(c) make compiled data publicly available through the common data platform or other communication and outreach tools as appropriate, to facilitate informed societal discussion and increase public awareness on the properties, use and safety aspects of specific chemicals, and regularly update that information.		
Chapter VI			

264	Chapter VI DATA GENERATION MECHANISM		
Article 21			
265	Article 21 Data generation mechanism	One delegation raised the question of the promotion of animal testing in relation to article 1. PRES understands that the type of tests are prescribed in each regulation mentioned in annex I, and thus this regulation is not modifying that. However, art.21 here is new, and thus the question of the minimization of animal testing might be relevant here. One delegation would like to know if commissioned animal studies will be notified → PRES requests written reactions and proposals on this matter. One delegation expressed the need to frame the mandate in such a way that the burden of proof on companies is preserved. One delegation insisted also on the burden of proof on industry and highlights the need for clarity on procedures and financing. → PRES invites for written comments and amendments proposals. Some Comments were received in relation to the involvement of MS, industry, stakeholders in the data generation mechanism. → PRES: discussion during the 2nd WP	
Article 21(1)			
266	1. Using the best independent resources available, the ECHA may commission scientific studies to support the implementation of Union acts on chemicals listed in Annex I within its mandate and to contribute to the support, evaluation or development of a Union chemicals policy.	One delegation requested clarity on the meaning of scientific studies, and which ones will not be covered. → PRES invites for written comments on this	
Article 21(2)			
267	2. The Commission may request the ECHA to commission the scientific studies referred to in paragraph 1.		
Article 21(3)			
268	3. The ECHA shall only commission scientific studies when results cannot be obtained through existing legal provisions or processes		

	under Union legislation listed in Annex I. It shall not commission studies with a predominant research objective.		
Article 21(4)			
269	4. The ECHA shall seek to avoid duplication with Member State or Union research or implementation programmes.		
Article 21(5)			
270	5. The ECHA shall commission these scientific studies in an open and transparent manner.	One delegation suggested to amend this to introduce compulsory prior MS consultation. → PRES scheduled this for discussion at the 2 nd WP	
Article 21(6)			
271	6. The ECHA and the EFSA shall closely cooperate with each other on the planning and commissioning of scientific studies undertaken by the ECHA in accordance with paragraph 1 and of studies undertaken by the EFSA in accordance with Article 32 of Regulation (EC) No 178/2002.		
Article 21(7)			
272	7. The ECHA shall make the results of the scientific studies performed under this Article available through the common data platform.		
Chapter VII			
273	Chapter VII NOTIFICATION OF STUDIES	Several comments were received on this chapter: on the legal scope and definition of studies to be notified, duplications, studies conducted outside the EU, late notifications, absence of a transitional period, practical arrangements for companies, the need for early access before publication in the data platform. → PRES scheduled this for discussion at the 2 nd WP	
Article 22			
274	Article 22 Notification of studies		AT would like to ask COM to confirm that Studies from business operators in the context of research and development are derogated from Art 22.

Article 22(1)			
275	1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, without undue delay, any studies on chemicals they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment , prior to placing on the market, under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.		
Article 22(2)			
276	2. For the purposes of paragraph 1, business operators shall notify to the Database of Study Notifications referred to in Article 9 the title, scope, laboratory, or testing facility carrying out the study, the intended starting and planned completion dates and, where relevant, whether the study is commissioned to comply with a decision of the ECHA pursuant to Articles 40, 41 or 46 of Regulation (EC) No 1907/2006.		
Article 22(3)			
277	3. Laboratories and testing facilities shall also, without undue delay, notify any study commissioned by business operators to support a regulatory dossier on which an Agency is required to provide a scientific output, including a scientific opinion, under the Union acts listed in Annex I. However, laboratories and testing facilities shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.		
Article 22(4)			
278	4. For the purposes of paragraph 3, laboratories and testing facilities shall notify to the Database of Study Notifications referred to in Article 9 the title, scope, intended starting and planned completion dates of any test they carry out, as well as the name of the business operator who commissioned the test.		

Article 22(5)			
279	5. Paragraphs 3 and 4 shall apply, mutatis mutandis, to laboratories and testing facilities located in third countries insofar as set out in relevant agreements with those third countries.		
Article 22(6)			
280	6. The obligations set under this article shall apply from [OP please insert date: 24 months after the date of entry into force of this Regulation].		
Article 22(7)			
281	7. The ECHA shall lay down the practical arrangements for implementing the provisions of this Article.		
Chapter VIII			
282	Chapter VIII DELEGATED POWERS		
Article 23			
283	Article 23 Amendment of Annexes I, II and III		
Article 23(1)			
284	1. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex I in order to adjust the content of that Annex to technical and scientific progress in the field of chemicals or, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it new Union acts under which relevant chemicals data is generated or submitted.		
Article 23(2)			
285	2. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex II by adding, where relevant, new categories of data types.		
Article			

23(3)			
286	3. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex III in order to adjust the content of that Annex to technical and scientific and technical progress in the field of chemicals and, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it Union acts relevant for data on new regulatory processes on chemicals.		
Article 24			
287	Article 24 Exercise of the delegation		
Article 24 (1)			
288	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.		
Article 24(2)			
289	2. The power to adopt delegated acts referred to in Article 23 shall be conferred on the Commission for a period of five years from [OP please insert: the date of the entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each five-year period.		
Article 24(3)			
290	3. The delegation of power referred to in Article 23 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.		
Article			

24(4)			
291	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.		
Article 24(5)			
292	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.		
Article 24(6)			
293	6. A delegated act adopted pursuant to Article 23 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.		
Chapter IX			
294	Chapter IX ENFORCEMENT AND PENALTIES	One delegation expressed concerns on enforcement for third countries; one delegation questioned the effectiveness of national sanctions. → PRES scheduled this for discussion at the 2 nd WP	
Article 25			
295	Article 25 Enforcement The Agencies shall cooperate with Member States' enforcement authorities and exchange information on the compliance, by business operators and laboratories, with the obligation to notify studies in accordance with Article 22.		
Article 26			

296	Article 26 Penalties for non-compliance		
Article 26(1)			
297	1. Member States shall introduce penalties for non-compliance, by business operators and laboratories, with the obligations laid out in Article 22 and shall take all necessary measures to ensure that they are implemented. The penalties provided for shall be effective, proportionate, and dissuasive.		
Article 26(2)			
298	2. Member States shall notify the Commission of those rules and of those measures by 30 June 2025 and shall notify to the Commission without delay any subsequent amendment affecting them.		
Article 27			
299	Article 27 Entry into force and application in time This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.		
Formula			
300	This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels, For the European Parliament For the Council The President The President		

	Presidency proposals: amendments (~~deletions~~ / additions)	Presidency proposals: follow-up or proposal to work on amendments, or requests for written comments	Reactions from the Commission and MS
Annex I			
301	Annex I UNION ACTS REFERRED TO IN ARTICLES 2, 3, 8, 11, 12, 15, 17, 21, 22 AND 23 Reference to each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.		
302	1. Council Directive 91/271/EEC of 21 May 1991 concerning urban wastewater treatment (OJ L 135, 30.5.1991, p. 40)		
303	2. Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources (OJ L 375, 31.12.1991, p.1)		
304	3. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1)		

305	4. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste		
306	5. Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11)		
307	6. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50)		
308	7. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34)		
309	8. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for the Community action in the field of water policy (OJ L 327, 22.12.2000, p.1)		
310	9. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1)		
311	10. Regulation (EC) No 178/2002 of the European		

	Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p. 1)		
312	11. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10)		
313	12. Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51)		
314	13. Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1)		
315	14. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29)		
316	15. Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (OJ L 309, 26.11.2003, p. 1)		
317	16. Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55)		
318	17. Regulation (EC) No 648/2004 of the European		

	Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1)		
319	18. Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1)		
320	19. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)		
321	20. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3)		
322	21. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 070, 16.3.2005, p. 1)		
323	22. Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC (OJ L 033, 4.2.2006, p. 1)		
324	23. Directive 2006/118/EC of the European Parliament		

	and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19)		
325	24. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)		
326	25. Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9)		
327	26. Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26)		
328	27. Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE) (OJ L 108, 25.4.2007, p. 1)		
329	~~28. Regulation (EC) No 108/2008 of the European Parliament and of the Council of 15 January 2008~~	One delegation highlighted the fact that regulation 108/2008 is mentioned in point 28	

	amending Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 39, 13.2.2008, p. 11)	of Annex I, whereas this regulation is already covered by regulation 1925/2006 mentioned in point 26 of Annex I. →PRES proposes to amend the text (deleting point 28).	
330	29. Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19)		
331	30. Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1)		
332	31. Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3)		
333	32. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84)		
334	33. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008		

	on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)		
335	34. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)		
336	35. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC, and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p.7)		
337	36. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16)		
338	37. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34)		
339	38. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a		

	framework for the setting of ecodesign requirements for energyrelated products		
340	39. Regulation (EC) No 401/2009 of the European Parliament and of the Council of 23 April 2009 on the European Environment Agency and the European Environment Information and Observation Network (OJ L 126, 21.5.2009, p. 13)		
341	40. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3)		
342	41. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1)		
343	42. Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (OJ L 300, 14.11.2009, p. 1)		
344	43. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)		

345	44. Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71)		
346	45. Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28)		
347	46. Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community ecomanagement and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC (OJ L 342, 22.12.2009, p. 1)		
348	47. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)		
349	48. Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17)		
350	49. Regulation (EC) No 66/210 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel (OJ L 027, 30.1.2010, p. 1)		
351	50. Directive 2011/65/EU of the European Parliament		

	and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)		
352	51. Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18)		
353	52. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)		
354	53. Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.7.2012, p. 1)		
355	54. Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38)		
356	55. Regulation (EU) No 649/2012 of the European		

	Parliament and of the Council of 4 July 2012 concerning the import and export of hazardous chemicals (OJ L 201, 27.7.2012, p. 60)		
357	56. Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35)		
358	57. Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (OJ L 96, 29.3.2014, p. 1)		
359	58. Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1)		
360	59. Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006 (OJ L 150, 20.5.2014, p.		

	195)		
361	60. Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1)		
362	61. Directive (EU) 2016/2284 of the European Parliament and of the Council of 14 December 2016 on the reduction of national emissions of certain atmospheric pollutants, amending Directive 2003/35/EC and repealing Directive 2001/81/EC (OJ L 344, 17.12.2016, p. 1)		
363	62. Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council,		

	Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 095, 7.4.2017, p. 1)		
364	63. Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1)		
365	64. Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008 (OJ L 137, 24.5.2017, p. 1)		
366	65. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).		
367	66. Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (OJ L 170, 25.6.2019, p. 1)		
368	67. Regulation (EU) 2019/1021 of the European		

	Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45)		
369	68. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435, 23.12.2020, p. 1)		
370	69. Regulation (EU) .../... of the European Parliament and of the Council on nature restoration (OJ .../ELI: ... [OP: please add number and publication reference].		
371	70. Regulation (EU) .../... of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (OJ .../ELI: ... [OP: please add number and publication reference]		
ANNEX II			
372	ANNEX II UNION ACTS REFERRED TO IN ARTICLES 2, 3, 12, 17 AND 23 AND REFERENCE VALUES REFERRED TO IN ARTICLE 8		AT thinks that in order to achieve a better functioning one stop shop references to studies concerning clinical data should also be included (e.g. in Annex II, Part 1 new point 4).
Part 1			
373	Part 1 - Specific data on relevant active substances to be identified in accordance with Article 4(5)(b) falling under the scope of this Regulation for the purposes of Article 3 for human and veterinary medicinal products		
374	1. Non-clinical safety data, including data related to		

	environmental risk assessments, compiled pursuant to Directive 2001/83/EC of the European Parliament and of the Council¹ and Regulation (EC) No 726/2004 of the European Parliament and of the Council²; ¹ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67). ² Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).		
375	2. Data related to environmental risk assessments, compiled pursuant to Regulation (EU) 2019/6 of the European Parliament and of the Council³; and ³ Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).		
376	3. Maximum residue levels data compiled pursuant to Regulation (EC) No 470/2009 of the European Parliament and of the Council⁴. ⁴ Regulation (EC) No 470/2009 of the European		

	Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).		
377	These data shall be limited to data submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation. Where relevant, the data held by the EMA resulting from procedures concluded before the entry into force of this Regulation may also be considered for inclusion into the common data platform.		
Part 2			
378	Part 2 - Reference values to be included in the repository of reference values following Article 8(3)		
379	1. Predicted no effect concentrations derived as part of the environmental risk assessment under Directive 2001/83/EC of the European		

	Parliament and of the Council, Regulation (EC) No 726/2004 of the European Parliament and of the Council and Regulation (EU) 2019/6 of the European Parliament and of the Council.		
380	These data shall be limited to data submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation. Where relevant, data held by the EMA resulting from procedures concluded before the date of entry into force of this Regulation shall also be considered for inclusion into the common data platform.		
Annex III			
381	Annex III UNION ACTS REFERRED TO IN ARTICLES 2, 10 AND 23		
382	Reference to each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.		
383	1. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1)		
384	2. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste		
385	3. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to		

	carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50)		
386	4. Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11)		
387	5. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34)		
388	6. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p. 1)		
389	7. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10)		
390	8. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29)		
391	9. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact		

	with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)		
392	10. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3)		
393	11. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1)		
394	12. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19)		
395	13. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)		
396	14. Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical		

	and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38)		
397	15. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84)		
398	16. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)		
399	17. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)		
380	18. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC, and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p.7)		

381	19. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16)		
382	20. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34)		
383	~~21. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)~~	Some delegations highlighted the fact that Regulation 1331/2008 is mentioned twice: in points 17 and 21 of Annex III. → PRES proposes to amend the text (deleting this repetition).	
384	22. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3)		
385	23. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energyrelated products		
386	24. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1)		

387	25. Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer (OJ L 286, 31.10.2009, p. 1)		
388	26. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)		
389	27. Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28)		
390	28. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)		
391	29. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)		
392	30. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)		
393	31. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018		

	on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).		
394	32. Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45)		
395	33. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435, 23.12.2020, p. 1)		
396	34. Regulation (EU) .../... of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (OJ .../ELI: ... [OP: please add number and publication reference].		

PUBLIC

PORTUGAL

Written Comments

“One Substance One Assessment package”

WPE (08.03.2024)

Reference documents

- doc. ST 16973/23, 19.12.2023; WK 3538/2024, 05.03.2024; WK 3719/2024 INIT, 07.03.2024 – Omnibus proposal
- doc. ST 16956/23, 19.12.2023; WK 3533/2024 REV 1, 07.03.2024 – RoHS proposal
- doc ST 16961/23 and ST 16961/23 add1, 18.12.2023; WK 3541/2024, 05.03.2024; WK 3718/2024 INIT, 07.03.2024 – Chemical’s platform proposal
- WK 4091/2024 INIT, 14.03.2024 – Commission’s presentations

PT thanks to the Belgian Presidency (PRES) for its work and for giving us the possibility to submit comments on the reference documents.

PT also thanks and welcomes the clarifications provided by the COM regarding the OSOA package and wish to reiterate their support for this initiative.

Following to the meeting that took place on the 8th March and taking into consideration the reference documents made available in this context, please find the general PT written comments on the “OSOA package” below; the specific PT written comments are addressed in the format provided by the PRES (in annex).

- **Omnibus Proposal (amending POP Regulation)**

PT agrees, in general, with all the PRES amendment proposals.

- **Amending Proposal to RoHS Directive**

PT keeps the opinion that REACH/RoHS alignment is as an important basis on the way forward, as we believe that: the primary purposes of both pieces of legislation are related to the protection of Human Health and the Environment, and; it will assure a better coherence between the risk management measures lay down in the REACH Regulation and the RoHS Directive, taking into account in particular that substances ruled under this directive are similar to those which are ruled under REACH Regulation.

We consider that major concerns transmitted by MS were in general put forward in the PRES proposal and addressed by COM when providing clarification on this matter.

- **Common Data Platform on Chemicals**

In general, we consider that clarifications provided by COM were very relevant for the discussions of this proposal. However, we still have some concerns/questions we would like PRES to put forward for discussion/clarification.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

establishing a common **data platform** on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

(Text with EEA relevance)



	Presidency proposals: amendments (~~deletions~~ / additions)	Presidency justification after WP1: follow-up or proposal to work on amendments, or requests for written comments	Delegates comments/proposals after WP2
Proposal Title			
1	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals)		
Formula			
2	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN		
Citation 1			
3	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114(1) thereof,		
Citation 2			
4	Having regard to the proposal from the European Commission,		
Citation 3			
5	After transmission of the draft legislative act to the national parliaments,		
Citation 4			
6	Having regard to the opinion of the European Economic and Social Committee ¹		
Citation 5			
7	Acting in accordance with the ordinary legislative procedure,		
Formula			
8	Whereas:		
Recital 1			
9	(1) The European Green Deal ³⁴ sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability ³⁵ is a crucial delivery of this zero-		

	pollution ambition and introduces the ‘one substance, one assessment’ approach, which aims to improve the efficiency, effectiveness, coherence, and transparency of safety assessments of chemicals across Union legislation. According to that Strategy, ‘safe and sustainable by design’ criteria should be developed to enable the production and use of chemicals that are safe and sustainable throughout their entire lifecycle. The Strategy also sets out that the interaction between scientific developments and policy-making should be strengthened by means of an early warning system for chemicals to ensure that Union policies address emerging chemical risks as soon as these are identified by monitoring and research, and that a framework of indicators should be developed to monitor the drivers and impacts of chemical pollution and to measure the effectiveness of chemicals legislation. This Regulation aims to implement these objectives.		
Recital 2			
10	(2) The main objective of this Regulation is to increase the level of protection of the environment and human health from the risks arising from hazardous chemicals, as well as to facilitate the functioning of the internal market for chemicals. For that purpose, this Regulation should establish a common data platform data on chemicals (‘the common data platform’), to be managed by the European Chemicals Agency (‘ECHA’). The common data platform is a digital infrastructure that brings together chemicals data and information generated under the Union chemicals acquis. This Regulation should also establish dedicated services within the common data platform and lay down rules on the accessibility and usability of the data contained in that platform. This Regulation aims to create a common knowledge base on chemicals available to authorities to enable better, complete, coherent and robust scientific assessments of chemicals and their impacts and to ensure the best use of existing information for the purpose of the implementation and the development of Union legislation on chemicals. Moreover, the Regulation aims to provide a one-stop-shop on chemicals data and information in the Union accessible to the general public and, thus, to increase the predictability and the transparency of regulatory processes on chemicals, as well as to strengthen public trust in the robustness of scientific decision-making.		

Recital 3			
11	(3) Under Decision (EU) 2022/591 of the European Parliament and of the Council ³⁶ , harnessing the potential of digital and data technologies to support environmental policy, including by delivering real-time data where possible and information on the state of ecosystems, while increasing efforts to minimise the environmental footprint of these technologies and ensuring transparency, authenticity, interoperability and public accessibility of the data and information is a long-term priority objective. Data and information on chemicals are therefore essential for the proper development and implementation of a Union environmental policy, and specifically of a chemicals policy.		
Recital 4			
12	(4) In its communication of 19 February 2020 on a European strategy for data ³⁷ , the Commission described its vision of a common European data space and highlighted the need for the development of sectoral data spaces in strategic areas, since not all sectors of the economy and society are moving at the same speed. This Regulation aims therefore to build a data space for chemicals by establishing a common data platform on chemicals ('common data platform'), which is also part of the Green Deal data space, as referred to in the European strategy for data. Furthermore, in that strategy, the Commission highlighted several issues concerning the availability of data for the public good, including data availability, data infrastructures and governance, interoperability, as well as the lack of adequate sharing of data between public authorities. This Regulation aims to increase data availability on chemicals by requiring the relevant Union agencies to make data available for integration in the common data platform on chemicals, to promote interoperability of that data by providing for the establishment of standard formats and controlled vocabularies, as well as to facilitate data exchange and use by public authorities to enable them to effectively carry out their regulatory and policy developing tasks.		
Recital 5			
13	(5) This Regulation also aims to implement into the chemicals sector the principles laid out in the proposal for an Interoperable Europe Act ³⁸ by strengthening the cross-border interoperability of network		

	and information systems used to provide or manage public services on chemicals in the Union. This Regulation will contribute to increased cross-border data flows for truly European digital services and broaden the access to publicly available chemicals data for utilisation in other sectors' applications.		
Recital 6			
14	(6) Business operators and Members States' competent authorities are required by various Union acts to submit data and information to a multitude of Union agencies, as well as to the Commission in specific cases. This generates a fragmentation of data and information on chemicals, which are held under various data sharing and use conditions and in different formats. Such fragmentation prevents public authorities, as well as the general public, from having a clear overview of what information is available on individual chemicals or groups of chemicals, of where and how information can be accessed and whether it can be used. This increases the likelihood of inconsistency between various assessments of the same chemical required by various Union acts on chemicals and of damaging the general public's trust in the scientific grounds for Union decisions on chemicals. In order to ensure that data on chemicals is easily findable, accessible, interoperable and usable, the ECHA should establish a common data platform on chemicals. The common data platform on chemicals should serve as a single point of reference and as a broadened and shared evidence base to enable the efficient delivery of coherent hazard and risk assessments of chemicals across various Union acts on chemicals, as well as to enable the timely identification of emerging chemical risks and the drivers and impact of chemical pollution.		
Recital 7			
15	The common data platform should contain chemicals-related data and information held by relevant Union agencies or the Commission generated or submitted as part of the implementation of Union chemicals legislation listed in Annex I. This includes, for instance, all regulatory dossiers or applications submitted to the relevant Union agencies, but also chemicals data on occurrence of chemicals submitted by Member States to Union agencies or the Commission in compliance with their reporting obligations. The common data		

	platform should also include chemicals data and information generated as part of Union, national or international programmes or research activities related to chemicals, where this data and information is held by the Commission or one of the relevant agencies.		
Recital 8			
16	Due to the different nature of the risk and hazard assessments performed under Union acts on medicinal products, when compared to those performed under the main Union acts on chemicals, for medicinal products, only chemicals data related to environmental risk assessments for human and veterinary medicines, non-clinical studies for human medicines and maximum residue limit values the European Medicines Agency ('EMA') holds, as well as specific reference values, should be included in the common data platform. For medicinal active substances, only data on relevant substances should be included. These concern active substances covered by the medicines legislation and also used for other applications regulated by other Union legislation identified in this Regulation, as well as other active substances with particular persistent, bio-accumulative and toxic properties or with a known high level of residues in the environment.	Some delegations expressed the need for a clarification of the scope and meaning of "relevant substances" for active substances → PRES: this is scheduled for discussion at the 2 nd WP	
Recital 9			
17	(9) These data should also be limited to data submitted to the EMA in the context of the relevant procedures that are finalised or submitted after the entry into force of this Regulation. At a later stage, it should also be possible to include in the common data platform, where relevant, data the EMA holds on procedures concluded before the entry into force of this Regulation.		
Recital 10			
18	(10) Due to the sensitivity of the information on the exact chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health or physical effects, submitted to the bodies appointed by the Member States under Article 45 of Regulation (EC) No 1272/2008 of the European Parliament and the Council ³⁹ , that information should not be included in the common data platform. Likewise, due to the commercial sensitiveness of data and information on final cosmetic products, the information related to		

	cosmetic products notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/200940 of the European Parliament and of the Council should not be included in the common data platform either. However, chemicals data and information on individual chemical ingredients of cosmetic products should be included in the common data platform.		
Recital 11			
19	(11) To safeguard the ability of the European Commission, of the Union agencies working on chemicals and of the competent Member State authorities (hereinafter 'the Authorities'), to carry out their tasks, documents with chemicals data relating to their internal work or decision-making should in principle not be included in the common data platform.		
Recital 12			
20	(12) In order to respond to the needs of the digital economy and to ensure a high level of protection of the environment and human health, it is necessary to lay down a harmonised framework specifying who is entitled to access and use the chemicals data contained in the common data platform, under which conditions, on what basis, and for which purposes. The Authorities that are entrusted with regulatory tasks related to chemicals should be allowed and encouraged to use the chemicals data and information contained in the common data platform to effectively fulfil their regulatory duties and tasks, in order to improve the effectiveness, efficiency, and coherence of chemicals-related assessments as well as the development of Union chemicals policies.		
Recital 13			
21	(13) Chemicals data and information generated as a result of obligations set by Union acts on chemicals may be protected by confidentiality claims on confidential business information. The public dissemination of such data may affect the commercial interest of private parties. To ensure legal certainty for duty holders and to protect their legitimate expectations, as well as to ensure industry's		

	competitiveness on the internal market, the ECHA, as a manager of the common data platform, should grant differentiated access rights to the data and information contained in the common data platform. To this end, the Authorities should have full access to all chemicals data and information contained in the common data platform, including access to confidential information, while business operators and the general public should have restricted access to that data and information, which does not include access to confidential information.		
Recital 14			
22	(14) When using data contained in the common data platform, the Authorities should respect the originator principle. Under this principle, the confidentiality marking of chemicals data as done by the originator and as correspondingly indicated by the Agency when it provides that data to the common data platform should be respected by the Authorities using that data or information to perform their regulatory functions or fulfil their tasks.		
Recital 15			
23	(15) To ensure the protection of legitimate expectations of duty holders when generating or submitting data or information under the Union acts listed in Annex I, as well as to protect the confidentiality of that information when used by the Authorities, exceptional grounds for disclosing confidential information laid down in the Union acts listed in Annex I should apply only to the disclosure of the data and information submitted or generated in compliance with those acts. For example, under Article 39(4) of Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁴¹ , where urgent action is essential to protect human health, animal health or the environment, such as in emergency situations, the European Food Safety Authority ('EFSA') may disclose information previously considered confidential under that Regulation and the EFSA is required to make public information, previously considered confidential, that forms part of conclusions of scientific outputs of the EFSA and relates to foreseeable effects on human health, animal health or the environment. Likewise, Article 118 of Regulation (EC) No 1907/2006 of the European Parliament and of		

	the Council ⁴² provides for the possibility for the ECHA to disclose confidential information submitted to it under that Regulation if urgent action is essential to protect human health, safety or the environment, such as in emergency situations.		
Recital 16			
24	(16) Taking into account that the Agencies would be required to store scientific data, which includes confidential and personal data, it is necessary to ensure that such storage is carried out in accordance with a high level of security of information systems and that access to confidential data is auditable.		
Recital 17			
25	(17) While the ECHA should identify and develop the technical functionalities of the common data platform in stages, certain dedicated services should be defined by this Regulation. As such, the common data platform should, in addition to providing access to chemicals-related data made available by the Agencies and the Commission, provide access to the chemicals data and information made available through its dedicated services. These dedicated services should be integrated into the common data platform and consist of the existing Information Platform for Chemical Monitoring ('IPCHEM'), a repository of reference values, a database of study notifications, a database with information on regulatory processes, a database with information on applicable legal obligations, a repository of standard formats and controlled vocabularies, a database on environmental sustainability related data, as well as a dashboard of indicators on chemicals.		
Recital 18			
26	(18) The Commission should adopt an implementation plan identifying initial datasets to be made accessible via the platform and the timeline for their integration, informed by the preparatory work of the Commission and the Agencies ⁴³ . The Commission should set up a governance scheme to support and steer the common data platform's operation and evolution covering the organisation of work structures		

	and coordination between ECHA and data providers, required rules, formats and vocabularies for data integration, and maintain a rolling implementation plan to ensure the progress in identification and integration of new datasets and services for inclusion. The governance scheme should be adopted and updated as necessary by the Commission, after consultation with a newly established platform steering committee composed of representatives from Union agencies and the Commission. In order to ensure uniform conditions for the implementation of the obligations to establish an implementation plan and a governance scheme, implementing powers should be conferred on the Commission.		
Recital 19			
27	(19) The common data platform should serve the widest possible community, with the ability to address new use cases, incorporate new relevant datasets, develop new functionalities, and respond to developing tools and applications.		
Recital 20			
28	(20) In order to bring together all relevant chemicals data and information in the common data platform, the Commission and Union agencies – notably the European Agency for Safety and Health at Work ('EU-OSHA'), the ECHA, the European Environment Agency ('EEA'), the EFSA, and the EMA ('the Agencies'), should act as data providers and make available any such relevant data they have or hold to the ECHA for integration in the common data platform. The Agencies, including the ECHA itself when making its own data available, should provide the necessary standard metadata, contextual information and relevant mapping to the platform's structure, and respect rules on standard formats and controlled vocabularies where available.		
Recital 21			
29	(21) To ensure that an adequate knowledge base on chemicals is available through the common data platform, the Commission should be able to request the Agencies to host, maintain and make available, via the common data platform, data generated as part of Union,		

	national or international programmes or research activities beyond the data already flowing to the Agencies as part of the obligations under the Union acts listed in Annex I. The Commission should make such requests to the Agencies in accordance with their mandates and allocated tasks.		
Recital 22			
30	(22) Some types of data are currently not within the mandate of any of the Agencies. In order to ensure clarity of responsibilities of the Agencies and efficient management of chemicals data, the Agencies should be required to host, maintain and provide specific data types to the common data platform. To this end, the ECHA should host and be a data provider to the common data platform for workplace monitoring data, and the EEA should host and be a data provider to the common data platform for data on indoor air quality and environment monitoring data, as well as data on concentrations of chemicals in human matrices such as blood or urine ('human biomonitoring data').		
Recital 23			
31	(23) To improve the uptake of academic data and to expand the knowledge base for chemicals safety assessments and environmental sustainability impacts of chemicals, researchers or research consortia funded by Union framework programmes should make available, in line with the 'as open as possible, as closed as necessary' principle, any human biomonitoring data they collect or generate resulting from research and development programmes to the EEA and any environmental sustainability data on chemicals or materials they collect or generate to the ECHA.		
Recital 24			
32	(24) The EEA, as the agency responsible for monitoring data and information on chemicals in the environment, should also be responsible for collecting, hosting, and maintaining human biomonitoring data. To the extent that human biomonitoring data constitutes a special category of personal data, namely, health data, the EEA should process that data only where the processing is		

	necessary for reasons of substantial public interest, as required by Article 10(2)(g) of the Regulation (EU) No 2018/1725 of the European Parliament and of the Council ⁴⁴ . This Regulation lays down the cases where there is such substantial public interest in processing human biomonitoring data: namely, where the EEA processes that data to assess the impact of chemicals on human health and the environment, to monitor time and spatial trends in exposure, to develop health risk and impact indicators, to monitor the impact of regulatory intervention, and to support regulatory risk assessments.		
Recital 25			
33	(25) In order to ensure that appropriate safeguards are in place to secure the protection of this sensitive type of personal data, the EEA should only provide anonymised human biomonitoring data to the ECHA for integration in IPCHEM and the common data platform. IPCHEM, currently operated by the Commission, gathers occurrence data on chemicals in different media, including water, soil, indoor and outdoor air, biota, food and feed, humans, and products. In order to take advantage of the integration of various information systems and to ensure that occurrence data on chemicals is made available for use together with the other chemicals data, the ECHA should take over from the Commission the operation of IPCHEM and integrate it in the common data platform as one of its main dedicated services.		
Recital 26			
34	(26) In order to prevent disruption to the existing operation and functioning of the IPCHEM, the ECHA should integrate the IPCHEM in the common data platform together with the data present in IPCHEM at the moment of integration. At the same time, in order to enable optimal hosting and management of occurrence data on chemicals, the Commission should also transfer the data present in IPCHEM to the ECHA, the EEA or the EFSA for hosting and future updating in accordance with their respective mandates. In order to ensure that the ECHA takes over from the Commission the operation of the IPCHEM, integrates it into the common data platform and takes over the initial data sets and sets up adequate data flows, it is necessary to allow the		

	ECHA an appropriate period of time to carry out these actions, of up to 3 years from the date of entry into force of this Regulation.		
Recital 27			
35	In order to promote the use and harmonisation of reference values among risk assessors and risk managers across different Union acts and to facilitate compliance with, and enforcement of, regulatory reference values, the ECHA should establish and maintain a repository of reference values established or adopted under the Union acts listed in Annexes I and II The Agencies should provide the ECHA with reference values they hold or establish as part of their activities. In addition, the ECHA should regularly screen Union acts for reference values adopted under them. To facilitate automatic access of the general public to up-to-date reference values, the ECHA should integrate the repository of reference values in the common data platform as a dedicated service, include in that repository all reference values together with the relevant context data it has received or retrieved and ensure that those values and that context data are machine readable.		
Recital 28			
36	(28) In order to increase transparency, as well as to enable Authorities to have complete prior knowledge of studies commissioned by business operators, irrespective of whether such studies are carried out by the business operator itself or are outsourced, business operators and laboratories should notify to a database of study notifications established and managed by the ECHA the studies on chemicals they commission for compliance with regulatory requirements under the Union acts listed in Annex I. For this purpose, the ECHA should establish and manage a database of study notifications, as a dedicated service of the common data platform, to store the information related to those studies. In order to allow business operators and laboratories sufficient time to prepare the notifications of studies, the obligation to notify studies should only start to apply two years after the date of entry into force of this Regulation.		
Recital 29			

37	(29) Under Regulation (EC) No 178/2002 of the European Parliament and of the Council, business operators and laboratories are obliged to notify to the database of study notifications established and managed by the EFSA the studies they commission to support an application or notification in relation to which Union law contains provisions for the EFSA to provide a scientific output. To avoid overburdening business operators and laboratories, they should therefore not be required to also notify those studies to the database of study notifications established and managed by the ECHA under this Regulation.		
Recital 30			
38	(30) To ensure the coherence between those two study notification mechanisms, as well as to ensure certainty for business operators submitting notifications, the rules on the public dissemination of study notifications should, where relevant, correspond in that the notifications should only be made available through the common data platform EN 27 EN once a corresponding registration, application, notification or other relevant regulatory dossier was submitted to the relevant Union or national institution and a decision on the confidentiality of the data contained in that regulatory dossier was taken by that Union or national institution. In addition, in order to facilitate compliance with the requirement to notify a study, the ECHA and the EFSA should cooperate to ensure a common approach for the identification of notified information in order to facilitate the traceability of studies notified to their respective databases.		
Recital 31			
39	(31) While the study notification obligation established in this Regulation should apply in the context of all the Union acts on chemicals listed in Annex I, the various relevant data collection and safety assessment processes under those acts may vary widely procedurally. The overarching aim of the database of study notifications established under this Regulation should be to bring together information on studies on chemicals being commissioned by business operators, such as to enable a centralised and complete		

	overview of the studies being performed to support regulatory compliance under Union acts on chemicals as listed in Annex I. On the basis of this objective and considering the fact that assessment procedures under Union acts on chemicals in Annex I may vary widely, it would be beyond the scope and aim of this Regulation to amend existing assessment processes set under those Union acts listed in Annex I by imposing additional conditions leading to potential market access consequences not foreseen in those Union acts. Consequently, it is not appropriate to introduce in this Regulation the consequences associated non-compliance with the study notification obligation as laid out in Article 32b of Regulation (EC) No 178/2002 of the European Parliament and of the Council.		
Recital 32			
40	(32) Nevertheless, to ensure compliance with the study notification obligation laid down in this Regulation, and to cater to the specificities of individual assessment processes, where existing, Member States should lay down rules on penalties applicable to the infringement of that obligation and take all necessary measures to ensure that those rules are complied with. Those penalties should be effective, proportionate, and dissuasive, since non-compliance with this Regulation could result in less robust chemicals risk assessments, creating potential risks and consequently adverse effects on human health and the environment.		
Recital 33			
41	(33) In order to facilitate enforcement by Member States, the Agencies responsible for assessing and providing scientific output, including scientific opinions, on regulatory dossiers containing studies subject to notification to ECHA should, where relevant, cooperate and exchange information with the Member State enforcement authorities on the compliance with the obligations laid out in Article 22.		
Recital 34			
42	(34) While Regulation (EC) No 178/2002 of the European Parliament and of the Council also requires the consultation of stakeholders and		

	the public following the notification to the EFSA of studies commissioned for the purposes of the renewal of an authorisation or approval, a similar requirement under this Regulation would lay a disproportionate administrative burden on the ECHA, given the wide scope of the studies that is to be notified under this Regulation.		
Recital 35			
43	(35) A mechanism related to study notifications exists in Regulation (EC) No 1907/2006 of the European Parliament and of the Council. Where registrants are required to perform studies to generate data in accordance with requirements in Annexes IX and X to that Regulation, they must first submit a testing proposal to the ECHA in order to receive a decision requiring them to perform a study. Such decision may also be issued as an outcome of compliance check or substance evaluation under that Regulation. In order to facilitate the transparency, traceability, and effective monitoring of studies commissioned or carried out pursuant to a decision of the ECHA in accordance with Articles 40, 41 or 46 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council, business operators should specify in their notifications of studies under this Regulation that those studies are being commissioned or carried out in compliance with those decisions.		
Recital 36			
44	(36) To strengthen the coordination and cooperation between the different bodies performing chemicals assessments in the Union, and to promote an increased transparency of chemicals assessments, the ECHA should establish and manage a database with information on regulatory processes or activities that are planned, ongoing or completed by Member States, the Commission and Agencies referred to in the Union acts listed in Annex III to this Regulation and integrate it into the common data platform for access by the authorities. The information on such regulatory processes or activities should include at least the substance identity and the identification, status and eventually the outcome of the regulatory process or activity. That information should also be made available without undue delay and		

	kept updated through the assessment process. Once the process or activity has formally started, that information should be shared also publicly on the common data platform.		
Recital 37			
45	(37) The existing 'The EU Chemicals Legislation Finder' ⁴⁵ project managed by the ECHA makes it easier to find and identify legal obligations related to the use of a specific chemical. The project is especially helpful for small and medium sized enterprises in identifying their legal obligations. To reinforce the supportive function of the project for business operators, it should be established on a permanent basis and more Union acts should be included in its scope. For this purpose, the ECHA should collect information on the legal obligations deriving from the Union acts on chemicals listed in Annex I to this Regulation and incorporate that information into the common data platform as a dedicated service.		
Recital 38			
46	(38) In order to ensure the interoperability and comparability of chemicals data and to facilitate their automatic and electronic exchange, the Agencies and the Commission should store chemicals data in adequate and mutually coherent and interoperable formats and use mutually coherent and interoperable controlled vocabularies. Some Union acts listed in Annex I or II set procedures to establish or make available data formats, in particular for the submission of chemicals data by business operators or Member States. Where such procedures do not exist in the Union acts listed in Annex I or II, the Agencies and the Commission should, where relevant, specify appropriate formats for chemicals data they receive and store, avoiding the use of proprietary standards while, as appropriate, using OECD or other internationally agreed formats, making use of existing formats and ensuring interoperability with existing data submission approaches.		
Recital 39			
47	(39) Likewise, the Agencies and the Commission should specify		

	appropriate controlled vocabularies for data they receive and store and, where relevant, integrate them in submission software or formats. Moreover, in order to facilitate a smooth electronic exchange of data through the common data platform, the Agencies and the Commission should agree on the required formats and controlled vocabularies for providing data to the common data platform. Whenever the Agencies or the Commission set formats or controlled vocabularies, they should cooperate with each other to ensure their coherence, consistency and interoperability. In order to ensure uniform conditions for resolving divergences in data formats and controlled vocabularies, implementing powers should be conferred on the Commission.		
Recital 40			
48	(40) In order to promote the interoperability of database systems on chemicals beyond the common data platform, the ECHA should establish a repository of standard formats and controlled vocabularies as part of the common data platform. The Agencies and the Commission should make the formats and controlled vocabularies they set available to the repository and the ECHA should make them available free of charge in electronic formats for use by developers of database systems and the general public.		
Recital 41			
49	(41) The International Uniform Chemical Information Database ('IUCLID') is a software application designed to record, store, maintain and exchange data on chemicals. The ECHA develops and maintains the IUCLID software and the underlying format in collaboration with the Organisation for Economic Cooperation and Development ('OECD'). The IUCLID implements all OECD-harmonised templates, which are harmonised formats agreed at the OECD level to facilitate structured and consistent documentation of test outputs and similar chemicals data. Since chemicals data is being submitted to the ECHA in IUCLID under Union acts such as Regulations (EC) No 1907/2006, (EC) No 1107/200946 and (EU) No 528/201247 of the European Parliament and of the Council, the ECHA is closely involved in the continued development of IUCLID, and IUCLID implements the standard formats		

	agreed at the OECD level, it is appropriate and necessary to require the Commission and the Agencies to use IUCLID for the relevant parts of dossiers under specified Union acts listed in Annex I when they make the data contained in those dossiers available to the ECHA .		
Recital 42			
50	(42) To increase the availability and facilitate the use of information on the environmental performance of chemicals throughout their lifecycle, and to enable a comprehensive assessment of the impacts of chemicals on the environment, the Commission should identify relevant data and information related to the environmental sustainability of chemicals, including, where available, information on their impact on climate change, for integration into the common data platform. Once the Commission has identified the relevant existing datasets on environmental sustainability related data and has designed the relevant related database functionalities, the ECHA should establish a database on environmental sustainability-related data, collect the data as made available by the Commission, the Agencies and, where relevant, by the researchers and research consortia funded by Union framework programmes, and integrate the content of that database into the common data platform as a dedicated service. In order to ensure uniform conditions for the implementation of the obligation to identify relevant environmental sustainability datasets, implementing powers should be conferred on the Commission.		
Recital 43			
51	(43) To monitor the impacts on humans and the environment, including the climate, of exposure to chemicals and to establish a knowledge base to measure the effectiveness of chemicals legislation in protecting human health and the environment, the EEA and the ECHA should jointly develop and regularly, at least every two years, update a set of indicators and present it in the form of a dashboard. The EFSA, the EMA, the EU-OSHA and the Commission shall regularly provide the EEA with any available data falling within their mandate and relevant for the establishment of the indicators. The EEA and the ECHA should integrate this dashboard of indicators into the common data platform.		

Recital 44			
52	(44) To enable the identification and evaluation of emerging chemical risks, the EEA should develop and compile information on early warning signals and draw up an annual summary report to inform regulatory follow-up actions. In its work, the EEA should include its own sources, targeted literature searches and make use of information from national early warning systems. It should also include relevant information made available by the related work of the ECHA, the EFSA, the EU-OSHA, the EMA and their networks, such as the EFSA's task of identifying and collecting information on emerging risks under Regulation 178/2002. The EEA should make the summary report and the underlying data available through the common data platform, ensuring public access and its use for further action on existing and emerging risks. In order to allow the EEA sufficient time to organise the collection of early warning signals and to compile and analyse the initial information the EEA should only deliver the first report six months after the end of the first calendar year after entry into force of this Regulation. This Regulation sets a deadline for the first report and associated data.		
Recital 45			
53	(45) In June 2017, at the Commission' request, the ECHA set up the European Observatory for Nanomaterials⁴⁸ ('EUON'), which collects existing data and information from databases, registries and studies and generates new data through studies and surveys on nanomaterials on the EU market.		
Recital 46			
54	(46) The ECHA should continue operating the EUON and transform it into an observatory for specific chemicals with potential contribution to emerging chemical risks ('the observatory'), which should cover also other chemicals and innovative (rationally designed complex 'advanced') materials selected by the Commission, using, as appropriate, signals from the early warning and action system. One of the criteria for selecting chemicals for the observatory should be their		

	novelty and disruptive potential that may contribute to an emerging chemical risk. Another criterion for that selection should be the higher degree of uncertainty surrounding them and, due to less regulatory experience regarding those chemicals, the resulting need for additional scrutiny and transparency. The observatory should facilitate regulatory implementation and responsible use of these chemicals by collecting, generating, and disseminating reliable information on selected chemicals' properties, uses and market presence to the general public.		
Recital 47			
55	(47) The observatory should not be regarded as a substitute for required risk management action on any chemical in cases where a hazard or risk has been identified. In order to provide for an efficient and consistent approach for the generation and dissemination of all such additional information, the ECHA should oversee the work of the observatory and make the regularly updated data and information it collects available through the common data platform, or by means of other communication channels, as appropriate. In order to ensure uniform conditions for the implementation of the requirement to select chemicals to be included in the observatory, implementing powers should be conferred on the Commission.		
Recital 48			
56	(48) Under Regulation (EC) No 178/2002, the EFSA is able to commission, in an open and transparent manner, the scientific studies it needs to accomplish its mission, while seeking to avoid duplication with Member States or Union research programmes. The ECHA should also be able to commission studies to obtain adequate data and information on chemicals within its mission, while maintaining the principle that the burden to prove compliance with Union chemicals legislation remains on the duty holder. Furthermore, the ECHA should commission such studies out of its own initiative or at the request of the Commission, with the objective of supporting the effective and efficient implementation and evaluation of Union acts on chemicals within its mandate and contributing the development of a Union chemicals policy.		

Recital 49			
57	(49) In order to adjust the contents of Annexes I and III to technical and scientific progress in the field of chemicals and to bring in the scope of this Regulation new Union acts under which relevant chemicals data and information is generated or submitted, and, where relevant, to expand the specific data types and reference values, listed in Annex II, to be made available by the EMA through the common data platform, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending Annexes I, II and III. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work in relation to the amendment of the Annexes by delegated act, including at expert level through the One-Substance One-Assessment Expert Group, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016⁴⁹. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.		
Recital 50			
58	(50) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States as Member States do not hold the data within the scope of this Regulation and cannot establish a Union wide common data platform, but can rather, by reason of chemicals data and information being hosted at Union level by the Agencies, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.		
Recital 51			

59	(51) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council and delivered an opinion on [OP: Please insert the date of the opinion of the EDPS].		
Formula			
60	HAVE ADOPTED THIS REGULATION:		
Chapter I			
61	Chapter I SUBJECT MATTER, SCOPE AND DEFINITIONS		
Article 1			
62	Article 1 Subject matter and scope		
Article 1(1)			
63	1. This Regulation aims to ensure the efficient delivery of coherent hazard and risk assessments of chemicals where those assessments are required by Union legal acts, to achieve a high level of protection of human health and the environment, to enable the development and use of sustainable chemicals, to ensure the proper functioning of the single market for chemicals, and to improve the Union's citizens' trust in the scientific base for the decisions taken under Union legal acts on chemicals.	One delegation proposed to include SSBD (safe and sustainable by design) as one of the roles for the platform. → PRES propose to work on an amendment introducing explicitly the safe and sustainable by design approach as one of the aims.	PT agrees with the proposal to include " Safe and Sustainable-by-Design" as a role to CDPC as this is one of the main pillars of the "Chemicals Strategy for Sustainability" (CSS), in which regulatory instruments to boost the industrial transition to the production and use of safe and sustainable chemicals should be explored.
Article 1(2)			
64	2. To achieve the objectives referred to in paragraph 1, this Regulation contains measures to:		
Article 1(2), point (a)			
65	(a) bring together data and information on chemicals and ensure that data and information are easily findable, accessible, interoperable and re-usable;		
Article 1(2),			

point (b)			
66	(b) keep records of studies commissioned or carried out by business operators in the context of fulfilling their obligations set under Union chemicals legislation;		
Article 1(2), point(c)			
67	(c) establish the widest possible scientific base for the implementation and development of Union legislation and policy on chemicals;		
Article 1(2), point (c)			
68	(d) establish an early warning and action system for emerging chemical risks.		
Article 1(3)			
69	The provisions laid down in this Regulation apply to chemicals data as laid out in Article 3(2).		
Article 2			
70	Article 2 Definitions	One delegation requested amending art.2 to clarify the meaning of “product” in this proposal. One delegation asked what is covered by the term “products” in art.7(1) One delegation requested examples of the meaning of “chemical products” in relation to mixtures, articles, substances. PRES highlights that the term occurs in recital (8), (10),(25),art.3(3), art.7(1), art.22(1). PRES highlights also that while some of those occurrences relates to cosmetic or medicinal products, other occurrences do not refer to a particular regulation and might have overlapping meaning with e.g. articles in REACH, or products under the ESPR. → PRES is working on an amendment proposal.	PT: We agree that an amendment is needed on term “product”, by including a definition on article 2 or/and by clarifying it’s meaning on recital (8), (10), (25), art.3(3), art.7(1), art.22(1).

Formula			
71	For the purpose of this Regulation, the following definitions shall apply:		
Article 2(1)			
72	1. 'Agencies' means the European Chemicals Agency ('ECHA'), the European Environment Agency ('EEA'), the European Food Safety Authority ('EFSA') and the European Medicines Agency ('EMA') and the European Agency for Safety and Health at Work ('EU-OSHA');		
Article 2(2)			
73	2. 'Authorities' means the European Commission, the competent authorities of the Member States as referred to in any of the Union acts listed in Annexes I and III, and the Agencies, excluding their management boards;		
Article 2(3)			
74	3. 'duty holder' means a natural or legal person responsible for meeting obligations under the Union acts listed in Annex I or II;		
Article 2(4)			
75	4. 'business operators' means duty holders which are private or public undertakings;	One delegation suggests to "use 'economic operators' instead of 'business operators' to ensure alignment with other relevant legislation". PRES highlights that the term "business operator" is used in recital (8),(13),(28),(29),(30),(31),(35),(37),(38), and articles 1(2), 22, 25, and 26. Those articles relates to studies commissioned, studies notifications, and related enforcement/penalties. PRES highlights that the term "duty holder" is defined in art. 2(3) in relation to obligations in acts mentioned in annex I or II. The terms is per se used	

		in recital (13), (15), (48), art 2(4), 15(5), and 17(2). Those later articles relate to the use of the controlled vocabularies, as well as the prohibition for Authorities to use data from the platform to fulfil legal obligations of duty holders. → PRES seeks written comments on the following: ESPR has a definition of “economic operator”: ‘economic operator’ means the manufacturer, the authorised representative, the importer, the distributor, the dealer and the fulfilment service provider. PRES understands that in the present regulation the meaning of it is much more narrow, and relates only to duty holders that at the same time are undertakings. → PRES seeks for agreement that in consequence there is no correspondence with other EU regulations, and thus no amendment here should be done.	
Article 2(5)			
76	5. ‘human biomonitoring data’ means concentrations of chemicals measured in human matrices such as blood or urine;		
Article 2(6)			
77	6. ‘reference value’ means an estimate of a maximum exposure to or emission level of a chemical below which no or only acceptable adverse effects on human health or the environment are expected, or below which risks related to the adverse effects on human health or the environment are considered acceptable or tolerable;	One delegation commented about “acceptable or tolerable” in relation to non-threshold cancerogenic substances. PRES understands that the intention is to avoid that reference values for non-threshold substances are published without mentioning as metadata the actual statistical risk they represent. → PRES proposes to work on an amendment of art	

		2(6), 8 and 14 for this.	
Article 2(7)			
78	7. 'originator' means the Commission, Agency, or Member State competent authority responsible for confidentiality assessments under any Union act listed in Annex I or Annex II;		
Article 2(8)			
79	8. 'originating Union act' means the Union act under which chemicals data and information were generated or submitted;		
Article 2(9)			
80	9. 'controlled vocabularies' means standardised and organised arrangements of words and phrases presented as lists of terms or as thesaurus and taxonomies with a hierarchical structure of broader and narrower terms;		
Article 2(10)			
81	10. 'chemicals data' means any representation of facts or information relating to chemicals and any compilation of such facts or information, including information on physico-chemical properties, hazard properties, use, exposure, risk, occurrence, emissions and manufacturing process of the chemicals, as well as environmental sustainability related information, including climate change related information, on those chemicals, regulatory process-related information on chemicals, standard formats, controlled vocabularies, or any information on applicable legal obligations related to chemicals;		
Article 2(11)			
82	11. 'environmental sustainability related data' means any data relevant for the environmental sustainability assessment of a chemical or material throughout its entire life cycle, including:	One delegation finds this definition vague, and proposes to add an annex (e.g. in Art. 13) which can be updated on a regular basis by means of Delegated Acts. This annex should contain the respective legal acts as well as the associated sustainability information.	PT: We are in favour to add a reference to a new annex IV, containing a list of legal acts relevant for environmental sustainability related data.

		PRES highlights that the definition here is used in a broader sense than the information available in legal acts (e.g. research in art.5(6), art 13(3) and potentially art.13(4)). → PRES requests written comments on the necessity to add a reference to a new annex IV, containing a list legal acts relevant for environmental sustainability related data. Such a reference would be added here as a new point 2(11)(d) along with related delegated powers in Chapter VIII. → PRES would also like to have comments on the provisions of art.13(4) as this partially overlaps with the concern raised by one delegation (by having the COM adopting an implementing decision for data not already hosted or hold by agencies/COM or not coming from EU research). Which relevant data are generated through legal acts but are not hold or hosted by COM/agencies listed in this proposal?	
Article 2(11), point (a)			
83	(a) data on resources, including raw materials, water, energy, fossil fuels and land;		
Article 2(11), point (b)			
84	(b) data on emissions, including greenhouse gases, eutrophication-relevant substances, dust and all other polluting substances; and		
Article 2(11), point (c)			

85	(c) data on by-products originating during the chemical's life cycle that can be used as resources for other production processes, including hydrogen and carbon monoxide.		
Article 2(12)			
86	12. 'personal data' means personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679 of the European Parliament and of the Council and as defined in Article 3, ~~point (16), of Regulation (EU) 2018/175~~ point (1), of Regulation (EU) 2018/1725 of the European Parliament and of the Council;	One delegation highlighted that this definition is specified in Article 3, point (1) of Regulation 2018/1725 and not in Article 3, point (16) of Regulation 2018/175. → PRES sees this as an editorial amendment and proposes to modify Article 2 (12) consequently.	
Article 2(13)			
87	13. 'processing' means processing as defined in Article 4, point (2), of Regulation (EU) 2016/679 of the European Parliament and of the Council and as defined in Article 3, point (3), of ~~Regulation (EU) 2018/175~~ Regulation (EU) 2018/1725 of the European Parliament and of the Council;	One delegation highlighted that the reference is to Regulation 2018/1725 and not to Regulation 2018/175. → PRES sees that this is an editorial amendment and proposes to modify Article 2 (13) consequently.	
Article 2(14)			
88	14. 'data controller' means controller as defined in Article 4, point (7), of Regulation (EU) 2016/679 and as defined in Article 3, point (8), of ~~Regulation (EU) 2018/175~~ Regulation (EU) 2018/1725 of the European Parliament and of the Council;	One delegation highlighted that the reference is to Regulation 2018/1725 and not to Regulation 2018/175. → PRES sees that this is an editorial amendment and proposes to modify Article 2 (14) consequently.	
Article 2(15)			
89	15. 'interoperability' means the ability of two or more data spaces or communication networks, systems, products, applications or components to exchange and use data in order to perform their	One delegation asked if advanced programming interfaces (API) will be used.	PT: We consider that is not necessary to amend the proposal to explicitly mention APIs and the conditions of their use for MS

	functions.	PRES highlights that API are tools that MSs may use amongst others in order to query the data platform from their own advanced knowledge management systems (i.e. machine readability) instead of relying on “manual” queries in a web interface like in ECHA web site today. PRES highlights that in the explanatory memorandum the COM mentions that “The proposal also contributes to the objectives of EU data and digital policies by promoting interoperability and machine readability”. However only interoperability is explicitly mentioned here. → PRES requests written comments on this and on the necessity to amend the proposal to explicitly mention APIs and the conditions of their use for MS and the public.	and the public.
Chapter II			
90	Chapter II INFORMATION SYSTEMS AND PLATFORMS		
Article 3			
91	Article 3 Common Data Platform on Chemicals		
Article 3(1)			
92	1. The ECHA shall establish and manage a common data platform on chemicals ('the common data platform').		
Article 3(2)			
93	2. The common data platform shall provide access to all chemicals data:	One delegation highlights that it is difficult to assess the exhaustiveness of annexes I and III.	

		PRES request written comments on any potentially missing relevant regulations in those annexes. One delegation questioned the differentiated approach between medicinal products and biocidal and phytopharmaceutical products. → PRES would like to receive further clarity in writing.	
Article 3(2), point (a)			
94	(a) generated or submitted as part of the implementation of the Union acts listed in Annex I to this Regulation and held by the Agencies or the Commission;		
Article 3(2), point (b)			
95	(b) generated as part of Union, national or international programmes or research activities in the sphere of chemicals and held by the ECHA, the EEA, the EFSA, the EU-OSHA or the Commission;		
Article 3(2), point (c)			
96	(c) listed in Annex II and held by the EMA;		
Article 3(3)			
97	3. The following information shall not be included in the common data platform:		
Article 3(3), point (a)			
98	(a) the information referred to in Article 45 of Regulation (EC) No 1272/2008 ⁵⁰ ;		

	50 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).		
Article 3(3), point (b)			
99	(b) the information related to cosmetic products and notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/2009 ⁵¹ of the European Parliament and of the Council. 51 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November on cosmetic products (OJ L 342 22.12.2009, p. 59).		
Article 3(4)			
100	4. Documents relating to Authorities' internal work or decision-making processes need not be included in the common data platform, unless required under Article 10.		
Article 3(5)			
101	5. The common data platform shall provide the dedicated services identified in the governance scheme referred to in Article 4(3) including:		
Article 3(5), point (a)			
102	(a) the Information Platform for Chemical Monitoring ('IPCHEM') referred to in Article 7;		
Article 3(5), point (b)			
103	(b) the repository of reference values referred to in Article 8;		
Article			

3(5), point (c)			
104	(c) the database of study notifications referred to in Article 9;		
Article 3(5), point (d)			
105	(d) information on regulatory processes referred to in Article 10;		
Article 3(5), point (e)			
106	(e) information on obligations under Union chemicals legislation referred to in Article 11;		
Article 3(5), point (f)			
107	(f) the repository of standard formats and controlled vocabularies referred to in Article 12;		
Article 3(5), point (g)			
108	(g) the database on environmental sustainability-related data referred to in Article 13.		
Article 3(6)			
109	6. The Authorities and the general public shall have access to the data contained in the common data platform in accordance with Article 16.		
Article 3(7)			
110	7. The data contained in the common data platform may be used in accordance with Article 17.		
Article 3(8)			
111	8. The data contained in the common data platform shall be made available in standard formats, where developed, and through controlled vocabularies where available.		

Article 3(9)			
112	9. The data contained in the common data platform shall be electronically accessible and searchable. The ECHA shall take measures to ensure a high standard of security appropriate to the security risks at stake for the storage of chemicals data in and transmission of chemicals data to the common data platform. The ECHA shall design the common data platform in a way that guarantees that any access to confidential data is auditable.		
Article 3(10)			
113	10. The Commission or Agency under whose authority chemicals data is included in the common data platform on chemicals shall remain responsible for handling any requests for access to documents made under Regulation (EC) No 1049/2001. ⁵² Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (. OJ L 145, 31.5.2001, p. 43).		
Article 3(11)			
114	11. The common data platform and its dedicated services shall be established by [OP: please insert date: three years after the date of entry into force of this Regulation], unless specified otherwise. The relevant datasets shall be integrated progressively into the common data platform by [OP please insert date: ten years from the date of entry into force of this Regulation] according to the implementation plan referred to in Article 4 (1), first sentence. Upon integration of those datasets in the common data platform, when the ECHA receives chemicals data in accordance with Article 5, it shall make that data available through the common data platform without undue delay.	One delegation requested clarifications on this paragraph (timing for the notification service, lack of specification of the timing for the rolling plans). This delegation proposed amendments accordingly → PRES: a more general discussion at the 2d WP took place regarding the timelines	
Article 4			
115	Article 4 Implementation plan and governance of the common data platform	One delegation proposed to include new provisions 5a,5b,5c in art.4., requesting that the COM prepares and presents a recommendation on “how to amend legislation listed in the Annexes to	PT: For us is also not clear if the proposal is to amend the annexes of the data platform proposal, or if the delegation meant to amend the listed pieces of legislation.

		this regulation”. → PRES would like to receive written comments on this as it is not clear for us if this means amending the annexes of the data platform proposal, or if the delegation meant to amend the listed regulations. One delegation raised concerns about the wording “implementing” appearing at several places and which is seen as “misleading” with respect to the legal definition of “implementing acts”. → PRES seeks legal advice on this. The Council legal services provided an opinion on this at the 2nd WP.	
Article 4(1)			
116	1. By [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall adopt and publish an implementation plan identifying datasets for inclusion in the common data platform together with a timeline for their inclusion by means of an implementing decision. Subsequent rolling implementation plans shall be adopted in line with the governance scheme referred to in paragraph 3.	One delegation questioned the procedure for adopting the plan, the consultation procedures and MS involvement. → PRES: WP2 discussion on the desired level of and procedures for MS participation took place.	PT: We agree that more discussion is needed regarding the COM response to FR’s comments, it was mentioned that no formal involvement of MS is needed for implemented decisions to be taken under Articles 4, 13 and 20. In particular considering article 20, it would be important that the MS would be consulted on the list of the selected chemicals with potential contribution to emerging chemical risks to be adopted and publish by implementing decision. In Article 4 is foreseen an implementation plan for data set inclusion in CDPC to be adopted and a governance scheme to be prepared by platform steering committee but is not foreseen the consultation of the MS on any of these decisions.
Article 4(2)			
117	2. The Commission shall, by means of an implementing decision, establish and manage a platform steering committee, which shall		

	include one representative from the ECHA, one representative from the EEA, one representative from the EFSA, one representative from the EMA, one representative from the EU-OSHA and five representatives from the Commission.		
Article 4(3)			
118	3. The platform steering committee shall advise the Commission in the preparation of the common data platform's governance scheme.		
Article 4(4)			
119	4. The Commission shall adopt and publish the governance scheme referred to in paragraph 3 and any revision thereof by means of an implementing decision		
Article 4(5)			
120	5. That governance scheme shall describe:		
Article 4(5), point (a)			
121	(a) the organisation of the main work structures supporting the development and implementation of the common data platform;		
Article 4(5), point (b)			
122	(b) the preparation and adoption of rolling implementation plans for the common data platform;		
Article 4(5), point (c)			
123	(c) the principles on data governance and the required standard formats, controlled vocabularies and further conditions for the provision of information and context data to the common data platform;		
Article 4(5),			

point (d)			
124	(d) the decision-making procedures for the development of new dedicated services and the inclusion of new functionalities of the platform;		
Article 4(5), point(e)			
125	(e) any other rules or requirements necessary for the operation of the common data platform such as the data update, archiving and deletion policy;		
Article 4(5), point (f)			
126	(f) the operation of the steering committee itself.		
Article 5			
127	Article 5 Data Flows for the purpose of the common data platform		
Article 5(1)			
128	1. At the Commission's request, the Agencies shall host and maintain chemicals data generated as part of Union, national or international legislation, programmes or research activities, corresponding to their mandate and the type of data they already hold.		
Article 5(2)			
129	2. Where the Commission or the Agencies hold data or information referred to in Article 3(2), they shall make that data available to the ECHA, in a standard format, where available, together with the relevant context data as ~~referred to in Article 4(4), point (c).~~ referred to in Article 4(5), point (c). The Commission and the Agencies shall indicate whether that data or information is made available to the public under the originating Union act.	One delegation highlighted that the reference should be to Article 4(5), point (c) and not Article 4(4), point (c). → PRES sees this as an editorial amendment and proposes to modify Article 5(2) consequently.	
Article 5(3)			
130	3. The ECHA shall host and maintain occurrence data related to		

	workplace monitoring.		
Article 5(4)			
131	4. The EEA shall host and maintain human biomonitoring data, occurrence data for the environment and occurrence data related to indoor air quality.	One delegation asked if Commission pursues plans for systematic or regular surveys of indoor air quality data → PRES is requesting written comments on this.	
Article 5(5)			
132	5. Researchers or research consortia funded by Union framework programmes shall make available to the EEA any human biomonitoring data they collect or generate from [OP please insert: date of the entry into force of this Regulation].		
Article 5(6)			
133	6. Researchers or research consortia funded by Union framework programmes shall make available to the ECHA any environmental sustainability data on chemicals or materials they collect or generate from [OP please insert: date of the entry into force of this Regulation].		
Article 5(7)			
134	7. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of the chemicals data provided in accordance with paragraph 2 in the common data platform as well as its publication through that platform.		
Article 5(8)			
135	8. For the purpose of paragraph 2, the Commission and the Agencies shall make chemicals data available to the ECHA without undue delay after collection or receipt of the data, after performance of validity and confidentiality assessments in accordance with applicable rules and once the corresponding dataset has been integrated in the common data platform.		
Article 5(9)			
136	9. The Commission and the Agencies shall ensure that data made		

	available to the ECHA shall be downloadable, machine readable and interoperable. They shall appropriately curate and validate the data before providing them to the ECHA.		
Article 6			
137	Article 6 Human biomonitoring data	→ PRES: given the numerous comments, questions and clarification requests received, PRES set this as a discussion point at the 2 nd WP (8/3), and invites MS and the COM to react to the EDPS recommendations.	PT: We don't oppose to amend the text in line with recommendations from the European Data Protection Supervisor.
Article 6(1)			
138	1. The EEA shall collect, host, and maintain human biomonitoring data generated within the territory of the EEA's member and cooperating countries.		
Article 6(2)			
139	2. At the latest by [OP please insert date: 3 years after entry into force of this Regulation] the Commission shall transfer any human biomonitoring data it holds to the EEA.		
Article 6(3)			
140	3. The EEA may process human biomonitoring data constituting personal data to support the Commission in its policy making or to support the Agencies in fulfilling their missions.		
Article 6(4)			
141	4. Human biomonitoring data constituting personal data may be processed by the EEA for the following purposes:		
Article 6(4), point (a)			
142	(a) assessing the impact of chemicals on human health and the environment;		
Article 6(4), point (b)			

143	(b) monitoring time and spatial trends in exposure;		
Article 6(4), point (c)			
144	(c) developing health risk and impact indicators;		
Article 6(4), point (d)			
145	(d) monitoring the impact of regulatory intervention;		
Article 6(4), point (e)			
146	(e) supporting regulatory risk assessments.		
146.a	(f) supporting regulatory risk management	One delegation proposed to add this amendment. PRES understands that HBM data are indeed useful for risk management, e.g. trend analysis will give an idea if policy actions are having an impact or not on reducing exposure → PRES proposes thus to add this paragraph (f)	PT: We support the introduction of a paragraph (f) to consider "supporting risk management regulation measures", as it is a different measure that could go beyond risk assessment.
Article 6(5)			
147	5. The EEA shall make human biomonitoring data they hold or host publicly available in anonymised form through the Information Platform for Chemical Monitoring.		
Article 6(6)			
148	6. The EEA shall act as data controller for the human biomonitoring personal data it holds or hosts and processes for the purposes referred to in paragraph 2. In paragraph 4.	Some delegations highlighted that the reference should be to para. 4. → PRES sees this as an editorial amendment and proposes to modify art.6(6) in consequence. One delegation proposed to add an additional reference to art.3 and 5 here. → PRES, up to his knowledge, understands that	

		from the definition of a data controller this is logical, but seeks for written opinions on this and will request a legal advice. Discussions at the 2nd WP on the EDPS recommendations might also contribute clarifications on this proposal. One delegation suggested to “include the same reference to Articles 6(3) and 6(4)” → PRES is keen to receive a written rationale for this as it seems to introduce a circular reference in the text.	
Article 7			
149	Article 7 Information Platform for Chemical Monitoring		
Article 7(1)			
150	1. The ECHA shall operate and maintain the Information Platform for Chemical Monitoring containing occurrence data on chemicals across different media, including water, soil, indoor air, outdoor air, biota, food and feed, humans, and products as part of the common data platform.	→ PRES: regarding the meaning of “products”, cfr art.2 (here in line 70).	
Article 7(2)			
151	2. At the latest by [OP please insert date: 3 years after the date of entry into force of this Regulation], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring at that moment to the ECHA for integration in the common data platform.		
Article 7(3)			
152	3. At the latest by [OP please insert date: 3 years after entry into force of this Regulation], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring to the ECHA, the EEA or the EFSA for hosting in accordance with the respective agencies’ mandate and in accordance with Article 5.		
Article 7(4)			

153	4. After the completion of the transfer referred to in paragraph 3, where the Commission or the Agencies host or hold occurrence data on chemicals and related chemicals data, they shall make that data available to the ECHA without undue delay for integration in the Information Platform for Chemical Monitoring.		
Article 7(5)			
154	5. The Commission and Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration and publication of occurrence data and related chemicals data they host or hold through the common data platform.		
Article 7(6)			
155	6. The ECHA shall ensure that the data contained in the Information Platform for Chemical Monitoring is machine readable and downloadable.		
Article 8			
156	Article 8 Repository of reference values	One delegation requested a amendment about the statistical (cancer) risk associated with some reference values. → PRES: see our proposal in art 2(6) here line 77	
Article 8(1)			
157	1. The ECHA shall establish and manage a repository of reference values as part of the common data platform.		
Article 8(2)			
158	2. The ECHA shall include any reference value adopted under Union acts listed in Annex I or Annex II, Part 1, in the repository of reference values without undue delay.		
Article 8(3)			
159	3. For reference values not falling under paragraph 2, the Agencies holding or establishing reference values as part of their activities under Union acts listed in Annex I, or the reference values referred to in Annex II, Part 2, shall make those reference values available to the		

	ECHA, in the standard formats provided for in Article 14, where developed, and without undue delay, for integration in the repository of reference values.		
Article 8(4)			
160	4. For the purpose of paragraph 3, where reference values are included in a regulatory dossier submitted to the Agencies, the Agencies shall share those reference values in the standard formats with ECHA without undue delay and once relevant validity and confidentiality assessments have been completed by the originator in accordance with applicable rules.		
Article 8(5)			
161	5. The ECHA shall ensure that the data contained in the repository of reference values is machine readable.		
Article 9			
162	Article 9 Database of Study Notifications		
Article 9(1)			
163	1. The ECHA shall establish and operate a Database of Study Notifications by [OP please insert date: two years after the date of entry into force of this Regulation].		
Article 9(2)			
164	2. The ECHA shall store in the Database of Study Notifications the data notified to it in accordance with Article 22.		
Article 9(3)			
165	3. The ECHA shall integrate the data contained in the Database of Study Notifications in the common data platform once a corresponding registration, application, notification or other relevant regulatory dossier was submitted to the relevant Union or national institution, agency, or body in accordance with corresponding Union law and after a decision was taken by that Union or national institution, agency, or body on the disclosure of the accompanying studies in accordance with	One delegation considers that this deserves clarification as it seems to prevent Member States authorities from getting relevant information on notified studies in time. PRES notes that this might be related to enforcement.	PT: We agree that Member States should have access to the database on study notifications immediately after notification occurs. This could be a similar process to the MS access to registration dossier data (REACH).

	the applicable rules on confidentiality.	→ PRES seeks further written comments on this → PRES is working on an amendment proposal	
Article 9(4)			
166	4. The EFSA shall make the data contained in the database referred to in Article 32b of Regulation (EC) No 178/2002 available to the ECHA for integration in the common data platform once it has received a corresponding application and after it has decided on the disclosure of the accompanying studies in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002.		
Article 9(5)			
167	5. The ECHA and the EFSA shall cooperate to ensure a common approach for the identification of information notified to them in accordance with Article 22 of this Regulation and Article 32b of Regulation (EC) No 178/2002, respectively and facilitate the traceability of the studies notified to their respective databases.		
Article 10			
168	Article 10 Information on regulatory processes on chemicals	→ PRES is seeking written comments on one delegation's question about already existing communication channels in certain regulations, related to the stage of evaluation, and the potential need to modify those regulations. → PRES highlights that this might be the case for TRIS notifications.	
Article 10(1)			
169	1. The ECHA shall establish and manage, as part of the common data platform, a new database containing information on regulatory processes on individual substances or groups of substances that are planned, ongoing or have been completed since the entry into force of this Regulation by the Member States or the Union institutions, agencies or committees referred to in the Union acts listed in Annex III.	→ PRES is seeking for written comments on one delegation's comment that it is not clear whether the scope of art 10(1) includes national regulations processes.	
Article 10(2)			

170	2. Where Member State competent authorities as referred to in any of the Union acts listed in Annex III hold the information referred to in paragraph 1, they shall make that information available to the Union agency responsible under the respective Union act listed in Annex III without undue delay.	→ PRES is seeking for written comments on one delegation's request to clarify the COM reference (during the 1 st WP) to voluntary notifications, including examples.	
Article 10(3)			
171	3. Where the ECHA, EEA, EFSA, EU-OSHA or the Commission hold the information referred to in paragraph 1, they shall make that information available to the ECHA for integration in the common data platform in the standard formats provided for in Article 14 without undue delay and, where relevant, once the responsible agency or the Commission has performed the validity assessment. For each regulatory process or activity, at least the following information shall be included:	→ PRES is seeking written comments on one delegation's question about which information EEA might have to make available to ECHA in this context, as EEA has no competences about chemical products.	
Article 10(3), point (a)			
172	(a) substance identity;		
Article 10(3), point (b)			
173	(b) the Union act and the regulatory process under which the activity takes place;		
Article 10(3), point (c)			
174	(c) submitter or actor responsible for the regulatory process or activity;		
Article 10(3), point (d)			
175	(d) status of the regulatory process or activity;		
Article 10(3), point (e)			
176	(e) where applicable , outcome of the regulatory process or activity	PRES understand from one delegation's	PT: We agree with PRES proposal.

	, including, where applicable, and reports or opinions adopted;	comment that it is not always possible to indicate the (future) outcome, so this provision is not always applicable. → PRES propose to amend art 10(3) by inserting “where applicable” as we see it more precise than “where appropriate”	
Article 10(3), point (f)			
177	(f) where applicable, date of intention to start the regulatory process or activity, completion and latest update.		
Article 10(4)			
178	4. The information referred to in paragraph 3, points (a) to (f), on a specific regulatory process or activity shall be made available to the public once that process or activity has formally started.		
Article 11			
179	Article 11 Information on the obligations under Union acts on chemicals	PRES notes one delegation’s comment on the potentiality of IA in this context.	
Article 11(1)			
180	1. The ECHA shall establish and manage, as part of the common data platform, a database with information on the provisions and legal obligations applicable to chemicals under the Union acts listed in Annex I.		
Article 11(2)			
181	2. The ECHA shall update the information in the database on a regular basis and in accordance with the governance scheme referred to in Article 4(3).		
Article 12			
182	Article 12 Repository of standards formats and controlled vocabularies		
Article 12(1)			
183	1. The ECHA shall establish and manage as part of the common data		

	platform a repository of standard formats and controlled vocabularies.		
Article 12(2)			
184	2. Where standard data formats are established under the Union acts listed in Annexes I and II, the ECHA shall include them in the common data platform.		
Article 12(3)			
185	3. Where the Commission or the Agencies specify a standard format or controlled vocabulary in accordance with Articles 14 or 15, the Commission or the Agency shall make it available to the ECHA without undue delay for integration in the common data platform.		
Article 13			
186	Article 13 Database on environmental sustainability related data	One delegation requested for a new annex on relevant legal acts, see discussion of Article 2(11) → PRES: see line 82 here above About the role of EIONET in this → PRES included this in the discussion at the WP2 (effort needed by MS)	
Article 13(1)			
187	1. At the latest within three years after the publication of the decision referred to in paragraph 4, the ECHA shall establish and manage, as part of the common data platform, a database containing environmental sustainability related data.		
Article 13(2)			
188	2. Where the Commission or the Agencies host or hold environmental sustainability related data in addition to the chemicals data already available in the common data platform, they shall make that data available to the ECHA without undue delay once the Commission or the Agency hosting or holding that data has completed, where relevant, validity and confidentiality assessments. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of environmental sustainability related data in		

	the database on environmental sustainability related data.		
Article 13(3)			
189	3. Where researchers or research consortia funded by Union framework programmes make available to the ECHA, under Article 5(6), any environmental sustainability data on chemicals or materials they collect or generate, the ECHA shall integrate the relevant data in the database on environmental sustainability related data.		
Article 13(4)			
190	4. By [OP please insert date: three years after the date of entry into force of this Regulation], the Commission shall adopt an implementing decision identifying existing datasets on environmental sustainability related data, other than those referred to in paragraph 2, for inclusion in the common data platform and shall design relevant related database functionalities.	→ PRES is seeking legal advice about the wording “implementing decision” (cfr delegation comment). Council legal services provided an opinion on this at the 2 nd WP.	
Chapter III			
191	Chapter III DATA FORMATS AND CONTROLLED VOCABULARIES	→ PRES seeks written comments on one delegation’s request to eventually have study reports and raw data provided → PRES seek written comments on the request by one delegation to investigate that there is no impact on the use of INCI names for cosmetics regulation, and no impact on substance identification and product labelling in that regulation.	
Article 14			
192	Article 14 Standard formats	One delegation amendment proposal on statistical risk: → PRES: see here Article 2(6) line 77	
Article 14(1)			
193	1. Without prejudice to Union provisions providing for the development or making available of data formats, the Commission and the Agencies shall specify, where relevant, for the data referred to in		

	Article 3 (2) and falling within their mandate, standard formats and software packages and make them available free of charge through the common data platform.		
Article 14(2)			
194	2. The standard formats referred to in paragraph 1 shall, to the extent possible:		
Article 14(2), point (a)			
195	(a) avoid the use of proprietary standards;		
Article 14(2), point (b)			
196	(b) re-use existing data formats or parts of them;		
Article 14(2), point (c)			
197	(c) use OECD or other internationally agreed formats;		
Article 14(2), point (d)			
198	(d) be coherent with other existing data formats;		
Article 14(2), point (e)			
199	(e) ensure interoperability with existing data submission approaches.		
Article 14(3)			
200	3. Those standard formats shall be interoperable with the common data platform and be user-friendly.		
Article 14(4)			
201	4. The Commission and the Agencies shall exchange data contained in the common data platform in the relevant standard format.		
Article			

14(5)			
202	5. The Commission and the Agencies shall use the International Uniform Chemical Information Database format (IUCLID) for making available to the ECHA for integration in the common data platform the relevant parts of dossiers under the following Union acts:		
Article 14(5), point (a)			
203	(a) Regulation (EC) No 1831/2003 of the European Parliament and of the Council ⁵³ ; ⁵³ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268 18.10.2003, p. 29).		
Article 14(5), point (b)			
204	(b) Regulation (EC) No 1935/2004 of the European Parliament and of the Council ⁵⁴ ; ⁵⁴ Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338 13.11.2004, p. 4).		
Article 14(5), point (c)			
205	(c) Regulation (EC) No 1331/2008 of the European Parliament and of the Council ⁵⁵ ; ⁵⁵ Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354 31.12.2008, p. 1).		
Article 14(5), point (d)			
206	(d) Regulation (EC) No 1332/2008 of the European Parliament		

	and of the Council ⁵⁶ ; ⁵⁶ Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354 31.12.2008, p. 7).		
Article 14(5), point (e)			
207	(e) Regulation (EC) No 1333/2008 of the European Parliament and of the Council ⁵⁷ ; ⁵⁷ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354 31.12.2008, p. 16).		
Article 14(5), point (f)			
208	(f) Regulation (EC) No 1334/2008 of the European Parliament and of the Council ⁵⁸ ; ⁵⁸ Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354 31.12.2008, p. 34).		
Article 14(5), point (g)			
209	(g) Regulation (EC) No 1223/2009 of the European Parliament and of the Council ⁵⁹ ; ⁵⁹ Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342 22.12.2009. p, 59).		
Article			

14(5), point (h)			
210	(h) Commission Regulation (EU) No 234/2011 ⁶⁰ ; ⁶⁰ Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 064 11.3.2011, p. 15).		
Article 14(5), point (i)			
211	(i) Directive 2009/48/EC of the European Parliament and of the Council. ⁶¹ ⁶¹ Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170 30.6.2009, p. 1).		
Article 14(6)			
212	6. The Commission and the Agencies shall cooperate when setting standard formats to ensure coherence with other formats and the interoperability of the standard formats with the common data platform and with existing data submission approaches.		
Article 14(7)			
213	7. The Commission and the Agencies shall take the necessary and appropriate measures to monitor and identify at an early stage any potential divergence between data formats that could cause interoperability problems. If a divergence is identified, the Agencies concerned shall cooperate to resolve it or, where the divergence is justified, explain the underlying reasons. Where the Agencies concerned are not able to resolve that divergence, they shall draw up a joint report and present it to the Commission. The report shall clearly outline the reasons for the divergence, clarify any underlying technical issue and make a proposal to remedy the divergence.		
Article 14(8)			

214	8. The Commission shall adopt an implementing decision to remedy the divergence.		
Article 15			
215	Article 15 Controlled vocabularies	→ PRES is seeking written comments on the remarks by one delegation about the difficulties related to differences in vocabularies between legislations. → PRES seeks for comments on the difficulties related to substances identification inconsistencies between regulations (see delegation comment). PRES highlights that this problem is also relevant for art.22,25,26 on studies notification (a lack of correct identification might render difficult to implement them)	PT: We are concerned that the aim of interoperability is not fully achieved if data harmonisation is not foreseen, namely concerning substances identification. We are aware that assuring the interoperability of such a platform will be quite challenging, as we are dealing with a significant amount of data coming from different sources and using different terminologies and formats (Art. 14 and 15). Additionally, we also have concerns relating to conflicting results and analyses of data from studies (art. 3(2)) and not only with harmonisation of vocabularies and formats.
Article 15(1)			
216	1. The Commission and the Agencies shall specify and regularly update controlled vocabularies within their mandate for the data referred to in Article 3(2), where relevant.		
Article 15(2)			
217	2. The Commission and the Agencies shall prioritise specifying controlled vocabularies for the identification of chemicals and the characterisation of their forms.		
Article 15(3)			
218	3. Those controlled vocabularies shall:		
Article 15(3), point (a)			
219	(a) avoid the use of proprietary controlled vocabularies to the extent possible;		

Article 15(3), point (b)			
220	(b) re-use existing substance identifiers and controlled vocabularies or parts of them to the extent possible;		
Article 15(3), point (c)			
221	(c) use OECD or other internationally agreed controlled vocabularies to the extent possible;		
Article 15(3), point (d)			
222	(d) ensure coherence with other relevant controlled vocabularies including by preparing alignment tables.		
Article 15(4)			
223	4. Those controlled vocabularies shall be interoperable with the common data platform.		
Article 15(5)			
224	5. Where controlled vocabularies are specified, the Commission and the Agencies shall:		
Article 15(5), point (a)			
225	(a) make them available free of charge through the common data platform and as open datasets;		
Article 15(5), point (b)			
226	(b) integrate them in any submission software or template to be used by duty holders under the Union acts listed in Annex I and referred to in Article 3(2); and		
Article			

15(5), point (c)			
227	(c) use them when exchanging data between them through the common data platform.		
Article 15(6)			
228	6. The Commission and the Agencies shall cooperate with each other in setting the controlled vocabularies.		
Article 15(7)			
229	7. The Commission and the Agencies shall take the necessary and appropriate measures to monitor and identify at an early stage any potential divergence between controlled vocabularies. If a divergence is identified, the Agencies concerned shall cooperate to resolve it or, where the divergence is justified, explain the underlying reasons. Where the Agencies concerned are not able to resolve that divergence, they shall draw up a joint report and present it to the Commission. The report shall clearly outline the reasons for the divergence, clarify any underlying technical issue and make a proposal to remedy the divergence.		
Article 15(8)			
230	8. The Commission shall adopt an implementing decision to remedy the divergence.		
Chapter IV			
231	Chapter IV CHEMICALS DATA CONFIDENTIALITY AND USE	→ PRES: some delegation's comments here were discussed at the WP2.	
Article 16			
232	Article 16 Access rights and transparency	→ PRES: One delegation request and questions (line 232 of the comments file) were discussed at the WP2.	
Article 16(1)			
233	1. The Authorities shall have access to all the chemicals data contained		

	in the common data platform, including data which is deemed to be confidential under Article 5(2), second sentence.		
Article 16(2)			
234	2. The Authorities shall take the necessary measures to ensure that information contained in the common data platform marked as confidential in accordance with Article 5(2) is not made public.	→ PRES: One delegation comment and questions were discussed at the WP2 (line 234 of the comments file)	
Article 16(3)			
235	3. The general public shall have access to all the chemicals data contained in the common data platform and considered as available to the public in accordance with the Union act under which the data was generated or submitted.		
Article 17			
236	Article 17 Use of chemicals data contained in the common data platform	One delegation comment on the meaning of “products” is addressed here in art.2 (see line 70). PRES: Regarding the other comments: → PRES seeks written comments on one delegation’s concern on the identification in the data platform of cosmetics ingredients that may have been tested on animals. → PRES invites the COM to update MS on the possibility of an overview table on confidentiality provisions requested by one delegation.	
Article 17(1)			
237	1. The Authorities may use the chemicals data contained in the common data platform in the performance of any of their activities, where those activities support the development or implementation of chemicals legislation and policy.	→ PRES: one delegation requested for amendment to explicitly allow national use of the data was set for discussion at WP2.	
Article 17(2)			
238	2. Without prejudice to existing provisions enabling the sharing and use of chemicals data under the Union acts listed in Annexes I and II, Authorities shall not use chemicals data contained in the common data	One delegation requested clarifications on the use of data in relation to duty holders obligations. → PRES invites for written comments on this.	

	platform to fulfil any legal obligations of duty holders.		
Article 17(3)			
239	3. When using chemicals data contained in the common data platform that is deemed confidential under Article 5(2), second sentence, the Authorities shall respect the confidentiality of information data as marked by the originator and shall not disclose that data to the public without the consent of the originator.		
Chapter V			
240	Chapter V MONITORING AND OUTLOOK FRAMEWORK FOR CHEMICALS		
Article 18			
241	Article 18 Framework of indicators	One delegation questioning the MS involvement was set for discussion at the 2nd WP → PRES put the question on EIONET impacts for discussion at the 2nd WP. One delegation comments on cosmetics: → PRES invites for written comments on questions raised by one delegation on cosmetics aspects (notification of undesirable effects, link to the Communication System for Market Surveillance (ICSMS) Art 23 Reg 1223/2009, consequences on the allowance of use for critical circumstances). One delegation comment on the relation to existing statistics systems → PRES invites for written comments	PT: We welcome the given examples on Eionet involvement in the framework of indicators, however, if possible, there could be more clarification on the impacts.
Article 18(1)			
242	1. The EEA, in collaboration with the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission, shall establish, operate, and maintain a framework of indicators to monitor the drivers and impacts of exposure to chemicals, measure the effectiveness of chemicals		

	legislation and measure the transition towards the production of safe and sustainable chemicals.		
Article 18(2)			
243	2. The framework of indicators referred to in paragraph 1 shall be accessible in the form of an indicator dashboard, which the EEA shall establish and which the ECHA shall make available through the common data platform.		
Article 18(3)			
243.b	3. The framework of indicators referred to in paragraph 1 shall be <i>shall established, operated, and maintained by [OP: please insert date: 3 years after the end of the first calendar year after entry into force of this Regulation].</i>	One delegation expressed concerns on the timescale for establishing the framework PRES highlights that several other articles contain indications on the timeframe → PRES submits this amendment for consideration, and discussion took place at the 2nd WP.	PT: We agree with the establishment of a timescale and propose an amendment: <i>“3. The framework of indicators referred to in paragraph 1 shall be ~~shall~~ established, operated, and maintained by [OP: please insert date: 3 years after the end of the first calendar year after entry into force of this Regulation].”</i> Considering that the work is ongoing, we propose that the timeframe is set to one year.
Article 19			
244	Article 19 Early warning and action system for emerging chemical risks	→ PRES: One delegation’s question on MS experts and RAC involvement was set for discussion at 2nd WP → PRES: One delegation’s request for clarification on implications/role of EIONET and MS was set for discussion at the 2nd WP Regarding the other comments: → PRES seeks written comments about one delegation’s question on the relation between the indicators and the early warning system (art.18,19). → PRES invites for written comments on the question regarding the level of ambition of the	PT: The early warning system is to be based on a framework of indicators that will monitor chemical pollution. In this sense, we would like to be informed about the level of ambition of this process taking into consideration those situations where: pollution source is not directly detected, and the cause-effect relationship is difficult to claim. And the cases where the risk is becoming more systemic (e.g. considering climate related risks). We also have some concerns on which will be the involvement of MS in the early warning

		system in relation to complex systemic risks. → PRES invites written comment on the proposal to include the word “prevention” in the proposal	and action system (art. 19), since details on the operation of the early warning and action system are lacking. We understand that some issues might have to be clarified during implementation, as this is a new task, however previous doubts remain about implications/role of EIONET and the Member States.
Article 19(1)			
245	1. The EEA shall establish, operate and maintain a Union early warning system for emerging chemical risks by [OP please insert date: one year after the date of entry into force of this Regulation].		
Article 19(2)			
246	2. For the purpose of paragraph 1, the EEA shall compile early warning signals, which shall include at least signals from:		
Article 19(2), point (a)			
247	(a) the EFSA’s emerging risks exchange network;		
Article 19(2), point (b)			
248	(b) existing national early warning systems;		
Article 19(2), point (c)			
249	(c) data that the EEA holds;		
Article 19(2), point (d)			
250	(d) targeted literature searches performed by the EEA;		
Article 19(2), point (e)			

251	(e) data made available by the ECHA, the EFSA, the EU-OSHA and the EMA in accordance with paragraph 3.		
Article 19(2)			
252	The early warning signals compiled by the EEA under the first subparagraph may be based on a positive identification of an emerging risk or on an uncertainty in the data leading to a potential positive identification of an emerging risk.		
Article 19(3)			
253	3. The ECHA, the EFSA, the EU-OSHA and the EMA shall identify and gather relevant available data on early warning signals from the field falling within their mandate and provide this data to the EEA.		
Article 19(4)			
254	4. The EEA shall draw up an annual report, compiling and analysing the data on early warning signals gathered in accordance with paragraphs 2 and 3. [The first report shall be prepared by [OP: please insert date: 6 months after the end of the first calendar year after entry into force of this Regulation]. The EEA shall present this report to the Commission, relevant Union agencies and ~~Member State competent authorities for consideration of the need~~ Member State competent authorities who shall consider the need for regulatory or policy action related to the early warning signals.	One delegation expressed questions the request to EEA to highlight areas on which to FOCUS, in the report. PRES suppose that this may be solved by a change in the wording (mostly editorial) → PRES proposes for consideration a proposed amendment to the text.	
Article 19(5)			
255	5. The EEA shall make all relevant data on early warning signals that it holds or hosts as well as the report referred to in paragraph 4 available to the ECHA for integration in the common data platform.		
Article 20			
256	Article 20 Observatory for specific chemicals with potential contribution to emerging chemical risks	PRES seeks written comments on one delegation's question about the type of risks covered here, and the interplay with existing chemicals legislation.	
Article 20(1)			
257	1. The ECHA shall establish, operate and maintain an observatory for		

	specific chemicals that the Commission considers as requiring additional scrutiny. The observatory shall include reliable information on the chemicals' properties, safety aspects, uses and market presence.		
Article 20(2)			
258	2. By [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall adopt and publish a list of the selected chemicals by means of an implementing decision. The Commission shall review the list of selected chemicals regularly and adopt any revision thereof by the same means.	One delegation highlighted that the linking word "and" is missing before the proposal "adopt any revision thereof by the same means". à PRES sees this as an editorial amendment and proposes to modify article 20(2) consequently (see <i>bold italic</i>). One delegation requested for amendments (implementing "decisions"). → PRES: questions on the meaning of "implementing", and MS participation were discussed at the 2nd WP.	
Article 20(3)			
259	3. The Commission shall select the chemicals referred to in paragraph 1 based on the scientific and technical progress and using the signals of the early warning system referred to in Article 19. The selection shall include potential contributors to new and emerging chemical risks among innovative rationally designed materials with new or enhanced properties or targeted or enhanced structural features at nanoscale.		
Article 20(4)			
260	4. For the purpose of operating the observatory referred to in paragraph 1, the ECHA shall:		
Article 20(4), point (a)			
261	(a) make use of relevant datasets integrated in the common data platform, and compile, analyse and curate further available data on		

	selected chemicals or classes of chemicals;		
Article 20(4), point (b)			
262	(b) commission studies and, where relevant, use the data generation mechanism established under Article 21 to address knowledge gaps or significant uncertainties;		
Article 20(4), point (c)			
263	(c) make compiled data publicly available through the common data platform or other communication and outreach tools as appropriate, to facilitate informed societal discussion and increase public awareness on the properties, use and safety aspects of specific chemicals, and regularly update that information.		
Chapter VI			
264	Chapter VI DATA GENERATION MECHANISM		
Article 21			
265	Article 21 Data generation mechanism	One delegation raised the question of the promotion of animal testing in relation to article 1. PRES understands that the type of tests are prescribed in each regulation mentioned in annex I, and thus this regulation is not modifying that. However, art.21 here is new, and thus the question of the minimization of animal testing might be relevant here. One delegation would like to know if commissioned animal studies will be notified → PRES requests written reactions and proposals on this matter. One delegation expressed the need to frame the mandate in such a way that the burden of proof on companies is preserved. One delegation insisted also on the burden of proof on industry and	

		highlights the need for clarity on procedures and financing. → PRES invites for written comments and amendments proposals. Some Comments were received in relation to the involvement of MS, industry, stakeholders in the data generation mechanism. → PRES: discussion during the 2nd WP	
Article 21(1)			
266	1. Using the best independent resources available, the ECHA may commission scientific studies to support the implementation of Union acts on chemicals listed in Annex I within its mandate and to contribute to the support, evaluation or development of a Union chemicals policy.	One delegation requested clarity on the meaning of scientific studies, and which ones will not be covered. → PRES invites for written comments on this	
Article 21(2)			
267	2. The Commission may request the ECHA to commission the scientific studies referred to in paragraph 1.		
Article 21(3)			
268	3. The ECHA shall only commission scientific studies when results cannot be obtained through existing legal provisions or processes under Union legislation listed in Annex I. It shall not commission studies with a predominant research objective.		
Article 21(4)			
269	4. The ECHA shall seek to avoid duplication with Member State or Union research or implementation programmes.		
Article 21(5)			
270	5. The ECHA shall commission these scientific studies in an open and transparent manner.	One delegation suggested to amend this to introduce compulsory prior MS consultation. → PRES scheduled this for discussion at the 2nd WP	
Article			

21(6)			
271	6. The ECHA and the EFSA shall closely cooperate with each other on the planning and commissioning of scientific studies undertaken by the ECHA in accordance with paragraph 1 and of studies undertaken by the EFSA in accordance with Article 32 of Regulation (EC) No 178/2002.		
Article 21(7)			
272	7. The ECHA shall make the results of the scientific studies performed under this Article available through the common data platform.		
Chapter VII			
273	Chapter VII NOTIFICATION OF STUDIES	Several comments were received on this chapter: on the legal scope and definition of studies to be notified, duplications, studies conducted outside the EU, late notifications, absence of a transitional period, practical arrangements for companies, the need for early access before publication in the data platform. → PRES scheduled this for discussion at the 2 nd WP	
Article 22			
274	Article 22 Notification of studies		
Article 22(1)			
275	1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, without undue delay, any studies on chemicals they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment, prior to placing on the market, under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.		
Article 22(2)			
276	2. For the purposes of paragraph 1, business operators shall notify to		

	the Database of Study Notifications referred to in Article 9 the title, scope, laboratory, or testing facility carrying out the study, the intended starting and planned completion dates and, where relevant, whether the study is commissioned to comply with a decision of the ECHA pursuant to Articles 40, 41 or 46 of Regulation (EC) No 1907/2006.		
Article 22(3)			
277	3. Laboratories and testing facilities shall also, without undue delay, notify any study commissioned by business operators to support a regulatory dossier on which an Agency is required to provide a scientific output, including a scientific opinion, under the Union acts listed in Annex I. However, laboratories and testing facilities shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.		
Article 22(4)			
278	4. For the purposes of paragraph 3, laboratories and testing facilities shall notify to the Database of Study Notifications referred to in Article 9 the title, scope, intended starting and planned completion dates of any test they carry out, as well as the name of the business operator who commissioned the test.		
Article 22(5)			
279	5. Paragraphs 3 and 4 shall apply, mutatis mutandis, to laboratories and testing facilities located in third countries insofar as set out in relevant agreements with those third countries.		
Article 22(6)			
280	6. The obligations set under this article shall apply from [OP please insert date: 24 months after the date of entry into force of this Regulation].		
Article 22(7)			
281	7. The ECHA shall lay down the practical arrangements for		

	implementing the provisions of this Article.		
Chapter VIII			
282	Chapter VIII DELEGATED POWERS		
Article 23			
283	Article 23 Amendment of Annexes I, II and III		
Article 23(1)			
284	1. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex I in order to adjust the content of that Annex to technical and scientific progress in the field of chemicals or, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it new Union acts under which relevant chemicals data is generated or submitted.		
Article 23(2)			
285	2. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex II by adding, where relevant, new categories of data types.		
Article 23(3)			
286	3. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex III in order to adjust the content of that Annex to technical and scientific and technical progress in the field of chemicals and, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it Union acts relevant for data on new regulatory processes on chemicals.		
Article 24			
287	Article 24 Exercise of the delegation		
Article 24 (1)			

288	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.		
Article 24(2)			
289	2. The power to adopt delegated acts referred to in Article 23 shall be conferred on the Commission for a period of five years from [OP please insert: the date of the entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each five-year period.		
Article 24(3)			
290	3. The delegation of power referred to in Article 23 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.		
Article 24(4)			
291	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.		
Article 24(5)			
292	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.		
Article 24(6)			
293	6. A delegated act adopted pursuant to Article 23 shall enter into force only if no objection has been expressed either by the European		

	Parliament or by the Council within a period of three months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.		
Chapter IX			
294	Chapter IX ENFORCEMENT AND PENALTIES	One delegation expressed concerns on enforcement for third countries; one delegation questioned the effectiveness of national sanctions. → PRES scheduled this for discussion at the 2 nd WP	
Article 25			
295	Article 25 Enforcement The Agencies shall cooperate with Member States' enforcement authorities and exchange information on the compliance, by business operators and laboratories, with the obligation to notify studies in accordance with Article 22.		
Article 26			
296	Article 26 Penalties for non-compliance		
Article 26(1)			
297	1. Member States shall introduce penalties for non-compliance, by business operators and laboratories, with the obligations laid out in Article 22 and shall take all necessary measures to ensure that they are implemented. The penalties provided for shall be effective, proportionate, and dissuasive.		
Article 26(2)			
298	2. Member States shall notify the Commission of those rules and of those measures by 30 June 2025 and shall notify to the Commission		

	without delay any subsequent amendment affecting them.		
Article 27			
299	Article 27 Entry into force and application in time This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.		
Formula			
300	This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels, For the European Parliament For the Council The President The President		

	Presidency proposals: amendments (~~deletions~~ / additions)	Presidency proposals: follow-up or proposal to work on amendments, or requests for written comments	Reactions from the Commission and MS

Annex I			
301	Annex I UNION ACTS REFERRED TO IN ARTICLES 2, 3, 8, 11, 12, 15, 17, 21, 22 AND 23 Reference to each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.		
302	1. Council Directive 91/271/EEC of 21 May 1991 concerning urban wastewater treatment (OJ L 135, 30.5.1991, p. 40)		
303	2. Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources (OJ L 375, 31.12.1991, p.1)		
304	3. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1)		
305	4. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste		
306	5. Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11)		
307	6. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection		

	of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50)		
308	7. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34)		
309	8. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for the Community action in the field of water policy (OJ L 327, 22.12.2000, p.1)		
310	9. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1)		
311	10. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p. 1)		
312	11. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10)		
313	12. Directive 2002/46/EC on the approximation of the laws of the Member States relating to food		

	supplements (OJ L 183, 12.7.2002, p. 51)		
314	13. Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1)		
315	14. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29)		
316	15. Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (OJ L 309, 26.11.2003, p. 1)		
317	16. Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55)		
318	17. Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1)		
319	18. Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1)		
320	19. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)		

321	20. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3)		
322	21. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 070, 16.3.2005, p. 1)		
323	22. Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC (OJ L 033, 4.2.2006, p. 1)		
324	23. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19)		
325	24. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC,		

	93/105/EC, and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)		
326	25. Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9)		
327	26. Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26)		
328	27. Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE) (OJ L 108, 25.4.2007, p. 1)		
329	~~28. Regulation (EC) No 108/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 39, 13.2.2008, p. 11)~~	One delegation highlighted the fact that regulation 108/2008 is mentioned in point 28 of Annex I, whereas this regulation is already covered by regulation 1925/2006 mentioned in point 26 of Annex I. →PRES proposes to amend the text (deleting point 28).	
330	29. Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19)		

331	30. Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1)		
332	31. Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3)		
333	32. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84)		
334	33. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)		
335	34. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)		
336	35. Regulation (EC) No 1332/2008 of the European		

	Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC, and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p.7)		
337	36. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16)		
338	37. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34)		
339	38. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energyrelated products		
340	39. Regulation (EC) No 401/2009 of the European Parliament and of the Council of 23 April 2009 on the European Environment Agency and the European Environment Information and Observation Network (OJ L 126, 21.5.2009, p. 13)		
341	40. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of		

	foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3)		
342	41. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1)		
343	42. Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (OJ L 300, 14.11.2009, p. 1)		
344	43. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)		
345	44. Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71)		
346	45. Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28)		
347	46. Regulation (EC) No 1221/2009 of the European		

	Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community ecomanagement and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC (OJ L 342, 22.12.2009, p. 1)		
348	47. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)		
349	48. Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17)		
350	49. Regulation (EC) No 66/210 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel (OJ L 027, 30.1.2010, p. 1)		
351	50. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)		
352	51. Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the		

	Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18)		
353	52. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)		
354	53. Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.7.2012, p. 1)		
355	54. Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38)		
356	55. Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the import and export of hazardous chemicals (OJ L 201, 27.7.2012, p. 60)		
357	56. Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009		

	and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35)		
358	57. Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (OJ L 96, 29.3.2014, p. 1)		
359	58. Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1)		
360	59. Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006 (OJ L 150, 20.5.2014, p. 195)		
361	60. Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1)		
362	61. Directive (EU) 2016/2284 of the European Parliament and of the Council of 14 December 2016		

	on the reduction of national emissions of certain atmospheric pollutants, amending Directive 2003/35/EC and repealing Directive 2001/81/EC (OJ L 344, 17.12.2016, p. 1)		
363	62. Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 095, 7.4.2017, p. 1)		
364	63. Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1)		
365	64. Regulation (EU) 2017/852 of the European		

	Parliament and of the Council of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008 (OJ L 137, 24.5.2017, p. 1)		
366	65. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).		
367	66. Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (OJ L 170, 25.6.2019, p. 1)		
368	67. Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45)		
369	68. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435, 23.12.2020, p. 1)		
370	69. Regulation (EU) .../... of the European Parliament and of the Council on nature restoration (OJ .../ELI: ... [OP: please add number and publication reference].		

371	70. Regulation (EU) .../... of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (OJ .../ELI: ... [OP: please add number and publication reference]		
ANNEX II			
372	ANNEX II UNION ACTS REFERRED TO IN ARTICLES 2, 3, 12, 17 AND 23 AND REFERENCE VALUES REFERRED TO IN ARTICLE 8		
Part 1			
373	Part 1 - Specific data on relevant active substances to be identified in accordance with Article 4(5)(b) falling under the scope of this Regulation for the purposes of Article 3 for human and veterinary medicinal products		
374	1. Non-clinical safety data, including data related to environmental risk assessments, compiled pursuant to Directive 2001/83/EC of the European Parliament and of the Council¹ and Regulation (EC) No 726/2004 of the European Parliament and of the Council²; ¹ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67). ² Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying		

	down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).		
375	2. Data related to environmental risk assessments, compiled pursuant to Regulation (EU) 2019/6 of the European Parliament and of the Council³; and ³ Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).		
376	3. Maximum residue levels data compiled pursuant to Regulation (EC) No 470/2009 of the European Parliament and of the Council⁴. ⁴ Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).		
377	These data shall be limited to data submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this		

	Regulation. Where relevant, the data held by the EMA resulting from procedures concluded before the entry into force of this Regulation may also be considered for inclusion into the common data platform.		
Part 2			
378	Part 2 - Reference values to be included in the repository of reference values following Article 8(3)		
379	1. Predicted no effect concentrations derived as part of the environmental risk assessment under Directive 2001/83/EC of the European Parliament and of the Council, Regulation (EC) No 726/2004 of the European Parliament and of the Council and Regulation (EU) 2019/6 of the European Parliament and of the Council.		
380	These data shall be limited to data submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation. Where relevant, data held by the EMA resulting from procedures concluded before the date of entry into force of this Regulation shall also be considered for inclusion into the common data platform.		

Annex III			
381	Annex III UNION ACTS REFERRED TO IN ARTICLES 2, 10 AND 23		
382	Reference to each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.		
383	1. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1)		
384	2. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste		
385	3. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50)		
386	4. Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11)		
387	5. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34)		

388	6. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p. 1)		
389	7. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10)		
390	8. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29)		
391	9. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)		
392	10. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3)		
393	11. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1)		

394	12. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19)		
395	13. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)		
396	14. Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38)		
397	15. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84)		
398	16. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals		

	of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)		
399	17. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)		
380	18. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC, and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p.7)		
381	19. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16)		
382	20. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34)		
383	~~21. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for~~	Some delegations highlighted the fact that Regulation 1331/2008 is mentioned twice: in points 17 and 21 of Annex III.	

	~~food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)~~	→ PRES proposes to amend the text (deleting this repetition).	
384	22. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3)		
385	23. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energyrelated products		
386	24. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1)		
387	25. Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer (OJ L 286, 31.10.2009, p. 1)		
388	26. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)		
389	27. Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the		

	protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28)		
390	28. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)		
391	29. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)		
392	30. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)		
393	31. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).		
394	32. Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45)		
395	33. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human		

	consumption (OJ L 435, 23.12.2020, p. 1)		
396	34. Regulation (EU) .../... of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (OJ .../ELI: ... [OP: please add number and publication reference].		

PUBLIC

PORTUGAL

14/3/2024

Proposal for a
DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
amending Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European
Chemicals Agency
(Text with EEA relevance)



PRESIDENCY PROPOSALS for written comments by 22 March 2024 1 PM

Delegations will find attached a **revised** Presidency compromise proposal on the above-mentioned Proposal.

Changes in comparison to the previous compromise proposal, document COM(2023) 781, are marked in **red bold underline** for additions and in ~~red strikethrough~~ for deletions.

	Commission Proposal	Presidency Justification	Delegations comments
Proposal Title			
1	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL Amending Directive 2011/65/EU control of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency (Text with EEA relevance)		
Formula			
2	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,		
Citation 1			
3	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,		
Citation 2			

4	Having regard to the proposal from the European Commission,		
Citation 3			
5	After transmission of the draft legislative act to the national parliaments,		
Citation 4			
6	Having regard to the opinion of the European Economic and Social Committee ¹		
Footnote 1			
7	¹ OJ C [...], [...], p. [...].		
Citation 5			
8	After consulting the Committee of the Regions,		
Citation 6			
9	Acting in accordance with the ordinary legislative procedure,		
Formula			
10	Whereas:		
Recital 1			

11	(1) The Commission has, in its Communication 'European Green Deal'², set an objective that chemical safety assessments should move towards a process of 'one-substance, one-assessment', calling for more transparent and simpler risk assessment processes in order to reduce the burden on all stakeholders, accelerate decision-making, as well as to increase consistency and predictability of scientific decisions and opinions. The Commission, in its Communication on Chemicals Strategy for Sustainability³ concludes that, in order to achieve that objective, part of the scientific and technical work on chemicals performed at Union level in support of Union legislation needs to be reattributed to the most suitable Union agencies. This would simplify the current set-up, improve quality and coherence of safety assessments across Union legislation, and ensure more efficient use of existing resources.		
Footnote 2			
	² Communication from the Commission to the European		

12	Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal (COM (2019) 640 final of 11 December 2019).		
Footnote 3			
13	³ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment (COM (2020) 667 final of 14 October 2020).		
Recital 2			
14	(2) The reattribution of certain scientific and technical tasks to the European Chemicals Agency is necessary in order to align processes and levels of scientific scrutiny and digitalisation with current standards and processes of the European Chemicals Agency. This is also necessary in order to ensure a consistent standard of scientific quality, transparency, data searchability and interoperability, in line with		

	the 'one-substance, one-assessment' ambition.		
Recital 3			
15	(3) Directive 2011/65/EU of the European Parliament and of the Council ⁴ contains two procedures related to the assessment of chemicals: the evaluation of economic operators' applications for granting, renewing or revoking an exemption from the substance restrictions pursuant to Article 5 of that Directive and the review of substances to be added to the list of restricted substances pursuant to Article 6 of that Directive. There is a need to increase transparency by setting detailed procedural steps for the process to review substances for a potential inclusion in the list of restricted substances.		
Footnote 4			
16	⁴ Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic		

	equipment – OJ L 174 1.7.2011, p 88.		
Recital 4			
17	(4) Data and information held by the European Chemicals Agency in the context of regulatory processes under Titles VII and VIII of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁵ can be usefully deployed for the assessment of potential substance restrictions and for assessing applications for exemption under Directive 2011/65/EU. Established structures and procedures can help to build on the existing knowledge base, maximise synergies, and make the best use of available expertise and resources.		
Footnote 5			
18	⁵ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and		

	repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC - OJ L 396 30.12.2006, p. 1.		
Recital 5			
19	(5) To ensure consistency between the evaluation of economic operators' applications for granting, renewing or revoking an exemption pursuant to Article 5 of the Directive 2011/65/EU, as well as to make the best use of existing chemicals-related expertise, the technical evaluation to assess the justification of such exemption requests should be carried out by the European Chemicals Agency and its committees in close coordination with the Commission.		
Recital 6			
	(6) To ensure that the restriction process referred to Article 6 in Directive 2011/65/EU is consistent with the restriction processes under other legislation		

20	related to chemicals, in particular with the substance restriction process laid down in Articles 69 to 73 of Regulation (EC) No 1907/2006, it is necessary to amend Directive 2011/65/EU to formally task the European Chemicals Agency with a role in the restriction process. In the light of experience obtained when carrying out substance reviews, it is essential for the quality of the related technical assessment, and for enabling synergies, to make use of information and tools being used in the context of assessments for chemical restrictions under Regulation (EC) No 1907/2006.		
Recital 7			
21	(7) The two procedures described under Article 5 and Article 6 are applicable at the EU level. National provisions should not deviate from these Articles set in Directive 2011/65/EU.		
Recital 8			
	(8) For amending procedural provisions under Directive 2011/65/EU, a transitional period of 12 months is necessary to allow for appropriate resource		

22	and task allocation for the European Chemicals Agency. That timeframe is considered sufficient to allow for amending procedural provisions under Directive 2011/65/EU, a transitional period of 12 months is necessary to allow for appropriate resource and task allocation for the European Chemicals Agency. That timeframe is considered sufficient to allow potential applicants or Member States to adjust to the modified procedural steps under that Directive.		
Recital 9			
23	(9) Directive 2011/65/EU should therefore be amended accordingly,		
Formula			
24	HAVE ADOPTED THIS DIRECTIVE:		
Article 1			
25	<i>Article 1</i> Amendments to Directive 2011/65/EU Directive 2011/65/EU is amended as follows:		
Article 1(1)			

26	(1)Article 5 is amended as follows:		
Article 1(1), point (a)			
27	(a) paragraphs 3 and 4 are replaced by the following		
Article 1(1), point (a), paragraph 3			
28	'3. An application for granting, renewing or revoking an exemption shall be made to the European Chemicals Agency set up pursuant to Article 75(1) of Regulation (EC) No 1907/2006 ('the Agency') in accordance with Annex V.		
Article 1(1), point (a), paragraph 4a			
29	4. The Agency shall: (a) acknowledge receipt of an application within 15 days of its receipt, stating the date of receipt of the application;		
Article 1(1), point (a), paragraph 4b			
30	(b) verify that the application contains all the elements laid out in Annex V;		
Article 1(1), point (a), paragraph 4c			

31	(c) if necessary, request the applicant to complete the application <u>within 45 days of receipt of the application</u> , and provide an appropriate deadline <u>of maximum 60 days</u> ;	Change proposed based on the comments from two delegations. One delegation suggested replacing the word “appropriate” with a specific deadline in order to improve legal certainty for the actors concerned. They motivated that this would also ensure that current applications are published on the Agency’s website in a timely manner. Additionally, other delegation motivated that the applicant should be given a deadline within which the application should be completed, since the exemption continue to apply during the process of evaluation of the application. The 45 days and 60 days were proposed based on the deadlines given in REACH Article 69 (4) for restrictions proposals, as there are no similar deadlines under the authorisation scheme in REACH. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	PT: We agree with the amendment proposed by DK/DE aiming to a more concrete obligation in terms of deadlines, in the light of the experience under the REACH Regulation; with regard to the alignment of the deadlines with the Restriction procedure, we would like to underline the great complexity on the analysis of this kind of procedure (involving sometimes hundreds of substances) which is known as not being less time consuming than those which are under the RoHS Directive.
Article 1(1), point (a), paragraph 4d			
32	(d) make the application and any supplementary information supplied by the applicant available to Member States;		
Article 1(1), point (a), paragraph 4^e			
	(e) make a summary of the application and a non-		

33	confidential version of the application as submitted by the applicant, as well as the date when the application is considered complete, available to the public on the Agency's website;		
Article 1(1), point (a), paragraph 4f			
34	(f) invite interested parties to submit information within 3 months of its publication on the Agency's website.		
Article 1(1), point (a), paragraph 4			
35	Where the applicant does not complete the application with the missing elements identified by the Agency in compliance with Annex V within the deadline provided in accordance with the first subparagraph, point (c), the Agency may reject such application. The Agency shall establish and communicate to the applicant without undue delay the date when the application is considered complete. Upon receipt of an application, the Agency shall notify the Commission of the application and keep it informed of any of		

	the procedural steps under points (b) to (f).';		
Article 1(1), point (b)			
36	b) the following paragraph 4a is inserted after paragraph 4:		
Article 1(1), point (b), regarding inclusion of article 4a			
37	4a. The Agency shall, after verifying the completeness of the application, request the opinion of the Committee for Socio-economic Analysis, set up pursuant to Article 76(1), point (d) of Regulation (EC) No 1907/2006. It shall request the opinion of the Committee for Risk Assessment, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006, in the case of an application for a new exemption or where otherwise considered appropriate. The Committee for Socio-economic Analysis and, where relevant, the Committee for Risk Assessment:	Two delegations suggested that it needs to be clearer when RAC shall evaluate an application for exemption. Therefore, they considered that it may be good to clarify that RAC shall evaluate applications for renewal of exemptions that have previously been evaluated by external consultants or where there are amendments in the exemption that have not been evaluated before. This would have the effect of increasing consistency between the evaluations. Alternatively, other delegation proposed in their comments to rather assign the tasks to ECHA (and its Expert Groups) than directly to RAC and SEAC. Their proposal was motivated by a concern related to the capacity of SEAC and RAC to perform the tasks under Art. 5 (lack of expertise in RoHS within the Committees, insufficient staff). In their opinion, the proposed change in the text would not preclude the Executive Director from requesting the assistance of the Committees of ECHA on a case-by-case basis.	PT: In our opinion there is a need to clarify when RAC should assess an exemption request. In this sense, we agree with DK/SE suggestion and COM's reaction. In particular, we support that RAC shall limit assessments to renewal of exemptions requests and to new requests just when they were previously assessed by external consultants (different criteria and expertise) and or when it is considered, in a case-by-case decision basis, that "major changes" are involved. With regard to some concerns that were transmitted related to the ability of SEAC/RAC to carry out the tasks set out in Article 5 (lack of RoHS expertise in committees, lack of staff) we believe that these technical and scientific committees are the right bodies for the tasks at stake, taking in consideration the expected amendments to the pieces of legislation regulating the agencies, as well as the experience held by these committees on chemicals, including on their life cycle.

		PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(1), point (b), regarding inclusion of article 4a (a)			
38	(a) shall draw up draft opinions within 9 months of the date the application has been considered complete by the Agency under paragraph 4, point (b);	One delegation proposed to align the deadline for RAC and SEAC for the assessment of exemptions with the authorisation scheme and assessment of authorisation under the REACH-Regulation (Article 64 (1) of the REACH Regulation). Other delegation proposed to specify that the opinions drawn shall be scientific and technical. This proposal is a consequence of their proposal above (line 37 of this document), where it is considered that tasks should be rather assigned to ECHA (and its Expert Groups) than directly to RAC and SEAC. PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	PT: We believe that the alignment with authorization procedure under REACH Regulation is an added value considering all the experience that has been gained in this context (article 64(1)). However, we understand the COM reaction on this, and agree that adjustments shall be made according to the RoHS Directive reality.
Article 1(1), point (b), regarding inclusion of article 4a (b)			

39	(b) shall assess whether the criteria in Article 5(1), point (a), are met and shall provide clear guidance to the Commission on granting, renewing or revoking an exemption;		
Article 1(1), point (b), regarding inclusion of article 4a (c)			
40	(c) may request the applicant or third parties to submit, within a specified period, additional information;		
Article 1(1), point (b), regarding inclusion of article 4a (d)			
41	(d) upon adopting the draft opinions, shall communicate those draft opinions to the applicant and shall allow the applicant the opportunity to comment within 4 weeks of the communication of the draft opinions to the applicant;	One delegation proposed to specify that the opinions drawn shall be scientific and technical. This proposal is a consequence of their proposal above (line 37 of this document), where it is considered that tasks should be rather assigned to ECHA (and its Expert Groups) than directly to RAC and SEAC. PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(1), point (b), regarding inclusion of article 4a (e)			
42	(e) shall adopt their final opinions, taking into account the comments from the applicant.		

Article 1(1), point (b), regarding inclusion of article 4a			
43	Each Committee shall take into account any information submitted by third parties in accordance with the second subparagraph, point (c). The Agency shall send the final opinion(s) of the Committees to the Commission within 12 months from the date an application has been considered complete by the Agency. The Agency shall identify which parts of its opinions and of any attachments thereto should be made publicly available on its website and shall make those parts publicly available on its website. For the purpose of adopting opinions pursuant to this paragraph, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.'	One delegation proposed to align the deadline for RAC and SEAC for the assessment of exemptions with the authorisation scheme and assessment of authorisation under the REACH-Regulation. Therefore, in their view the deadline for sending the final opinion to the Commission should be set to 14 months. This will assure that ECHA will have at least the same time period as is given under Article 64 (5) in REACH, where the Committees shall adopt their final opinion within two months after receiving the comments from the applicant and send it to the Commission within 15 days after this. Additionally, other delegation proposed to specify that the opinions drawn shall be scientific and technical. This proposal is a consequence of their proposal above (line 37 of this document), where it is considered that tasks should be rather assigned to ECHA (and its Expert Groups) than directly to RAC and SEAC. PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	PT: We agree with the DK proposal, for the same reasons mentioned in the A37.
Article 1(1), point (c)			

44	(c) paragraph 8 is replaced by the following:		
Article 1(1), point (c), paragraph 8			
45	8. The Agency shall, in agreement with the Commission, provide a harmonised format for the applications referred to in paragraph 3 of this Article as well as comprehensive guidelines for such applications, taking into account the situation of SMEs. Any submission to the Agency shall be made using the format and the submission tools made available by the Agency.’;	One delegation considered that a clarification is needed in relation to third criterion in Art. 5(1)(a) of the RoHS Directive: <i>‘the total negative environmental, health and consumer protection impact as a result of the substitution is likely to be greater than the total environmental, health and consumer protection benefits thereof’</i>. In their view many exemptions are granted or renewed with reference to this criterion, not infrequently, where the other criteria do not apply i.e. where substitution is possible or reliable alternatives are available, in spite of the weight of substitution in RoHS as reflected in recital 8 <i>the most effective way of ensuring a significant reduction of risks to health and the environment relating to those substances, in order to achieve the chosen level of protection in the Union, is the substitution of those substances in EEE by safe or safer materials</i>. The criterion is often applied based on energy considerations. It is unclear if this was the intention of this criteria and, which weight to assign energy considerations compared to chemicals considerations within the frame of RoHS. In light of the experienced difficulty concerning collection of information from	

		applicants as identified during the RoHS review process, priority should be given to clarifying the applicability of this criterion. Therefore, there is a need to clarify the applicability of this criteria and it is important that ECHA does so through following this re-attribution of tasks. ECHA should revise this guidance and that the guidance should be adopted by the expert committee (see proposal for reference to this committee in under article 20). PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(2)			
46	(2) in Annex V, the following paragraph is added: 'In cases referred to in the first paragraph, point (h), the applicant shall submit a non-confidential version of the application.'		
Article 1(3)			
47	(3) Article 6 is amended as follows:		

Article 1(3), point (a)			
48	(a) in paragraph 1, the first subparagraph is replaced by the following: ‘With a view to achieving the objectives set out in Article 1 and taking account of the precautionary principle, a review, based on a thorough assessment, and an amendment of the list of restricted substances in Annex II shall be considered by the Commission <u>every five years</u> ~~periodically~~ on its own initiative or following the submission of a restriction dossier prepared by a Member State containing the information referred to in paragraph 2.’;	Change proposed based on the comment from one delegation. One delegation considered that the list of substances restricted under the ROHS directive should be evaluated on a more regular basis. Here a 5-year period is suggested. It is not paramount that it should be a 5-year period, however, a timeline is needed. Staff working document p. 119 assesses the impact for ECHA. Here it says: <i>As the assessments are to be done ca. every 5 years.</i> Therefore, a time limit of 5 years is considered appropriate. eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52023SC0850 One delegation proposed also some additional changes (introduction of subparagraph 1a) as they considered that the substances restricted in the POP-regulation, and where the use in EEE is exempted, should be considered for Annex II in the RoHS-Directive. PRES did not modify the proposal and welcomes delegations’ views/comments.	PT: We agree with DK concern with the need to introduce legal clarity to the term "periodically". However, we agree with the COM that some flexibility to react according to technical and scientific progress and market developments should be kept, taking also into account that restrictions can always be initiated or are dependent on other legislative proposals to address horizontal risks, in particular REACH, and that MS can always initiate the restriction procedure under RoHS. <u>Finally, we must pay close attention to medical devices that takes many years of research.</u>

		Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(3), point (b)			
49	(b) in paragraph 1, the fourth subparagraph is deleted.		
Article 1(3), point (c)			
50	(c) paragraph 2 is replaced by the following: '2. The review and amendment of the list of restricted substances, <u>or a group of similar substances</u>, in Annex II shall be based on restriction dossiers prepared by the Agency at the request of the Commission or prepared by a Member State. The Agency or a Member State shall take into account any available information and any relevant risk assessment submitted for the purposes of other Union legislation covering the life cycle of the substance used in EEE, in particular the waste phase. To this end, other bodies established under Union law and carrying out a similar	Change proposed based on the comment of one delegation. One delegation considered that the reference to the assessment of groups of substances should not be deleted as it is in the current COM's proposal. Additionally, one delegation considered that any relevant assessment, including assessments of waste handling, should be included in a restriction dossier, therefore DK proposed to delete "risk" from the text. PRES did not modify the proposal and welcomes delegations' views/comments.	PT: In our opinion, from the outset, this amendment would not be necessary on a legal level, however it is understood that the DK proposal amendment will emphasize that "group of similar substances" are also considered in the list of restricted substances in Annex II. We agree with COM comment (doc. WK3533/2024 rev1) regarding the DK proposals in this article for deleting the word 'risk' from the text and to exclude the requirement in relation to assessing the risk.

	task shall, on request, provide information to the Agency or Member State concerned. The restriction dossier shall comply with the requirements set out in Part II, point 3, of Annex XV to Regulation (EC) No 1907/2006 for those requirements that relate to the criteria set out in Article 6(1) and shall, in addition, contain the following information: (a) information on the use of the substance or the group of similar substances in EEE; (b) information on detrimental effects and exposure in particular during waste EEE management operations.'	Change based on the proposal of the COM received prior to the 2nd Ad Hoc WP and discussed during that meeting. This proposal intended to accommodate the concern of one delegation regarding re-shifting of focus of assessment required under the RoHS Directive when aligning restriction procedure with the REACH restriction. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(4)			
51	(4) the following Articles 6a, 6b and 6c are inserted:		
Article 1(4), regarding insertion of Article 6a			
52	'Article 6a Initiation of procedure for review and amendment of the list of restricted substances		
Article 1(4), regarding insertion of Article 6a, point (1)			

53	1. Within 12 months of receipt of the request from the Commission referred to in Article 6(2), first subparagraph, the Agency shall prepare a restriction dossier conforming to the requirements referred to in Article 6(2), third subparagraph, and suggest restrictions in order to initiate the restriction process.		
Article 1(4), regarding insertion of Article 6a, point (2)			
54	2. A Member State shall notify the Agency that it proposes to prepare a restriction dossier which conforms to the requirements referred to in Article 6(2), third subparagraph, within 12 months. If that dossier demonstrates that action on a Union-wide basis is necessary, beyond any measures already in place, the Member State shall submit it to the Agency in order to initiate the restriction process.		
Article 1(4), regarding insertion of Article 6a, point (3)			
55	3. The Agency shall publish without delay the intention of the Commission or the Member State to initiate the process to review and amend the list of restricted substances in Annex II <u>on the Agency's website.</u>	Change proposed based on the comment from one delegation and in line with the text proposed in Art. 5 (see line 28 of this document). One delegation considered that it was not clear where the intention to review and amend	PT: We agree with DE proposal regarding the inclusion of a specific reference to where the publication on the intention of the COM or the MS to initiate the process of revision or amendment of the list of restricted substances will take place.

		the list of restricted substances will be published. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(4), regarding insertion of Article 6a, point (4)			
56	4. The Agency shall establish and maintain a list of substances for which a restriction dossier conforming to the requirements of Article 6(2) is planned or underway by either the Agency or a Member State for the purposes of a proposed restriction.		
Article 1(4), regarding insertion of Article 6a, point (5), paragraph 1			
57	5. The Agency shall consult the Committee for Risk Assessment, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006, and the Committee for Socio-economic Analysis, set up pursuant to Article 76(1), point (d), of that Regulation. The Committees shall verify whether the restriction dossier submitted conforms to the requirements referred to in Article 6(2), third subparagraph.		

Article 1(4), regarding insertion of Article 6a, point (5), paragraph 2

58	Within 30 days of receipt of the restriction dossier, the respective Committee shall inform the Agency or the Member State proposing restrictions whether the dossier conforms to the requirements referred to in Article 6(2), third subparagraph. If the dossier does not conform to those requirements, the reasons shall be given to the Agency or the Member State in writing within 45 days of receipt of that dossier. The Agency or the Member State shall bring the dossier into conformity within 60 days of the date of receipt of the reasons from the Committees, otherwise the procedure under this Article shall be terminated.		

Article 1(4), regarding insertion of Article 6a, point (6)

59	Where the dossier meets the requirements referred to in Article 6(2), third subparagraph, the Agency shall make it publicly available without delay, clearly indicating the date of publication. The Agency shall invite all interested parties, including economic operators, recyclers, treatment operators, environmental organisations and		

	employee and consumer associations to submit, individually or jointly, within 4 months from the date of the publication of the dossier, the following:		
Article 1(4), regarding insertion of Article 6a, point (6a)			
60	(a) comments on dossiers and the suggested restrictions;		
Article 1(4), regarding insertion of Article 6a, point (6b)			
61	(b) a socio-economic analysis including an analysis of alternatives, or information which can contribute to ~~one of~~ the suggested restrictions, examining the advantages and drawbacks of the proposed restrictions.	Changes partially modified based on the comment from one delegation. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(4), regarding insertion of Article 6a			
62	The analysis referred to in the first subparagraph, point (b), shall conform to the requirements in Annex XVI to Regulation (EC) No 1907/2006.	One delegation suggested to delete this text, as they consider that the restriction process in RoHS may be too extensive compared to the restriction process in REACH. They were also concerned that having in mind future revision of the REACH Regulation, it is not clear how the restriction process will look like in the future.	PT: We understand SE concern related to the uncertainties on REACH revision outcome. However, since this revision is expected to take place only in the medium term and there are no weaknesses in REACH of such a nature as to undermine the objective, it is considered to that the alignment of the processes is the best way forward. We do not agree with the deletion of the text as suggested by SE. From our best

		PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	knowledge and foresight, RoHS restriction process does not seem to become more extensive than the restriction process under REACH Regulation.
Article 1(4), regarding insertion of Article 6b			
63	<i>Article 6b</i> Opinion of the Agency's Committees		
Article 1(4), regarding insertion of Article 6b, point (1)			
64	1. Within 12 months from the date of publication referred to in Article 6a(6), the Committee for Risk Assessment shall adopt an opinion as to whether the restriction is appropriate in reducing the risk to human health or the environment, specifically ~~by reference to the risks set out in Article 6(1)~~ <u>for those requirements that relate to the criteria set out in Article 6(1)</u>, third subparagraph, based on its consideration of the relevant parts of the dossier. This opinion shall take account of the restriction dossier prepared by the Agency at the request of the Commission or by the Member State, and the views of interested	Change proposed by PRES to align the text with Article 1(3), point (c) (line 50 of this document). This proposal intended to accommodate the concern of one delegation regarding re-shifting of focus of assessment required under the RoHS Directive when aligning restriction procedure with the REACH restriction. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	PT: We do not agree with DK proposal amendment. In fact, and as COM argued, RAC major role stands by developing "risk assessment" which includes to assess whether a restriction is appropriate in reducing risks to human health and the environment, including the environmentally sound recovery and disposal of waste EEE. The use of hazardous substances in EEE is restricted due to the risks it poses to human health and environment and therefore, reducing those risks results in a direct contribution to the protection of human health and the environment. Against this background, it is clear to us that "reducing the risk" is the appropriate wording and therefore shall be kept in the text.

	parties referred to in Article 6a(6), point (a).		
Article 1(4), regarding insertion of Article 6b, point (2)			
65	2. Within 15 months from the date of publication referred to in Article 6a(6), the Committee for Socio-economic Analysis, shall adopt an opinion on the proposed restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. Prior to that, it shall prepare a draft opinion on the suggested restrictions and on the related socio-economic impact, taking account any existing analysis or information according to Article 6a(6), point (b).		
Article 1(4), regarding insertion of Article 6b, point (3)			
66	3. The Agency shall publish the draft opinion of the Committee for Socio-economic Analysis on its website without delay and invite interested parties to provide their comments on the draft opinion no later than 60 days from its publication.		
Article 1(4), regarding insertion of Article 6b, point (4)			

67	4. The Committee for Socio-economic Analysis shall without delay adopt its opinion, taking into account where appropriate further comments received by the deadline set in paragraph 3. This opinion shall take into account the comments of interested parties submitted under Article 6a(6), point (a), and paragraph 3 of this Article.		
Article 1(4), regarding insertion of Article 6b, point (5)			
68	5. Where the opinion of the Committee for Risk Assessment diverges significantly from the restrictions proposed, the Agency shall postpone the deadline for the opinion of the Committee responsible for Socio-economic Analysis by a maximum of 90 days.		
Article 1(4), regarding insertion of Article 6b, point (6)			
69	6. For the purpose of adopting opinions pursuant to this article, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.	One delegation proposed some additional suggestions to provide for legislative provisions for the remuneration of tasks by Rapporteurs within the OSOA Package. PRES did not modify the proposal, as this is covered by mutatis mutandis application of Art. 87 of Regulation (EC) No 1907/2006 .	PT: These issues are addressed under REACH Regulation.

		Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(4), regarding insertion of Article 6c			
70	Article 6c Submission of an opinion to the Commission		
Article 1(4), regarding insertion of Article 6c, point (1)			
71	1. The Agency shall submit to the Commission, without delay, the opinions of the Committees for Risk Assessment and Socio-economic Analysis on the restrictions suggested pursuant to Article 6b. Where the opinions of the Committees for Risk Assessment and Socio-economic Analysis diverge significantly from the restrictions suggested by the dossier, the Agency shall submit an explanatory note to the Commission providing a detailed explanation of the reasons for such differences. If one or both of the Committees do not adopt an opinion by the deadlines set in Article 6b(1) and (2) the Agency shall inform the Commission accordingly, stating the reasons.		

Article 1(4), regarding insertion of Article 6c, point (2)

72	2. The Agency shall publish the opinions of both Committees on its website without delay.		

Article 1(4), regarding insertion of Article 6c, point (3)

73	3. The Agency shall, on request, provide the Commission or Member State with all documents and evidence submitted to or considered by it.';		

Article 2

74	The provisions under this Directive shall be applicable from [OJ: 12 months after the publication of this Directive].		

Article 3

75	This Directive shall enter into force on the twentieth day following that of its publication in the <i>Official Journal of the European Union</i> .		

Article 4

76	This Directive is addressed to the Member States. Done at Brussels, <i>For the European Parliament For the Council</i> <i>The President The President</i>		
Additional recommendations (changes proposed regarding articles that were not included in the current COM's proposal)			
Concerning amendments of Article 5(5):			
77	An application for renewal of an exemption shall be made no later than 18 months before the exemption expires.	One delegation proposed extension of the deadline to 24 months as they are concerned that by aligning the exemptions assessment process with REACH, the Commission will be phased with the issue of expediting delegated directives before the expiration of the concerned exemption. Therefore it was suggested to increase the deadline in order to leave more room for the assessment procedure. PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	PT: From our experience regarding REACH authorisations, we have been observing that developing technologies and alternatives happens each time faster in the industrial sectors which, along with the time length of the procedure, might lead to decision making to be based on non-updated information/data.
Concerning amendments of Article 20:			

78	Exercise of the delegation 1. The powers to adopt the delegated acts referred to in Article 4(2), Article 5(1) and Article 6 shall be conferred on the Commission for a period of 5 years from 21 July 2011. The Commission shall draw up a report in respect of delegated powers at the latest 6 months before the end of the 5-year period. The delegation of power shall be ~~automatically~~ <u>tacitly</u> extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 21. <u>1a. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of</u>	Change proposed based on the comments from one delegation. The COM agreed to the proposed changes, prior to the 2nd Ad Hoc WP. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	PT: We agree with the DK proposal as it gives the possibility for Member States to express an opinion when considered to be appropriate/needed.

13 April 2016 on Better Law-Making.

PUBLIC

PORTUGAL

14/03/2024

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals

(Text with EEA relevance)



Line nr.		Presidency proposal: amendments (~~deletions~~ /additions)	Presidency justification after WP1: follow-up or proposal to work on amendments, or requests for written comments	Delegates comments/proposals after WP2
1		THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 43, 114, 168(4)(c), 192(1) and 207 thereof, Having regard to the proposal from the European Commission, After transmission of the draft legislative act to the national parliaments, Having regard to the opinion of the European Economic and Social Committee, Having regard to the opinion of the Committee of the Regions, Acting in accordance with the ordinary legislative procedure, Whereas:		
2	Recital 1	The European Green Deal¹ sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability² ('the Strategy') is a crucial delivery of the zero-pollution ambition and introduces the 'one		

		substance, one assessment' approach, which aims to improve the efficiency, effectiveness, coherence, and transparency of safety assessments of chemicals across Union legislation. ¹Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal. COM (2019) 640 final. ²Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment. COM (2020) 667 final		
3	Recital 2	In order to achieve this objective, a part of the scientific and technical work on chemicals performed at Union level in support of Union legislation needs to be consolidated in the relevant Union agencies, while obligations on Union agencies to cooperate for the development of assessment methodologies and exchange of data and information should be introduced. This would simplify the current set-up, improve quality and coherence of safety assessments across Union legislation and ensure more efficient use of existing resources.		
4	Recital 3	The reattribution of certain existing scientific and technical tasks to the	Many concerns were raised during the commenting about:	

		European Chemicals Agency, as well as the attribution of new tasks, were proposed as part of ongoing revisions of Union acts. This horizontal proposal aims to provide for further attribution of tasks in respect of those Union acts which are not in the process of being revised and is necessary in order to ensure that the European Chemicals Agency is involved in tasks pertaining to its expertise and developed capacities on chemicals. This is in line with the ‘one substance, one assessment’ aim to ensure that technical and scientific work is performed by the appropriate Union agency, benefiting from demonstrated experience and established tools in its field. The proposal for a Regulation is accompanied by a proposal for a Directive for the amendment of Directive 2011/65/EU of the European Parliament and of the Council³, aiming to achieve the same objectives. ³Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency	Concerns on ECHA’s capacity, budget (including budget for technical and infrastructure requirements and training), workload, committees, expertise to take on the extra tasks. This relates amongst others to the expertise of committee members (and not only the number of experts), potential establishment of technical expert groups (and how they relate to the Committees’ role), what is to be left for the founding regulation, potential targeted REACH amendments, ECHA and committees expertise in medical devices and in POP-waste. Some specific elements for discussion: One delegation proposed it would be more appropriate to assign the task(s) to prepare opinions to ECHA, and allow ECHA to best determine the most efficient and appropriate way to deliver a robust opinion. For example, ECHA’s technical experts could draft opinions and establish technical expert working groups to consult with in order for scientific opinions to be delivered. In certain cases, the Executive Director can still use their powers under REACH’s Article 77 (3) to issue a request to RAC and SEAC, thus negating the need for all tasks to have a RAC and/or SEAC opinion. This delegation also prefers that the legislative package makes provisions for	

			ECHA to prepare opinions in some circumstances without the explicit need for those opinions to be drafted by RAC and SEAC. In addition, they explained that their concern is with the capacity of the individual members to deliver the expected workload, even if both Committees were at full capacity. Therefore, they see a need for provisions to be included to allow for amending the composition of the current ECHA's committees to cover also any ad-hoc Article 77(3) requests in light of requests from the Executive Director. Finally, the inclusion of remuneration for Committee Rapporteurs for all tasks needs to be provided for. They also recommend the OSOA legislation package amends Article 85 and 87 of REACH to provide for additional experts to cover the additional work and its associated remuneration. PRES: Discussion took place during WP2	
5	Recital 4	As part of the coordinated consolidation and attribution of tasks under the 'one substance, one assessment' approach, provisions to allocate a mandate to the European Medicines Agency to develop and cooperate on the development of assessment methodologies, standard		

		formats and controlled vocabularies and exchange of data and information on chemicals have been introduced in Article 138(1), subparagraphs (zd) and (ze), as well as new procedures for ensuring the coherence between scientific opinions in Article 139 of the proposal for a Regulation amending Union pharmaceutical legislation.⁴ ⁴Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006, COM(2023) 193 final. [OJ:Please insert correct reference once the Regulation is adopted].		
6	Recital 5	To ensure the coherence of methodologies for assessments related to chemicals at Union level, all relevant Union agencies should have an equal mandate to develop such methodologies in the areas falling within their respective missions and should be subject to the same obligations to cooperate amongst each other to develop such methodologies.		
7	Recital 6	To ensure the coherence and efficiency of assessments related to chemicals		

		across Union legislation, it is also important to enable data interoperability and easy exchange of data between the relevant Union agencies, as well as to encourage cooperation on the development of standard formats and controlled vocabularies. Thus, to facilitate data exchange between agencies, any new data formats defined by the European Food Safety Authority or by the European Environmental Agency should be set in cooperation with other relevant Union agencies working on chemicals. To this end, relevant provisions should be introduced in Regulation (EC) No 401/2009 of the European Parliament and of the Council and, in Regulation (EC) No 178/2002 of the European Parliament and of the Council, existing provisions should be strengthened and, where relevant, new ones be introduced. Similar provisions should also be considered to be proposed for a strengthened mandate of the European Chemicals Agency in its founding regulation.		
8	Recital 7	To promote the coherence and efficiency of assessments related to chemicals across Union legislation, steps should be taken by the relevant Union agencies to avoid divergent scientific opinions. Existing cases of divergent opinions have lead to increased uncertainty for operators, as well as to declined public		

		trust in the scientific robustness and coherence of scientific decision making. Proposals to address and strengthen procedures for resolving divergence of scientific opinions concerning the European Medicines Agency with other scientific bodies is proposed as part of the revision of Union pharmaceutical legislation. Similar provisions should also be considered to be proposed for a strengthened mandate of the European Chemicals Agency in its founding regulation, whilst such provisions are not relevant and applicable to the European Environmental Agency, since this agency does not issue scientific opinions on individual chemicals such as to be part in divergent outcomes.		
9	Recital 8	Correspondingly, this Regulation aims to address the eventual divergence between scientific opinions of the European Food Safety Authority and those of other Union agencies. Regulation (EC) No 178/2002 of the European Parliament and Council already contains provisions establishing a procedure to solve divergent scientific opinions. Those resolution procedures should be reinforced, in that the European Food Safety Authority and the other dissenting agency should be bound to make their best effort to resolve the divergence on general scientific issues, and only when they are not able to resolve the		

		divergence, should they refer to risk managers.		
10	Recital 9	In the more specific case of scientific divergence pertaining to the hazard identification of chemical substances, a new procedure enabling the resolution of the divergence should be established. This procedure should enable the Commission to request the European Chemicals Agency, as the Union agency most equipped with expertise and capacity in hazard assessment, as well as long-standing experience with the harmonised classification and labelling process, to develop a proposal for harmonised classification and labelling, in accordance the Regulation (EC) No 1272/2008 of the European Parliament and Council, moving closer to the ‘one substance, one assessment’ vision as regards uniformity of hazard assessments of chemicals across the Union. This possibility should be reflected in the relevant provision providing for the resolution of diverging scientific opinions laid down in Regulation (EC) No 178/2002.		
11	Recital 10	To comply with the obligation laid down in Section 10.4.3 of Annex I to Regulation (EU) 2017/745 of the European Parliament and of the Council ⁵ , the Commission has provided the Scientific Committee on Health,		

	Environmental and Emerging Risks ('SCHEER') with a mandate to prepare guidelines on the benefit-risk assessment of the presence of phthalates which are classified as either carcinogenic, mutagenic or toxic to reproduction category 1A or 1B, or which have endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁶. The SCHEER issued those guidelines in 2019 and the Commission has issued a mandate to the SCHEER to perform a first update of those guidelines. ⁵ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1). ⁶ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives	

		91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1–849).		
12	Recital 11	To comply with the obligation laid out in Section 10.4.4. of Annex I to Regulation (EU) 2017/745, the Commission should mandate the relevant scientific committee to prepare guidelines for substances other than phthalates and which are classified as either carcinogenic, mutagenic or toxic to reproduction category 1A or 1B, or which have endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council.		
13	Recital 12	The European Chemicals Agency already provides scientific advice on chemical substances, including on phthalates, endocrine disruptors and carcinogens, mutagens and reproductive toxicants under Regulation (EC) No 1907/2006. Several key capacities of the agency can be reused, including hazard, risk, exposure and socio-economic assessment capacities, the Committee opinion development and IT capabilities for stakeholder consultation and dissemination. To enable timely future updates on the presence of phthalates and		

		to ensure that the appropriate Union agency develops new guidelines on other substances on the basis of the latest scientific evidence, these tasks should be attributed to the European Chemicals Agency.		
14	Recital 13	Taking account of the new hazard classes and criteria for classification, labelling and packaging of substances introduced by Commission Delegated Regulation (EU) 2023/707 of 19 December 2022⁷, reference to endocrine disruptors for human health, of Category 1, should be specified in 10.4.1., point (b) of Annex I of Regulation (EU) 2017/745 in light of the relevance of that hazard class to the type of substances in medical devices. ⁷ Commission Delegated Regulation (EU) 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures (OJ L 93, 31.3.2023, p. 7–39).		
15	Recital 14	To make best use of the European Chemicals Agency's knowledge and expertise gained through its involvement in the nomination and assessment processes under the Stockholm Convention on Persistent Organic Pollutants, the European Chemicals Agency should, upon request, assist the Commission in complying with its		

		obligation to amend Annexes IV and V to Regulation (EU) 2019/1021⁸. Where the opinion of the Committee for Socio-Economic analysis is required, and in order to allow for the necessary capacity and resources for the effective functioning of that committee, Member States should be given the opportunity to cover for the specific expertise required for the effective performance of the task by nominating experts. In order to ensure that the Committee for Socio-Economic analysis benefits from sufficient resources, when the committee appoints one of their members as a rapporteur, that person, or his employer should be remunerated. ⁸ Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45).		
16	Recital 15	In order to amend certain non-essential elements of Regulation (EU) 2019/1021 of the European Parliament and of the Council, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending Annexes IV and V in order to adapt them to the changes to the list of substances set out in the Annexes to the Stockholm Convention or the Protocol or adapt them to scientific and technical progress.		

17	Recital 16	As part of their reporting obligations under the Regulation (EU) 2019/1021 of the European Parliament and of the Council, Member States must report to the European Chemicals Agency information on the presence of substances listed in Part A of Annex III in the environment. The use of the Information Platform for Chemical Monitoring ('IPCHEM') is encouraged as a means for Member States to comply with their obligations to report that chemical occurrence data and to simplify and reduce their reporting obligations. Where Member States make data available through IPCHEM, they no longer need to report it to the European Chemicals Agency, as the agency may retrieve it from the platform.		
18	Recital 17	The revision of the Directive (EU) 2020/2184 of the European Parliament and of the Council ⁹ requires Member States to share with European Environmental Agency all chemical occurrence or monitoring data in water. Additionally, the monitoring data on the presence of POPs in air are already being reported by Member States to the EEA as part of the Union air quality legislation. The proposal for a Regulation of the European Parliament and the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable,		

		accessible, interoperable, and reusable and establishing a monitoring and outlook framework for chemicals¹⁰ will require all chemical occurrence data to be held by the EEA. As a result, chemical occurrence data provided to and held in IPCHEM by the Commission will thus be collected and held by the EEA, instead of by the Commission. Therefore, it is necessary to simplify the reporting obligations for Member States to ensure that, where Member States have already submitted that information to the EEA as part of fulfilling obligations required by the provisions of other pieces of Union environmental legislation, Member States should be considered to have fulfilled their reporting obligations under Regulation (EU) 2019/1021. ⁹ Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast), (OJ L 435, 23.12.2020, p. 1–62). ¹⁰ [OJ Please insert reference once proposal is adopted]		
19	Recital 18	Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 should therefore be amended accordingly,		
20	Articles	HAVE ADOPTED THIS REGULATION:		

21	1	Amendments to Regulation (EC) No 178/2002		
22		Regulation (EC) No 178/2002 is amended as follows:		
23	(1)	in Article 23, the following point (m) is added:		
24		‘(m) to cooperate with the competent bodies in the Member States that carry out similar tasks to those of the Authority and to cooperate with other scientific bodies established under Union law, notably the European Chemicals Agency, the European Medicines Agency, and the European Environment Agency on the provision of relevant scientific opinions, on the exchange of data and information, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and on the development of scientific methodologies for the assessment of chemicals.’;		
25	(2)	Article 30 is replaced by the following:	Question were raised by a delegation on whether the EFSA procedure for risk assessment must not be changed as a result of this proposal and it must be ensured that the assessment of EFSA, and if applicable, other EU authorities are properly and appropriately taken into account by ECHA. How is this ensured by the provisions in Article 30?	

			PRES: Discussion took place during WP2	
26		‘Article 30 Diverging scientific opinions	One delegation requested an example of what could be considered diverging scientific opinions. PRES: Discussion took place during WP2.	
27		1. The Authority shall take the necessary and appropriate measures to monitor and identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks.		
28		2. Where the Authority identifies a potential source of divergence, it shall contact the body concerned in order to ensure that all relevant scientific or technical information is shared and in order to identify the potentially contentious scientific or technical issues. The Authority and the body concerned shall cooperate to resolve the divergence. If the Authority and the body concerned are not able to resolve the divergence, they shall draw up a joint report. The report shall clearly outline the contentious scientific issues and identify the relevant uncertainties in the data and be made publicly available. Where the body concerned is a Union agency or a scientific committee, the		

		Authority shall present the joint report to the Commission.		
29		3. Where relevant, and where the divergence concerns conflicting scientific opinions of the Authority and another Union body or agency on whether a substance fulfils the criteria laid out in Annex I of Regulation (EC) No 1272/2008 of the European Parliament and of the Council ¹¹ , the Commission may request the European Chemicals Agency to prepare a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof following the procedure laid out in Article 37 of Regulation (EC) No 1272/2008. The Authority and the Union body or agency concerned shall co-operate with the European Chemicals Agency in developing that proposal.’.		
30		¹¹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353 31.12.2008, p. 1 – 1355.		
31	2	Amendments to Regulation (EC) No 401/2009	One delegation asked for clarification why the EEA’s cooperation with ECHA is	

			supposed to be regulated in Article 15(5) of the EEA Regulation. Systematically, paragraph 1 with a new letter c seems closer. In addition, it would be clear that paragraph 4 also refers to this cooperation. One delegation has doubts about the impact of the Eionet Network's involvement in this cooperation. PRES: Discussion took place during WP2	
32		Regulation (EC) No 401/2009 is amended as follows:		
33	(1)	in Article 2, the following point (p) is added:		
34		‘(p) to develop assessment methodologies related to chemicals in the fields falling within its mission.’;		
35	(2)	in Article 15, the following paragraph 5 is added:		
36		‘5. The Agency shall cooperate with other scientific bodies established under Union law, notably the European Chemicals Agency, the European Food Safety Authority, and the European Medicines Agency, on the exchange of data and information on chemicals, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and on the development of		

		scientific methodologies for the assessment of chemicals.’.		
37	3	Amendments to Regulation (EU) 2017/745	One delegation questions ECHA’s expertise regarding medical devices. PRES: Discussion took place during WP2	
38		Annex I to Regulation (EU) 2017/745 is amended as follows:		
39	(1)	in Section 10.4.1, point (b) is replaced by the following:		
40		‘(b) substances which are identified as endocrine disruptors for human health, of Category 1, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ¹² and substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council or substances having endocrine disrupting properties relevant to human health identified in accordance with Regulation (EU) No 528/2012.’		
41		¹² Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending		

		Regulation (EC) No 1907/2006(OJ L 353 31.12.2008, p. 1).		
42	(2)	in Section 10.4.2, point (d) is replaced by the following:		
43		‘(d) where applicable and available, the latest relevant guidelines in accordance with Sections 10.4.3. and 10.4.4.’;		
44	(3)	Section 10.4.3 is replaced by the following:		
45		‘10.4.3. Guidelines on phthalates When deemed appropriate based on the latest scientific evidence, but at least every 5 years, the Commission shall request the European Chemicals Agency (ECHA) to update guidelines on the benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in Section 10.4.1., points (a) and (b). The benefit-risk assessment shall consider the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments When appropriate or when requested by the Commission, ECHA shall consult the Committee for Risk Assessment and the Committee for Socio-economic Analysis.’;		
46	(4)	Section 10.4.4 is replaced by the following:		
47		‘10.4.4. Guidelines on other CMR and endocrine-disrupting substances		

		The Commission shall request ECHA to prepare guidelines as referred to in Section 10.4.3. and following the process described therein also for other substances referred to in Section 10.4.1., points (a) and (b), where appropriate.’		
48	4	Amendments to Regulation (EU) 2019/1021	A delegation proposed that Article 4 of the POP Regulation would be amended to give the Commission the possibility to request ECHA to carry out the assessment required to amend the concentration limit values in the Annexes IV and V to the POP regulation It is further proposed (article 13 paragraph 2) that this provision would also introduce the adoption of amendments to Annexes IV and V by means of delegated act. Moreover, they believe that the delegation of legislative powers to the Commission in POP-regulation Article 15 needs further consideration This delegation sees the role of the POP-CA (competent authorities) very important in preparation of the delegated acts. In case the above described amendments would be accepted, what would be the role of the POP-CA in the future? Would the Commission still consult the experts	

			designated by each Member State and closely collaborate with POP-CA before adopting a delegated act? One delegation proposes that ECHA is also given the task to determine limit values and amending Annex I and not only Annexes IV and V to the POP regulation. They also ask whether ECHA will have the knowledge on the impact of adjusting Annex IV values on the waste and recycling phase, while another delegate questions the knowledge of SEAC on waste management. PRES: Discussion took place during WP2. PRES proposes amendments to be made to the proposal. Written comments are welcomed.	
49		Regulation (EU) 2019/1021 is amended as follows:		
50	(1)	Article 8(1) is amended as follows:		
51	(a)	the following point (i) is added:		
52		‘(i) upon request from the Commission, and within 12 months from that request, draw up and ~~provide~~ submit a report on the human health, environmental and socio-economic impacts of introducing or modifying concentration limit values specified in Annex IV or V.’	One delegation proposes to change ‘draw up and provide a report’ to ‘draw up and submit a report.’ PRES proposed a change to the text.	

53	(2)	Article 8(1a) is added:		
54		‘1a. The report referred to in Article 8(1), point (i), shall contain the following information:		PT: Article 3(4) and Article 8(1)(a), (b), (c) and (e) of the POP Regulation create conditions for ECHA's participation in various instances of this Regulation. In this sense, we are making internal reflections to better conclude if additional data regarding the socio-economic impacts resulting from the different UTCs is needed, and therefore if SEAC intervention would be an added value in the process (as proposed for concentration limits in annexes IV and V).
55		(a) as appropriate, information on human health and environmental impacts of waste consisting of, containing or contaminated with POPs, including impacts on waste management;		
56		(b) information on concentrations and mass flows of POPs in relevant waste streams and on waste treatment and treatment capacities;		
57		(c) an analysis of the impacts of the different concentration limit values considered;		
58		(d) a duly motivated proposal for concentration limit values to be introduced in Annex IV and, as appropriate, in Annex V.		
59		The Agency shall, as soon as it receives the request referred to ~~in the first subparagraph~~ Article 8(1) , point (i),	One delegation proposed to change the reference, to clarify and to use the same	

		publish on its website a notice that a report on a possible amendment of Annex IV or V will be prepared inviting all interested parties, including waste operators and users of recycled materials, to submit comments within 8 weeks. The Agency shall publish those comments on its website.	kind of reference as is used in the paragraph above. PRES proposed change accordingly	
60		At the latest 9 months following the submission of the ~~at~~ report <i>referred to in Article (8(1), point (i))</i> , the Committee for Socio-economic Analysis of the Agency, set up pursuant to Article 76(1), point (d), of Regulation (EC) No 1907/2006 shall adopt an opinion on the report and on the concentration limit values proposed therein. For the purpose of adopting an opinion on the report, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.	One delegation proposed to clarify which submission it is referred to given that it is mentioned in several paragraphs earlier in the text. The proposed change would help to clarify this together with a consequential amendment in Article 8(1) point (i) to change the word 'provide' to 'submit' PRES proposed change.	
61		The Agency shall submit the report and the opinion of the Committee for the Socio-economic Analysis on the concentration limit values to the Commission without delay.';		
62	(3)	in Article 13, paragraph 2 is replaced by the following:	One delegation further proposed (Article 13 paragraph 2) that this provision would also introduce the adoption of amendments to Annexes IV and V by means of delegated acts. PRES requires further clarification (potential text proposal).	

63		‘2. Where a Member State shares the information referred to in paragraph 1, point (e), with the European Environmental Agency, that Member State shall indicate that in the report and the Member State shall be considered to have fulfilled its reporting obligations under that point.		
64		Where the information referred to in paragraph 1, point (e), is contained in the report of a Member State provided to the Agency, the Agency shall transmit the information to the European Environmental Agency for compiling, storing and sharing that information’;		
65	(4)	in Article 15, paragraph 2 is replaced by the following:		
66		‘2. The Commission is empowered to adopt delegated acts in accordance with Article 18, to amend Annexes IV and V to this Regulation to adapt them to the changes to the list of substances set out in the Annexes to the Convention or the Protocol or to adapt them to scientific and technical progress.’	One delegation proposed the amendment in order to clarify that the reference is to the Annexes in this Regulation. PRES changed the text. One delegation would like confirmation of the Commission’s obligation to consult MS experts before adopting delegated acts as appears to be provided in Article 18(4) of the POP Regulation. Another delegation considers it of high importance to preserve the expertise of the Meeting of the Competent	PT keeps a positive view regarding the possibility given to the COM to amend annexes IV and V through a delegated act. In accordance with section II (para. 4-12) of the Annex to the “Interinstitutional Agreement between the European Parliament, the Council of the European Union and the Commission on Better Law-Making, of 13th April 2016”, the COM consults MS experts during the preparation of the delegated act. In this context, we would like to be clarified if consultation criteria established under Section V(28) of the Agreement are binding or voluntary.

			Authorities for Regulation (EU) 2019/1021 on POPs and would like to know in which stage of the future amendments of the annexes the experts from the CAs will be consulted and whether additional POP experts will be incorporated to SEAC and/or RAC. One delegation asked for the delegation of legislative powers to the COM in POP regulation article 15 to be further considered. They see the role of the POP-CA very important in the preparation of the delegated acts. PRES: Discussion took place during WP2. Written comments are welcome.	
67	(5)	Article 18 is amended as follows:	One delegation suggests no changes to be made to Article 18, they don't want to delegate this regulatory authority to the COM. PRES: Discussion took place during WP2. Written comments are welcome.	
68	(a)	The first sentence of paragraph 2 is replaced by the following:		
69		'2. The power to adopt delegated acts referred to in Articles 4(3), 10(2) and 15 shall be conferred on the Commission for a period of five years from 15 July 2019.'	A delegation considers that this 5-year term is very likely to have passed before the proposed delegation of authority takes effect. Therefore, they suggest adjusting the period in order to have effect in practice.	

			PRES: Discussion took place during WP2 Written comments are welcome	
70	(b)	The first sentence of paragraph 3 is replaced by the following:		
71		‘3. The delegation of power referred to in Articles 4(3), 10(2) and 15 may be revoked at any time by the European Parliament or by the Council.’.		
72	(c)	Paragraph 6 is replaced by the following:		
73		‘6. A delegated act adopted pursuant to Articles 4(3), 10(2) and 15 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object.’.		
74	6	Entry into force		
		This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.		
		Done at Brussels,		
		For the European Parliament		

[illegible]

SLOVENIA

Comments from the Slovenian delegation in accordance with the Presidency note (WK 4185/2024 INIT) on »One Substance One assessment« - OSOA legislative package:

1. RoHS Directive

Slovenia has examined the COM proposal for the directive and can fully support it as it is. We welcome the improved and refined process for restricting new substances. Nevertheless we still have some specific comments:

Article 1 (1a)(4c) – we support “appropriate deadline” as it is in COM proposal; flexibility for ECHA and pragmatic approach is needed

Article 1 (1b) shall draw up draft opinions within 9 months

In principle we agree that the deadline is the same as for the opinions in REACH but we wish to express that with RoHS we will have very specific uses, especially for medical equipment and very broad spectrum of those uses. This is very complex and we see that there will be a need to prolong that deadline and we can support prolongation of that deadline.

We would like to stress that there is a difference between cost - benefit in case of authorization for chemicals under REACH and in case of this proposal where we will deal also with medical where the benefit for a patient always needs to be first. We would like to ask the COM if all that has been taken into account.

Article 2 -Transition period

With regard to transition period we believe that the proposed timeline is sufficient for the transposition of rules into national legislation of respected Member States. However, we can understand that other countries might be in a different situation and we can be flexible with the prolongation to address the concerns of other Member States.

Article 6 - We can support that criteria can be defined more in a detail.

2. Regulation on Data platform

The Republic of Slovenia has examined the proposal for a regulation and fully supports it. Nonetheless, we would provide some comments regarding:

Line 10

Recital 2, para 2

We propose to insert the following sentence “modernizing the integration of information with a view to reducing the administrative burden”, as shown below:

(2) The main objective of this Regulation is to increase the level of protection of the environment and human health from the risks arising from hazardous chemicals, as well as **"modernizing the integration of information with a view to reducing the administrative burden"** to facilitate the functioning of the internal market for chemicals. For that purpose, this Regulation should establish a common data platform data on chemicals (‘the common data platform’), to be managed by the European Chemicals Agency (‘ECHA’). The common data platform is a digital infrastructure that brings together chemicals data and information generated

under the Union chemicals acquis. This Regulation should also establish dedicated services within the common data platform and lay down rules on the accessibility and usability of the data contained in that platform. This Regulation aims to create a common knowledge base on chemicals available to authorities to enable better, complete, coherent and robust scientific assessments of chemicals and their impacts and to ensure the best use of existing information for the purpose of the implementation and the development of Union legislation on chemicals. Moreover, the Regulation aims to provide a one-stop-shop on chemicals data and information in the Union accessible to the general public and, thus, to increase the predictability and the transparency of regulatory processes on chemicals, as well as to strengthen public trust in the robustness of scientific decision-making.

Line 239

Article 17 para 3

When using chemicals data contained in the common data platform that is deemed confidential under Article 5(2), second sentence, the Authorities shall respect the confidentiality of information data as marked by the originator and *shall not disclose that data to the public without the consent of the originator*.

Our comment is concerning the sentence “*shall not disclose that data to the public without the consent of the originator*”. The current practice in case of biocides legislation is that if there is data available the authority can inform an applicant about the availability of data and who the originator of it is, and that the applicant can ask the originator for a letter of access to fill in its data gaps. So far however, there is no evidence that this practice had been done already by any authority.

In connection with human biomonitoring data, SI has provided data to COM database and it is very important for us that those data are anonymized and we specially support this part of COM proposal, for which we understand that the highest protection of personal data was taken into account.

3. Regulation on Reattribution of tasks

Slovenia has examined the proposal for a regulation and can support it. The Republic of Slovenia believes that the proposal improves the current chemical assessment system, which will bring a unified methodology for substance assessment at the EU level and a more efficient use of human resources and specific knowledge at the EU level.

We would, however, like to provide some specific comments:

Line 25

Article 1 (2)

New Article 30 in EFSA regulation “Diverging scientific opinions” – para 3 it is not clear to us and we propose to re-write it a clearer way (lex certa).

Line 45

Article 3 Amendments to Regulation (EU) 2017/745

10.4.3. Guidance on phthalates

Upon request by the Commission, ECHA will update the guidance every 5 years. There is part of a sentence “*The benefit – risk assessment shall consider*” which is not clear.

We believe it needs to be re-written in a way to convey the message that that benefit of a patient is of most importance. Saving life or prevention of health issue situation is more important than risk due to exposure to a chemical - blood bags as an example.

‘10.4.3. Guidelines on phthalates When deemed appropriate based on the latest scientific evidence, but at least every 5 years, the Commission shall request the European Chemicals Agency (ECHA) to update guidelines on the benefit -risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in Section 10.4.1., points (a) and (b). *The benefit -risk assessment shall consider* the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments. When appropriate or when requested by the Commission, ECHA shall consult the Committee for Risk Assessment and the Committee for Socio -economic Analysis.’;

SLOVAKIA

14/3/2024

Proposal for a
DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
amending Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European
Chemicals Agency
(Text with EEA relevance)



PRESIDENCY PROPOSALS for written comments by 22 March 2024 1 PM

Delegations will find attached a **revised** Presidency compromise proposal on the above-mentioned Proposal.

Changes in comparison to the previous compromise proposal, document COM(2023) 781, are marked in **red bold underline** for additions and in ~~red strikethrough~~ for deletions.

	Commission Proposal	Presidency Justification	Delegations comments
Proposal Title			
1	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL Amending Directive 2011/65/EU control of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency (Text with EEA relevance)		
Formula			
2	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,		
Citation 1			
3	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,		
Citation 2			

4	Having regard to the proposal from the European Commission,		
Citation 3			
5	After transmission of the draft legislative act to the national parliaments,		
Citation 4			
6	Having regard to the opinion of the European Economic and Social Committee ¹		
Footnote 1			
7	¹ OJ C [...], [...], p. [...].		
Citation 5			
8	After consulting the Committee of the Regions,		
Citation 6			
9	Acting in accordance with the ordinary legislative procedure,		
Formula			
10	Whereas:		
Recital 1			

11	(1) The Commission has, in its Communication 'European Green Deal'², set an objective that chemical safety assessments should move towards a process of 'one-substance, one-assessment', calling for more transparent and simpler risk assessment processes in order to reduce the burden on all stakeholders, accelerate decision-making, as well as to increase consistency and predictability of scientific decisions and opinions. The Commission, in its Communication on Chemicals Strategy for Sustainability³ concludes that, in order to achieve that objective, part of the scientific and technical work on chemicals performed at Union level in support of Union legislation needs to be reattributed to the most suitable Union agencies. This would simplify the current set-up, improve quality and coherence of safety assessments across Union legislation, and ensure more efficient use of existing resources.		
Footnote 2			
	² Communication from the Commission to the European		

12	Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal (COM (2019) 640 final of 11 December 2019).		
Footnote 3			
13	³ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment (COM (2020) 667 final of 14 October 2020).		
Recital 2			
14	(2) The reattribution of certain scientific and technical tasks to the European Chemicals Agency is necessary in order to align processes and levels of scientific scrutiny and digitalisation with current standards and processes of the European Chemicals Agency. This is also necessary in order to ensure a consistent standard of scientific quality, transparency, data searchability and interoperability, in line with		

	the 'one-substance, one-assessment' ambition.		
Recital 3			
15	(3) Directive 2011/65/EU of the European Parliament and of the Council ⁴ contains two procedures related to the assessment of chemicals: the evaluation of economic operators' applications for granting, renewing or revoking an exemption from the substance restrictions pursuant to Article 5 of that Directive and the review of substances to be added to the list of restricted substances pursuant to Article 6 of that Directive. There is a need to increase transparency by setting detailed procedural steps for the process to review substances for a potential inclusion in the list of restricted substances.		
Footnote 4			
16	⁴ Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment – OJ L 174 1.7.2011, p 88.		

Recital 4

17	(4) Data and information held by the European Chemicals Agency in the context of regulatory processes under Titles VII and VIII of Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁵ can be usefully deployed for the assessment of potential substance restrictions and for assessing applications for exemption under Directive 2011/65/EU. Established structures and procedures can help to build on the existing knowledge base, maximise synergies, and make the best use of available expertise and resources.		

Footnote 5

18	⁵ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as		

	well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC - OJ L 396 30.12.2006, p. 1.		
Recital 5			
19	(5) To ensure consistency between the evaluation of economic operators' applications for granting, renewing or revoking an exemption pursuant to Article 5 of the Directive 2011/65/EU, as well as to make the best use of existing chemicals-related expertise, the technical evaluation to assess the justification of such exemption requests should be carried out by the European Chemicals Agency and its committees in close coordination with the Commission.		
Recital 6			
	(6) To ensure that the restriction process referred to Article 6 in Directive 2011/65/EU is consistent with the restriction processes under other legislation related to chemicals, in particular with the substance restriction process laid down in Articles 69		

20	to 73 of Regulation (EC) No 1907/2006, it is necessary to amend Directive 2011/65/EU to formally task the European Chemicals Agency with a role in the restriction process. In the light of experience obtained when carrying out substance reviews, it is essential for the quality of the related technical assessment, and for enabling synergies, to make use of information and tools being used in the context of assessments for chemical restrictions under Regulation (EC) No 1907/2006.		
Recital 7			
21	(7) The two procedures described under Article 5 and Article 6 are applicable at the EU level. National provisions should not deviate from these Articles set in Directive 2011/65/EU.		
Recital 8			
22	(8) For amending procedural provisions under Directive 2011/65/EU, a transitional period of 12 months is necessary to allow for appropriate resource and task allocation for the European Chemicals Agency. That timeframe is considered sufficient		

	to allow for amending procedural provisions under Directive 2011/65/EU, a transitional period of 12 months is necessary to allow for appropriate resource and task allocation for the European Chemicals Agency. That timeframe is considered sufficient to allow potential applicants or Member States to adjust to the modified procedural steps under that Directive.		
Recital 9			
23	(9) Directive 2011/65/EU should therefore be amended accordingly,		
Formula			
24	HAVE ADOPTED THIS DIRECTIVE:		
Article 1			
25	<i>Article 1</i> Amendments to Directive 2011/65/EU Directive 2011/65/EU is amended as follows:		
Article 1(1)			
26	(1)Article 5 is amended as follows:		

Article 1(1), point (a)			
27	(a) paragraphs 3 and 4 are replaced by the following		
Article 1(1), point (a), paragraph 3			
28	'3. An application for granting, renewing or revoking an exemption shall be made to the European Chemicals Agency set up pursuant to Article 75(1) of Regulation (EC) No 1907/2006 ('the Agency') in accordance with Annex V.		
Article 1(1), point (a), paragraph 4a			
29	4. The Agency shall: (a) acknowledge receipt of an application within 15 days of its receipt, stating the date of receipt of the application;		
Article 1(1), point (a), paragraph 4b			
30	(b) verify that the application contains all the elements laid out in Annex V;		
Article 1(1), point (a), paragraph 4c			
	(c) if necessary, request the applicant to complete the application <u>within 45 days of</u>	Change proposed based on the comments from two delegations.	

31	<u>receipt of the application</u> , and provide an appropriate deadline of maximum 60 days;	One delegation suggested replacing the word “appropriate” with a specific deadline in order to improve legal certainty for the actors concerned. They motivated that this would also ensure that current applications are published on the Agency’s website in a timely manner. Additionally, other delegation motivated that the applicant should be given a deadline within which the application should be completed, since the exemption continue to apply during the process of evaluation of the application. The 45 days and 60 days were proposed based on the deadlines given in REACH Article 69 (4) for restrictions proposals, as there are no similar deadlines under the authorisation scheme in REACH. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(1), point (a), paragraph 4d			
32	(d) make the application and any supplementary information supplied by the applicant available to Member States;		
Article 1(1), point (a), paragraph 4e			
33	(e) make a summary of the application and a non-confidential version of the application as submitted by the applicant, as well as the date when the application is		

	considered complete, available to the public on the Agency's website;		
Article 1(1), point (a), paragraph 4f			
34	(f) invite interested parties to submit information within 3 months of its publication on the Agency's website.		
Article 1(1), point (a), paragraph 4			
35	Where the applicant does not complete the application with the missing elements identified by the Agency in compliance with Annex V within the deadline provided in accordance with the first subparagraph, point (c), the Agency may reject such application. The Agency shall establish and communicate to the applicant without undue delay the date when the application is considered complete. Upon receipt of an application, the Agency shall notify the Commission of the application and keep it informed of any of the procedural steps under points (b) to (f).';		
Article 1(1), point (b)			

36	b) the following paragraph 4a is inserted after paragraph 4:		
Article 1(1), point (b), regarding inclusion of article 4a			
37	4a. The Agency shall, after verifying the completeness of the application, request the opinion of the Committee for Socio-economic Analysis, set up pursuant to Article 76(1), point (d) of Regulation (EC) No 1907/2006. It shall request the opinion of the Committee for Risk Assessment, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006, in the case of an application for a new exemption or where otherwise considered appropriate. The Committee for Socio-economic Analysis and, where relevant, the Committee for Risk Assessment:	Two delegations suggested that it needs to be clearer when RAC shall evaluate an application for exemption. Therefore, they considered that it may be good to clarify that RAC shall evaluate applications for renewal of exemptions that have previously been evaluated by external consultants or where there are amendments in the exemption that have not been evaluated before. This would have the effect of increasing consistency between the evaluations. Alternatively, other delegation proposed in their comments to rather assign the tasks to ECHA (and its Expert Groups) than directly to RAC and SEAC. Their proposal was motivated by a concern related to the capacity of SEAC and RAC to perform the tasks under Art. 5 (lack of expertise in RoHS within the Committees, insufficient staff). In their opinion, the proposed change in the text would not preclude the Executive Director from requesting the assistance of the Committees of ECHA on a case-by-case basis. PRES did not modify the proposal and welcomes delegations' views/comments.	SK agrees with the PRES - not to modify the proposal, that is I line with REACH Article 76(1), point (c)

		Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(1), point (b), regarding inclusion of article 4a (a)			
38	(a) shall draw up draft opinions within 9 months of the date the application has been considered complete by the Agency under paragraph 4, point (b);	One delegation proposed to align the deadline for RAC and SEAC for the assessment of exemptions with the authorisation scheme and assessment of authorisation under the REACH-Regulation (Article 64 (1) of the REACH Regulation). Other delegation proposed to specify that the opinions drawn shall be scientific and technical. This proposal is a consequence of their proposal above (line 37 of this document), where it is considered that tasks should be rather assigned to ECHA (and its Expert Groups) than directly to RAC and SEAC. PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	SK agrees with the PRES - not to modify the proposal
Article 1(1), point (b), regarding inclusion of article 4a (b)			
39	(b) shall assess whether the criteria in Article 5(1), point (a), are met and shall provide clear guidance to the Commission on		

	granting, renewing or revoking an exemption;		
Article 1(1), point (b), regarding inclusion of article 4a (c)			
40	(c) may request the applicant or third parties to submit, within a specified period, additional information;		
Article 1(1), point (b), regarding inclusion of article 4a (d)			
41	(d) upon adopting the draft opinions, shall communicate those draft opinions to the applicant and shall allow the applicant the opportunity to comment within 4 weeks of the communication of the draft opinions to the applicant;	One delegation proposed to specify that the opinions drawn shall be scientific and technical. This proposal is a consequence of their proposal above (line 37 of this document), where it is considered that tasks should be rather assigned to ECHA (and its Expert Groups) than directly to RAC and SEAC. PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	SK agrees with the PRES - not to modify the proposal
Article 1(1), point (b), regarding inclusion of article 4a (e)			
42	(e) shall adopt their final opinions, taking into account the comments from the applicant.		
Article 1(1), point (b), regarding inclusion of article 4a			
			In order to determine the deadline for sending the final RAC and SEAC opinions

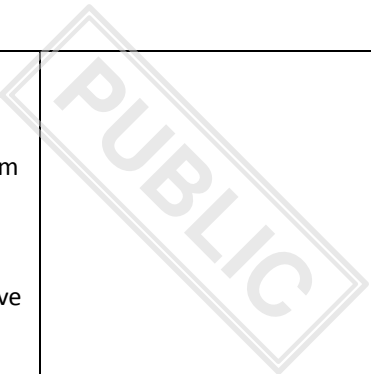
43	Each Committee shall take into account any information submitted by third parties in accordance with the second subparagraph, point (c). The Agency shall send the final opinion(s) of the Committees to the Commission within 12 months from the date an application has been considered complete by the Agency. The Agency shall identify which parts of its opinions and of any attachments thereto should be made publicly available on its website and shall make those parts publicly available on its website. For the purpose of adopting opinions pursuant to this paragraph, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.'	One delegation proposed to align the deadline for RAC and SEAC for the assessment of exemptions with the authorisation scheme and assessment of authorisation under the REACH-Regulation. Therefore, in their view the deadline for sending the final opinion to the Commission should be set to 14 months. This will assure that ECHA will have at least the same time period as is given under Article 64 (5) in REACH, where the Committees shall adopt their final opinion within two months after receiving the comments from the applicant and send it to the Commission within 15 days after this. Additionally, other delegation proposed to specify that the opinions drawn shall be scientific and technical. This proposal is a consequence of their proposal above (line 37 of this document), where it is considered that tasks should be rather assigned to ECHA (and its Expert Groups) than directly to RAC and SEAC. PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	to the Commission, it is necessary to consider the actual capacities of ECHA's committees (and in this sense also the experts from the Member States as members of the committees).
Article 1(1), point (c)			
44	(c) paragraph 8 is replaced by the following:		

Article 1(1), point (c), paragraph 8

45	8. The Agency shall, in agreement with the Commission, provide a harmonised format for the applications referred to in paragraph 3 of this Article as well as comprehensive guidelines for such applications, taking into account the situation of SMEs. Any submission to the Agency shall be made using the format and the submission tools made available by the Agency.’;	One delegation considered that a clarification is needed in relation to third criterion in Art. 5(1)(a) of the RoHS Directive: <i>‘the total negative environmental, health and consumer protection impact as a result of the substitution is likely to be greater than the total environmental, health and consumer protection benefits thereof’</i>. In their view many exemptions are granted or renewed with reference to this criterion, not infrequently, where the other criterions do not apply i.e. where substitution is possible or reliable alternatives are available, in spite of the weight of substitution in RoHS as reflected in recital 8 <i>the most effective way of ensuring a significant reduction of risks to health and the environment relating to those substances, in order to achieve the chosen level of protection in the Union, is the substitution of those substances in EEE by safe or safer materials</i>. The criterion is often applied based on energy considerations. It is unclear if this was the intention of this criteria and, which weight to assign energy considerations compared to chemicals considerations within the frame of RoHS. In light of the experienced difficulty concerning collection of information from applicants as identified during the RoHS review process, priority should be given to clarifying the applicability of this criterion.	

PUBLIC

		Therefore, there is a need to clarify the applicability of this criteria and it is important that ECHA does so through following this re-attribution of tasks. ECHA should revise this guidance and that the guidance should be adopted by the expert committee (see proposal for reference to this committee in under article 20). PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(2)			
46	(2) in Annex V, the following paragraph is added: 'In cases referred to in the first paragraph, point (h), the applicant shall submit a non-confidential version of the application.'		
Article 1(3)			
47	(3) Article 6 is amended as follows:		
Article 1(3), point (a)			

48	(a) in paragraph 1, the first subparagraph is replaced by the following: ‘With a view to achieving the objectives set out in Article 1 and taking account of the precautionary principle, a review, based on a thorough assessment, and an amendment of the list of restricted substances in Annex II shall be considered by the Commission <u>every five years</u> ~~periodically~~ on its own initiative or following the submission of a restriction dossier prepared by a Member State containing the information referred to in paragraph 2.’;	Change proposed based on the comment from one delegation. One delegation considered that the list of substances restricted under the ROHS directive should be evaluated on a more regular basis. Here a 5-year period is suggested. It is not paramount that it should be a 5-year period, however, a timeline is needed. Staff working document p. 119 assesses the impact for ECHA. Here it says: <i>As the assessments are to be done ca. every 5 years.</i> Therefore, a time limit of 5 years is considered appropriate. eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52023SC0850 One delegation proposed also some additional changes (introduction of subparagraph 1a) as they considered that the substances restricted in the POP-regulation, and where the use in EEE is exempted, should be considered for Annex II in the RoHS-Directive. PRES did not modify the proposal and welcomes delegations’ views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(3), point (b)			

49	(b) in paragraph 1, the fourth subparagraph is deleted.		
Article 1(3), point (c)			
50	(c) paragraph 2 is replaced by the following: '2. The review and amendment of the list of restricted substances, <u>or a group of similar substances</u>, in Annex II shall be based on restriction dossiers prepared by the Agency at the request of the Commission or prepared by a Member State. The Agency or a Member State shall take into account any available information and any relevant risk assessment submitted for the purposes of other Union legislation covering the life cycle of the substance used in EEE, in particular the waste phase. To this end, other bodies established under Union law and carrying out a similar task shall, on request, provide information to the Agency or Member State concerned.	Change proposed based on the comment of one delegation. One delegation considered that the reference to the assessment of groups of substances should not be deleted as it is in the current COM's proposal. Additionally, one delegation considered that any relevant assessment, including assessments of waste handling, should be included in a restriction dossier, therefore DK proposed to delete "risk" from the text. PRES did not modify the proposal and welcomes delegations' views/comments. Change based on the proposal of the COM received prior to the 2nd Ad Hoc WP and discussed during that meeting. This proposal intended to accommodate the	

	The restriction dossier shall comply with the requirements set out in Part II, point 3, of Annex XV to Regulation (EC) No 1907/2006 <u>for those requirements that relate to the criteria set out in Article 6(1)</u> and shall, in addition, contain the following information: (a) information on the use of the substance or the group of similar substances in EEE; (b) information on detrimental effects and exposure in particular during waste EEE management operations.'	concern of one delegation regarding re-shifting of focus of assessment required under the RoHS Directive when aligning restriction procedure with the REACH restriction. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(4)			
51	(4) the following Articles 6a, 6b and 6c are inserted:		
Article 1(4), regarding insertion of Article 6a			
52	'Article 6a Initiation of procedure for review and amendment of the list of restricted substances		
Article 1(4), regarding insertion of Article 6a, point (1)			
53	1. Within 12 months of receipt of the request from the Commission referred to in Article 6(2), first subparagraph, the Agency shall prepare a restriction dossier		

	conforming to the requirements referred to in Article 6(2), third subparagraph, and suggest restrictions in order to initiate the restriction process.		
Article 1(4), regarding insertion of Article 6a, point (2)			
54	2. A Member State shall notify the Agency that it proposes to prepare a restriction dossier which conforms to the requirements referred to in Article 6(2), third subparagraph, within 12 months. If that dossier demonstrates that action on a Union-wide basis is necessary, beyond any measures already in place, the Member State shall submit it to the Agency in order to initiate the restriction process.		
Article 1(4), regarding insertion of Article 6a, point (3)			
55	3. The Agency shall publish without delay the intention of the Commission or the Member State to initiate the process to review and amend the list of restricted substances in Annex II <u>on the Agency's website</u> .	Change proposed based on the comment from one delegation and in line with the text proposed in Art. 5 (see line 28 of this document). One delegation considered that it was not clear where the intention to review and amend the list of restricted substances will be published.	

		Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(4), regarding insertion of Article 6a, point (4)			
56	4. The Agency shall establish and maintain a list of substances for which a restriction dossier conforming to the requirements of Article 6(2) is planned or underway by either the Agency or a Member State for the purposes of a proposed restriction.		
Article 1(4), regarding insertion of Article 6a, point (5), paragraph 1			
57	5. The Agency shall consult the Committee for Risk Assessment, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006, and the Committee for Socio-economic Analysis, set up pursuant to Article 76(1), point (d), of that Regulation. The Committees shall verify whether the restriction dossier submitted conforms to the requirements referred to in Article 6(2), third subparagraph.		
Article 1(4), regarding insertion of Article 6a, point (5), paragraph 2			
	Within 30 days of receipt of the restriction dossier, the respective		

58	Committee shall inform the Agency or the Member State proposing restrictions whether the dossier conforms to the requirements referred to in Article 6(2), third subparagraph. If the dossier does not conform to those requirements, the reasons shall be given to the Agency or the Member State in writing within 45 days of receipt of that dossier. The Agency or the Member State shall bring the dossier into conformity within 60 days of the date of receipt of the reasons from the Committees, otherwise the procedure under this Article shall be terminated.		
Article 1(4), regarding insertion of Article 6a, point (6)			
59	Where the dossier meets the requirements referred to in Article 6(2), third subparagraph, the Agency shall make it publicly available without delay, clearly indicating the date of publication. The Agency shall invite all interested parties, including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations to submit, individually or jointly, within 4 months from the date of the		

	publication of the dossier, the following:		
Article 1(4), regarding insertion of Article 6a, point (6a)			
60	(a) comments on dossiers and the suggested restrictions;		
Article 1(4), regarding insertion of Article 6a, point (6b)			
61	(b) a socio-economic analysis including an analysis of alternatives, or information which can contribute to ~~one of~~ the suggested restrictions, examining the advantages and drawbacks of the proposed restrictions.	Changes partially modified based on the comment from one delegation. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(4), regarding insertion of Article 6a			
62	The analysis referred to in the first subparagraph, point (b), shall conform to the requirements in Annex XVI to Regulation (EC) No 1907/2006.	One delegation suggested to delete this text, as they consider that the restriction process in RoHS may be too extensive compared to the restriction process in REACH. They were also concerned that having in mind future revision of the REACH Regulation, it is not clear how the restriction process will look like in the future. PRES did not modify the proposal and welcomes delegations' views/comments.	

		Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(4), regarding insertion of Article 6b			
63	Article 6b Opinion of the Agency's Committees		
Article 1(4), regarding insertion of Article 6b, point (1)			
64	1. Within 12 months from the date of publication referred to in Article 6a(6), the Committee for Risk Assessment shall adopt an opinion as to whether the restriction is appropriate in reducing the risk to human health or the environment, specifically <u>by reference to the risks set out in Article 6(1) for those requirements that relate to the criteria set out in Article 6(1)</u>, third subparagraph, based on its consideration of the relevant parts of the dossier. This opinion shall take account of the restriction dossier prepared by the Agency at the request of the Commission or by the Member State, and the views of interested parties referred to in Article 6a(6), point (a).	Change proposed by PRES to align the text with Article 1(3), point (c) (line 50 of this document). This proposal intended to accommodate the concern of one delegation regarding re-shifting of focus of assessment required under the RoHS Directive when aligning restriction procedure with the REACH restriction. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(4), regarding insertion of Article 6b, point (2)			

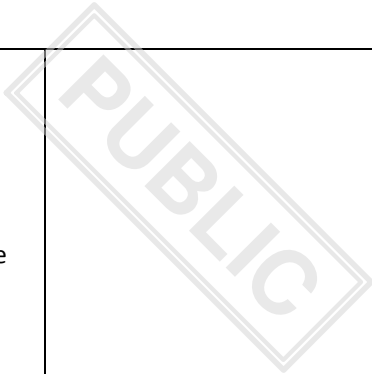
65	2. Within 15 months from the date of publication referred to in Article 6a(6), the Committee for Socio-economic Analysis, shall adopt an opinion on the proposed restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. Prior to that, it shall prepare a draft opinion on the suggested restrictions and on the related socio-economic impact, taking account any existing analysis or information according to Article 6a(6), point (b).		
Article 1(4), regarding insertion of Article 6b, point (3)			
66	3. The Agency shall publish the draft opinion of the Committee for Socio-economic Analysis on its website without delay and invite interested parties to provide their comments on the draft opinion no later than 60 days from its publication.		
Article 1(4), regarding insertion of Article 6b, point (4)			
67	4. The Committee for Socio-economic Analysis shall without delay adopt its opinion, taking into account where appropriate further comments received by		

	the deadline set in paragraph 3. This opinion shall take into account the comments of interested parties submitted under Article 6a(6), point (a), and paragraph 3 of this Article.		
Article 1(4), regarding insertion of Article 6b, point (5)			
68	5. Where the opinion of the Committee for Risk Assessment diverges significantly from the restrictions proposed, the Agency shall postpone the deadline for the opinion of the Committee responsible for Socio-economic Analysis by a maximum of 90 days.		
Article 1(4), regarding insertion of Article 6b, point (6)			
69	6. For the purpose of adopting opinions pursuant to this article, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.	One delegation proposed some additional suggestions to provide for legislative provisions for the remuneration of tasks by Rapporteurs within the OSOA Package. PRES did not modify the proposal, as this is covered by mutatis mutandis application of Art. 87 of Regulation (EC) No 1907/2006 . Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	SK agrees with the PRES - not to modify the proposal
Article 1(4), regarding insertion of Article 6c			

70	<i>Article 6c</i> Submission of an opinion to the Commission		
Article 1(4), regarding insertion of Article 6c, point (1)			
71	1. The Agency shall submit to the Commission, without delay, the opinions of the Committees for Risk Assessment and Socio-economic Analysis on the restrictions suggested pursuant to Article 6b. Where the opinions of the Committees for Risk Assessment and Socio-economic Analysis diverge significantly from the restrictions suggested by the dossier, the Agency shall submit an explanatory note to the Commission providing a detailed explanation of the reasons for such differences. If one or both of the Committees do not adopt an opinion by the deadlines set in Article 6b(1) and (2) the Agency shall inform the Commission accordingly, stating the reasons.		
Article 1(4), regarding insertion of Article 6c, point (2)			

72	2. The Agency shall publish the opinions of both Committees on its website without delay.		
Article 1(4), regarding insertion of Article 6c, point (3)			
73	3. The Agency shall, on request, provide the Commission or Member State with all documents and evidence submitted to or considered by it.;		
Article 2			
74	The provisions under this Directive shall be applicable from [OJ: 12 months after the publication of this Directive].		
Article 3			
75	This Directive shall enter into force on the twentieth day following that of its publication in the <i>Official Journal of the European Union</i> .		
Article 4			

76	This Directive is addressed to the Member States. Done at Brussels, <i>For the European Parliament For the Council</i> <i>The President The President</i>		
Additional recommendations (changes proposed regarding articles that were not included in the current COM's proposal)			
Concerning amendments of Article 5(5):			
77	An application for renewal of an exemption shall be made no later than 18 months before the exemption expires.	One delegation proposed extension of the deadline to 24 months as they are concerned that by aligning the exemptions assessment process with REACH, the Commission will be phased with the issue of expediting delegated directives before the expiration of the concerned exemption. Therefore it was suggested to increase the deadline in order to leave more room for the assessment procedure. PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Concerning amendments of Article 20:			

78	Exercise of the delegation 1. The powers to adopt the delegated acts referred to in Article 4(2), Article 5(1) and Article 6 shall be conferred on the Commission for a period of 5 years from 21 July 2011. The Commission shall draw up a report in respect of delegated powers at the latest 6 months before the end of the 5-year period. The delegation of power shall be ~~automatically~~ <u>tacitly</u> extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 21. <u>1a. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of</u>	Change proposed based on the comments from one delegation. The COM agreed to the proposed changes, prior to the 2nd Ad Hoc WP. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	

13 April 2016 on Better Law-Making.

PUBLIC

SWEDEN

14/03/2024

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals

(Text with EEA relevance)



MS delegations are requested to send in written, article by article, comments and text proposals using the table provided below at the latest by Friday 22 March 2024, 1 pm.

Line nr.		Presidency proposal: amendments (~~deletions~~ /additions)	Presidency justification after WP1: follow-up or proposal to work on amendments, or requests for written comments	Delegates comments/proposals after WP2
1		THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 43, 114, 168(4)(c), 192(1) and 207 thereof, Having regard to the proposal from the European Commission, After transmission of the draft legislative act to the national parliaments, Having regard to the opinion of the European Economic and Social Committee, Having regard to the opinion of the Committee of the Regions, Acting in accordance with the ordinary legislative procedure, Whereas:		
2	Recital 1	The European Green Deal¹ sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability² ('the Strategy') is a crucial delivery of the zero-pollution		

		ambition and introduces the ‘one substance, one assessment’ approach, which aims to improve the efficiency, effectiveness, coherence, and transparency of safety assessments of chemicals across Union legislation. ¹Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal. COM (2019) 640 final. ²Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment. COM (2020) 667 final		
3	Recital 2	In order to achieve this objective, a part of the scientific and technical work on chemicals performed at Union level in support of Union legislation needs to be consolidated in the relevant Union agencies, while obligations on Union agencies to cooperate for the development of assessment methodologies and exchange of data and information should be introduced. This would simplify the current set-up, improve quality and coherence of safety assessments across Union legislation and ensure more efficient use of existing resources.		

4	Recital 3	The reattribution of certain existing scientific and technical tasks to the European Chemicals Agency, as well as the attribution of new tasks, were proposed as part of ongoing revisions of Union acts. This horizontal proposal aims to provide for further attribution of tasks in respect of those Union acts which are not in the process of being revised and is necessary in order to ensure that the European Chemicals Agency is involved in tasks pertaining to its expertise and developed capacities on chemicals. This is in line with the ‘one substance, one assessment’ aim to ensure that technical and scientific work is performed by the appropriate Union agency, benefiting from demonstrated experience and established tools in its field. The proposal for a Regulation is accompanied by a proposal for a Directive for the amendment of Directive 2011/65/EU of the European Parliament and of the Council³, aiming to achieve the same objectives. ³Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency	Many concerns were raised during the commenting about: Concerns on ECHA’s capacity, budget (including budget for technical and infrastructure requirements and training), workload, committees, expertise to take on the extra tasks. This relates amongst others to the expertise of committee members (and not only the number of experts), potential establishment of technical expert groups (and how they relate to the Committees’ role), what is to be left for the founding regulation, potential targeted REACH amendments, ECHA and committees expertise in medical devices and in POP-waste. Some specific elements for discussion: One delegation proposed it would be more appropriate to assign the task(s) to prepare opinions to ECHA, and allow ECHA to best determine the most efficient and appropriate way to deliver a robust opinion. For example, ECHA’s technical experts could draft opinions and establish technical expert working groups to consult with in order for scientific opinions to be delivered. In certain cases, the Executive Director can still use their powers under REACH’s Article 77 (3) to issue a request to RAC and SEAC, thus negating the need for all tasks to have a RAC and/or SEAC opinion.	Sweden considers that it is important for the implementation of the CSS in general, and particularly for OSOA, that ECHA’s workload and resources are in balance both in the immediate future and in the long run. SE notes that ECHA and its committees have either recently been given or will soon be given a significantly increased amount of extra work from over ten different pieces of legislation (for example, the RoHS-directive, the medical devices regulation and the drinking water directive). The application of some provisions shall take place within three years (and will continue to increase for up to 10 years). Furthermore, the bulk of the work related to establishing, developing and administrating the Common Data Platform will fall to ECHA. ECHA’s ability to fulfill these new responsibilities in accordance with the OSOA packet will not just depend upon its capacity but will also depend upon having competencies available, especially for areas where there is no designated EU Agency, for example, for medical devices and cosmetic products. Sweden notes that the Commission considers that the development of guidance under the Medical Devices Regulation has to do with the chemicals and their properties. Sweden considers that product-specific knowledge is necessary to be able to assess exposure and therefore the associated risks from using medical devices.

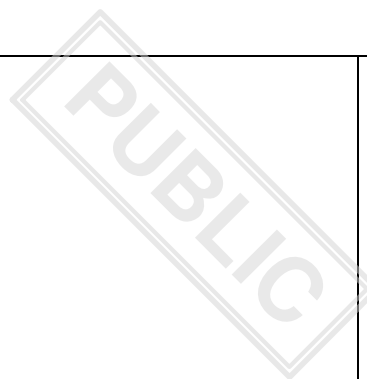
			This delegation also prefers that the legislative package makes provisions for ECHA to prepare opinions in some circumstances without the explicit need for those opinions to be drafted by RAC and SEAC. In addition, they explained that their concern is with the capacity of the individual members to deliver the expected workload, even if both Committees were at full capacity. Therefore, they see a need for provisions to be included to allow for amending the composition of the current ECHA's committees to cover also any ad-hoc Article 77(3) requests in light of requests from the Executive Director. Finally, the inclusion of remuneration for Committee Rapporteurs for all tasks needs to be provided for. They also recommend the OSA legislation package amends Article 85 and 87 of REACH to provide for additional experts to cover the additional work and its associated remuneration. PRES: Discussion took place during WP2	We consider that it is not clear in the proposals how such sectors will be represented, for example, when assessments from different sectors have come to diverging opinions.
5	Recital 4	As part of the coordinated consolidation and attribution of tasks under the 'one substance, one assessment' approach, provisions to allocate a mandate to the European Medicines Agency to develop		

		and cooperate on the development of assessment methodologies, standard formats and controlled vocabularies and exchange of data and information on chemicals have been introduced in Article 138(1), subparagraphs (zd) and (ze), as well as new procedures for ensuring the coherence between scientific opinions in Article 139 of the proposal for a Regulation amending Union pharmaceutical legislation.⁴ ⁴Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006, COM(2023) 193 final. [OJ: <i>Please insert correct reference once the Regulation is adopted</i>].		
6	Recital 5	To ensure the coherence of methodologies for assessments related to chemicals at Union level, all relevant Union agencies should have an equal mandate to develop such methodologies in the areas falling within their respective missions and should be subject to the same obligations to cooperate amongst each other to develop such methodologies.		

7	Recital 6	To ensure the coherence and efficiency of assessments related to chemicals across Union legislation, it is also important to enable data interoperability and easy exchange of data between the relevant Union agencies, as well as to encourage cooperation on the development of standard formats and controlled vocabularies. Thus, to facilitate data exchange between agencies, any new data formats defined by the European Food Safety Authority or by the European Environmental Agency should be set in cooperation with other relevant Union agencies working on chemicals. To this end, relevant provisions should be introduced in Regulation (EC) No 401/2009 of the European Parliament and of the Council and, in Regulation (EC) No 178/2002 of the European Parliament and of the Council, existing provisions should be strengthened and, where relevant, new ones be introduced. Similar provisions should also be considered to be proposed for a strengthened mandate of the European Chemicals Agency in its founding regulation.		
8	Recital 7	To promote the coherence and efficiency of assessments related to chemicals across Union legislation, steps should be taken by the relevant Union agencies to avoid divergent scientific opinions. Existing cases of divergent opinions have		

		lead to increased uncertainty for operators, as well as to declined public trust in the scientific robustness and coherence of scientific decision making. Proposals to address and strengthen procedures for resolving divergence of scientific opinions concerning the European Medicines Agency with other scientific bodies is proposed as part of the revision of Union pharmaceutical legislation. Similar provisions should also be considered to be proposed for a strengthened mandate of the European Chemicals Agency in its founding regulation, whilst such provisions are not relevant and applicable to the European Environmental Agency, since this agency does not issue scientific opinions on individual chemicals such as to be part in divergent outcomes.		
9	Recital 8	Correspondingly, this Regulation aims to address the eventual divergence between scientific opinions of the European Food Safety Authority and those of other Union agencies. Regulation (EC) No 178/2002 of the European Parliament and Council already contains provisions establishing a procedure to solve divergent scientific opinions. Those resolution procedures should be reinforced, in that the European Food Safety Authority and the other dissenting agency should be bound to make their best effort to resolve the divergence on		

		general scientific issues, and only when they are not able to resolve the divergence, should they refer to risk managers.		
10	Recital 9	In the more specific case of scientific divergence pertaining to the hazard identification of chemical substances, a new procedure enabling the resolution of the divergence should be established. This procedure should enable the Commission to request the European Chemicals Agency, as the Union agency most equipped with expertise and capacity in hazard assessment, as well as long-standing experience with the harmonised classification and labelling process, to develop a proposal for harmonised classification and labelling, in accordance the Regulation (EC) No 1272/2008 of the European Parliament and Council, moving closer to the ‘one substance, one assessment’ vision as regards uniformity of hazard assessments of chemicals across the Union. This possibility should be reflected in the relevant provision providing for the resolution of diverging scientific opinions laid down in Regulation (EC) No 178/2002.		
11	Recital 10	To comply with the obligation laid down in Section 10.4.3 of Annex I to Regulation (EU) 2017/745 of the European Parliament and of the		



	Council⁵, the Commission has provided the Scientific Committee on Health, Environmental and Emerging Risks (‘SCHEER’) with a mandate to prepare guidelines on the benefit-risk assessment of the presence of phthalates which are classified as either carcinogenic, mutagenic or toxic to reproduction category 1A or 1B, or which have endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁶. The SCHEER issued those guidelines in 2019 and the Commission has issued a mandate to the SCHEER to perform a first update of those guidelines. ⁵ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1). ⁶ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation	

		(EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1–849).		
12	Recital 11	To comply with the obligation laid out in Section 10.4.4. of Annex I to Regulation (EU) 2017/745, the Commission should mandate the relevant scientific committee to prepare guidelines for substances other than phthalates and which are classified as either carcinogenic, mutagenic or toxic to reproduction category 1A or 1B, or which have endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council.		
13	Recital 12	The European Chemicals Agency already provides scientific advice on chemical substances, including on phthalates, endocrine disruptors and carcinogens, mutagens and reproductive toxicants under Regulation (EC) No 1907/2006. Several key capacities of the agency can be reused, including hazard, risk, exposure and socio-economic assessment capacities, the Committee opinion development and IT capabilities for stakeholder consultation and		

		dissemination. To enable timely future updates on the presence of phthalates and to ensure that the appropriate Union agency develops new guidelines on other substances on the basis of the latest scientific evidence, these tasks should be attributed to the European Chemicals Agency.		
14	Recital 13	Taking account of the new hazard classes and criteria for classification, labelling and packaging of substances introduced by Commission Delegated Regulation (EU) 2023/707 of 19 December 2022⁷, reference to endocrine disruptors for human health, of Category 1, should be specified in 10.4.1., point (b) of Annex I of Regulation (EU) 2017/745 in light of the relevance of that hazard class to the type of substances in medical devices. ⁷ Commission Delegated Regulation (EU) 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures (OJ L 93, 31.3.2023, p. 7–39).		
15	Recital 14	To make best use of the European Chemicals Agency's knowledge and expertise gained through its involvement in the nomination and assessment processes under the Stockholm Convention on Persistent Organic Pollutants, the European Chemicals		

		Agency should, upon request, assist the Commission in complying with its obligation to amend Annexes IV and V to Regulation (EU) 2019/1021⁸. Where the opinion of the Committee for Socio-Economic analysis is required, and in order to allow for the necessary capacity and resources for the effective functioning of that committee, Member States should be given the opportunity to cover for the specific expertise required for the effective performance of the task by nominating experts. In order to ensure that the Committee for Socio-Economic analysis benefits from sufficient resources, when the committee appoints one of their members as a rapporteur, that person, or his employer should be remunerated. ⁸ Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45).		
16	Recital 15	In order to amend certain non-essential elements of Regulation (EU) 2019/1021 of the European Parliament and of the Council, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending Annexes IV and V in order to adapt them to the changes to the list of substances set out in the Annexes to the Stockholm Convention or		

		the Protocol or adapt them to scientific and technical progress.		
17	Recital 16	As part of their reporting obligations under the Regulation (EU) 2019/1021 of the European Parliament and of the Council, Member States must report to the European Chemicals Agency information on the presence of substances listed in Part A of Annex III in the environment. The use of the Information Platform for Chemical Monitoring ('IPCHEM') is encouraged as a means for Member States to comply with their obligations to report that chemical occurrence data and to simplify and reduce their reporting obligations. Where Member States make data available through IPCHEM, they no longer need to report it to the European Chemicals Agency, as the agency may retrieve it from the platform.		
18	Recital 17	The revision of the Directive (EU) 2020/2184 of the European Parliament and of the Council ⁹ requires Member States to share with European Environmental Agency all chemical occurrence or monitoring data in water. Additionally, the monitoring data on the presence of POPs in air are already being reported by Member States to the EEA as part of the Union air quality legislation. The proposal for a Regulation of the European Parliament and the Council		

		establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable, and reusable and establishing a monitoring and outlook framework for chemicals¹⁰ will require all chemical occurrence data to be held by the EEA. As a result, chemical occurrence data provided to and held in IPCHEM by the Commission will thus be collected and held by the EEA, instead of by the Commission. Therefore, it is necessary to simplify the reporting obligations for Member States to ensure that, where Member States have already submitted that information to the EEA as part of fulfilling obligations required by the provisions of other pieces of Union environmental legislation, Member States should be considered to have fulfilled their reporting obligations under Regulation (EU) 2019/1021. ⁹ Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast), (OJ L 435, 23.12.2020, p. 1–62). ¹⁰ [OJ Please insert reference once proposal is adopted]		
19	Recital 18	Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU)		

		2019/1021 should therefore be amended accordingly,		
20	Articles	HAVE ADOPTED THIS REGULATION:		
21	1	Amendments to Regulation (EC) No 178/2002		
22		Regulation (EC) No 178/2002 is amended as follows:		
23	(1)	in Article 23, the following point (m) is added:		
24		‘(m) to cooperate with the competent bodies in the Member States that carry out similar tasks to those of the Authority and to cooperate with other scientific bodies established under Union law, notably the European Chemicals Agency, the European Medicines Agency, and the European Environment Agency on the provision of relevant scientific opinions, on the exchange of data and information, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and on the development of scientific methodologies for the assessment of chemicals.’;		
25	(2)	Article 30 is replaced by the following:	Question were raised by a delegation on whether the EFSA procedure for risk assessment must not be changed as a result of this proposal and it must be ensured that the assessment of EFSA, and if applicable, other EU authorities	

			are properly and appropriately taken into account by ECHA. How is this ensured by the provisions in Article 30?	
			PRES: Discussion took place during WP2	
26		‘Article 30 Diverging scientific opinions	One delegation requested an example of what could be considered diverging scientific opinions. PRES: Discussion took place during WP2.	
27		1. The Authority shall take the necessary and appropriate measures to monitor and identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks.		
28		2. Where the Authority identifies a potential source of divergence, it shall contact the body concerned in order to ensure that all relevant scientific or technical information is shared and in order to identify the potentially contentious scientific or technical issues. The Authority and the body concerned shall cooperate to resolve the divergence. If the Authority and the body concerned are not able to resolve the divergence, they shall draw up a joint report. The report shall clearly outline the contentious scientific issues and identify		

		the relevant uncertainties in the data and be made publicly available. Where the body concerned is a Union agency or a scientific committee, the Authority shall present the joint report to the Commission.		
29		3. Where relevant, and where the divergence concerns conflicting scientific opinions of the Authority and another Union body or agency on whether a substance fulfils the criteria laid out in Annex I of Regulation (EC) No 1272/2008 of the European Parliament and of the Council¹¹, the Commission may request the European Chemicals Agency to prepare a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof following the procedure laid out in Article 37 of Regulation (EC) No 1272/2008. The Authority and the Union body or agency concerned shall co-operate with the European Chemicals Agency in developing that proposal.’		
30		¹¹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353 31.12.2008, p. 1 – 1355.		

31	2	Amendments to Regulation (EC) No 401/2009	One delegation asked for clarification why the EEA's cooperation with ECHA is supposed to be regulated in Article 15(5) of the EEA Regulation. Systematically, paragraph 1 with a new letter c seems closer. In addition, it would be clear that paragraph 4 also refers to this cooperation. One delegation has doubts about the impact of the Eionet Network's involvement in this cooperation. PRES: Discussion took place during WP2	
32		Regulation (EC) No 401/2009 is amended as follows:		
33	(1)	in Article 2, the following point (p) is added:		
34		‘(p) to develop assessment methodologies related to chemicals in the fields falling within its mission.’;		
35	(2)	in Article 15, the following paragraph 5 is added:		
36		‘5. The Agency shall cooperate with other scientific bodies established under Union law, notably the European Chemicals Agency, the European Food Safety Authority, and the European Medicines Agency, on the exchange of data and information on chemicals, including the possible establishment of related data formats and controlled		

		vocabularies to facilitate such an exchange, and on the development of scientific methodologies for the assessment of chemicals.’.		
37	3	Amendments to Regulation (EU) 2017/745	One delegation questions ECHA’s expertise regarding medical devices. PRES: Discussion took place during WP2	
38		Annex I to Regulation (EU) 2017/745 is amended as follows:		
39	(1)	in Section 10.4.1, point (b) is replaced by the following:		
40		‘(b) substances which are identified as endocrine disruptors for human health, of Category 1, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ¹² and substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council or substances having endocrine disrupting properties relevant to human health identified in accordance with Regulation (EU) No 528/2012.’		
41		¹² Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures,		

		amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006(OJ L 353 31.12.2008, p. 1).		
42	(2)	in Section 10.4.2, point (d) is replaced by the following:		
43		‘(d) where applicable and available, the latest relevant guidelines in accordance with Sections 10.4.3. and 10.4.4.’;		
44	(3)	Section 10.4.3 is replaced by the following:		
45		‘10.4.3. Guidelines on phthalates When deemed appropriate based on the latest scientific evidence, but at least every 5 years, the Commission shall request the European Chemicals Agency (ECHA) to update guidelines on the benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in Section 10.4.1., points (a) and (b). The benefit-risk assessment shall consider the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments When appropriate or when requested by the Commission, ECHA shall consult the Committee for Risk Assessment and the Committee for Socio-economic Analysis.’;		
46	(4)	Section 10.4.4 is replaced by the following:		

47		‘10.4.4. Guidelines on other CMR and endocrine-disrupting substances The Commission shall request ECHA to prepare guidelines as referred to in Section 10.4.3. and following the process described therein also for other substances referred to in Section 10.4.1., points (a) and (b), where appropriate.’.		
48	4	Amendments to Regulation (EU) 2019/1021	A delegation proposed that Article 4 of the POP Regulation would be amended to give the Commission the possibility to request ECHA to carry out the assessment required to amend the concentration limit values in the Annexes IV and V to the POP regulation It is further proposed (article 13 paragraph 2) that this provision would also introduce the adoption of amendments to Annexes IV and V by means of delegated act. Moreover, they believe that the delegation of legislative powers to the Commission in POP-regulation Article 15 needs further consideration This delegation sees the role of the POP-CA (competent authorities) very important in preparation of the delegated acts. In case the above described amendments would be accepted, what would be the role of the	

			POP-CA in the future? Would the Commission still consult the experts designated by each Member State and closely collaborate with POP-CA before adopting a delegated act? One delegation proposes that ECHA is also given the task to determine limit values and amending Annex I and not only Annexes IV and V to the POP regulation. They also ask whether ECHA will have the knowledge on the impact of adjusting Annex IV values on the waste and recycling phase, while another delegate questions the knowledge of SEAC on waste management. PRES: Discussion took place during WP2. PRES proposes amendments to be made to the proposal. Written comments are welcomed.	
49		Regulation (EU) 2019/1021 is amended as follows:		
50	(1)	Article 8(1) is amended as follows:		
51	(a)	the following point (i) is added:		
52		‘(i) upon request from the Commission, and within 12 months from that request, draw up and ~~provide-submit~~ a report on the human health, environmental and socio-economic impacts of introducing	One delegation proposes to change ‘draw up and provide a report’ to ‘draw up and submit a report.’ PRES proposed a change to the text.	Sweden supports the proposal.

		or modifying concentration limit values specified in Annex IV or V.’		
53	(2)	Article 8(1a) is added:		
54		‘1a. The report referred to in Article 8(1), point (i), shall contain the following information:		
55		(a) as appropriate, information on human health and environmental impacts of waste consisting of, containing or contaminated with POPs, including impacts on waste management;		
56		(b) information on concentrations and mass flows of POPs in relevant waste streams and on waste treatment and treatment capacities;		
57		(c) an analysis of the impacts of the different concentration limit values considered;		
58		(d) a duly motivated proposal for concentration limit values to be introduced in Annex IV and, as appropriate, in Annex V.		
59		The Agency shall, as soon as it receives the request referred to ~~in the first subparagraph~~ Article 8(1) , point (i), publish on its website a notice that a report on a possible amendment of Annex IV or V will be prepared inviting all interested parties, including waste operators and users of recycled materials, to submit comments within 8 weeks. The	One delegation proposed to change the reference, to clarify and to use the same kind of reference as is used in the paragraph above. PRES proposed change accordingly	Sweden supports the proposal

		Agency shall publish those comments on its website.		
60		At the latest 9 months following the submission of the ~~at~~ report <i>referred to in Article (8(1), point (i))</i> , the Committee for Socio-economic Analysis of the Agency, set up pursuant to Article 76(1), point (d), of Regulation (EC) No 1907/2006 shall adopt an opinion on the report and on the concentration limit values proposed therein. For the purpose of adopting an opinion on the report, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.	One delegation proposed to clarify which submission it is referred to given that it is mentioned in several paragraphs earlier in the text. The proposed change would help to clarify this together with a consequential amendment in Article 8(1) point (i) to change the word 'provide' to 'submit' PRES proposed change.	Sweden supports the proposal
61		The Agency shall submit the report and the opinion of the Committee for the Socio-economic Analysis on the concentration limit values to the Commission without delay.';		
62	(3)	in Article 13, paragraph 2 is replaced by the following:	One delegation further proposed (Article 13 paragraph 2) that this provision would also introduce the adoption of amendments to Annexes IV and V by means of delegated acts. PRES requires further clarification (potential text proposal).	
63		'2. Where a Member State shares the information referred to in paragraph 1, point (e), with the European Environmental Agency, that Member State shall indicate that in the report and the Member State shall be considered to		

		have fulfilled its reporting obligations under that point.		
64		Where the information referred to in paragraph 1, point (e), is contained in the report of a Member State provided to the Agency, the Agency shall transmit the information to the European Environmental Agency for compiling, storing and sharing that information’;		
65	(4)	in Article 15, paragraph 2 is replaced by the following:		
66		‘2. The Commission is empowered to adopt delegated acts in accordance with Article 18, to amend Annexes IV and V to this Regulation to adapt them to the changes to the list of substances set out in the Annexes to the Convention or the Protocol or to adapt them to scientific and technical progress.’	One delegation proposed the amendment in order to clarify that the reference is to the Annexes in this Regulation. PRES changed the text. One delegation would like confirmation of the Commission’s obligation to consult MS experts before adopting delegated acts as appears to be provided in Article 18(4) of the POP Regulation. Another delegation considers it of high importance to preserve the expertise of the Meeting of the Competent Authorities for Regulation (EU) 2019/1021 on POPs and would like to know in which stage of the future amendments of the annexes the experts from the CAs will be consulted and	Text proposal: ‘2. The Commission is empowered to adopt delegated acts in accordance with Article 18, to amend Annexes IV and V to this Regulation to adapt them to the changes to the list of substances set out in the Annexes I, II or III to this Regulation ~~to the Convention or the Protocol~~ or to modify existing entries in Annexes IV and V to this Regulation to adapt them to scientific and technical progress.’ Justification: Sweden considers that the reference should be to Annexes I, II and III rather than to the Convention. This ensures that the substance has already been included in the POPs regulation before Annexes IV or V are amended. If the reference is to the Convention we think that the Commission would need to receive a mandate from the Council.

			whether additional POP experts will be incorporated to SEAC and/or RAC. One delegation asked for the delegation of legislative powers to the COM in POP regulation article 15 to be further considered. They see the role of the POP-CA very important in the preparation of the delegated acts. PRES: Discussion took place during WP2. Written comments are welcome.	The second proposal is intended to clarify the basis of the derogation. Sweden is also of the opinion that the Commission should use the current expert group comprising of MS Competent Authorities, amongst others, for consultation before the adoption of delegated acts.
67	(5)	Article 18 is amended as follows:	One delegation suggests no changes to be made to Article 18, they don't want to delegate this regulatory authority to the COM. PRES: Discussion took place during WP2. Written comments are welcome.	Sweden supports the Commission's proposal for delegated powers. We understand the sensitivity of the subject matter, but we consider that the changes are too technical to be suitable for discussion in the Working Party of the Council. Furthermore, the delegated act procedure would be more efficient and more flexible, allowing amendment of the annexes sooner after scientific and technical advances.
68	(a)	The first sentence of paragraph 2 is replaced by the following:		
69		'2. The power to adopt delegated acts referred to in Articles 4(3), 10(2) and 15 shall be conferred on the Commission for a period of five years from 15 July 2019.'	A delegation considers that this 5-year term is very likely to have passed before the proposed delegation of authority takes effect. Therefore, they suggest adjusting the period in order to have effect in practice.	Sweden supports this proposal.

			PRES: Discussion took place during WP2 Written comments are welcome	
70	(b)	The first sentence of paragraph 3 is replaced by the following:		
71		‘3. The delegation of power referred to in Articles 4(3), 10(2) and 15 may be revoked at any time by the European Parliament or by the Council.’.		
72	(c)	Paragraph 6 is replaced by the following:		
73		‘6. A delegated act adopted pursuant to Articles 4(3), 10(2) and 15 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object.’.		
74	6	Entry into force		Text proposal: Article ~~6~~ <u>5</u> Justification: There seems not to be an Article 5 in the Commission’s proposal so Article 6 should be renumbered.
		This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.		
		Done at Brussels,		

[illegible]

SWEDEN

14/3/2024

PUBLIC

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

establishing a common **data platform** on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

(Text with EEA relevance)



MS delegations are requested to send in, article per article, comments and text proposals using the table provided here below, at the latest by Friday 22 March 2024, 1 pm.

	Presidency proposals: amendments (~~deletions~~ /additions)	Presidency justification after WP1: follow-up or proposal to work on amendments, or requests for written comments	Delegates comments/proposals after WP2
Proposal Title			
1	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals)		General comments 1. We have in text proposals on several recitals and articles sought to clarify the difference between making data available to the public and, on the other hand, the response of an authority to requests for access to data. 2. Scope: We have made several text proposals in recitals, articles and the annexes in line with our position on the inclusion of all medicinal active substances within the scope of the Regulation. 3. We have also made several text proposals in articles where we consider that the delegation of powers to the Commission should specify a procedure where Member States are involved in the decision-making process. We appreciate that these proposals would require further changes in the text and the relevant references to Decision 1999/468/EC. We will be happy to support the Presidency with the necessary additional text amendments if so desired. 4. Sweden considers that it would be appropriate for the Commission to be required to submit a report regarding the progress of the implementation of this Regulation every five years from the date of entry into force.
Formula			

2	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN		
Citation 1			
3	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114(1) thereof,		
Citation 2			
4	Having regard to the proposal from the European Commission,		
Citation 3			
5	After transmission of the draft legislative act to the national parliaments,		
Citation 4			
6	Having regard to the opinion of the European Economic and Social Committee ¹		
Citation 5			
7	Acting in accordance with the ordinary legislative procedure,		
Formula			
8	Whereas:		
Recital 1			
9	(1) The European Green Deal ³⁴ sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability ³⁵ is a crucial delivery of this zero-pollution ambition and introduces the ‘one substance, one assessment’ approach, which aims to improve the efficiency, effectiveness, coherence, and transparency of safety assessments of chemicals across Union legislation. According to that Strategy, ‘safe and sustainable by design’ criteria should be developed to enable the production and use of chemicals that are safe and sustainable throughout their entire lifecycle. The Strategy also sets out that the		

	interaction between scientific developments and policy-making should be strengthened by means of an early warning system for chemicals to ensure that Union policies address emerging chemical risks as soon as these are identified by monitoring and research, and that a framework of indicators should be developed to monitor the drivers and impacts of chemical pollution and to measure the effectiveness of chemicals legislation. This Regulation aims to implement these objectives.		
Recital 2			
10	(2) The main objective of this Regulation is to increase the level of protection of the environment and human health from the risks arising from hazardous chemicals, as well as to facilitate the functioning of the internal market for chemicals. For that purpose, this Regulation should establish a common data platform data on chemicals ('the common data platform'), to be managed by the European Chemicals Agency ('ECHA'). The common data platform is a digital infrastructure that brings together chemicals data and information generated under the Union chemicals acquis. This Regulation should also establish dedicated services within the common data platform and lay down rules on the accessibility and usability of the data contained in that platform. This Regulation aims to create a common knowledge base on chemicals available to authorities to enable better, complete, coherent and robust scientific assessments of chemicals and their impacts and to ensure the best use of existing information for the purpose of the implementation and the development of Union legislation on chemicals. Moreover, the Regulation aims to provide a one-stop-shop on chemicals data and information in the Union accessible to the		

	general public and, thus, to increase the predictability and the transparency of regulatory processes on chemicals, as well as to strengthen public trust in the robustness of scientific decision-making.		
Recital 3			
11	(3) Under Decision (EU) 2022/591 of the European Parliament and of the Council ³⁶ , harnessing the potential of digital and data technologies to support environmental policy, including by delivering real-time data where possible and information on the state of ecosystems, while increasing efforts to minimise the environmental footprint of these technologies and ensuring transparency, authenticity, interoperability and public accessibility of the data and information is a long-term priority objective. Data and information on chemicals are therefore essential for the proper development and implementation of a Union environmental policy, and specifically of a chemicals policy.		
Recital 4			
12	(4) In its communication of 19 February 2020 on a European strategy for data ³⁷ , the Commission described its vision of a common European data space and highlighted the need for the development of sectoral data spaces in strategic areas, since not all sectors of the economy and society are moving at the same speed. This Regulation aims therefore to build a data space for chemicals by establishing a common data platform on chemicals ('common data platform'), which is also part of the Green Deal data space, as referred to in the European strategy for data. Furthermore, in that strategy, the Commission highlighted several issues concerning the availability of data		

	for the public good, including data availability, data infrastructures and governance, interoperability, as well as the lack of adequate sharing of data between public authorities. This Regulation aims to increase data availability on chemicals by requiring the relevant Union agencies to make data available for integration in the common data platform on chemicals, to promote interoperability of that data by providing for the establishment of standard formats and controlled vocabularies, as well as to facilitate data exchange and use by public authorities to enable them to effectively carry out their regulatory and policy developing tasks.		
Recital 5			
13	(5) This Regulation also aims to implement into the chemicals sector the principles laid out in the proposal for an Interoperable Europe Act ³⁸ by strengthening the cross-border interoperability of network and information systems used to provide or manage public services on chemicals in the Union. This Regulation will contribute to increased cross-border data flows for truly European digital services and broaden the access to publicly available chemicals data for utilisation in other sectors' applications.		
Recital 6			
14	(6) Business operators and Members States' competent authorities are required by various Union acts to submit data and information to a multitude of Union agencies, as well as to the Commission in specific cases. This generates a fragmentation of data and information on chemicals, which are held under various data sharing and use conditions and in different formats. Such fragmentation prevents public authorities, as well as the general public, from		

	having a clear overview of what information is available on individual chemicals or groups of chemicals, of where and how information can be accessed and whether it can be used. This increases the likelihood of inconsistency between various assessments of the same chemical required by various Union acts on chemicals and of damaging the general public's trust in the scientific grounds for Union decisions on chemicals. In order to ensure that data on chemicals is easily findable, accessible, interoperable and usable, the ECHA should establish a common data platform on chemicals. The common data platform on chemicals should serve as a single point of reference and as a broadened and shared evidence base to enable the efficient delivery of coherent hazard and risk assessments of chemicals across various Union acts on chemicals, as well as to enable the timely identification of emerging chemical risks and the drivers and impact of chemical pollution.		
Recital 7			
15	The common data platform should contain chemicals-related data and information held by relevant Union agencies or the Commission generated or submitted as part of the implementation of Union chemicals legislation listed in Annex I. This includes, for instance, all regulatory dossiers or applications submitted to the relevant Union agencies, but also chemicals data on occurrence of chemicals submitted by Member States to Union agencies or the Commission in compliance with their reporting obligations. The common data platform should also include chemicals data and information generated as part of Union, national or international		

	programmes or research activities related to chemicals, where this data and information is held by the Commission or one of the relevant agencies.		
Recital 8			
16	Due to the different nature of the risk and hazard assessments performed under Union acts on medicinal products, when compared to those performed under the main Union acts on chemicals, for medicinal products, only chemicals data related to environmental risk assessments for human and veterinary medicines, non-clinical studies for human medicines and maximum residue limit values the European Medicines Agency ('EMA') holds, as well as specific reference values, should be included in the common data platform. For medicinal active substances, only data on relevant substances should be included. These concern active substances covered by the medicines legislation and also used for other applications regulated by other Union legislation identified in this Regulation, as well as other active substances with particular persistent, bio-accumulative and toxic properties or with a known high level of residues in the environment.	Some delegations expressed the need for a clarification of the scope and meaning of "relevant substances" for active substances → PRES: this is scheduled for discussion at the 2nd WP	Text proposal: Due to the <u>particular</u> different nature of <u>some of the data submitted</u> the risk and hazard assessments performed under Union acts on medicinal products, when compared to those performed under the main Union acts on chemicals, <u>clinical data</u> for medicinal products, <u>only chemicals data related to environmental risk assessments for human and veterinary medicines, non-clinical studies for human medicines and maximum residue limit values the European Medicines Agency ('EMA') holds, as well as specific reference values,</u> should <u>not</u> be included in the common data platform. For medicinal active substances, <u>only data on relevant substances should be included. These concern active substances covered by the medicines legislation and also used for other applications regulated by other Union legislation identified in this Regulation, as well as other active substances with particular persistent, bio-accumulative and toxic properties or with a known high level of residues in the environment.</u> Justification: Sweden proposes that the scope of the regulation with regards to medicines shall be somewhat wider. Data on all medicinal active substances should be included so that the environmental consequences of their use and environmental exposures of them can be more properly ascertained in accordance with environmental legislation.
Recital 9			
17	(9) These data should also be limited to data submitted to the EMA in the context of the		Text proposal:

	relevant procedures that are finalised or submitted after the entry into force of this Regulation. At a later stage, it should also be possible to include in the common data platform, where relevant, data the EMA holds on procedures concluded before the entry into force of this Regulation.		(9) ~~These data should also be limited to data submitted to the EMA in the context of the relevant procedures that are finalised or submitted after the entry into force of this Regulation. At a later stage, it should also be possible to include in the common data platform, where relevant, data the EMA holds on procedures concluded before the entry into force of this Regulation.~~ Justification: That the requirements for data on medicinal active substances shall be laid out in line with those for other studies – that is to be included and handled in the same way as for other chemicals except for aspects where an exception can be motivated.
Recital 10			
18	(10) Due to the sensitivity of the information on the exact chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health or physical effects, submitted to the bodies appointed by the Member States under Article 45 of Regulation (EC) No 1272/2008 of the European Parliament and the Council ³⁹ , that information should not be included in the common data platform. Likewise, due to the commercial sensitiveness of data and information on final cosmetic products, the information related to cosmetic products notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/2009 ⁴⁰ of the European Parliament and of the Council should not be included in the common data platform either. However, chemicals data and information on individual chemical ingredients of cosmetic products should be included in the common data platform.		

Recital 11			
19	(11) To safeguard the ability of the European Commission, of the Union agencies working on chemicals and of the competent Member State authorities (hereinafter 'the Authorities'), to carry out their tasks, documents with chemicals data relating to their internal work or decision-making should in principle not be included in the common data platform.		
Recital 12			
20	(12) In order to respond to the needs of the digital economy and to ensure a high level of protection of the environment and human health, it is necessary to lay down a harmonised framework specifying who is entitled to access and use the chemicals data contained in the common data platform, under which conditions, on what basis, and for which purposes. The Authorities that are entrusted with regulatory tasks related to chemicals should be allowed and encouraged to use the chemicals data and information contained in the common data platform to effectively fulfil their regulatory duties and tasks, in order to improve the effectiveness, efficiency, and coherence of chemicals-related assessments as well as the development of Union chemicals policies.		
Recital 13			
21	(13) Chemicals data and information generated as a result of obligations set by Union acts on chemicals may be protected by confidentiality claims on confidential business information. The public dissemination of such data may affect the		

	commercial interest of private parties. To ensure legal certainty for duty holders and to protect their legitimate expectations, as well as to ensure industry's competitiveness on the internal market, the ECHA, as a manager of the common data platform, should grant differentiated access rights to the data and information contained in the common data platform. To this end, the Authorities should have full access to all chemicals data and information contained in the common data platform, including access to confidential information, while business operators and the general public should have restricted access to that data and information, which does not include access to confidential information.		
Recital 14			
22	(14) When using data contained in the common data platform, the Authorities should respect the originator principle. Under this principle, the confidentiality marking of chemicals data as done by the originator and as correspondingly indicated by the Agency when it provides that data to the common data platform should be respected by the Authorities using that data or information to perform their regulatory functions or fulfil their tasks.		Text proposal: When using data contained in the common data platform, the Authorities should respect the originator principle. Under this principle, the confidentiality marking of chemicals data as done by the originator and as correspondingly indicated by the Agency when it provides that data to the common data platform should be respected by the Authorities using that data or information to perform their regulatory functions or fulfil their tasks. <u>This includes using data to the disadvantage of a duty holder. When the Authorities use data in the common data platform they shall respect Intellectual Property Rights and data protection.</u> Justification: Sweden proposes to add a clarification that data can be used to the disadvantage of a duty holder and

			that intellectual property right as well as data protection need to be respected when using the data.
Recital 15			
23	(15) To ensure the protection of legitimate expectations of duty holders when generating or submitting data or information under the Union acts listed in Annex I, as well as to protect the confidentiality of that information when used by the Authorities, exceptional grounds for disclosing confidential information laid down in the Union acts listed in Annex I should apply only to the disclosure of the data and information submitted or generated in compliance with those acts. For example, under Article 39(4) of Regulation (EC) No 178/2002 of the European Parliament and of the Council⁴¹, where urgent action is essential to protect human health, animal health or the environment, such as in emergency situations, the European Food Safety Authority ('EFSA') may disclose information previously considered confidential under that Regulation and the EFSA is required to make public information, previously considered confidential, that forms part of conclusions of scientific outputs of the EFSA and relates to foreseeable effects on human health, animal health or the environment. Likewise, Article 118 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁴² provides for the possibility for the ECHA to disclose confidential information submitted to it under that Regulation if urgent action is essential to protect human health, safety or the environment, such as in emergency situations.		
Recital 16			

24	(16) Taking into account that the Agencies would be required to store scientific data, which includes confidential and personal data, it is necessary to ensure that such storage is carried out in accordance with a high level of security of information systems and that access to confidential data is auditable.		
Recital 17			
25	(17) While the ECHA should identify and develop the technical functionalities of the common data platform in stages, certain dedicated services should be defined by this Regulation. As such, the common data platform should, in addition to providing access to chemicals-related data made available by the Agencies and the Commission, provide access to the chemicals data and information made available through its dedicated services. These dedicated services should be integrated into the common data platform and consist of the existing Information Platform for Chemical Monitoring ('IPCHEM'), a repository of reference values, a database of study notifications, a database with information on regulatory processes, a database with information on applicable legal obligations, a repository of standard formats and controlled vocabularies, a database on environmental sustainability related data, as well as a dashboard of indicators on chemicals.		
Recital 18			
26	(18) The Commission should adopt an implementation plan identifying initial datasets to be made accessible via the platform and the timeline for their integration, informed by the		Text proposal: ... The governance scheme should be adopted and updated as necessary by the Commission, after consultation with a newly established platform steering committee composed

	preparatory work of the Commission and the Agencies⁴³. The Commission should set up a governance scheme to support and steer the common data platform's operation and evolution covering the organisation of work structures and coordination between ECHA and data providers, required rules, formats and vocabularies for data integration, and maintain a rolling implementation plan to ensure the progress in identification and integration of new datasets and services for inclusion. The governance scheme should be adopted and updated as necessary by the Commission, after consultation with a newly established platform steering committee composed of representatives from Union agencies and the Commission. In order to ensure uniform conditions for the implementation of the obligations to establish an implementation plan and a governance scheme, implementing powers should be conferred on the Commission.		of representatives from Union agencies and the Commission. <u>The Commission shall represent work areas remaining directly under its responsibility. This is relevant for work areas that have not been brought under the responsibility of an EU agency.</u> In order to ensure uniform conditions for the implementation of the obligations to establish an implementation plan and a governance scheme, implementing powers should be conferred on the Commission. Justification: To clarify that in these matters the Commission shall represent the work areas not covered by the areas of responsibility for the EU agencies.
Recital 19			
27	(19) The common data platform should serve the widest possible community, with the ability to address new use cases, incorporate new relevant datasets, develop new functionalities, and respond to developing tools and applications.		
Recital 20			
28	(20) In order to bring together all relevant chemicals data and information in the common data platform, the Commission and Union agencies – notably the European Agency for Safety and Health at Work ('EU-OSHA'), the ECHA, the European Environment Agency ('EEA'), the EFSA, and the EMA ('the Agencies'), should act as data		Text proposal: In order to bring together all relevant chemicals data and information in the common data platform, the Commission and Union agencies – notably the European Agency for Safety and Health at Work ('EU-OSHA'), the ECHA, the European Environment Agency ('EEA'), the EFSA, and the

	providers and make available any such relevant data they have or hold to the ECHA for integration in the common data platform. The Agencies, including the ECHA itself when making its own data available, should provide the necessary standard metadata, contextual information and relevant mapping to the platform's structure, and respect rules on standard formats and controlled vocabularies where available.		EMA ('the Agencies'), should act as data providers and make available any such relevant data they have or hold to the ECHA for integration in the common data platform. The Agencies, including the ECHA itself when making its own data available, should provide the necessary standard metadata, contextual information and relevant mapping to the platform's structure, and respect rules on standard formats and controlled vocabularies where available. <u>Other functions, such as the quality control of data and the completeness of data submissions, shall be controlled by the originator in accordance with the originating Union act under which it was submitted.</u> Justification: An addition to reflect the Commission's explanations that aspects such as quality control shall continue to be dealt with under the original legislation.
Recital 21			
29	(21) To ensure that an adequate knowledge base on chemicals is available through the common data platform, the Commission should be able to request the Agencies to host, maintain and make available, via the common data platform, data generated as part of Union, national or international programmes or research activities beyond the data already flowing to the Agencies as part of the obligations under the Union acts listed in Annex I. The Commission should make such requests to the Agencies in accordance with their mandates and allocated tasks.		
Recital 22			
30	(22) Some types of data are currently not within the mandate of any of the Agencies. In order to		

	ensure clarity of responsibilities of the Agencies and efficient management of chemicals data, the Agencies should be required to host, maintain and provide specific data types to the common data platform. To this end, the ECHA should host and be a data provider to the common data platform for workplace monitoring data, and the EEA should host and be a data provider to the common data platform for data on indoor air quality and environment monitoring data, as well as data on concentrations of chemicals in human matrices such as blood or urine ('human biomonitoring data').		
Recital 23			
31	(23) To improve the uptake of academic data and to expand the knowledge base for chemicals safety assessments and environmental sustainability impacts of chemicals, researchers or research consortia funded by Union framework programmes should make available, in line with the 'as open as possible, as closed as necessary' principle, any human biomonitoring data they collect or generate resulting from research and development programmes to the EEA and any environmental sustainability data on chemicals or materials they collect or generate to the ECHA.		
Recital 24			
32	(24) The EEA, as the agency responsible for monitoring data and information on chemicals in the environment, should also be responsible for collecting, hosting, and maintaining human biomonitoring data. To the extent that human biomonitoring data constitutes a special category of personal data, namely, health data, the EEA		

	should process that data only where the processing is necessary for reasons of substantial public interest, as required by Article 10(2)(g) of the Regulation (EU) No 2018/1725 of the European Parliament and of the Council ⁴⁴ . This Regulation lays down the cases where there is such substantial public interest in processing human biomonitoring data: namely, where the EEA processes that data to assess the impact of chemicals on human health and the environment, to monitor time and spatial trends in exposure, to develop health risk and impact indicators, to monitor the impact of regulatory intervention, and to support regulatory risk assessments.		
Recital 25			
33	(25) In order to ensure that appropriate safeguards are in place to secure the protection of this sensitive type of personal data, the EEA should only provide anonymised human biomonitoring data to the ECHA for integration in IPCHEM and the common data platform. IPCHEM, currently operated by the Commission, gathers occurrence data on chemicals in different media, including water, soil, indoor and outdoor air, biota, food and feed, humans, and products. In order to take advantage of the integration of various information systems and to ensure that occurrence data on chemicals is made available for use together with the other chemicals data, the ECHA should take over from the Commission the operation of IPCHEM and integrate it in the common data platform as one of its main dedicated services.		
Recital 26			
34	(26) In order to prevent disruption to the existing		

	operation and functioning of the IPCHEM, the ECHA should integrate the IPCHEM in the common data platform together with the data present in IPCHEM at the moment of integration. At the same time, in order to enable optimal hosting and management of occurrence data on chemicals, the Commission should also transfer the data present in IPCHEM to the ECHA, the EEA or the EFSA for hosting and future updating in accordance with their respective mandates. In order to ensure that the ECHA takes over from the Commission the operation of the IPCHEM, integrates it into the common data platform and takes over the initial data sets and sets up adequate data flows, it is necessary to allow the ECHA an appropriate period of time to carry out these actions, of up to 3 years from the date of entry into force of this Regulation.		
Recital 27			
35	In order to promote the use and harmonisation of reference values among risk assessors and risk managers across different Union acts and to facilitate compliance with, and enforcement of, regulatory reference values, the ECHA should establish and maintain a repository of reference values established or adopted under the Union acts listed in Annexes I and II. The Agencies should provide the ECHA with reference values they hold or establish as part of their activities. In addition, the ECHA should regularly screen Union acts for reference values adopted under them. To facilitate automatic access of the general public to up-to-date reference values, the ECHA should integrate the repository of reference values in the common data platform as a dedicated service, include in that repository all reference values together with		

	the relevant context data it has received or retrieved and ensure that those values and that context data are machine readable.		
Recital 28			
36	(28) In order to increase transparency, as well as to enable Authorities to have complete prior knowledge of studies commissioned by business operators, irrespective of whether such studies are carried out by the business operator itself or are outsourced, business operators and laboratories should notify to a database of study notifications established and managed by the ECHA the studies on chemicals they commission for compliance with regulatory requirements under the Union acts listed in Annex I. For this purpose, the ECHA should establish and manage a database of study notifications, as a dedicated service of the common data platform, to store the information related to those studies. In order to allow business operators and laboratories sufficient time to prepare the notifications of studies, the obligation to notify studies should only start to apply two years after the date of entry into force of this Regulation.		
Recital 29			
37	(29) Under Regulation (EC) No 178/2002 of the European Parliament and of the Council, business operators and laboratories are obliged to notify to the database of study notifications established and managed by the EFSA the studies they commission to support an application or notification in relation to which Union law contains provisions for the EFSA to provide a scientific output. To avoid overburdening business operators and		

	laboratories, they should therefore not be required to also notify those studies to the database of study notifications established and managed by the ECHA under this Regulation.		
Recital 30			
38	(30) To ensure the coherence between those two study notification mechanisms, as well as to ensure certainty for business operators submitting notifications, the rules on the public dissemination of study notifications should, where relevant, correspond in that the notifications should only be made available through the common data platform EN 27 EN once a corresponding registration, application, notification or other relevant regulatory dossier was submitted to the relevant Union or national institution and a decision on the confidentiality of the data contained in that regulatory dossier was taken by that Union or national institution. In addition, in order to facilitate compliance with the requirement to notify a study, the ECHA and the EFSA should cooperate to ensure a common approach for the identification of notified information in order to facilitate the traceability of studies notified to their respective databases.		
Recital 31			
39	(31) While the study notification obligation established in this Regulation should apply in the context of all the Union acts on chemicals listed in Annex I, the various relevant data collection and safety assessment processes under those acts may vary widely procedurally. The overarching aim of the database of study notifications established under this Regulation should be to bring together		

	information on studies on chemicals being commissioned by business operators, such as to enable a centralised and complete overview of the studies being performed to support regulatory compliance under Union acts on chemicals as listed in Annex I. On the basis of this objective and considering the fact that assessment procedures under Union acts on chemicals in Annex I may vary widely, it would be beyond the scope and aim of this Regulation to amend existing assessment processes set under those Union acts listed in Annex I by imposing additional conditions leading to potential market access consequences not foreseen in those Union acts. Consequently, it is not appropriate to introduce in this Regulation the consequences associated non-compliance with the study notification obligation as laid out in Article 32b of Regulation (EC) No 178/2002 of the European Parliament and of the Council.		
Recital 32			
40	(32) Nevertheless, to ensure compliance with the study notification obligation laid down in this Regulation, and to cater to the specificities of individual assessment processes, where existing, Member States should lay down rules on penalties applicable to the infringement of that obligation and take all necessary measures to ensure that those rules are complied with. Those penalties should be effective, proportionate, and dissuasive, since non-compliance with this Regulation could result in less robust chemicals risk assessments, creating potential risks and consequently adverse effects on human health and the environment.		
Recital 33			

41	(33) In order to facilitate enforcement by Member States, the Agencies responsible for assessing and providing scientific output, including scientific opinions, on regulatory dossiers containing studies subject to notification to ECHA should, where relevant, cooperate and exchange information with the Member State enforcement authorities on the compliance with the obligations laid out in Article 22.		
Recital 34			
42	(34) While Regulation (EC) No 178/2002 of the European Parliament and of the Council also requires the consultation of stakeholders and the public following the notification to the EFSA of studies commissioned for the purposes of the renewal of an authorisation or approval, a similar requirement under this Regulation would lay a disproportionate administrative burden on the ECHA, given the wide scope of the studies that is to be notified under this Regulation.		
Recital 35			
43	(35) A mechanism related to study notifications exists in Regulation (EC) No 1907/2006 of the European Parliament and of the Council. Where registrants are required to perform studies to generate data in accordance with requirements in Annexes IX and X to that Regulation, they must first submit a testing proposal to the ECHA in order to receive a decision requiring them to perform a study. Such decision may also be issued as an outcome of compliance check or substance evaluation under that Regulation. In order to facilitate the transparency, traceability, and effective monitoring of studies commissioned or		

	carried out pursuant to a decision of the ECHA in accordance with Articles 40, 41 or 46 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council, business operators should specify in their notifications of studies under this Regulation that those studies are being commissioned or carried out in compliance with those decisions.		
Recital 36			
44	(36) To strengthen the coordination and cooperation between the different bodies performing chemicals assessments in the Union, and to promote an increased transparency of chemicals assessments, the ECHA should establish and manage a database with information on regulatory processes or activities that are planned, ongoing or completed by Member States, the Commission and Agencies referred to in the Union acts listed in Annex III to this Regulation and integrate it into the common data platform for access by the authorities. The information on such regulatory processes or activities should include at least the substance identity and the identification, status and eventually the outcome of the regulatory process or activity. That information should also be made available without undue delay and kept updated through the assessment process. Once the process or activity has formally started, that information should be shared also publicly on the common data platform.		
Recital 37			
45	(37) The existing 'The EU Chemicals Legislation Finder' 45 project managed by the ECHA makes it easier to find and identify legal obligations related		

	to the use of a specific chemical. The project is especially helpful for small and medium sized enterprises in identifying their legal obligations. To reinforce the supportive function of the project for business operators, it should be established on a permanent basis and more Union acts should be included in its scope. For this purpose, the ECHA should collect information on the legal obligations deriving from the Union acts on chemicals listed in Annex I to this Regulation and incorporate that information into the common data platform as a dedicated service.		
Recital 38			
46	(38) In order to ensure the interoperability and comparability of chemicals data and to facilitate their automatic and electronic exchange, the Agencies and the Commission should store chemicals data in adequate and mutually coherent and interoperable formats and use mutually coherent and interoperable controlled vocabularies. Some Union acts listed in Annex I or II set procedures to establish or make available data formats, in particular for the submission of chemicals data by business operators or Member States. Where such procedures do not exist in the Union acts listed in Annex I or II, the Agencies and the Commission should, where relevant, specify appropriate formats for chemicals data they receive and store, avoiding the use of proprietary standards while, as appropriate, using OECD or other internationally agreed formats, making use of existing formats and ensuring interoperability with existing data submission approaches.		
Recital 39			

47	(39) Likewise, the Agencies and the Commission should specify appropriate controlled vocabularies for data they receive and store and, where relevant, integrate them in submission software or formats. Moreover, in order to facilitate a smooth electronic exchange of data through the common data platform, the Agencies and the Commission should agree on the required formats and controlled vocabularies for providing data to the common data platform. Whenever the Agencies or the Commission set formats or controlled vocabularies, they should cooperate with each other to ensure their coherence, consistency and interoperability. In order to ensure uniform conditions for resolving divergences in data formats and controlled vocabularies, implementing powers should be conferred on the Commission.		
Recital 40			
48	(40) In order to promote the interoperability of database systems on chemicals beyond the common data platform, the ECHA should establish a repository of standard formats and controlled vocabularies as part of the common data platform. The Agencies and the Commission should make the formats and controlled vocabularies they set available to the repository and the ECHA should make them available free of charge in electronic formats for use by developers of database systems and the general public.		
Recital 41			
49	(41) The International Uniform Chemical Information Database ('IUCLID') is a software application designed to record, store, maintain and exchange data on chemicals. The ECHA develops		

	and maintains the IUCLID software and the underlying format in collaboration with the Organisation for Economic Cooperation and Development ('OECD'). The IUCLID implements all OECD-harmonised templates, which are harmonised formats agreed at the OECD level to facilitate structured and consistent documentation of test outputs and similar chemicals data. Since chemicals data is being submitted to the ECHA in IUCLID under Union acts such as Regulations (EC) No 1907/2006, (EC) No 1107/200946 and (EU) No 528/201247 of the European Parliament and of the Council, the ECHA is closely involved in the continued development of IUCLID, and IUCLID implements the standard formats agreed at the OECD level, it is appropriate and necessary to require the Commission and the Agencies to use IUCLID for the relevant parts of dossiers under specified Union acts listed in Annex I when they make the data contained in those dossiers available to the ECHA .		
Recital 42			
50	(42) To increase the availability and facilitate the use of information on the environmental performance of chemicals throughout their lifecycle, and to enable a comprehensive assessment of the impacts of chemicals on the environment, the Commission should identify relevant data and information related to the environmental sustainability of chemicals, including, where available, information on their impact on climate change, for integration into the common data platform. Once the Commission has identified the relevant existing datasets on environmental sustainability related data and has		

	designed the relevant related database functionalities, the ECHA should establish a database on environmental sustainability-related data, collect the data as made available by the Commission, the Agencies and, where relevant, by the researchers and research consortia funded by Union framework programmes, and integrate the content of that database into the common data platform as a dedicated service. In order to ensure uniform conditions for the implementation of the obligation to identify relevant environmental sustainability datasets, implementing powers should be conferred on the Commission.		
Recital 43			
51	(43) To monitor the impacts on humans and the environment, including the climate, of exposure to chemicals and to establish a knowledge base to measure the effectiveness of chemicals legislation in protecting human health and the environment, the EEA and the ECHA should jointly develop and regularly, at least every two years, update a set of indicators and present it in the form of a dashboard. The EFSA, the EMA, the EU-OSHA and the Commission shall regularly provide the EEA with any available data falling within their mandate and relevant for the establishment of the indicators. The EEA and the ECHA should integrate this dashboard of indicators into the common data platform.		
Recital 44			
52	(44) To enable the identification and evaluation of emerging chemical risks, the EEA should develop and compile information on early warning signals and draw up an annual summary report to inform		

	regulatory follow-up actions. In its work, the EEA should include its own sources, targeted literature searches and make use of information from national early warning systems. It should also include relevant information made available by the related work of the ECHA, the EFSA, the EU-OSHA, the EMA and their networks, such as the EFSA's task of identifying and collecting information on emerging risks under Regulation 178/2002. The EEA should make the summary report and the underlying data available through the common data platform, ensuring public access and its use for further action on existing and emerging risks. In order to allow the EEA sufficient time to organise the collection of early warning signals and to compile and analyse the initial information the EEA should only deliver the first report six months after the end of the first calendar year after entry into force of this Regulation. This Regulation sets a deadline for the first report and associated data.		
Recital 45			
53	(45) In June 2017, at the Commission' request, the ECHA set up the European Observatory for Nanomaterials⁴⁸ ('EUON'), which collects existing data and information from databases, registries and studies and generates new data through studies and surveys on nanomaterials on the EU market.		
Recital 46			
54	(46) The ECHA should continue operating the EUON and transform it into an observatory for specific chemicals with potential contribution to emerging chemical risks ('the observatory'), which should cover also other chemicals and innovative		

	(rationally designed complex ‘advanced’) materials selected by the Commission, using, as appropriate, signals from the early warning and action system. One of the criteria for selecting chemicals for the observatory should be their novelty and disruptive potential that may contribute to an emerging chemical risk. Another criterion for that selection should be the higher degree of uncertainty surrounding them and, due to less regulatory experience regarding those chemicals, the resulting need for additional scrutiny and transparency. The observatory should facilitate regulatory implementation and responsible use of these chemicals by collecting, generating, and disseminating reliable information on selected chemicals’ properties, uses and market presence to the general public.		
Recital 47			
55	(47) The observatory should not be regarded as a substitute for required risk management action on any chemical in cases where a hazard or risk has been identified. In order to provide for an efficient and consistent approach for the generation and dissemination of all such additional information, the ECHA should oversee the work of the observatory and make the regularly updated data and information it collects available through the common data platform, or by means of other communication channels, as appropriate. In order to ensure uniform conditions for the implementation of the requirement to select chemicals to be included in the observatory, implementing powers should be conferred on the Commission.		
Recital			

48			
56	(48) Under Regulation (EC) No 178/2002, the EFSA is able to commission, in an open and transparent manner, the scientific studies it needs to accomplish its mission, while seeking to avoid duplication with Member States or Union research programmes. The ECHA should also be able to commission studies to obtain adequate data and information on chemicals within its mission, while maintaining the principle that the burden to prove compliance with Union chemicals legislation remains on the duty holder. Furthermore, the ECHA should commission such studies out of its own initiative or at the request of the Commission, with the objective of supporting the effective and efficient implementation and evaluation of Union acts on chemicals within its mandate and contributing the development of a Union chemicals policy.		
Recital 49			
57	(49) In order to adjust the contents of Annexes I and III to technical and scientific progress in the field of chemicals and to bring in the scope of this Regulation new Union acts under which relevant chemicals data and information is generated or submitted, and, where relevant, to expand the specific data types and reference values, listed in Annex II, to be made available by the EMA through the common data platform, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending Annexes I, II and III. It is of particular importance that the Commission carry out appropriate consultations during its preparatory		

	work in relation to the amendment of the Annexes by delegated act, including at expert level through the One-Substance One-Assessment Expert Group, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016 ⁴⁹ . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.		
Recital 50			
58	(50) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States as Member States do not hold the data within the scope of this Regulation and cannot establish a Union wide common data platform, but can rather, by reason of chemicals data and information being hosted at Union level by the Agencies, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.		
Recital 51			
59	(51) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council and delivered an opinion on [OP: Please insert the date of the		Text proposal for a new recital: <u>(52) It is important that sufficient resources be made available to the Agencies given the extensive increase in tasks apportioned to the Agencies, especially the ECHA, as a consequence of the provisions in this Regulation,</u>

	opinion of the EDPS].		<u>involving not only transient tasks but even a permanently increased workload.</u> Justification: We suggest that to reflect that Member States have considered the extra burden to EU agencies, not least ECHA and the resource that shall be required to fulfil the provisions of this regulation, it is appropriate to include a recital that addresses the subject.
Formula			
60	HAVE ADOPTED THIS REGULATION:		
Chapter I			
61	Chapter I SUBJECT MATTER, SCOPE AND DEFINITIONS		
Article 1			
62	Article 1 Subject matter and scope		
Article 1(1)			
63	1. This Regulation aims to ensure the efficient delivery of coherent hazard and risk assessments of chemicals where those assessments are required by Union legal acts, to achieve a high level of protection of human health and the environment, to enable the development and use of sustainable chemicals, to ensure the proper functioning of the single market for chemicals, and to improve the Union's citizens' trust in the scientific base for the decisions taken under Union legal acts on chemicals.	One delegation proposed to include SSBD (safe and sustainable by design) as one of the roles for the platform. → PRES propose to work on an amendment introducing explicitly the safe and sustainable by design approach as one of the aims.	Sweden supports this proposal
Article 1(2)			
64	2. To achieve the objectives referred to in paragraph 1, this Regulation contains measures to:		

Article 1(2), point (a)			
65	(a) bring together data and information on chemicals and ensure that data and information are easily findable, accessible, interoperable and re-usable;		
Article 1(2), point (b)			
66	(b) keep records of studies commissioned or carried out by business operators in the context of fulfilling their obligations set under Union chemicals legislation;		
Article 1(2), point(c)			
67	(c) establish the widest possible scientific base for the implementation and development of Union legislation and policy on chemicals;		
Article 1(2), point (c)			
68	(d) establish an early warning and action system for emerging chemical risks.		
Article 1(3)			
69	The provisions laid down in this Regulation apply to chemicals data as laid out in Article 3(2).		
Article 2			
70	Article 2 Definitions	One delegation requested amending art.2 to clarify the meaning of “product” in this proposal. One delegation asked what is covered by the term “products” in art.7(1) One delegation requested examples of the	Text proposal: Additional definition: <u>Article 2(16): 'The public' means one or more natural or legal persons, and associations, organisations or groups of such persons.</u>

		meaning of “chemical products” in relation to mixtures, articles, substances. PRES highlights that the term occurs in recital (8), (10),(25),art.3(3), art.7(1), art.22(1). PRES highlights also that while some of those occurrences relates to cosmetic or medicinal products, other occurrences do not refer to a particular regulation and might have overlapping meaning with e.g. articles in REACH, or products under the ESPR. → PRES is working on an amendment proposal.	Justification: Sweden considers that the provisions in Articles 16 and 17 could benefit if 'the public' was defined. For example, from Directive 2003/4/EC.
Formula			
71	For the purpose of this Regulation, the following definitions shall apply:		
Article 2(1)			
72	1. ‘Agencies’ means the European Chemicals Agency (‘ECHA’), the European Environment Agency (‘EEA’), the European Food Safety Authority (‘EFSA’) and the European Medicines Agency (‘EMA’) and the European Agency for Safety and Health at Work (‘EU-OSHA’);		
Article 2(2)			
73	2. ‘Authorities’ means the European Commission, the competent authorities of the Member States as referred to in any of the Union acts listed in Annexes I and III, and the Agencies, excluding their management boards;		
Article 2(3)			
74	3. ‘duty holder’ means a natural or legal person responsible for meeting obligations under the Union acts listed in Annex I or II;		

Article 2(4)			
75	4. 'business operators' means duty holders which are private or public undertakings;	One delegation suggests to "use 'economic operators' instead of 'business operators' to ensure alignment with other relevant legislation". PRES highlights that the term "business operator" is used in recital (8),(13),(28),(29),(30),(31),(35),(37),(38), and articles 1(2), 22, 25, and 26. Those articles relates to studies commissioned, studies notifications, and related enforcement/penalties. PRES highlights that the term "duty holder" is defined in art. 2(3) in relation to obligations in acts mentioned in annex I or II. The terms is per se used in recital (13), (15), (48), art 2(4), 15(5), and 17(2). Those later articles relate to the use of the controlled vocabularies, as well as the prohibition for Authorities to use data from the platform to fulfil legal obligations of duty holders. → PRES seeks written comments on the following: ESPR has a definition of "economic operator": 'economic operator' means the manufacturer, the authorised representative, the importer, the distributor, the dealer and the fulfilment service provider. PRES understands that in the present regulation the meaning of it is much more narrow, and relates only to duty holders that at the same time are undertakings. → PRES seeks for agreement that in consequence there is no correspondence with other EU regulations, and thus no amendment here should be done.	The term 'economic operator' is not a term that is used in all the Union acts listed in Annex I. Therefore, Sweden does not find that the proposal provides any advantage. From our point of view, it might be easier to only use the term 'duty holder' even instead of 'business operator'.

Article 2(5)			
76	5. 'human biomonitoring data' means concentrations of chemicals measured in human matrices such as blood or urine;		
Article 2(6)			
77	6. 'reference value' means an estimate of a maximum exposure to or emission level of a chemical below which no or only acceptable adverse effects on human health or the environment are expected, or below which risks related to the adverse effects on human health or the environment are considered acceptable or tolerable;	One delegation commented about "acceptable or tolerable" in relation to non-threshold cancerogenic substances. PRES understands that the intention is to avoid that reference values for non-threshold substances are published without mentioning as metadata the actual statistical risk they represent. → PRES proposes to work on an amendment of art 2(6), 8 and 14 for this.	
Article 2(7)			
78	7. 'originator' means the Commission, Agency, or Member State competent authority responsible for confidentiality assessments under any Union act listed in Annex I or Annex II;		
Article 2(8)			
79	8. 'originating Union act' means the Union act under which chemicals data and information were generated or submitted;		
Article 2(9)			
80	9. 'controlled vocabularies' means standardised and organised arrangements of words and phrases presented as lists of terms or as thesaurus and taxonomies with a hierarchical structure of broader		

	and narrower terms;		
Article 2(10)			
81	10. 'chemicals data' means any representation of facts or information relating to chemicals and any compilation of such facts or information, including information on physico-chemical properties, hazard properties, use, exposure, risk, occurrence, emissions and manufacturing process of the chemicals, as well as environmental sustainability related information, including climate change related information, on those chemicals, regulatory process-related information on chemicals, standard formats, controlled vocabularies, or any information on applicable legal obligations related to chemicals;		
Article 2(11)			
82	11. 'environmental sustainability related data' means any data relevant for the environmental sustainability assessment of a chemical or material throughout its entire life cycle, including:	One delegation finds this definition vague, and proposes to add an annex (e.g. in Art. 13) which can be updated on a regular basis by means of Delegated Acts. This annex should contain the respective legal acts as well as the associated sustainability information. PRES highlights that the definition here is used in a broader sense than the information available in legal acts (e.g. research in art.5(6), art 13(3) and potentially art.13(4)). → PRES requests written comments on the necessity to add a reference to a new annex IV, containing a list legal acts relevant for environmental sustainability related data. Such a reference would be added here as a new point 2(11)(d) along with related delegated powers in	

		Chapter VIII. → PRES would also like to have comments on the provisions of art.13(4) as this partially overlaps with the concern raised by one delegation (by having the COM adopting an implementing decision for data not already hosted or hold by agencies/COM or not coming from EU research). Which relevant data are generated through legal acts but are not hold or hosted by COM/agencies listed in this proposal?	
Article 2(11), point (a)			
83	(a) data on resources, including raw materials, water, energy, fossil fuels and land;		
Article 2(11), point (b)			
84	(b) data on emissions, including greenhouse gases, eutrophication-relevant substances, dust and all other polluting substances; and		
Article 2(11), point (c)			
85	(c) data on by-products originating during the chemical's life cycle that can be used as resources for other production processes, including hydrogen and carbon monoxide.		
Article 2(12)			
86	12. 'personal data' means personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679 of the European Parliament and of the Council and	One delegation highlighted that this definition is specified in Article 3, point (1) of Regulation 2018/1725 and not in Article 3, point (16) of	

	as defined in Article 3, ~~point (16), of Regulation (EU) 2018/175~~ point (1), of Regulation (EU) 2018/1725 of the European Parliament and of the Council;	Regulation 2018/175. → PRES sees this as an editorial amendment and proposes to modify Article 2 (12) consequently.	
Article 2(13)			
87	13. 'processing' means processing as defined in Article 4, point (2), of Regulation (EU) 2016/679 of the European Parliament and of the Council and as defined in Article 3, point (3), of ~~Regulation (EU) 2018/175~~ Regulation (EU) 2018/1725 of the European Parliament and of the Council;	One delegation highlighted that the reference is to Regulation 2018/1725 and not to Regulation 2018/175. → PRES sees that this is an editorial amendment and proposes to modify Article 2 (13) consequently.	
Article 2(14)			
88	14. 'data controller' means controller as defined in Article 4, point (7), of Regulation (EU) 2016/679 and as defined in Article 3, point (8), of ~~Regulation (EU) 2018/175~~ Regulation (EU) 2018/1725 of the European Parliament and of the Council;	One delegation highlighted that the reference is to Regulation 2018/1725 and not to Regulation 2018/175. → PRES sees that this is an editorial amendment and proposes to modify Article 2 (14) consequently.	
Article 2(15)			
89	15. 'interoperability' means the ability of two or more data spaces or communication networks, systems, products, applications or components to exchange and use data in order to perform their functions.	One delegation asked if advanced programming interfaces (API) will be used. PRES highlights that API are tools that MSs may use amongst others in order to query the data platform from their own advanced knowledge management systems (i.e. machine readability) instead of relying on "manual" queries in a web interface like in ECHA web site today. PRES highlights that in the explanatory	

		memorandum the COM mentions that “The proposal also contributes to the objectives of EU data and digital policies by promoting interoperability and machine readability”. However only interoperability is explicitly mentioned here. → PRES requests written comments on this and on the necessity to amend the proposal to explicitly mention APIs and the conditions of their use for MS and the public.	
Chapter II			
90	Chapter II INFORMATION SYSTEMS AND PLATFORMS		
Article 3			
91	Article 3 Common Data Platform on Chemicals		
Article 3(1)			
92	1. The ECHA shall establish and manage a common data platform on chemicals (‘the common data platform’).		
Article 3(2)			
93	2. The common data platform shall provide access to all chemicals data:	One delegation highlights that it is difficult to assess the exhaustiveness of annexes I and III. PRES request written comments on any potentially missing relevant regulations in those annexes. One delegation questioned the differentiated approach between medicinal products and biocidal and phytopharmaceutical products.	

PUBLIC

		→ PRES would like to receive further clarity in writing.	
Article 3(2), point (a)			
94	(a) generated or submitted as part of the implementation of the Union acts listed in Annex I to this Regulation and held by the Agencies or the Commission;		
Article 3(2), point (b)			
95	(b) generated as part of Union, national or international programmes or research activities in the sphere of chemicals and held by the ECHA, the EEA, the EFSA, the EU-OSHA or the Commission;		
Article 3(2), point (c)			
96	(c) listed in Annex II and held by the EMA;		Text proposal: ~~(c) listed in Annex II and held by the EMA;~~ Justification: this reference to inclusion will not be necessary if the provisions regarding data on active substances is handled the same as for other legislations.
Article 3(3)			
97	3. The following information shall not be included in the common data platform:		
Article 3(3), point (a)			

98	(a) the information referred to in Article 45 of Regulation (EC) No 1272/2008 ⁵⁰ ; 50 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).		Comment: We wonder if the Commission has considered also including Article 9 of Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents in this article?
Article 3(3), point (b)			
99	(b) the information related to cosmetic products and notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/2009 ⁵¹ of the European Parliament and of the Council. 51 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November on cosmetic products (OJ L 342 22.12.2009, p. 59).		
			Text proposal – extra paragraph. <u>(c) clinical data held by EMA under Directive 2001/83/EC of the European Parliament and of the Council¹ and Regulation (EC) No 726/2004 of the European Parliament and of the Council², Regulation (EU) 2019/6 of the European Parliament and of the Council³ and Regulation (EC) No 470/2009 of the European Parliament and of the</u>

¹ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

² Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

³ Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

			<u>Council</u>⁴ Justification: To exempt specific data from the medicines legislations.
Article 3(4)			
100	4. Documents relating to Authorities' internal work or decision-making processes need not be included in the common data platform, unless required under Article 10.		
Article 3(5)			
101	5. The common data platform shall provide the dedicated services identified in the governance scheme referred to in Article 4(3) including:		
Article 3(5), point (a)			
102	(a) the Information Platform for Chemical Monitoring ('IPCHEM') referred to in Article 7;		
Article 3(5), point (b)			
103	(b) the repository of reference values referred to in Article 8;		
Article 3(5), point (c)			
104	(c) the database of study notifications referred to in Article 9;		
Article			

⁴ Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

3(5), point (d)			
105	(d) information on regulatory processes referred to in Article 10;		
Article 3(5), point (e)			
106	(e) information on obligations under Union chemicals legislation referred to in Article 11;		
Article 3(5), point (f)			
107	(f) the repository of standard formats and controlled vocabularies referred to in Article 12;		
Article 3(5), point (g)			
108	(g) the database on environmental sustainability-related data referred to in Article 13.		
Article 3(6)			
109	6. The Authorities and the general public shall have access to the data contained in the common data platform in accordance with Article 16.		Text proposal: 6. The Authorities and the ~~general~~ public shall have access to the data contained in the common data platform in accordance with Article 16. Justification: Sweden proposes to remove the word 'general' to align with the proposed wording in Articles 16 and 17.
Article 3(7)			
110	7. The data contained in the common data platform may be used in accordance with Article 17.		
Article			

3(8)			
111	8. The data contained in the common data platform shall be made available in standard formats, where developed, and through controlled vocabularies where available.		
Article 3(9)			
112	9. The data contained in the common data platform shall be electronically accessible and searchable. The ECHA shall take measures to ensure a high standard of security appropriate to the security risks at stake for the storage of chemicals data in and transmission of chemicals data to the common data platform. The ECHA shall design the common data platform in a way that guarantees that any access to confidential data is auditable.		
Article 3(10)			
113	10. The Commission or Agency under whose authority chemicals data is included in the common data platform on chemicals shall remain responsible for handling any requests for access to documents made under Regulation (EC) No 1049/2001 ⁵ . ⁵² Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (. OJ L 145, 31.5.2001, p. 43).		Text proposal: The Commission or Agency~~ies~~y under whose authority chemicals data is included in the common data platform on chemicals shall remain responsible for handling any requests for access to documents made under Regulation (EC) No 1049/2001⁵. <u>Where environmental information is concerned, Regulation (EC) No 1367/2006⁶ shall also apply.</u> ⁶ REGULATION (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the

⁵ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (. OJ L 145, 31.5.2001, p. 43).

⁶

			application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies Justification: Sweden suggests that this paragraph is moved to Article 16 which regulates access to data in the platform. Sweden also proposes to change 'Agency' to 'Agencies' to align with the definition. We consider it necessary to include a reference to this Regulation in order to ensure that it is taken into account when assessing requests for access to documents.
Article 3(11)			
114	11. The common data platform and its dedicated services shall be established by [OP: please insert date: three years after the date of entry into force of this Regulation], unless specified otherwise. The relevant datasets shall be integrated progressively into the common data platform by [OP please insert date: ten years from the date of entry into force of this Regulation] according to the implementation plan referred to in Article 4 (1), first sentence. Upon integration of those datasets in the common data platform, when the ECHA receives chemicals data in accordance with Article 5, it shall make that data available through the common data platform without undue delay.	One delegation requested clarifications on this paragraph (timing for the notification service, lack of specification of the timing for the rolling plans). This delegation proposed amendments accordingly → PRES: a more general discussion at the 2d WP took place regarding the timelines	Text proposal: The common data platform and its dedicated services shall be established by [<i>OP: please insert date: three years after the date of entry into force of this Regulation</i>], unless specified otherwise. The relevant ~~datasets~~ chemicals data submitted under any of the Union acts listed in Annex I before the entry into force of this Regulation shall be integrated progressively into the common data platform by [<i>OP please insert date: ten years from the date of entry into force of this Regulation</i>] according to the implementation plan referred to in Article 4 (1), first sentence. Upon integration of those datasets in the common data platform, when the ECHA receives chemicals data in accordance with

			Article 5, it shall make that data available through the common data platform without undue delay. Justification: Sweden proposes to clarify that existing data or information shall be included in the platform and use the wording 'chemicals data' which is used in other parts of the Regulation.
Article 4			
115	Article 4 Implementation plan and governance of the common data platform	One delegation proposed to include new provisions 5a,5b,5c in art.4., requesting that the COM prepares and presents a recommendation on "how to amend legislation listed in the Annexes to this regulation". → PRES would like to receive written comments on this as it is not clear for us if this means amending the annexes of the data platform proposal, or if the delegation meant to amend the listed regulations. One delegation raised concerns about the wording "implementing" appearing at several places and which is seen as "misleading" with respect to the legal definition of "implementing acts". → PRES seeks legal advice on this. The Council legal services provided an opinion on this at the 2nd WP.	
Article 4(1)			
116	1. By [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall adopt and publish an implementation plan identifying datasets for inclusion in the common data platform together with a timeline for their inclusion by means of an	One delegation questioned the procedure for adopting the plan, the consultation procedures and MS involvement. → PRES: WP2 discussion on the desired level of and procedures for MS participation took place.	Text proposal: By [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall adopt and publish an implementation plan identifying datasets for inclusion in the common data platform together with a

	implementing decision. Subsequent rolling implementation plans shall be adopted in line with the governance scheme referred to in paragraph 3.		timeline for their inclusion by means of an implementing ~~act decision~~. Subsequent rolling implementation plans shall be adopted in line with the governance scheme referred to in paragraph 3. Justification: We suggest that decisions about i) implementation plans (Article 4(1)), ii) the establishment and management of a steering committee (Article 4(2)) and iii) governance scheme (Article 4(4)) are significant, and that Member States should be involved in the decision process, be it an implementing act or a delegated act. This should be the case for all proposals regarding 'implementing decision'.
Article 4(2)			
117	2. The Commission shall, by means of an implementing decision, establish and manage a platform steering committee, which shall include one representative from the ECHA, one representative from the EEA, one representative from the EFSA, one representative from the EMA, one representative from the EU-OSHA and five representatives from the Commission.		Text proposal: 1. The Commission shall, by means of an implementing ~~act decision~~, establish and manage a platform steering committee, which shall include one representative from the ECHA, one representative from the EEA, one representative from the EFSA, one representative from the EMA, one representative from the EU-OSHA and five representatives from the Commission. <u>The Commission shall represent the work areas that remain directly under its responsibility.</u> Justification: To clarify that in these matters the Commission shall represent the work areas not covered by the areas of responsibility for the EU agencies.
Article 4(3)			
118	3. The platform steering committee shall advise the Commission in the preparation of the common data platform's governance scheme.		
Article			

4(4)			
119	4. The Commission shall adopt and publish the governance scheme referred to in paragraph 3 and any revision thereof by means of an implementing decision		Text proposal: 4. The Commission shall adopt and publish the governance scheme referred to in paragraph 3 and any revision thereof by means of an implementing <u>act</u> ~~decision~~ Justification: We suggest that decisions about the governance scheme are significant and that Member States should be involved in the decision process, be it an implementing act or a delegated act.
Article 4(5)			
120	5. That governance scheme shall describe:		
Article 4(5), point (a)			
121	(a) the organisation of the main work structures supporting the development and implementation of the common data platform;		
Article 4(5), point (b)			
122	(b) the preparation and adoption of rolling implementation plans for the common data platform;		
Article 4(5), point (c)			
123	(c) the principles on data governance and the required standard formats, controlled vocabularies and further conditions for the provision of information and context data to the common data platform;		
Article			

4(5), point (d)			
124	(d) the decision-making procedures for the development of new dedicated services and the inclusion of new functionalities of the platform;		
Article 4(5), point(e)			
125	(e) any other rules or requirements necessary for the operation of the common data platform such as the data update, archiving and deletion policy;		
Article 4(5), point (f)			
126	(f) the operation of the steering committee itself.		
Article 5			
127	Article 5 Data Flows for the purpose of the common data platform		
Article 5(1)			
128	1. At the Commission's request, the Agencies shall host and maintain chemicals data generated as part of Union, national or international legislation, programmes or research activities, corresponding to their mandate and the type of data they already hold.		
Article 5(2)			
129	2. Where the Commission or the Agencies hold data or information referred to in Article 3(2), they shall make that data available to the ECHA, in a standard format, where available, together with the relevant context data as referred to in Article 4(4), point (c). referred to in Article 4(5), point (c).	One delegation highlighted that the reference should be to Article 4(5), point (c) and not Article 4(4), point (c). → PRES sees this as an editorial amendment and proposes to modify Article 5(2) consequently.	Text proposal: 2. Where the Commission or the Agencies hold data or information referred to in Article 3(2), they shall make that data available to the ECHA, in a standard format, where available, together with the relevant context data as referred to in Article 4(4), point (c).

	The Commission and the Agencies shall indicate whether that data or information is made available to the public under the originating Union act.		<u>2a.</u> The Commission and the Agencies shall indicate whether that data or information ~~shall not be~~ made available to the public <u>in accordance with provisions on confidentiality</u> under the originating Union act. Justification: We propose moving the provision on confidentiality to a new paragraph 2a in order to ensure legal certainty. We also propose amending the wording to be consistent with Article 16 which refers to confidentiality in those legal acts referred to in Annex I rather than making data available.
Article 5(3)			
130	3. The ECHA shall host and maintain occurrence data related to workplace monitoring.		
Article 5(4)			
131	4. The EEA shall host and maintain human biomonitoring data, occurrence data for the environment and occurrence data related to indoor air quality.	One delegation asked if Commission pursues plans for systematic or regular surveys of indoor air quality data → PRES is requesting written comments on this.	
Article 5(5)			
132	5. Researchers or research consortia funded by Union framework programmes shall make available to the EEA any human biomonitoring data they collect or generate from [OP please insert: date of the entry into force of this Regulation].		
Article 5(6)			
133	6. Researchers or research consortia funded by Union framework programmes shall make available to the ECHA any environmental sustainability data on chemicals or materials they collect or generate		

	from [OP please insert: date of the entry into force of this Regulation].		
Article 5(7)			
134	7. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of the chemicals data provided in accordance with paragraph 2 in the common data platform as well as its publication through that platform.		
Article 5(8)			
135	8. For the purpose of paragraph 2, the Commission and the Agencies shall make chemicals data available to the ECHA without undue delay after collection or receipt of the data, after performance of validity and confidentiality assessments in accordance with applicable rules and once the corresponding dataset has been integrated in the common data platform.		
Article 5(9)			
136	9. The Commission and the Agencies shall ensure that data made available to the ECHA shall be downloadable, machine readable and interoperable. They shall appropriately curate and validate the data before providing them to the ECHA.		
Article 6			
137	Article 6 Human biomonitoring data	→ PRES: given the numerous comments, questions and clarification requests received, PRES set this as a discussion point at the 2 nd WP (8/3), and invites MS and the COM to react to the EDPS recommendations.	
Article 6(1)			

138	1. The EEA shall collect, host, and maintain human biomonitoring data generated within the territory of the EEA's member and cooperating countries.		
Article 6(2)			
139	2. At the latest by [OP please insert date: 3 years after entry into force of this Regulation] the Commission shall transfer any human biomonitoring data it holds to the EEA.		
Article 6(3)			
140	3. The EEA may process human biomonitoring data constituting personal data to support the Commission in its policy making or to support the Agencies in fulfilling their missions.		
Article 6(4)			
141	4. Human biomonitoring data constituting personal data may be processed by the EEA for the following purposes:		
Article 6(4), point (a)			
142	(a) assessing the impact of chemicals on human health and the environment;		
Article 6(4), point (b)			
143	(b) monitoring time and spatial trends in exposure;		
Article 6(4), point (c)			
144	(c) developing health risk and impact indicators;		
Article 6(4), point (d)			

145	(d) monitoring the impact of regulatory intervention;		
Article 6(4), point (e)			
146	(e) supporting regulatory risk assessments.		
146.a	(f) supporting regulatory risk management	One delegation proposed to add this amendment. PRES understands that HBM data are indeed useful for risk management, e.g. trend analysis will give an idea if policy actions are having an impact or not on reducing exposure → PRES proposes thus to add this paragraph (f)	Sweden supports the proposal.
Article 6(5)			
147	5. The EEA shall make human biomonitoring data they hold or host publicly available in anonymised form through the Information Platform for Chemical Monitoring.		
Article 6(6)			
148	6. The EEA shall act as data controller for the human biomonitoring personal data it holds or hosts and processes for the purposes referred to ~~in paragraph 2.~~ in paragraph 4.	Some delegations highlighted that the reference should be to para. 4. → PRES sees this as an editorial amendment and proposes to modify art.6(6) in consequence. One delegation proposed to add an additional reference to art.3 and 5 here. → PRES, up to his knowledge, understands that from the definition of a data controller this is logical, but seeks for written opinions on this and will request a legal advice. Discussions at the 2nd WP on the EDPS recommendations might also contribute clarifications on this proposal.	

		One delegation suggested to “include the same reference to Articles 6(3) and 6(4)” → PRES is keen to receive a written rationale for this as it seems to introduce a circular reference in the text.	
Article 7			
149	Article 7 Information Platform for Chemical Monitoring		
Article 7(1)			
150	1. The ECHA shall operate and maintain the Information Platform for Chemical Monitoring containing occurrence data on chemicals across different media, including water, soil, indoor air, outdoor air, biota, food and feed, humans, and products as part of the common data platform.	→ PRES: regarding the meaning of “products”, cfr art.2 (here in line 70).	
Article 7(2)			
151	2. At the latest by [OP please insert date: 3 years after the date of entry into force of this Regulation], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring at that moment to the ECHA for integration in the common data platform.		
Article 7(3)			
152	3. At the latest by [OP please insert date: 3 years after entry into force of this Regulation], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring to the ECHA, the EEA or the EFSA for hosting in accordance with the respective agencies’ mandate and in accordance with Article 5.		
Article			

PUBLIC

7(4)			
153	4. After the completion of the transfer referred to in paragraph 3, where the Commission or the Agencies host or hold occurrence data on chemicals and related chemicals data, they shall make that data available to the ECHA without undue delay for integration in the Information Platform for Chemical Monitoring.		
Article 7(5)			
154	5. The Commission and Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration and publication of occurrence data and related chemicals data they host or hold through the common data platform.		
Article 7(6)			
155	6. The ECHA shall ensure that the data contained in the Information Platform for Chemical Monitoring is machine readable and downloadable.		
Article 8			
156	Article 8 Repository of reference values	One delegation requested a amendment about the statistical (cancer) risk associated with some reference values. → PRES: see our proposal in art 2(6) here line 77	
Article 8(1)			
157	1. The ECHA shall establish and manage a repository of reference values as part of the common data platform.		
Article 8(2)			
158	2. The ECHA shall include any reference value adopted under Union acts listed in Annex I or Annex II, Part 1, in the repository of reference values without undue delay.		

Article 8(3)			
159	3. For reference values not falling under paragraph 2, the Agencies holding or establishing reference values as part of their activities under Union acts listed in Annex I, or the reference values referred to in Annex II, Part 2, shall make those reference values available to the ECHA, in the standard formats provided for in Article 14, where developed, and without undue delay, for integration in the repository of reference values.		
Article 8(4)			
160	4. For the purpose of paragraph 3, where reference values are included in a regulatory dossier submitted to the Agencies, the Agencies shall share those reference values in the standard formats with ECHA without undue delay and once relevant validity and confidentiality assessments have been completed by the originator in accordance with applicable rules.		Text proposal: 4. For the purpose of paragraph 3, where reference values are included in a regulatory dossier submitted to the Agencies by business operators, the Agencies shall share those reference values in the standard formats with ECHA without undue delay and once relevant validity and confidentiality assessments have been completed by the originator in accordance with applicable rules. Justification: Background: To clarify and to distinguish from the provision in paragraph 8(2).
Article 8(5)			
161	5. The ECHA shall ensure that the data contained in the repository of reference values is machine readable.		
Article 9			
162	Article 9 Database of Study Notifications		
Article 9(1)			
163	1. The ECHA shall establish and operate a Database		

	of Study Notifications by [OP please insert date: two years after the date of entry into force of this Regulation].		
Article 9(2)			
164	2. The ECHA shall store in the Database of Study Notifications the data notified to it in accordance with Article 22.		
Article 9(3)			
165	3. The ECHA shall integrate the data contained in the Database of Study Notifications in the common data platform once a corresponding registration, application, notification or other relevant regulatory dossier was submitted to the relevant Union or national institution, agency, or body in accordance with corresponding Union law and after a decision was taken by that Union or national institution, agency, or body on the disclosure of the accompanying studies in accordance with the applicable rules on confidentiality.	One delegation considers that this deserves clarification as it seems to prevent Member States authorities from getting relevant information on notified studies in time. PRES notes that this might be related to enforcement. → PRES seeks further written comments on this → PRES is working on an amendment proposal	
Article 9(4)			
166	4. The EFSA shall make the data contained in the database referred to in Article 32b of Regulation (EC) No 178/2002 available to the ECHA for integration in the common data platform once it has received a corresponding application and after it has decided on the disclosure of the accompanying studies in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002.		
Article 9(5)			
167	5. The ECHA and the EFSA shall cooperate to ensure a common approach for the identification		

	of information notified to them in accordance with Article 22 of this Regulation and Article 32b of Regulation (EC) No 178/2002, respectively and facilitate the traceability of the studies notified to their respective databases.		
Article 10			
168	Article 10 Information on regulatory processes on chemicals	→ PRES is seeking written comments on one delegation's question about already existing communication channels in certain regulations, related to the stage of evaluation, and the potential need to modify those regulations. → PRES highlights that this might be the case for TRIS notifications.	
Article 10(1)			
169	1. The ECHA shall establish and manage, as part of the common data platform, a new database containing information on regulatory processes on individual substances or groups of substances that are planned, ongoing or have been completed since the entry into force of this Regulation by the Member States or the Union institutions, agencies or committees referred to in the Union acts listed in Annex III.	→ PRES is seeking for written comments on one delegation's comment that it is not clear whether the scope of art 10(1) includes national regulations processes.	
Article 10(2)			
170	2. Where Member State competent authorities as referred to in any of the Union acts listed in Annex III hold the information referred to in paragraph 1, they shall make that information available to the Union agency responsible under the respective Union act listed in Annex III without undue delay.	→ PRES is seeking for written comments on one delegation's request to clarify the COM reference (during the 1 st WP) to voluntary notifications, including examples.	
Article 10(3)			
171	3. Where the ECHA, EEA, EFSA, EU-OSHA or the	→ PRES is seeking written comments on one	

	Commission hold the information referred to in paragraph 1, they shall make that information available to the ECHA for integration in the common data platform in the standard formats provided for in Article 14 without undue delay and, where relevant, once the responsible agency or the Commission has performed the validity assessment. For each regulatory process or activity, at least the following information shall be included:	delegation's question about which information EEA might have to make available to ECHA in this context, as EEA has no competences about chemical products.	
Article 10(3), point (a)			
172	(a) substance identity;		
Article 10(3), point (b)			
173	(b) the Union act and the regulatory process under which the activity takes place;		
Article 10(3), point (c)			
174	(c) submitter or actor responsible for the regulatory process or activity;		
Article 10(3), point (d)			
175	(d) status of the regulatory process or activity;		
Article 10(3), point (e)			
176	(e) where applicable , outcome of the regulatory process or activity ~~, including, where applicable, and~~ reports or opinions adopted;	PRES understand from one delegation's comment that it is not always possible to indicate the (future) outcome, so this provision is not always applicable. → PRES propose to amend art 10(3) by inserting	Sweden supports the proposal

		"where applicable" as we see it more precise than "where appropriate"	
Article 10(3), point (f)			
177	(f) where applicable, date of intention to start the regulatory process or activity, completion and latest update.		
Article 10(4)			
178	4. The information referred to in paragraph 3, points (a) to (f), on a specific regulatory process or activity shall be made available to the public once that process or activity has formally started.		
Article 11			
179	Article 11 Information on the obligations under Union acts on chemicals	PRES notes one delegation's comment on the potentiality of IA in this context.	
Article 11(1)			
180	1. The ECHA shall establish and manage, as part of the common data platform, a database with information on the provisions and legal obligations applicable to chemicals under the Union acts listed in Annex I.		
Article 11(2)			
181	2. The ECHA shall update the information in the database on a regular basis and in accordance with the governance scheme referred to in Article 4(3).		
Article 12			
182	Article 12 Repository of standards formats and controlled vocabularies		
Article 12(1)			

183	1. The ECHA shall establish and manage as part of the common data platform a repository of standard formats and controlled vocabularies.		
Article 12(2)			
184	2. Where standard data formats are established under the Union acts listed in Annexes I and II, the ECHA shall include them in the common data platform.		
Article 12(3)			
185	3. Where the Commission or the Agencies specify a standard format or controlled vocabulary in accordance with Articles 14 or 15, the Commission or the Agency shall make it available to the ECHA without undue delay for integration in the common data platform.		
Article 13			
186	Article 13 Database on environmental sustainability related data	One delegation requested for a new annex on relevant legal acts, see discussion of Article 2(11) → PRES: see line 82 here above • About the role of EIONET in this → PRES included this in the discussion at the WP2 (effort needed by MS)	
Article 13(1)			
187	1. At the latest within three years after the publication of the decision referred to in paragraph 4, the ECHA shall establish and manage, as part of the common data platform, a database containing environmental sustainability related data.		
Article 13(2)			
188	2. Where the Commission or the Agencies host or hold environmental sustainability related data in		

	addition to the chemicals data already available in the common data platform, they shall make that data available to the ECHA without undue delay once the Commission or the Agency hosting or holding that data has completed, where relevant, validity and confidentiality assessments. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of environmental sustainability related data in the database on environmental sustainability related data.		
Article 13(3)			
189	3. Where researchers or research consortia funded by Union framework programmes make available to the ECHA, under Article 5(6), any environmental sustainability data on chemicals or materials they collect or generate, the ECHA shall integrate the relevant data in the database on environmental sustainability related data.		
Article 13(4)			
190	4. By [OP please insert date: three years after the date of entry into force of this Regulation], the Commission shall adopt an implementing decision identifying existing datasets on environmental sustainability related data, other than those referred to in paragraph 2, for inclusion in the common data platform and shall design relevant related database functionalities.	→ PRES is seeking legal advice about the wording “implementing decision” (cfr delegation comment). Council legal services provided an opinion on this at the 2 nd WP.	Text proposal: By [OP please insert date: three years after the date of entry into force of this Regulation], the Commission shall adopt an implementing <u>act</u> ~~decision~~ identifying existing datasets on environmental sustainability related data, other than those referred to in paragraph 2, for inclusion in the common data platform and shall design relevant related database functionalities. Justification: We would suggest that decisions about the identifying of existing datasets on environmental sustainability related data, other than those referred to in paragraph 2, for inclusion in the common data platform are

			significant and that Member States should be involved in the decision process, be it an implementing act or a delegated act.
Chapter III			
191	Chapter III DATA FORMATS AND CONTROLLED VOCABULARIES	→ PRES seeks written comments on one delegation's request to eventually have study reports and raw data provided → PRES seek written comments on the request by one delegation to investigate that there is no impact on the use of INCI names for cosmetics regulation, and no impact on substance identification and product labelling in that regulation.	
Article 14			
192	Article 14 Standard formats	One delegation amendment proposal on statistical risk: → PRES: see here Article 2(6) line 77	
Article 14(1)			
193	1. Without prejudice to Union provisions providing for the development or making available of data formats, the Commission and the Agencies shall specify, where relevant, for the data referred to in Article 3 (2) and falling within their mandate, standard formats and software packages and make them available free of charge through the common data platform.		
Article 14(2)			
194	2. The standard formats referred to in paragraph 1 shall, to the extent possible:		
Article 14(2), point (a)			

195	(a) avoid the use of proprietary standards;		
Article 14(2), point (b)			
196	(b) re-use existing data formats or parts of them;		
Article 14(2), point (c)			
197	(c) use OECD or other internationally agreed formats;		
Article 14(2), point (d)			
198	(d) be coherent with other existing data formats;		
Article 14(2), point (e)			
199	(e) ensure interoperability with existing data submission approaches.		
Article 14(3)			
200	3. Those standard formats shall be interoperable with the common data platform and be user-friendly.		
Article 14(4)			
201	4. The Commission and the Agencies shall exchange data contained in the common data platform in the relevant standard format.		
Article 14(5)			
202	5. The Commission and the Agencies shall use the International Uniform Chemical Information Database format (IUCLID) for making available to the ECHA for integration in the common data platform the relevant parts of dossiers under the		

	following Union acts:		
Article 14(5), point (a)			
203	(a) Regulation (EC) No 1831/2003 of the European Parliament and of the Council ⁵³ ; ⁵³ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268 18.20.2003, p. 29).		
Article 14(5), point (b)			
204	(b) Regulation (EC) No 1935/2004 of the European Parliament and of the Council ⁵⁴ ; ⁵⁴ Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338 13.11.2004, p. 4).		
Article 14(5), point (c)			
205	(c) Regulation (EC) No 1331/2008 of the European Parliament and of the Council ⁵⁵ ; ⁵⁵ Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354 31.12.2008, p. 1).		
Article 14(5), point (d)			
206	(d) Regulation (EC) No 1332/2008 of the		

	European Parliament and of the Council ⁵⁶ ; Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354 31.12.2008, p. 7).		
Article 14(5), point (e)			
207	(e) Regulation (EC) No 1333/2008 of the European Parliament and of the Council ⁵⁷ ; Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354 31.12.2008, p. 16).		
Article 14(5), point (f)			
208	(f) Regulation (EC) No 1334/2008 of the European Parliament and of the Council ⁵⁸ ; Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354 31.12.2008, p. 34).		
Article 14(5), point (g)			
209	(g) Regulation (EC) No 1223/2009 of the		

	European Parliament and of the Council 59; ⁵⁹ Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342 22.12.2009, p, 59).		
Article 14(5), point (h)			
210	(h) Commission Regulation (EU) No 234/2011 ⁶⁰ ; ⁶⁰ Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 064 11.3.2011, p. 15).		
Article 14(5), point (i)			
211	(i) Directive 2009/48/EC of the European Parliament and of the Council. ⁶¹ ⁶¹ Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170 30.6.2009, p. 1).		
Article 14(6)			
212	6. The Commission and the Agencies shall cooperate when setting standard formats to ensure coherence with other formats and the interoperability of the standard formats with the common data platform and with existing data submission approaches.		
Article 14(7)			

213	7. The Commission and the Agencies shall take the necessary and appropriate measures to monitor and identify at an early stage any potential divergence between data formats that could cause interoperability problems. If a divergence is identified, the Agencies concerned shall cooperate to resolve it or, where the divergence is justified, explain the underlying reasons. Where the Agencies concerned are not able to resolve that divergence, they shall draw up a joint report and present it to the Commission. The report shall clearly outline the reasons for the divergence, clarify any underlying technical issue and make a proposal to remedy the divergence.		
Article 14(8)			
214	8. The Commission shall adopt an implementing decision to remedy the divergence.		
Article 15			
215	Article 15 Controlled vocabularies	→ PRES is seeking written comments on the remarks by one delegation about the difficulties related to differences in vocabularies between legislations. → PRES seeks for comments on the difficulties related to substances identification inconsistencies between regulations (see delegation comment). PRES highlights that this problem is also relevant for art.22,25,26 on studies notification (a lack of correct identification might render difficult to implement them)	
Article 15(1)			
216	1. The Commission and the Agencies shall specify and regularly update controlled vocabularies within their mandate for the data referred to in		

PUBLIC

	Article 3(2), where relevant.		
Article 15(2)			
217	2. The Commission and the Agencies shall prioritise specifying controlled vocabularies for the identification of chemicals and the characterisation of their forms.		
Article 15(3)			
218	3. Those controlled vocabularies shall:		
Article 15(3), point (a)			
219	(a) avoid the use of proprietary controlled vocabularies to the extent possible;		
Article 15(3), point (b)			
220	(b) re-use existing substance identifiers and controlled vocabularies or parts of them to the extent possible;		
Article 15(3), point (c)			
221	(c) use OECD or other internationally agreed controlled vocabularies to the extent possible;		
Article 15(3), point (d)			
222	(d) ensure coherence with other relevant controlled vocabularies including by preparing alignment tables.		
Article 15(4)			
223	4. Those controlled vocabularies shall be		

	interoperable with the common data platform.		
Article 15(5)			
224	5. Where controlled vocabularies are specified, the Commission and the Agencies shall:		
Article 15(5), point (a)			
225	(a) make them available free of charge through the common data platform and as open datasets;		
Article 15(5), point (b)			
226	(b) integrate them in any submission software or template to be used by duty holders under the Union acts listed in Annex I and referred to in Article 3(2); and		
Article 15(5), point (c)			
227	(c) use them when exchanging data between them through the common data platform.		
Article 15(6)			
228	6. The Commission and the Agencies shall cooperate with each other in setting the controlled vocabularies.		
Article 15(7)			
229	7. The Commission and the Agencies shall take the necessary and appropriate measures to monitor and identify at an early stage any potential divergence between controlled vocabularies. If a divergence is identified, the Agencies concerned shall cooperate to resolve it or, where the		

	divergence is justified, explain the underlying reasons. Where the Agencies concerned are not able to resolve that divergence, they shall draw up a joint report and present it to the Commission. The report shall clearly outline the reasons for the divergence, clarify any underlying technical issue and make a proposal to remedy the divergence.		
Article 15(8)			
230	8. The Commission shall adopt an implementing decision to remedy the divergence.		Text proposal: 8. The Commission shall adopt an implementing act ~~decision~~ to remedy the divergence. Justification: We would suggest that decisions about diverging controlled vocabularies could be significant and that Member States should be involved in the decision process, be it an implementing act or a delegated act.
Chapter IV			
231	Chapter IV CHEMICALS DATA CONFIDENTIALITY AND USE	→ PRES: some delegation's comments here were discussed at the WP2.	
Article 16			
232	Article 16 Access rights and transparency	→ PRES: One delegation request and questions (line 232 of the comments file) were discussed at the WP2.	
Article 16(1)			
233	1. The Authorities shall have access to all the chemicals data contained in the common data platform, including data which is deemed to be confidential under Article 5(2), second sentence.		Text proposal: The Authorities shall have access to all the chemicals data contained in the common data platform, including data which is deemed to be confidential under Article 5(2<u>a</u>), ~~second sentence~~. Justification: Article 5(2) regulates whether data or

			information is made available to the public, not if it has been deemed confidential or not. This reference is therefore unclear and should be aligned with our proposal for the wording of Article 5(2) and 2a.
Article 16(2)			
234	2. The Authorities shall take the necessary measures to ensure that information contained in the common data platform marked as confidential in accordance with Article 5(2) is not made public.	→ PRES: One delegation comment and questions were discussed at the WP2 (line 234 of the comments file)	Text proposal: 2. The Authorities shall take the necessary measures to ensure that information contained in the common data platform marked as confidential in accordance with Article 5(2a), is not made available to the public. Justification: To align the wording here with our proposal for Article 5(2). The series of proposals will clarify who 'the public' refers to and make its application throughout the proposal more consistent.
Article 16(3)			
235	3. The general public shall have access to all the chemicals data contained in the common data platform and considered as available to the public in accordance with the Union act under which the data was generated or submitted.		Text proposal: ~~The general public shall have access to a~~ All the chemicals data contained in the common data platform, excluding data which is deemed to be confidential under Article 5(2a), and considered as available to the public in accordance with the Union act under which the data was generated or submitted, shall be made available to the public. Justification: Article 5(2) regulates whether data or information is made available to the public, not if it has been deemed confidential or not. This reference is therefore unclear and should be aligned with the wording of Article 5(2).

			We propose moving Article 5(2), second sentence, to a new paragraph, whereby the change to 2a. New Article 16(4) <u>4. Requests for access to chemicals data held by Member States that is included in the common data platform shall be assessed in accordance with Directive 2003/4/EC and national law.</u> Justification: We propose adding a new paragraph in order to differentiate between making data available to the public through the platform on one hand and handling requests for access on the other. When handling requests for access to data, it is crucial that Member States are able to consider national law. Additionally, a reference to Directive 2003/4/EC has been included to ensure that those provisions are considered when handling such requests.
Article 17			
236	Article 17 Use of chemicals data contained in the common data platform	One delegation comment on the meaning of “products” is addressed here in art.2 (see line 70). PRES: Regarding the other comments: → PRES seeks written comments on one delegation’s concern on the identification in the data platform of cosmetics ingredients that may have been tested on animals. → PRES invites the COM to update MS on the possibility of an overview table on confidentiality provisions requested by one delegation.	
Article			

17(1)			
237	1. The Authorities may use the chemicals data contained in the common data platform in the performance of any of their activities, where those activities support the development or implementation of chemicals legislation and policy.	→ PRES: one delegation requested for amendment to explicitly allow national use of the data was set for discussion at WP2.	Text proposal: 1. The Authorities may use the chemicals data contained in the common data platform in the performance of any of their activities, where those activities support the development or implementation of chemicals policy and legislation, and policy, including the handling of matters. Justification: Sweden suggests clarifying that the data can be used for example, in applications for approvals or for enforcement.
Article 17(2)			
238	2. Without prejudice to existing provisions enabling the sharing and use of chemicals data under the Union acts listed in Annexes I and II, Authorities shall not use chemicals data contained in the common data platform to fulfil any legal obligations of duty holders.	One delegation requested clarifications on the use of data in relation to duty holders obligations. → PRES invites for written comments on this.	
Article 17(3)			
239	3. When using chemicals data contained in the common data platform that is deemed confidential under Article 5(2), second sentence, the Authorities shall respect the confidentiality of information data as marked by the originator and shall not disclose that data to the public without the consent of the originator.		Text proposal: When making data used by the Authorities available to the public, ~~using chemicals data contained in the common data platform s deemed confidential under Article 5(2a), second sentence, the Authorities shall respect the confidentiality of information or data as marked by the originator and~~ as confidential shall not be disclosed ~~that data to the public, without prior~~

			<u>consultation with the consent of originator, taking due consideration of Directive 2003/4/EC⁷.</u> <u>7. Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC</u> Justification: The proposal clarifies that the paragraph regulates when authorities can make data available to the public. In Regulation (EC) No. 1049/2001 it states that when a Member State receives a request, it should consult with the institution concerned. Therefore, a similar wording should be used here. Proposal for new text: <u>Article 17(4) The provision shall not prevent Authorities from securing the right of party insight.</u> Justification: The restrictions on making data available cannot be allowed to compromise party insight.
Chapter V			
240	Chapter V MONITORING AND OUTLOOK FRAMEWORK FOR CHEMICALS		
Article 18			
241	Article 18 Framework of indicators	One delegation questioning the MS involvement was set for discussion at the 2nd WP → PRES put the question on EIONET impacts for discussion at the 2nd WP. One delegation comments on cosmetics:	

Commented [LH1]: Eftersom denna bestämmelse också handlar om 'Authoroties' inklusive KOM och byråerna bör man i sådana fall även här lägga till Århusförordningen (Regulation (EC) No 1367/2006 of the European Parliament and of the Council).

		→ PRES invites for written comments on questions raised by one delegation on cosmetics aspects (notification of undesirable effects, link to the Communication System for Market Surveillance (ICSMS) Art 23 Reg 1223/2009, consequences on the allowance of use for critical circumstances). One delegation comment on the relation to existing statistics systems → PRES invites for written comments	
Article 18(1)			
242	1. The EEA, in collaboration with the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission, shall establish, operate, and maintain a framework of indicators to monitor the drivers and impacts of exposure to chemicals, measure the effectiveness of chemicals legislation and measure the transition towards the production of safe and sustainable chemicals.		
Article 18(2)			
243	2. The framework of indicators referred to in paragraph 1 shall be accessible in the form of an indicator dashboard, which the EEA shall establish and which the ECHA shall make available through the common data platform.		
Article 18(3)			
243.b	3. The framework of indicators referred to in paragraph 1 shall be established, operated, and maintained by [OP: please insert date: 3 years after the end of the first calendar year after entry into force of this Regulation].	One delegation expressed concerns on the timescale for establishing the framework PRES highlights that several other articles contain indications on the timeframe	Comment: Sweden can support this clarification. Editorial – ‘...shall be ~~shall~~ established ...’

		→ PRES submits this amendment for consideration, and discussion took place at the 2 nd WP.	
Article 19			
244	Article 19 Early warning and action system for emerging chemical risks	→ PRES: One delegation's question on MS experts and RAC involvement was set for discussion at 2nd WP → PRES: One delegation's request for clarification on implications/role of EIONET and MS was set for discussion at the 2nd WP Regarding the other comments: → PRES seeks written comments about one delegation's question on the relation between the indicators and the early warning system (art.18,19). → PRES invites for written comments on the question regarding the level of ambition of the system in relation to complex systemic risks. → PRES invites written comment on the proposal to include the word "prevention" in the proposal	
Article 19(1)			
245	1. The EEA shall establish, operate and maintain a Union early warning system for emerging chemical risks by [OP please insert date: one year after the date of entry into force of this Regulation].		
Article 19(2)			
246	2. For the purpose of paragraph 1, the EEA shall compile early warning signals, which shall include at least signals from:		
Article 19(2),			

point (a)			
247	(a) the EFSA's emerging risks exchange network;		
Article 19(2), point (b)			
248	(b) existing national early warning systems;		
Article 19(2), point (c)			
249	(c) data that the EEA holds;		
Article 19(2), point (d)			
250	(d) targeted literature searches performed by the EEA;		
Article 19(2), point (e)			
251	(e) data made available by the ECHA, the EFSA, the EU-OSHA and the EMA in accordance with paragraph 3.		
Article 19(2)			
252	The early warning signals compiled by the EEA under the first subparagraph may be based on a positive identification of an emerging risk or on an uncertainty in the data leading to a potential positive identification of an emerging risk.		
Article 19(3)			
253	3. The ECHA, the EFSA, the EU-OSHA and the EMA shall identify and gather relevant available data on early warning signals from the field falling within their mandate and provide this data to the EEA.		
Article 19(4)			

254	4. The EEA shall draw up an annual report, compiling and analysing the data on early warning signals gathered in accordance with paragraphs 2 and 3. [The first report shall be prepared by [OP: please insert date: 6 months after the end of the first calendar year after entry into force of this Regulation]. The EEA shall present this report to the Commission, relevant Union agencies and ~~Member State competent authorities for consideration of the need~~ Member State competent authorities who shall consider the need for regulatory or policy action related to the early warning signals.	One delegation expressed questions the request to EEA to highlight areas on which to FOCUS, in the report. PRES suppose that this may be solved by a change in the wording (mostly editorial) → PRES proposes for consideration a proposed amendment to the text.	Sweden supports this proposal.
Article 19(5)			
255	5. The EEA shall make all relevant data on early warning signals that it holds or hosts as well as the report referred to in paragraph 4 available to the ECHA for integration in the common data platform.		
Article 20			
256	Article 20 Observatory for specific chemicals with potential contribution to emerging chemical risks	PRES seeks written comments on one delegation's question about the type of risks covered here, and the interplay with existing chemicals legislation.	
Article 20(1)			
257	1. The ECHA shall establish, operate and maintain an observatory for specific chemicals that the Commission considers as requiring additional scrutiny. The observatory shall include reliable information on the chemicals' properties, safety aspects, uses and market presence.		
Article 20(2)			
258	2. By [OP please insert date: 6 months after the date of entry into force of this Regulation] the	One delegation highlighted that the linking word "and" is missing before the proposal "adopt any	Text proposal: By [OP please insert date: 6 months after the date of entry

	Commission shall adopt and publish a list of the selected chemicals by means of an implementing decision. The Commission shall review the list of selected chemicals regularly and adopt any revision thereof by the same means.	revision thereof by the same means". à PRES sees this as an editorial amendment and proposes to modify article 20(2) consequently (see <i>bold italic</i>). One delegation requested for amendments (implementing "decisions"). → PRES: questions on the meaning of "implementing", and MS participation were discussed at the 2 nd WP.	into force of this Regulation] the Commission shall adopt and publish a list of the selected chemicals by means of an implementing act decision . The Commission shall review the list of selected chemicals regularly and adopt any revision thereof by the same means. Justification: We would suggest that decisions about the choice of substances requiring additional scrutiny is significant and that Member States should be involved in the decision process, be it an implementing act or a delegated act.
Article 20(3)			
259	3. The Commission shall select the chemicals referred to in paragraph 1 based on the scientific and technical progress and using the signals of the early warning system referred to in Article 19. The selection shall include potential contributors to new and emerging chemical risks among innovative rationally designed materials with new or enhanced properties or targeted or enhanced structural features at nanoscale.		
Article 20(4)			
260	4. For the purpose of operating the observatory referred to in paragraph 1, the ECHA shall:		
Article 20(4), point (a)			
261	(a) make use of relevant datasets integrated in the common data platform, and compile, analyse and curate further available data on selected chemicals or classes of chemicals;		
Article 20(4),			

point (b)			
262	(b) commission studies and, where relevant, use the data generation mechanism established under Article 21 to address knowledge gaps or significant uncertainties;		
Article 20(4), point (c)			
263	(c) make compiled data publicly available through the common data platform or other communication and outreach tools as appropriate, to facilitate informed societal discussion and increase public awareness on the properties, use and safety aspects of specific chemicals, and regularly update that information.		Text proposal: (c) make compiled data publicly available through the common data platform or other communication and outreach tools as appropriate, to facilitate <u>the identification of further risk management measures by the originator and to increase</u> informed societal discussion and ~~increase~~ public awareness on the properties, use and safety aspects of specific chemicals, and regularly update that information. Justification: This addition introduces to the provisions the intention that is already expressed in the recitals. It better describes the intention with establishing the observatory.
Chapter VI			
264	Chapter VI DATA GENERATION MECHANISM		
Article 21			
265	Article 21 Data generation mechanism	One delegation raised the question of the promotion of animal testing in relation to article 1. PRES understands that the type of tests are prescribed in each regulation mentioned in annex I, and thus this regulation is not modifying that. However, art.21 here is new, and thus the question of the minimization of animal testing might be relevant here. One delegation would like to know if commissioned animal studies will be notified	

		→ PRES requests written reactions and proposals on this matter. One delegation expressed the need to frame the mandate in such a way that the burden of proof on companies is preserved. One delegation insisted also on the burden of proof on industry and highlights the need for clarity on procedures and financing. → PRES invites for written comments and amendments proposals. Some Comments were received in relation to the involvement of MS, industry, stakeholders in the data generation mechanism. → PRES: discussion during the 2nd WP	
Article 21(1)			
266	1. Using the best independent resources available, the ECHA may commission scientific studies to support the implementation of Union acts on chemicals listed in Annex I within its mandate and to contribute to the support, evaluation or development of a Union chemicals policy.	One delegation requested clarity on the meaning of scientific studies, and which ones will not be covered. → PRES invites for written comments on this	
Article 21(2)			
267	2. The Commission may request the ECHA to commission the scientific studies referred to in paragraph 1.		
Article 21(3)			
268	3. The ECHA shall only commission scientific studies when results cannot be obtained through existing legal provisions or processes under Union legislation listed in Annex I. It shall not commission studies with a predominant research objective.		

Article 21(4)			
269	4. The ECHA shall seek to avoid duplication with Member State or Union research or implementation programmes.		Text proposal: <u>Article 21(4a): The ECHA shall avoid animal testing. Testing on vertebrates for the purposes of this Regulation shall be undertaken only as a last resort.</u> Justification: To clarify that this provision will maintain the policy of avoiding animal testing as far as possible.
Article 21(5)			
270	5. The ECHA shall commission these scientific studies in an open and transparent manner.	One delegation suggested to amend this to introduce compulsory prior MS consultation. → PRES scheduled this for discussion at the 2 nd WP	Comment: Sweden would support that Member States should be consulted before ECHA commissions a study.
Article 21(6)			
271	6. The ECHA and the EFSA shall closely cooperate with each other on the planning and commissioning of scientific studies undertaken by the ECHA in accordance with paragraph 1 and of studies undertaken by the EFSA in accordance with Article 32 of Regulation (EC) No 178/2002.		
Article 21(7)			
272	7. The ECHA shall make the results of the scientific studies performed under this Article available through the common data platform.		
Chapter VII			
273	Chapter VII NOTIFICATION OF STUDIES	Several comments were received on this chapter: on the legal scope and definition of studies to be notified, duplications, studies conducted outside	

		the EU, late notifications, absence of a transitional period, practical arrangements for companies, the need for early access before publication in the data platform. → PRES scheduled this for discussion at the 2 nd WP	
Article 22			
274	Article 22 Notification of studies		
Article 22(1)			
275	1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, without undue delay, any studies on chemicals they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment, prior to placing on the market, under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.		
Article 22(2)			
276	2. For the purposes of paragraph 1, business operators shall notify to the Database of Study Notifications referred to in Article 9 the title, scope, laboratory, or testing facility carrying out the study, the intended starting and planned completion dates and, where relevant, whether the study is commissioned to comply with a decision of the ECHA pursuant to Articles 40, 41 or 46 of Regulation (EC) No 1907/2006.		Text proposal: 2. For the purposes of paragraph 1, business operators shall notify to the Database of Study Notifications referred to in Article 9 the identity of the chemical(s) concerned , title, scope, laboratory, or testing facility carrying out the study, the intended starting and planned completion dates and, where relevant, whether the study is commissioned to comply with

			a decision of the ECHA pursuant to Articles 40, 41 or 46 of Regulation (EC) No 1907/2006. Justification: Sweden considers it necessary that the chemical identity is required to be included in the notification.
Article 22(3)			
277	3. Laboratories and testing facilities shall also, without undue delay, notify any study commissioned by business operators to support a regulatory dossier on which an Agency is required to provide a scientific output, including a scientific opinion, under the Union acts listed in Annex I. However, laboratories and testing facilities shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.		
Article 22(4)			
278	4. For the purposes of paragraph 3, laboratories and testing facilities shall notify to the Database of Study Notifications referred to in Article 9 the title, scope, intended starting and planned completion dates of any test they carry out, as well as the name of the business operator who commissioned the test.		Text proposal: 4. For the purposes of paragraph 3, laboratories and testing facilities shall notify to the Database of Study Notifications referred to in Article 9 the <u>identity of the chemical(s) concerned</u>, title, scope, intended starting and planned completion dates of any test they carry out, as well as the name of the business operator who commissioned the test. Justification: Sweden considers it necessary that the chemical identity is required to be included in the notification.
Article 22(5)			

279	5. Paragraphs 3 and 4 shall apply, mutatis mutandis, to laboratories and testing facilities located in third countries insofar as set out in relevant agreements with those third countries.		
Article 22(6)			
280	6. The obligations set under this article shall apply from [OP please insert date: 24 months after the date of entry into force of this Regulation].		
Article 22(7)			
281	7. The ECHA shall lay down the practical arrangements for implementing the provisions of this Article.		Comment: Article 22(7): Is it the intention of the Commission that ECHA will implement control of compliance with paragraphs 2 and 4 by digital means? Sweden considers that it would be most appropriate and efficient if ECHA conducted completeness checks digitally. We do not see that this task would impose an unreasonable burden if conducted manually. We wonder if studies that will form the basis of a read-across argument or modelling data will also need to be notified.
Chapter VIII			
282	Chapter VIII DELEGATED POWERS		
Article 23			
283	Article 23 Amendment of Annexes I, II and III		
Article 23(1)			
284	1. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex I in order to adjust the content of that Annex to technical and scientific progress in		Text proposal: 1. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex I

	the field of chemicals or, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it new Union acts under which relevant chemicals data is generated or submitted.		~~of that Annex to technical and scientific progress in the field of chemicals or, where the development of Union chemicals legislation so requires, to~~ of this Regulation in order to, ~~adjust the content of that Annex to technical and scientific progress in the field of chemicals or, where the development of Union chemicals legislation so requires, to~~ supplement that Annex by adding to it new Union acts under which relevant chemicals data is generated or submitted. Justification: Sweden does not see the need for the Commission to adjust Annex I and III by other cases than adding new Union acts to them.
Article 23(2)			
285	2. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex II by adding, where relevant, new categories of data types.		Comment. 'of this Regulation' should be inserted after Annex II.
Article 23(3)			
286	3. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex III in order to adjust the content of that Annex to technical and scientific and technical progress in the field of chemicals and, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it Union acts relevant for data on new regulatory processes on chemicals.		Text proposal: 3. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex III of this Regulation in order to, ~~adjust the content of that Annex to technical and scientific and technical progress in the field of chemicals and, where the development of Union chemicals legislation so requires, to~~ supplement that Annex by adding to it Union acts relevant for data on new regulatory processes on chemicals. Justification: Sweden does not see the need for the Commission to adjust Annex I and III by other cases

			than adding new Union acts to them.
Article 24			
287	Article 24 Exercise of the delegation		
Article 24 (1)			
288	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.		
Article 24(2)			
289	2. The power to adopt delegated acts referred to in Article 23 shall be conferred on the Commission for a period of five years from [OP please insert: the date of the entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each five-year period.		
Article 24(3)			
290	3. The delegation of power referred to in Article 23 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.		
Article 24(4)			

291	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.		
Article 24(5)			
292	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.		
Article 24(6)			
293	6. A delegated act adopted pursuant to Article 23 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.		
Chapter IX			
294	Chapter IX ENFORCEMENT AND PENALTIES	One delegation expressed concerns on enforcement for third countries; one delegation questioned the effectiveness of national sanctions. → PRES scheduled this for discussion at the 2 nd WP	
Article 25			
295	Article 25 Enforcement		

	The Agencies shall cooperate with Member States' enforcement authorities and exchange information on the compliance, by business operators and laboratories, with the obligation to notify studies in accordance with Article 22.		
Article 26			
296	Article 26 Penalties for non-compliance		SE has a scrutiny reserve on this article and will need to get back later in the negotiations about this. Refers also to obligations concerning this in article 22.
Article 26(1)			
297	1. Member States shall introduce penalties for non-compliance, by business operators and laboratories, with the obligations laid out in Article 22 and shall take all necessary measures to ensure that they are implemented. The penalties provided for shall be effective, proportionate, and dissuasive.		
Article 26(2)			
298	2. Member States shall notify the Commission of those rules and of those measures by 30 June 2025 and shall notify to the Commission without delay any subsequent amendment affecting them.		
Article 27			
299	Article 27 Entry into force and application in time This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.		
Formula			

300	This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels, For the European Parliament For the Council The President The President		

	Presidency proposals: amendments (~~deletions~~ / additions)	Presidency proposals: follow-up or proposal to work on amendments, or requests for written comments	Reactions from the Commission and MS
Annex I			
301	Annex I UNION ACTS REFERRED TO IN ARTICLES 2, 3, 8, 11, 12, 15, 17, 21, 22 AND 23 Reference to each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.		

302	1. Council Directive 91/271/EEC of 21 May 1991 concerning urban wastewater treatment (OJ L 135, 30.5.1991, p. 40)		
303	2. Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources (OJ L 375, 31.12.1991, p.1)		
304	3. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1)		
305	4. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste		
306	5. Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11)		
307	6. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50)		
308	7. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34)		

309	8. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for the Community action in the field of water policy (OJ L 327, 22.12.2000, p.1)		
310	9. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1)		
311	10. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p. 1)		
312	11. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10)		
313	12. Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51)		
314	13. Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1)		
315	14. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268,		

	18.10.2003, p. 29)		
316	15. Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (OJ L 309, 26.11.2003, p. 1)		
317	16. Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55)		
318	17. Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1)		
319	18. Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1)		
320	19. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)		
321	20. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3)		
322	21. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food		

	and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 070, 16.3.2005, p. 1)		
323	22. Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC (OJ L 033, 4.2.2006, p. 1)		
324	23. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19)		
325	24. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)		
326	25. Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9)		
327	26. Regulation (EC) No 1925/2006 of the European		

	Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26)		
328	27. Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE) (OJ L 108, 25.4.2007, p. 1)		
329	~~28. Regulation (EC) No 108/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 39, 13.2.2008, p. 11)~~	One delegation highlighted the fact that regulation 108/2008 is mentioned in point 28 of Annex I, whereas this regulation is already covered by regulation 1925/2006 mentioned in point 26 of Annex I. →PRES proposes to amend the text (deleting point 28).	
330	29. Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19)		
331	30. Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1)		
332	31. Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3)		

333	32. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84)		
334	33. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)		
335	34. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)		
336	35. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC, and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p.7)		
337	36. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16)		

338	37. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34)		
339	38. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energyrelated products		
340	39. Regulation (EC) No 401/2009 of the European Parliament and of the Council of 23 April 2009 on the European Environment Agency and the European Environment Information and Observation Network (OJ L 126, 21.5.2009, p. 13)		
341	40. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3)		
342	41. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1)		
343	42. Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for		

	human consumption and repealing Regulation (EC) No 1774/2002 (OJ L 300, 14.11.2009, p. 1)		
344	43. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)		
345	44. Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71)		
346	45. Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28)		
347	46. Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community ecomanagement and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC (OJ L 342, 22.12.2009, p. 1)		
348	47. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)		

349	48. Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17)		
350	49. Regulation (EC) No 66/210 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel (OJ L 027, 30.1.2010, p. 1)		
351	50. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)		
352	51. Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18)		
353	52. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)		
354	53. Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of		

	major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.7.2012, p. 1)		
355	54. Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38)		
356	55. Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the import and export of hazardous chemicals (OJ L 201, 27.7.2012, p. 60)		
357	56. Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35)		
358	57. Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (OJ L 96, 29.3.2014, p. 1)		
359	58. Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the		

	approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1)		
360	59. Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006 (OJ L 150, 20.5.2014, p. 195)		
361	60. Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1)		
362	61. Directive (EU) 2016/2284 of the European Parliament and of the Council of 14 December 2016 on the reduction of national emissions of certain atmospheric pollutants, amending Directive 2003/35/EC and repealing Directive 2001/81/EC (OJ L 344, 17.12.2016, p. 1)		
363	62. Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No		

	999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 095, 7.4.2017, p. 1)		
364	63. Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1)		
365	64. Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008 (OJ L 137, 24.5.2017, p. 1)		
366	65. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).		

367	66. Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (OJ L 170, 25.6.2019, p. 1)		
368	67. Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45)		
369	68. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435, 23.12.2020, p. 1)		
370	69. Regulation (EU) .../... of the European Parliament and of the Council on nature restoration (OJ .../ELI: ... [OP: please add number and publication reference].		
371	70. Regulation (EU) .../... of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (OJ .../ELI: ... [OP: please add number and publication reference]		Comment Sweden proposes that the following Union acts be added to Annex I: <u>71. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).</u>

			<u>72. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).</u> <u>73. Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).</u> <u>74. Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and</u>

			<u>of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).</u>
ANNEX II			
372	ANNEX II UNION ACTS REFERRED TO IN ARTICLES 2, 3, 12, 17 AND 23 AND REFERENCE VALUES REFERRED TO IN ARTICLE 8		
Part 1			
373	~~Part 1— Specific data on relevant active substances to be identified in accordance with Article 4(5)(b) falling under the scope of this Regulation for the purposes of Article 3 for human and veterinary medicinal products~~		Sweden proposes that Part 1 is deleted.
374	1. Non-clinical safety data, including data related to environmental risk assessments, compiled pursuant to Directive 2001/83/EC of the European Parliament and of the Council ¹ and Regulation (EC) No 726/2004 of the European Parliament and of the Council ² ; ¹ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).		

	² Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).		
375	2. Data related to environmental risk assessments, compiled pursuant to Regulation (EU) 2019/6 of the European Parliament and of the Council²; and ² Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).		
376	3. Maximum residue levels data compiled pursuant to Regulation (EC) No 470/2009 of the European Parliament and of the Council⁴; ⁴ Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).		
377	These data shall be limited to data submitted to the		

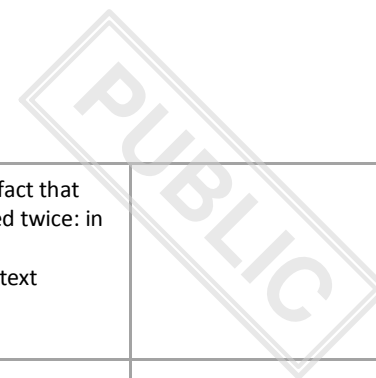
	EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation. Where relevant, the data held by the EMA resulting from procedures concluded before the entry into force of this Regulation may also be considered for inclusion into the common data platform.		
Part 2			
378	Part 2 - Reference values to be included in the repository of reference values following Article 8(3)		
379	1. Predicted no effect concentrations derived as part of the environmental risk assessment under Directive 2001/83/EC of the European Parliament and of the Council, Regulation (EC) No 726/2004 of the European Parliament and of the Council and Regulation (EU) 2019/6 of the European Parliament and of the Council.		
380	These data shall be limited to data submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation. Where relevant, data held by the EMA resulting from procedures concluded before the date of entry into force of this Regulation shall also be		

	considered for inclusion into the common data platform.		
Annex III			
381	Annex III UNION ACTS REFERRED TO IN ARTICLES 2, 10 AND 23		
382	Reference to each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.		
383	1. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1)		
384	2. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste		
385	3. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50)		
386	4. Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11)		

387	5. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34)		
388	6. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p. 1)		
389	7. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10)		
390	8. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29)		
391	9. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)		
392	10. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3)		
393	11. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on		

	maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1)		
394	12. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19)		
395	13. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)		
396	14. Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38)		
397	15. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84)		

398	16. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)		
399	17. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)		
380	18. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC, and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p.7)		
381	19. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16)		
382	20. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34)		



383	~~21. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)~~	Some delegations highlighted the fact that Regulation 1331/2008 is mentioned twice: in points 17 and 21 of Annex III. → PRES proposes to amend the text (deleting this repetition).	
384	22. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3)		
385	23. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energyrelated products		
386	24. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1)		
387	25. Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer (OJ L 286, 31.10.2009, p. 1)		
388	26. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)		

389	27. Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28)		
390	28. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)		
391	29. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)		
392	30. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)		
393	31. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 1831/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).		
394	32. Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45)		
395	33. Directive (EU) 2020/2184 of the European		

PUBLIC

	Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435, 23.12.2020, p. 1)		
396	34. Regulation (EU) .../... of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (OJ .../ELI: ... [OP: please add number and publication reference].		

SWEDEN

14/3/2024

Proposal for a
DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
amending Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European
Chemicals Agency
(Text with EEA relevance)



PRESIDENCY PROPOSALS for written comments by 22 March 2024 1 PM

Delegations will find attached a **revised** Presidency compromise proposal on the above-mentioned Proposal.

Changes in comparison to the previous compromise proposal, document COM(2023) 781, are marked in **red bold underline** for additions and in ~~red strikethrough~~ for deletions.

Delegations are invited to send written comments, possible text suggestions on all articles and to react on the amendments already proposed by the Presidency **at the latest by Friday 22 March 2024, at 13h00**. On the basis of which the Presidency will decide on the topics to be discussed at the next Ad Hoc Working Party meeting, scheduled for the 12th of April 2024.

	Commission Proposal	Presidency Justification	Delegations comments
Proposal Title			
1	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ~~a~~ Amending Directive 2011/65/EU ~~cent~~ rof the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency (Text with EEA relevance)		Issuing exemptions as regulations Amendments of annex III and IV require that the - national provisions implementing these delegated acts must be amended accordingly. The process is rather resource demanding. Therefore, SE has asked if it would be possible to issue the exemptions according to Article 5 as regulations instead of directives. We understand that that would be an uncommon solution, but it seems to be formally possible. A comparison is the procedure under the Ecodesign-directive (Directive 2009/125/EC), where certain implementing measures (Article 15) are adopted as regulations.
Formula			
2	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,		

Citation 1			
3	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,		
Citation 2			
4	Having regard to the proposal from the European Commission,		
Citation 3			
5	After transmission of the draft legislative act to the national parliaments,		
Citation 4			
6	Having regard to the opinion of the European Economic and Social Committee ¹		
Footnote 1			
7	¹ OJ C [...], [...], p. [...].		
Citation 5			
8	After consulting the Committee of the Regions,		
Citation 6			

9	Acting in accordance with the ordinary legislative procedure,		
Formula			
10	Whereas:		
Recital 1			
11	(1) The Commission has, in its Communication 'European Green Deal'², set an objective that chemical safety assessments should move towards a process of 'one-substance, one-assessment', calling for more transparent and simpler risk assessment processes in order to reduce the burden on all stakeholders, accelerate decision-making, as well as to increase consistency and predictability of scientific decisions and opinions. The Commission, in its Communication on Chemicals Strategy for Sustainability³ concludes that, in order to achieve that objective, part of the scientific and technical work on chemicals performed at Union level in support of Union legislation needs to be reattributed to the most suitable Union agencies. This would simplify the current set-up, improve quality and coherence of		

	safety assessments across Union legislation, and ensure more efficient use of existing resources.		
Footnote 2			
12	² Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal (COM (2019) 640 final of 11 December 2019).		
Footnote 3			
13	³ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment (COM (2020) 667 final of 14 October 2020).		
Recital 2			
	(2) The reattribution of certain scientific and technical tasks to the European Chemicals Agency is necessary in order to align processes and levels of scientific		

14	scrutiny and digitalisation with current standards and processes of the European Chemicals Agency. This is also necessary in order to ensure a consistent standard of scientific quality, transparency, data searchability and interoperability, in line with the 'one-substance, one-assessment' ambition.		
Recital 3			
15	(3) Directive 2011/65/EU of the European Parliament and of the Council ⁴ contains two procedures related to the assessment of chemicals: the evaluation of economic operators' applications for granting, renewing or revoking an exemption from the substance restrictions pursuant to Article 5 of that Directive and the review of substances to be added to the list of restricted substances pursuant to Article 6 of that Directive. There is a need to increase transparency by setting detailed procedural steps for the process to review substances for a potential inclusion in the list of restricted substances.		
Footnote 4			

16	⁴ Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment – OJ L 174 1.7.2011, p 88.		
Recital 4			
17	(4) Data and information held by the European Chemicals Agency in the context of regulatory processes under Titles VII and VIII of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁵ can be usefully deployed for the assessment of potential substance restrictions and for assessing applications for exemption under Directive 2011/65/EU. Established structures and procedures can help to build on the existing knowledge base, maximise synergies, and make the best use of available expertise and resources.		
Footnote 5			
	⁵ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration,		

18	Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC - OJ L 396 30.12.2006, p. 1.		
Recital 5			
19	(5) To ensure consistency between the evaluation of economic operators' applications for granting, renewing or revoking an exemption pursuant to Article 5 of the Directive 2011/65/EU, as well as to make the best use of existing chemicals-related expertise, the technical evaluation to assess the justification of such exemption requests should be carried out by the European Chemicals Agency and its committees in close coordination with the Commission.		
Recital 6			

PUBLIC

20	(6) To ensure that the restriction process referred to Article 6 in Directive 2011/65/EU is consistent with the restriction processes under other legislation related to chemicals, in particular with the substance restriction process laid down in Articles 69 to 73 of Regulation (EC) No 1907/2006, it is necessary to amend Directive 2011/65/EU to formally task the European Chemicals Agency with a role in the restriction process. In the light of experience obtained when carrying out substance reviews, it is essential for the quality of the related technical assessment, and for enabling synergies, to make use of information and tools being used in the context of assessments for chemical restrictions under Regulation (EC) No 1907/2006.		
Recital 7			
21	(7) The two procedures described under Article 5 and Article 6 are applicable at the EU level. National provisions should not deviate from these Articles set in Directive 2011/65/EU.		
Recital 8			

22	(8) For amending procedural provisions under Directive 2011/65/EU, a transitional period of 12 months is necessary to allow for appropriate resource and task allocation for the European Chemicals Agency. That timeframe is considered sufficient to allow for amending procedural provisions under Directive 2011/65/EU, a transitional period of 12 months is necessary to allow for appropriate resource and task allocation for the European Chemicals Agency. That timeframe is considered sufficient to allow potential applicants or Member States to adjust to the modified procedural steps under that Directive.		
Recital 9			
23	(9) Directive 2011/65/EU should therefore be amended accordingly,		
Formula			
24	HAVE ADOPTED THIS DIRECTIVE:		
Article 1			
25	<i>Article 1</i> Amendments to Directive 2011/65/EU		

	Directive 2011/65/EU is amended as follows:		
Article 1(1)			
26	(1)Article 5 is amended as follows:		
Article 1(1), point (a)			
27	(a) paragraphs 3 and 4 are replaced by the following		
Article 1(1), point (a), paragraph 3			
28	'3. An application for granting, renewing or revoking an exemption shall be made to the European Chemicals Agency set up pursuant to Article 75(1) of Regulation (EC) No 1907/2006 ('the Agency') in accordance with Annex V.		
Article 1(1), point (a), paragraph 4a			
29	4. The Agency shall: (a) acknowledge receipt of an application within 15 days of its receipt, stating the date of receipt of the application;		
Article 1(1), point (a), paragraph 4b			
30			

	(b) verify that the application contains all the elements laid out in Annex V;		
Article 1(1), point (a), paragraph 4c			
31	(c) if necessary, request the applicant to complete the application <u>within 45 days of receipt of the application</u> , and provide an appropriate deadline <u>of maximum 60 days</u> ;	Change proposed based on the comments from two delegations. One delegation suggested replacing the word “appropriate” with a specific deadline in order to improve legal certainty for the actors concerned. They motivated that this would also ensure that current applications are published on the Agency’s website in a timely manner. Additionally, other delegation motivated that the applicant should be given a deadline within which the application should be completed, since the exemption continue to apply during the process of evaluation of the application. The 45 days and 60 days were proposed based on the deadlines given in REACH Article 69 (4) for restrictions proposals, as there are no similar deadlines under the authorisation scheme in REACH. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	SE supports the suggested amendments.
Article 1(1), point (a), paragraph 4d			
32	(d) make the application and any supplementary information supplied by the applicant available to Member States;		

Article 1(1), point (a), paragraph 4e			
33	(e) make a summary of the application and a non-confidential version of the application as submitted by the applicant, as well as the date when the application is considered complete, available to the public on the Agency's website;		“(e) make a summary of the application and a non-confidential version of the application as submitted by the applicant, as well as the date when the application is considered complete, available to the public on the Agency's website; <u>The applicant may request that certain information is not to be made publicly available. The request for confidentiality shall be accompanied by a justification as to why the disclosure of the information could be harmful to the commercial interests of the applicant. The assessment of confidentiality shall be carried out in accordance with Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.</u> Justification: SE suggests referring to the Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents to clarify according to what criteria confidentiality regarding applications of exemptions should be assessed. The suggested addition may also be included elsewhere where suited.
Article 1(1), point (a), paragraph 4f			

34	(f) invite interested parties to submit information within 3 months of its publication on the Agency's website.		
Article 1(1), point (a), paragraph 4			
35	Where the applicant does not complete the application with the missing elements identified by the Agency in compliance with Annex V within the deadline provided in accordance with the first subparagraph, point (c), the Agency may reject such application. The Agency shall establish and communicate to the applicant without undue delay the date when the application is considered complete. Upon receipt of an application, the Agency shall notify the Commission of the application and keep it informed of any of the procedural steps under points (b) to (f).';		
Article 1(1), point (b)			
36	b) the following paragraph 4a is inserted after paragraph 4:		
Article 1(1), point (b), regarding inclusion of article 4a			

37	4a. The Agency shall, after verifying the completeness of the application, request the opinion of the Committee for Socio-economic Analysis, set up pursuant to Article 76(1), point (d) of Regulation (EC) No 1907/2006. It shall request the opinion of the Committee for Risk Assessment, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006, in the case of an application for a new exemption or where otherwise considered appropriate. The Committee for Socio-economic Analysis and, where relevant, the Committee for Risk Assessment:	Two delegations suggested that it needs to be clearer when RAC shall evaluate an application for exemption. Therefore, they considered that it may be good to clarify that RAC shall evaluate applications for renewal of exemptions that have previously been evaluated by external consultants or where there are amendments in the exemption that have not been evaluated before. This would have the effect of increasing consistency between the evaluations. Alternatively, other delegation proposed in their comments to rather assign the tasks to ECHA (and its Expert Groups) than directly to RAC and SEAC. Their proposal was motivated by a concern related to the capacity of SEAC and RAC to perform the tasks under Art. 5 (lack of expertise in RoHS within the Committees, insufficient staff). In their opinion, the proposed change in the text would not preclude the Executive Director from requesting the assistance of the Committees of ECHA on a case-by-case basis. PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	"4a. The Agency shall, after verifying the completeness of the application, request the opinion of the Committee for Socio-economic Analysis, set up pursuant to Article 76(1), point (d) of Regulation (EC) No 1907/2006. It shall request the opinion of the Committee for Risk Assessment, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006, in the case of an application for a new <u>exemption or an application for a renewal of</u> an exemption <u>submitted to the Agency for the first time</u>, or where <u>there are amendments in an exemption that RAC has not evaluated</u> before ~~otherwise considered appropriate.~~ " Justification: SE suggests that it needs to be clearer when RAC shall evaluate an application for exemption. Therefore, it is needed to clarify that RAC shall evaluate applications for renewal of exemptions that have previously been evaluated by external consultants or where there are amendments in the exemption that have not been evaluated before. This would have the effect of increasing consistency between the evaluations, since applications evaluated by external consultants may differ from the ones evaluated by ECHA.
Article 1(1), point (b), regarding inclusion of article 4a (a)			

38	(a) shall draw up draft opinions within 9 months of the date the application has been considered complete by the Agency under paragraph 4, point (b);	One delegation proposed to align the deadline for RAC and SEAC for the assessment of exemptions with the authorisation scheme and assessment of authorisation under the REACH-Regulation (Article 64 (1) of the REACH Regulation). Other delegation proposed to specify that the opinions drawn shall be scientific and technical. This proposal is a consequence of their proposal above (line 37 of this document), where it is considered that tasks should be rather assigned to ECHA (and its Expert Groups) than directly to RAC and SEAC. PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	SE strongly supports the proposal by the Commission and that the Presidency has not made any amendments. SE does not support alignment with REACH or that the opinions drawn shall be scientific and technical.
Article 1(1), point (b), regarding inclusion of article 4a (b)			
39	(b) shall assess whether the criteria in Article 5(1), point (a), are met and shall provide clear guidance to the Commission on granting, renewing or revoking an exemption;		
Article 1(1), point (b), regarding inclusion of article 4a (c)			
40	(c) may request the applicant or third parties to submit, within a		

	specified period, additional information;		
Article 1(1), point (b), regarding inclusion of article 4a (d)			
41	(d) upon adopting the draft opinions, shall communicate those draft opinions to the applicant and shall allow the applicant the opportunity to comment within 4 weeks of the communication of the draft opinions to the applicant;	One delegation proposed to specify that the opinions drawn shall be scientific and technical. This proposal is a consequence of their proposal above (line 37 of this document), where it is considered that tasks should be rather assigned to ECHA (and its Expert Groups) than directly to RAC and SEAC. PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	SE strongly supports the proposal by the Commission and that the Presidency has not made any amendments.
Article 1(1), point (b), regarding inclusion of article 4a (e)			
42	(e) shall adopt their final opinions, taking into account the comments from the applicant.		
Article 1(1), point (b), regarding inclusion of article 4a			
	Each Committee shall take into account any information submitted by third parties in accordance with the second subparagraph, point (c). The Agency shall send the final opinion(s) of the Committees to	One delegation proposed to align the deadline for RAC and SEAC for the assessment of exemptions with the authorisation scheme and assessment of authorisation under the REACH-Regulation. Therefore, in their view the deadline for sending the final opinion to the Commission should be set to 14 months. This will assure that ECHA will have at least the	SE strongly supports the proposal by the Commission and that the Presidency has not made any amendments. SE does not support alignment with REACH or that the opinions drawn shall be scientific and technical.

43	the Commission within 12 months from the date an application has been considered complete by the Agency. The Agency shall identify which parts of its opinions and of any attachments thereto should be made publicly available on its website and shall make those parts publicly available on its website. For the purpose of adopting opinions pursuant to this paragraph, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.'	same time period as is given under Article 64 (5) in REACH, where the Committees shall adopt their final opinion within two months after receiving the comments from the applicant and send it to the Commission within 15 days after this. Additionally, other delegation proposed to specify that the opinions drawn shall be scientific and technical. This proposal is a consequence of their proposal above (line 37 of this document), where it is considered that tasks should be rather assigned to ECHA (and its Expert Groups) than directly to RAC and SEAC. PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	If the time to finalise the opinion(s) is prolonged, the whole process will take more time leading to an unnecessary delay until a decision is taken. This could lead to a delay in the phase out of the hazardous substances from the exempted use.
Article 1(1), point (c)			
44	(c) paragraph 8 is replaced by the following:		
Article 1(1), point (c), paragraph 8			
	8. The Agency shall, in agreement with the Commission, provide a harmonised format for the applications referred to in paragraph 3 of this Article as well as comprehensive guidelines for	One delegation considered that a clarification is needed in relation to third criterion in Art. 5(1)(a) of the RoHS Directive: <i>'the total negative environmental, health and consumer protection impact as a result of the</i>	SE supports that, following the adoption of the proposal, COM assisted by ECHA publishes guidelines to facilitate the harmonised application of Article 5(1)(a), including consultation of experts

45	such applications, taking into account the situation of SMEs. Any submission to the Agency shall be made using the format and the submission tools made available by the Agency.’;	<i>substitution is likely to be greater than the total environmental, health and consumer protection benefits thereof’.</i> In their view many exemptions are granted or renewed with reference to this criterion, not infrequently, where the other criterions do not apply i.e. where substitution is possible or reliable alternatives are available, in spite of the weight of substitution in RoHS as reflected in recital 8 <i>the most effective way of ensuring a significant reduction of risks to health and the environment relating to those substances, in order to achieve the chosen level of protection in the Union, is the substitution of those substances in EEE by safe or safer materials.</i> The criterion is often applied based on energy considerations. It is unclear if this was the intention of this criteria and, which weight to assign energy considerations compared to chemicals considerations within the frame of RoHS. In light of the experienced difficulty concerning collection of information from applicants as identified during the RoHS review process, priority should be given to clarifying the applicability of this criterion. Therefore, there is a need to clarify the applicability of this criteria and it is important that ECHA does so through following this re-attribution of tasks. ECHA should revise this guidance and that the guidance should be adopted by the expert committee (see	designated by each MS (please see proposal for Article 20).

		proposal for reference to this committee in under article 20). PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(2)			
46	(2) in Annex V, the following paragraph is added: 'In cases referred to in the first paragraph, point (h), the applicant shall submit a non-confidential version of the application.'		
Article 1(3)			
47	(3) Article 6 is amended as follows:		
Article 1(3), point (a)			
48	(a) in paragraph 1, the first subparagraph is replaced by the following: 'With a view to achieving the objectives set out in Article 1 and taking account of the	Change proposed based on the comment from one delegation.	"With a view to achieving the objectives set out in Article 1 and taking account of the precautionary principle, a review, based on a thorough assessment, and an amendment of the list of restricted substances in Annex II shall be considered by the Commission at the latest every five

	precautionary principle, a review, based on a thorough assessment, and an amendment of the list of restricted substances in Annex II shall be considered by the Commission <u>every five years</u> ~~periodically~~ on its own initiative or following the submission of a restriction dossier prepared by a Member State containing the information referred to in paragraph 2.’;	One delegation considered that the list of substances restricted under the ROHS directive should be evaluated on a more regular basis. Here a 5-year period is suggested. It is not paramount that it should be a 5-year period, however, a timeline is needed. Staff working document p. 119 assesses the impact for ECHA. Here it says: <i>As the assessments are to be done ca. every 5 years.</i> Therefore, a time limit of 5 years is considered appropriate. eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52023SC0850 One delegation proposed also some additional changes (introduction of subparagraph 1a) as they considered that the substances restricted in the POP-regulation, and where the use in EEE is exempted, should be considered for Annex II in the RoHS-Directive. PRES did not modify the proposal and welcomes delegations’ views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	<u>years</u> on its own initiative or following the submission of a restriction dossier prepared by a Member State containing the information referred to in paragraph 2.’; SE would like to see a specification when a review of the list of restricted substances should occur. We note that adoptions of new restrictions have still not been decided on since the last review 2018.
Article 1(3), point (b)			
49	(b) in paragraph 1, the fourth subparagraph is deleted.		
Article 1(3), point (c)			

50	(c) paragraph 2 is replaced by the following: '2. The review and amendment of the list of restricted substances, <u>or a group of similar substances</u>, in Annex II shall be based on restriction dossiers prepared by the Agency at the request of the Commission or prepared by a Member State. The Agency or a Member State shall take into account any available information and any relevant risk assessment submitted for the purposes of other Union legislation covering the life cycle of the substance used in EEE, in particular the waste phase. To this end, other bodies established under Union law and carrying out a similar task shall, on request, provide information to the Agency or Member State concerned. The restriction dossier shall comply with the requirements set out in Part II, point 3, of Annex XV to Regulation (EC) No 1907/2006 <u>for those requirements that</u>	Change proposed based on the comment of one delegation. One delegation considered that the reference to the assessment of groups of substances should not be deleted as it is in the current COM's proposal. Additionally, one delegation considered that any relevant assessment, including assessments of waste handling, should be included in a restriction dossier, therefore DK proposed to delete "risk" from the text. PRES did not modify the proposal and welcomes delegations' views/comments. Change based on the proposal of the COM received prior to the 2nd Ad Hoc WP and discussed during that meeting. This proposal intended to accommodate the concern of one delegation regarding re-shifting of focus of assessment required under the RoHS Directive when aligning	SE supports to delete "risk". "2. The review and amendment of the list of restricted substances, <u>or a group of similar substances</u>, in Annex II shall be based on restriction dossiers prepared by the Agency at the request of the Commission or prepared by a Member State. The Agency or a Member State shall take into account ~~any~~ available information, <u>data or and any relevant risk</u> assessment submitted for the purposes of other Union legislation covering ~~the life cycle of the~~ substance used in EEE, in particular the waste phase. To this end, other bodies established under Union law and carrying out a similar task shall, on request, provide information to the Agency or Member State concerned. The restriction dossier shall comply with the requirements set out in Annex IX <i>[insert a new annex to the RoHS Directive]</i> Part II, point 3, of Annex XV to Regulation (EC) No 1907/2006 <u>for those requirements that relate to the criteria set out in Article 6(1)</u> and shall, in addition, contain the following information: ~~(a) information on the use of the substance or the group of similar substances in EEE;~~

	relate to the criteria set out in Article 6(1) and shall, in addition, contain the following information: (a) information on the use of the substance or the group of similar substances in EEE; (b) information on detrimental effects and exposure in particular during waste EEE management operations.'	restriction procedure with the REACH restriction. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	(b) information on detrimental effects and exposure in particular during waste EEE management operations.' <u>ANNEX IX</u> <u>Dossiers for restriction proposals</u> <u>The proposals to review and amend the list of restricted substances, or a group of similar substances, in Annex II shall contain at least the following information:</u> <u>1. The identity of the substance;</u> <u>2. a precise and clear wording of the entry of the proposed restriction in Annex II;</u> <u>3. references and scientific evidence for the restriction;</u> <u>4. information on the use of the substance or the group of similar substances in EEE;</u> <u>5. information on detrimental effects and exposure in particular during waste EEE management operations;</u> <u>6. information on possible substitutes and other alternatives, their availability and reliability;</u> <u>7. justification for considering a Union-wide restriction as the most appropriate measure;</u> <u>8. socioeconomic assessment."</u> Justification: SE does not support the Commission proposal nor the proposal by the Presidency to refer to Annex XV in REACH. The Commission has explained that the proposal is aimed to include

		changes only on procedural provisions, not on substantial content. Consequently, no extra provisions would be needed. We consider that there are substantial amendments in that proposal compared to the current RoHS Directive. Referring to all provisions for a restriction dossier in Annex XV in REACH with additional provisions for RoHS on top of that is disproportionate. This would mean that the restriction process in RoHS would be heavier than the same restriction process under REACH. Furthermore, there are provisions in Annex XV in REACH that are not relevant for restrictions in RoHS. For example, the Annex XV in REACH refers to Annex I, Part B, the Chemical Safety Report in which format hazard and risk assessments shall be documented. All points in this Chemical Safety Report are not applicable to RoHS Directive or are difficult to apply. Another example is that "Available information on alternative substances and techniques shall be provided, including: — information on the risks to human health and the environment related to the manufacture or use of the alternatives,..." where "the risks to human health and the environment related to the manufacture...of the alternatives..." is not part of the aim of the RoHS Directive. A final example is that "Evidence shall be provided that implemented risk management measures (including those

		identified in registrations under Articles 10 to 14) are not sufficient.”, which is not applicable to the RoHS Directive. When referring to Annex XV in Reach without specifying exactly what a RoHS restriction proposal shall contain, especially now when another organisation (ECHA), without earlier experience in RoHS, is taking over this task from the Commission (external consultants), there is a risk that the RoHS restriction dossier will be more streamlined with REACH unintentionally, which is not the aim of this revision, since it is just a procedural amendment. Referring to “requirements that relate to the criteria set out in Article 6(1)” means that ECHA or a MS when writing a restriction dossier have to make their own interpretation on what is relevant and what is not. This would be inefficient, taking unnecessary time in the implementation phase, and there may be different interpretations for different dossiers. If we are not able to define the requirements together in the council, we should not expect ECHA and the MS to decide on it when implementing the provisions. The legislation should be as clear as possible from start. Another drawback is that if the restriction process in REACH is changed in a revision, we will not know if this will fit to the specific design of the RoHS Directive.

			Therefore, SE suggests a new Annex IX with all the requirements from the current RoHS Directive so that it is clear and transparent what a RoHS restriction dossier shall contain. Additionally, this structure with a new Annex IX enables adaptation of the requirements in case of a revision of the legislation, with substantial amendments.
Article 1(4)			
51	(4) the following Articles 6a, 6b and 6c are inserted:		
Article 1(4), regarding insertion of Article 6a			
52	'Article 6a Initiation of procedure for review and amendment of the list of restricted substances		
Article 1(4), regarding insertion of Article 6a, point (1)			
53	1. Within 12 months of receipt of the request from the Commission referred to in Article 6(2), first subparagraph, the Agency shall prepare a restriction dossier conforming to the requirements referred to in Article 6(2), third subparagraph, and suggest restrictions in order to initiate the restriction process.		
Article 1(4), regarding insertion of Article 6a, point (2)			

54	2. A Member State shall notify the Agency that it proposes to prepare a restriction dossier which conforms to the requirements referred to in Article 6(2), third subparagraph, within 12 months. If that dossier demonstrates that action on a Union-wide basis is necessary, beyond any measures already in place, the Member State shall submit it to the Agency in order to initiate the restriction process.		
Article 1(4), regarding insertion of Article 6a, point (3)			
55	3. The Agency shall publish without delay the intention of the Commission or the Member State to initiate the process to review and amend the list of restricted substances in Annex II on the Agency's website .	Change proposed based on the comment from one delegation and in line with the text proposed in Art. 5 (see line 28 of this document). One delegation considered that it was not clear where the intention to review and amend the list of restricted substances will be published. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	SE supports this amendment.
Article 1(4), regarding insertion of Article 6a, point (4)			
56	4. The Agency shall establish and maintain a list of substances for which a restriction dossier conforming to the requirements		

	of Article 6(2) is planned or underway by either the Agency or a Member State for the purposes of a proposed restriction.		
Article 1(4), regarding insertion of Article 6a, point (5), paragraph 1			
57	5. The Agency shall consult the Committee for Risk Assessment, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006, and the Committee for Socio-economic Analysis, set up pursuant to Article 76(1), point (d), of that Regulation. The Committees shall verify whether the restriction dossier submitted conforms to the requirements referred to in Article 6(2), third subparagraph.		
Article 1(4), regarding insertion of Article 6a, point (5), paragraph 2			
58	Within 30 days of receipt of the restriction dossier, the respective Committee shall inform the Agency or the Member State proposing restrictions whether the dossier conforms to the requirements referred to in Article 6(2), third subparagraph. If the dossier does not conform to those requirements, the reasons shall be given to the Agency or the Member State in writing		

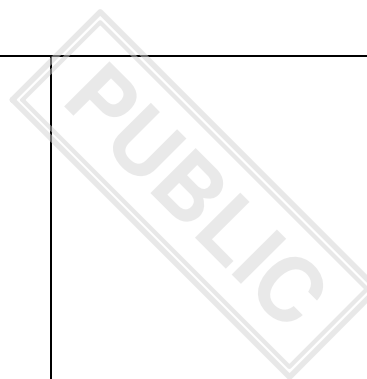
	within 45 days of receipt of that dossier. The Agency or the Member State shall bring the dossier into conformity within 60 days of the date of receipt of the reasons from the Committees, otherwise the procedure under this Article shall be terminated.		
Article 1(4), regarding insertion of Article 6a, point (6)			
59	Where the dossier meets the requirements referred to in Article 6(2), third subparagraph, the Agency shall make it publicly available without delay, clearly indicating the date of publication. The Agency shall invite all interested parties, including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations to submit, individually or jointly, within 4 months from the date of the publication of the dossier, the following:		
Article 1(4), regarding insertion of Article 6a, point (6a)			
60	(a) comments on dossiers and the suggested restrictions;		
Article 1(4), regarding insertion of Article 6a, point (6b)			

61	(b) a socio-economic analysis including an analysis of alternatives, or information which can contribute to ~~one of~~ the suggested restrictions, examining the advantages and drawbacks of the proposed restrictions.	Changes partially modified based on the comment from one delegation. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	SE supports the amendment.
Article 1(4), regarding insertion of Article 6a			
62	The analysis referred to in the first subparagraph, point (b), shall conform to the requirements in Annex XVI to Regulation (EC) No 1907/2006.	One delegation suggested to delete this text, as they consider that the restriction process in RoHS may be too extensive compared to the restriction process in REACH. They were also concerned that having in mind future revision of the REACH Regulation, it is not clear how the restriction process will look like in the future. PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	"The analysis referred to in the first subparagraph, point (b), ~~shall~~ could conform to the requirements in Annex XVI to Regulation (EC) No 1907/2006. " SE is of the opinion that "shall" should be replaced by "could" or a similar word indicating that a stakeholder contribution does not need to comply to a socioeconomic analysis according to REACH Annex XVI. The aim of the stakeholder consultation should be to encourage stakeholders to send relevant information, not to hinder them from doing it.
Article 1(4), regarding insertion of Article 6b			
63	<i>Article 6b</i> Opinion of the Agency's Committees		
Article 1(4), regarding insertion of Article 6b, point (1)			

64	1. Within 12 months from the date of publication referred to in Article 6a(6), the Committee for Risk Assessment shall adopt an opinion as to whether the restriction is appropriate in reducing the risk to human health or the environment, specifically ~~by reference to the risks set out in Article 6(1) for those requirements that relate to the criteria set out in Article 6(1).~~ third subparagraph, based on its consideration of the relevant parts of the dossier. This opinion shall take account of the restriction dossier prepared by the Agency at the request of the Commission or by the Member State, and the views of interested parties referred to in Article 6a(6), point (a).	Change proposed by PRES to align the text with Article 1(3), point (c) (line 50 of this document). This proposal intended to accommodate the concern of one delegation regarding re-shifting of focus of assessment required under the RoHS Directive when aligning restriction procedure with the REACH restriction. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	“1. Within 12 months from the date of publication referred to in Article 6a(6), the Committee for Risk Assessment shall adopt an opinion as to whether the restriction is appropriate in reducing the risk to human health or the environment, ~~specifically by reference to the risks set out in Article 6(1) for those requirements that relate to the criteria set out in Article 6(1).~~ third subparagraph, based on its consideration of the relevant parts of the dossier. ~~according to Annex IX.~~ This opinion shall take account of the restriction dossier prepared by the Agency at the request of the Commission or by the Member State, and the views of interested parties referred to in Article 6a(6), point (a). “ Please, see comment above on line 50.
Article 1(4), regarding insertion of Article 6b, point (2)			
65	2. Within 15 months from the date of publication referred to in Article 6a(6), the Committee for Socio-economic Analysis, shall adopt an opinion on the proposed restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. Prior to that, it shall prepare a draft opinion on the suggested		

	restrictions and on the related socio-economic impact, taking account any existing analysis or information according to Article 6a(6), point (b).		
Article 1(4), regarding insertion of Article 6b, point (3)			
66	3. The Agency shall publish the draft opinion of the Committee for Socio-economic Analysis on its website without delay and invite interested parties to provide their comments on the draft opinion no later than 60 days from its publication.		
Article 1(4), regarding insertion of Article 6b, point (4)			
67	4. The Committee for Socio-economic Analysis shall without delay adopt its opinion, taking into account where appropriate further comments received by the deadline set in paragraph 3. This opinion shall take into account the comments of interested parties submitted under Article 6a(6), point (a), and paragraph 3 of this Article.		
Article 1(4), regarding insertion of Article 6b, point (5)			
68	5. Where the opinion of the Committee for Risk Assessment diverges significantly from the		

	restrictions proposed, the Agency shall postpone the deadline for the opinion of the Committee responsible for Socio-economic Analysis by a maximum of 90 days.		
Article 1(4), regarding insertion of Article 6b, point (6)			
69	6. For the purpose of adopting opinions pursuant to this article, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.	One delegation proposed some additional suggestions to provide for legislative provisions for the remuneration of tasks by Rapporteurs within the OSOA Package. PRES did not modify the proposal, as this is covered by mutatis mutandis application of Art. 87 of Regulation (EC) No 1907/2006 . Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	
Article 1(4), regarding insertion of Article 6c			
70	<i>Article 6c</i> Submission of an opinion to the Commission		
Article 1(4), regarding insertion of Article 6c, point (1)			



71	1. The Agency shall submit to the Commission, without delay, the opinions of the Committees for Risk Assessment and Socio-economic Analysis on the restrictions suggested pursuant to Article 6b. Where the opinions of the Committees for Risk Assessment and Socio-economic Analysis diverge significantly from the restrictions suggested by the dossier, the Agency shall submit an explanatory note to the Commission providing a detailed explanation of the reasons for such differences. If one or both of the Committees do not adopt an opinion by the deadlines set in Article 6b(1) and (2) the Agency shall inform the Commission accordingly, stating the reasons.		
Article 1(4), regarding insertion of Article 6c, point (2)			
72	2. The Agency shall publish the opinions of both Committees on its website without delay.		
Article 1(4), regarding insertion of Article 6c, point (3)			

73	3. The Agency shall, on request, provide the Commission or Member State with all documents and evidence submitted to or considered by it.';		
Article 2			
74	The provisions under this Directive shall be applicable from [OJ: 12 months after the publication of this Directive].		
Article 3			
75	This Directive shall enter into force on the twentieth day following that of its publication in the <i>Official Journal of the European Union</i> .		
Article 4			
76	This Directive is addressed to the Member States. Done at Brussels, <i>For the European Parliament For the Council</i> <i>The President The President</i>		
Additional recommendations (changes proposed regarding articles that were not included in the current COM's proposal)			

Concerning amendments of Article 5(5):

77	An application for renewal of an exemption shall be made no later than 18 months before the exemption expires.	One delegation proposed extension of the deadline to 24 months as they are concerned that by aligning the exemptions assessment process with REACH, the Commission will be phased with the issue of expediting delegated directives before the expiration of the concerned exemption. Therefore it was suggested to increase the deadline in order to leave more room for the assessment procedure. PRES did not modify the proposal and welcomes delegations' views/comments. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	SE supports the COM proposal on 18 months. The aim with applying for renewal 18 months before the old one expires should be to allow a decision on prolongation or refusal before the date of expire.

Concerning amendments of Article 20:

78	Exercise of the delegation 1. The powers to adopt the delegated acts referred to in Article 4(2), Article 5(1) and Article 6 shall be conferred on the Commission for a period of 5 years from 21 July 2011. The Commission shall draw up	Change proposed based on the comments from one delegation. The COM agreed to the proposed changes, prior to the 2nd Ad Hoc WP. Note: COM answer to the proposal made can be found in the document WK 3533 2024 Rev. 1.	SE supports the amendments.

a report in respect of delegated powers at the latest 6 months before the end of the 5-year period. The delegation of power shall be ~~automatically~~ tacitly extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 21.

1a. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

PUBLIC