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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 CZ and the Commission.

CZECH REPUBLIC

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 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. [1]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. [2]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		
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 Council[3], aiming to achieve the same objectives. [3]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	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] [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 Council[6]. 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 2022[7], 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) 2019/1021[8]. 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 chemicals[10] 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	• **CZ: We do not consider such amendment of Article 4 as necessary since the original proposal covers *the Commison to ask the Agency for changes regarding annexes IV and V of the Regulation* in the proposal of point (i) of Article 8(1). It would be an unnecessary duplication.**

			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:		• **CZ: We welcome the amendments to Article 8 and we also agree with the latest changes to the text.**
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.	

		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	

		Agency shall publish those comments on its website.		
60		At the latest 9 months following the submission of th~~e~~***at*** 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 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).	• **CZ: We agree with the change in the wording of Article 13 paragraph 2.**
63		'2. Where a Member State shares the information referred to in paragraph 1, point €, 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 €, 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	• **CZ: Scrutiny reservation. Further discussion on this change is necessary.** • **CZ: We share the concerns of other MS and we support the opinion that the expertise of the meeting of Competent Authorities for the POP Regulation must be sustained.** • **On the possibility of accepting adoption of amendments to Annexes IV and V by the means of delegated acts, we request further discussion to clarify the proposal.** • **Question to the COM: If the procedure should change to DA, what would happen to the Committee under Directive 2008/98/EC in Article 20(2) as there is no voting under**

			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.	**delegated acts? Will the reference remain?**
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.	• **CZ: Scrutiny reservation. Further discussion is required.** • **CZ: We consider it necessary to keep the wording of paragraph 4 of Article 18.**
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		

COMMISSION

4/3/2024

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)

ANNEX II to the Steering note:
PRESIDENCY PROPOSALS for consideration at the OSOA AHWP
8/3/2024

A) Proposed blocs of discussion at the 2nd WP- details and presidency expectations for the discussions.

a) **<u>Data/metadata to be included in the data platform (art.3), and the effort requested from MS (art.3,6,13,18,19) and agencies/committees (art.19)</u>**

PRES EXPECTATIONS: seeks reactions on whether the concerns are clarified, and if not, to ear which amendments are suggested.

PRES would like to focus on the following topics:

- Opportunity to request explicitly in the proposal to tag, highlight or prioritize data evaluated by authorities or agencies (should this be left for the implementation?);
- Implications of the proposal on data related to mixtures and in particular in authorizations of plant protection products at national level;
- Potential alignment between the approaches taken for data related to medicinal products and biocidal and phytopharmaceutical products data;
- Links between this proposal and the EHDS (European Health Data Space)
- Potential inclusion of the national emissions notifications into the scope and the level of effort required for that
- Clarification of EIONET role, potential impacts on EIONET resources (art 6/HBM, art 13/sustainability data, art.18 framework indicators, art.19 early warning system), data collection by MS (art.19).
- Impacts of the early warning and action system on MS and RAC (MS experts' role + is there any RAC involvement?)

b) **<u>Amendment proposals by the presidency</u>**

PRES EXPECTATIONS: determine the level of support to the track changes in the table here below (i.e. ***additions***/~~deletions~~).

PRES EXPECTATIONS: clarity on the support to the proposed amendments

c) <u>Medicinal products and cosmetics provisions in COM proposal</u>: chemicals data that should be included in the platform (scope)

PRES EXPECTATIONS: close subject OR enough support for amendments from MS

This includes a discussion on the need for a definition of "relevant substances" with regard to medicinal active substances, the obligations for EMA regarding data submitted before the entry into force of the medicines regulation, and the environmental data contained in the monographs.

d) **<u>HBM data constituting personal data subject to protection</u>**

PRES EXPECTATIONS: reactions to the EDPS report and other topics identified here below, tours the table on concrete amendments responding to the remaining concerns. Based on the discussions and suggestions from MS, the PRES might work on amendments related to this topic (if that is the case, written comments afterwards will be requested).

For discussion:

- Clarity of the differences between anonymised, pseudonymised, aggregated data and how this is take into account in the proposal regarding personal data.
- Member states raised several questions, concerns and clarification needs on human biomonitoring data. Amongst others, PRES highlights: how to cope with the needed study participants consent? Is it required to provide national programs data? Compliance with EUDPR, GDPR. Sources of data, roles of EEA and other institutions. Unclear specification of the use of personal data. SI requests that the right to access personal data in art.16 is limited to the purpose claimed.
- There is a suggestion of amendment by ## to introduce provisions to prevent the sharing of such data by EEA with "third parties", a term ## suggests to define in art.2. PRES understands that this concerns only personal data and at the same time that under the current practices, HBM data are used and

needed by several actors that might fall under the definition of "third parties" (e.g. PARC research publications, authorities research subcontractors, RAC).

- In addition, recommendations were received from the EDPS (European Data Protection Supervisor) the protection of personal data in the framework of the OSOA proposals.

e) **<u>Confidentiality and data use (art 16,17)</u>**

PRES EXPECTATIONS: overview of the positions related to possible amendments.

Topics for discussion:

- ## already proposed to amend art.17(1) to explicitly allow national use of the data
- COM response to MS questions/concerns on art.16 and 17
- MS indications on remaining concerns about:
- the intellectual property and data ownership in the context of data re-use (##/## comments).
- the data confidentiality (## comments)
- the alignment between REACH art.25(3) on the use of (robust) summaries after 12y, and the present proposal (## comments). PRES understands that this relates also to art.17(2) of the present proposal regarding the fulfilment of duty holders obligations.
- the use of data by scientific bodies (##)? Or by authorities for national legislation and policy (##)? PRES understands that ## questions are related to confidential data and also to HBM data as the rest is public, or maybe also to API access. PRES highlights that ## question may also be related to existing provisions or contractual practices linked to regulations listed in annex I (like the limitations to the use of REACH-IT data by MS), or to the use of data in international processes.

f) **<u>The desired level of MS participation or consultation in the foreseen processes, and the legal procedures choice</u> (delegated acts / implementing acts or decisions / commission decisions / EG opinions).**

PRES EXPECTATIONS: tour the table on the level of participation of MS, the desired legal procedures, the specific processes were more participation is eventually requested, and amendment suggestions.

For discussion:

- ##, ##, ## raise questions on the participation of MS in the implementation and other aspects of the proposal (art.4,14,15,13,18,20,20(2),21(5) are mentioned). ## would like to know if MS will be able to use the data generation mechanism.
- ## also raised concerns about the legal procedures mentioned in the proposal, namely the meaning of "implementing" in this context (art.4(1), 4(2),13). ## finds that the use wording refers to "internal decisions" to the COM rather than to implementing acts and the procedures following. ## requests to consider the possibility to use implementing "decisions" in art.20(2) and in accordance with Regulation (EU) No 182/2011. ## supports delegation in art.23.
- **PRES is seeking legal advice (SCG LS)** on comments from ## about the "implementing" wording. PRES highlights that the wording "implementing decision" also appears in art.4(4), art.14(8), art.15(8), art.20(2).

g) **<u>The timeline of the proposal</u> -** clarification and potential need for amendments of art.3(11), 4, 7, 13, 19, 20,22 that contains time specifications.

PRES EXPECTATIONS: clarification of the timeline, indications on the feasibility of the proposed timeline and the necessity for amendments modifying the proposed timeline (including opinions on the ## and ## amendment proposals to art.3(11), art4), ## comments on art.18 and PRES amendment proposal to art.18).

PRES highlights that the timeline is a subject which can be raised potentially in several places in the proposal: the establishment of the platform; integration of the data, actual availability of the data; start of the implementation plan; the timing for the subsequent rolling implementation plans, the transfer of monitoring data from the COM to the ECHA,EEA,EFSA for integration/hosting/making available; establishment of the environmental sustainability database and identification of additional datasets on that subject; establishment of the early warning system; first annual report on early warning signals; the publication of the list of selected chemicals for the observatory; and the application of the obligations of studies notifications.

h) **<u>Studies notification & enforcement</u>**

MS expressed several requests for clarification on notifications (legal scope and definition of studies to be notified, duplications, notification and enforcement for studies conducted outside the EU, late notifications, absence of a transitional period, practical arrangements for companies)

PRES EXPECTATIONS:

→ **PRES invites the COM** to respond to MS comments received.

→ **PRES invites MS** to clarify if there are still remaining concerns.

- ## expressed the need for at least an early access for authorities to the notifications before the publication in the data platform, and possibly early access to operators.

→ PRES invites **COM to react** and **MS to express the need for amending** the text on this.

- ## questions the effectiveness of national sanctions

→ PRES invites **COM to react** and **MS to express the need for amending** the text on this.

B) PRESIDENCY PROPOSALS ARTICLE PER ARTICLE AND REACTIONS FROM MS AND COM TO BE PROVIDED IN WRITTEN

MS delegations and COM will be requested to send in written, article per article, comments and possible amendment texts using the table provided here below, at the latest by Friday 22 March 2024, 1 pm, on the basis of which the Presidency will decide on the follow-up and topics to be discussed at the next Working Party meeting, scheduled for the 12th of April 2024.

	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 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 data37, 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 Act38 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	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 2nd WP	Discussed at 2nd WP

	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.		
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 Council39, 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 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 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.		
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 Council44. 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	## propose to include SSBD (safe and sustainable by design) as one of the roles for the platform. à PRES propose to work on an amendment introducing explicitly the safe and sustainable by design approach as one of the aims.	Since the SSbD framework assesses safety and sustainability throughout the chemical life cycle, the proposal provides provisions enabling the inclusion of datasets generated through implementation of the SSbD framework. In particular, the establishment 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.		the repository of the environmental sustainability data will allow for the inclusion of data on environmental sustainability impacts along the entire chemical life cycle, generated by means of a life cycle assessment ('LCA'), in line with the SSbD framework. This is also reflected in Article 1(1) which uses the wording 'to enable the development and use of sustainable chemicals', and as such, the Commission does not see a need to make any further amendments in this regard.
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	• ## request amending art.2 to clarify the meaning of "product" in this proposal. • ## query what is covered by the term "products" in art.7(1) • ## 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.	The term 'products' would cover substances, mixtures and articles, as well as 'complex products'. Within REACH terminology, we would normally refer to 'articles' or 'complex product' made of multiple articles. However, since this term does not exist under product legislation – Cosmetics, Toys, Detergents etc, we have opted for 'products', to have the widest possible coverage. As the PRES points out, not all occurrences refer to a particular regulation, and occurrences may have overlapping (as well as differing) meaning. In order to avoid confusion or setting unwarranted precedents with regard to potential discussions under individual pieces of legislation, COM suggests refraining from establishing a definition in this proposal, and providing further explanation e.g. in guidance.
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;	• ## 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.	COM agrees with PRES understanding and confirms that there is no need for amendment

		→ 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;	• ## 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.	In the case of reference values without a toxicological threshold, the statistical cancer risk will need to be provided in the context data (cfr Article 5(2) and Article 4(4)(c)). This will be specified in the implementation phase/governance scheme. COM does not see the need for amendment in Article 8. If really considered necessary, a clarification in Article 3 could be foreseen to ensure that context data at large, i.e. not only for reference values, is also accessible through the platform.
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:	• ## 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	The proposal outlines the types of data that should be considered as environmental sustainability related data. However, it is important to note that there are various initiatives, such as the Commission Recommendation on "establishing a framework for safe and sustainable by design chemicals and materials" and the Corporate

		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 ## (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?	Sustainable Reporting Directive, which will also require reporting on environmental sustainability data. Therefore, to ensure that all relevant datasets identified for inclusion during the implementation phase can be considered, a certain level of flexibility is necessary. Indeed, the field of environmental sustainability related data is much less well established and defined than e.g. the field of chemical safety. Article 13(4) was also introduced in this regard: while COM at the moment does not have any specific examples in mind, Article 13(4) was introduced to have the flexibility to cover datasets that may currently be unknown but may be developed in a later stage.
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;	• ## 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.	COM agrees – 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 ~~Regulation (EU) 2018/175~~ ***Regulation (EU) 2018/1725*** of the European Parliament and of the Council;	• ## 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.	COM agrees – editorial amendment
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;	• ## 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.	COM agrees – 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.	• ## 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	Written response to ## provided in RCOM On APIs: For bringing data into the CDPC, ECHA is expected to work with data providers on setting efficient data flows supported by automated data tools. Different use cases for data in the CDPC may include support to the CDPC ecosystem through APIs, but specific solutions would need to be designed as API

		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.	application has implications in system demand and may deteriorate into data syphon for unauthorized data re-use. COM does not see the necessity to explicitly refer to API as one of technical means through which interoperability is exercised. They are certainly not excluded and it is expected that API will be part of CDPC toolbox box to support efficient integration of datasets by ECHA and data providers, and as support to the CDPC 'ecosystem' and both the authorities and general public user experience. However, decisions on specific functionality requiring an API solution are part of CDPC implementation.
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:	• ## 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. • ## question the differentiated approach between medicinal products and biocidal and phytopharmaceutical products.	• COM is not aware of any missing relevant regulations in the annexes • Discussed at 2nd WP

		→ PRESID would like to know if ## 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 chemicals data in accordance with Article 5, it shall make that data available through the common data platform without undue delay.	• ## requested clarifications on this paragraph (timing for the notification service, lack of specification of the timing for the rolling plans). • ## 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.	Discussed at 2nd WP
Article 4			

115	Article 4 Implementation plan and governance of the common data platform	• ## 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 ## meant to amend the listed regulations. • ## 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.	The amendment of the individual pieces of legislation listed in the Annexes is beyond the scope of this proposal. We are not harmonising individual procedures, but merely giving a legal basis for assessors to use data contained in the CDPC. We consider this to meet the intended objective. COM does not support the proposed amendment. Questions on implementing powers discussed at 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.	• ## 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.	Questions on implementing powers discussed at 2nd WP
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.	• ## 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.	COM agrees- 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.	• ## ask if Commission pursue plans for systematic or regular surveys of indoor air quality data → PRES is requesting written comments on this.	Response provided in written RCOM
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 proposes to set this as a discussion point at the 2nd WP (8/3), and invites MS and the COM to react to the EDPS recommendations.	Discussed at 2nd WP
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***	• ## 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)	COM sees merit in this amendment
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.***	• ## and ## 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. • ## 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	COM agrees – editorial amendment EDPS recommendations discussed at 2nd WP – amendments may need to be made following those recommendations

		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. • ## 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).	The term 'products' would cover substances, mixtures and articles, as well as 'complex products'. Within REACH terminology, we would normally refer to 'articles' or 'complex product' made of multiple articles. However, since this term does not exist under product legislation – Cosmetics, Toys, Detergents etc, we have opted for 'products', to have the widest possible coverage. As the PRES points out, not all occurrences refer to a particular regulation, and occurrences may have overlapping (as well as differing) meaning. In order to avoid confusion or setting unwarranted precedents with regard to potential discussions under individual pieces of legislation, COM suggests refraining from establishing a definition in this proposal, and providing further explanation e.g. in guidance.

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	• ## requested and amendment about the statistical (cancer) risk associated with some reference values. → PRES: see our proposal in art 2(6) here line 77	See previous response on contextual data
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.	• ## 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	While it is expected that enforcement will become principally evoked at the time of regulatory dossier submission/application, it is not excluded it might be of relevance before (i.e. implementation by CRO in MS, and of course processing of the application itself). MS will need to have access to the database on study notifications, already before a corresponding regulatory dossier is submitted (access likely with restrictions, i.e. limited to a specific regulatory dossier under scrutiny). 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. Amendment could be considered if helpful
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 ## 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.	Written response provided in RCOM + addressed at 2nd WP
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 ## comment that it is not clear whether the scope of art 10(1) includes national regulations processes.	Written response provided in RCOM + addressed at 2nd WP
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	→ PRES is seeking for written comments on ## request to clarify the COM reference (during the 1st WP) to voluntary notifications, including examples.	Written response provided in RCOM

	information available to the Union agency responsible under the respective Union act listed in Annex III without undue delay.		
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 ## question about which information EEA might have to make available to ECHA in this context, as EEA has no competences about chemical products.	Written response provided in RCOM
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	• PRES understand from ## comment that it is not	COM sees merit in amendment

	activity ~~, including, where applicable~~, ***and*** reports or opinions adopted;	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 ## comment on the potentiality of IA in this context.	Written response provided in RCOM + discussed at 2nd WP
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	• ## 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 ## question) → PRES include this in the discussion at the WP (effort needed by MS)	See previous response on first bullet point For second bullet point, written response provided in RCOM + discussed at 2nd WP
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 "implanting decision" (cfr ## comment). Council legal services will give an opinion on this at the 2nd WP.	Questions on implementing powers discussed at 2nd WP
Chapter III			
191	Chapter III DATA FORMATS AND CONTROLLED VOCABULARIES	→ PRES seeks written comments on ## request to eventually have study reports and raw data provided → PRES seek written comments on the request by ## 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.	Written response provided in RCOM
Article 14			
192	Article 14 Standard formats	• ## amendment proposal on statistical risk: → PRES: see here Article 2(6) line 77	See previous comment on this topic
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 234/2011[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 ## 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 ## 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)	Written response provided in RCOM
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: ## and ## comments here are to be discussed at the WP.	Discussed at 2nd WP
Article 16			
232	Article 16 Access rights and transparency	→ PRES: ## request and ## questions (line 232 of the comments file) are to be discussed at the WP	Discussed at 2nd 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: ## comments and ## questions are to be discussed at the WP (line 234 of the comments file)	Discussed at 2nd WP
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	• ## 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 ## 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	See earlier response to question on 'products' Written response provided in RCOM to other questions

		by ## •	
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: ## request for amendment to explicitly allow national use of the data is set for discussion at the WP.	Discussed at 2nd WP The possibility to use the data for implementation and policy development at national level is implied through the legal wording. COM does not favour the proposed amendment, as it would exclude use of data contained in the platform for e.g. policy making at international level
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.	• ## requested clarifications on the use of data in relation to duty holders obligations. → PRES invites for written comments on this.	Written response provided in RCOM
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	• ## question on MS involvement is set of discussion	Written response provided in RCOM +

	Framework of indicators	at the 2nd WP → PRES sets ## question on EIONET impacts for discussion at the 2nd WP. • ## comments on cosmetics: → PRES invites for written comments on questions raised by ## 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). • ## comment on the relation to existing statistics systems → PRES invites for written comments	discussed at 2nd WP
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 shall established, operated, and maintained by [OP: please insert date: 3 years after the end of the first***	• ## expressed concerns on the timescale for establishing the framework • PRES highlights that several other articles contain	The commitment to establish an Indicator Framework follows ongoing work on chemical indicators, which is almost completed. We

	calendar year after entry into force of this Regulation].	indications on the timeframe → PRES submits this amendment for consideration, and set this for discussion at the 2nd WP.	expect to publish the indicator framework in April 2024. COM does not see the need to include provision on timing.
Article 19			
244	Article 19 Early warning and action system for emerging chemical risks	→ PRES: ## question on MS experts and RAC involvement is set for discussion at 2nd WP → PRES: ## request for clarification on implications/role of EIONET and MS is set for discussion at the 2nd WP • Regarding the other comments: → PRES seeks written comments about ## question on the relation between the indicators and the early warning system (art.18,19). → PRES invites for written comments on ## question about the level of ambition of the system in relation to complex systemic risks. → PRES invites written comment on ## proposal to include the word "prevention" in the proposal	Written responses provided in RCOM + Discussed at 2nd WP The early warning and action system will complement the implementation of EU legislation on chemicals by adopting a proactive and systemic approach to identifying emerging chemical risks. The system will be developed progressively, initially relying on existing early warning systems and signals, national warning systems, targeted literature searches, etc. Chemical indicators may serve as a basis for early warning signals, but other signals will also be considered, such as new scientific knowledge leading to a more critical risk assessment, industry data, or biological signals, where the cause-effect relationship is not always evident. The provisions included in Art.19 explicitly state that the Commission, relevant Union agencies, and Member State competent authorities will consider the need for regulatory or policy action related to the early warning signals, implying that preventive action can be taken if deemed necessary. Therefore, the inclusion of "prevention of emerging risks related to chemicals" would be redundant in this context.
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.	• ## 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	COM notes that proposed wording is strengthening the obligation.
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 ## 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.	• ## 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 modify article 20(2) consequently (see ***bold italic***). • ## request for amendments (implementing "decisions"). → PRES: questions on the meaning of "implementing", and MS participation are set for discussion at the 2nd WP.	COM agrees – editorial amendment Topic of implementing powers was discussed at 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	• ## 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. ## would like to know if commissioned animal studies will be notified → PRES requests written reactions and proposals on this matter. • ## expressed the need to frame the mandate in such a way that the burden of proof on companies	• COM agrees with Pres' understanding. • With regard to notification of animal studies under data generation mechanism, strictly legally speaking, there is only an obligation on business operators to notify studies they commission. The primary objective is to avoid the withholding of results by business operators. If the idea would rather be to create an overview of studies commissioned, and an obligation on ECHA to notify were to be included, by extension it would only be logical to extend this

		is preserved. ## 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. → PRES schedule a discussion on this at the 2nd WP	obligation also to Member States and the COM. This would be disproportionate in relation to the objective. COM is not in favour of this amendment. • Written response provided in RCOM. COM does not see a need for amendment • Discussed at 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.	• ## requests clarity on the meaning of scientific studies, and which one will not be covered. → PRES invites for written comments on this	Written response provided in RCOM
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.	• ## suggests to amend this to introduce compulsory prior MS consultation.	COM does not see the need for such amendment. EFSA does not have any such legal

		→ PRES schedules this for discussion at the 2nd WP	obligation for the studies they commission.
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 2nd WP	Discussed at 2nd 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	• ## expressed concerns on enforcement for third countries; ## questions the effectiveness of national sanctions. → PRES schedules this for discussion at the 2nd WP	Discussed at 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)~~	• ## 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).	COM agrees
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 andveterinary 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 Council[3]; 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 Council[4]. [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 relevantprocedures that are concluded after the date of entry into force of this Regulation. Whererelevant, the data held by the EMA resulting from procedures concluded before the entry intoforce 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 followingArticle 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 relevantprocedures that are concluded after the date of entry into force of this Regulation. Whererelevant, data held by the EMA resulting from procedures concluded before the date of entryinto 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 toall 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)~~	• ## and ## 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).	COM agrees
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].		