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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Ad hoc Working Party on One Substance One Assessment
N° Cion doc.:	ST 16973/23
Subject:	OSOA Package: AHWP on 8 March 2024: Proposal for a Regulation as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals - Presidency's steering note - CALL FOR COMMENTS

With a view to the above Ad Hoc Working Party, delegations will find attached the Presidency's steering note together with its Annexes.

Delegations are invited to send written comments and possible text suggestions on all articles using the table provided in ANNEX II, to the Presidency ([REDACTED] , [REDACTED])

copying the Commission ([REDACTED] , [REDACTED]) and [REDACTED]) and the Council Secretariat ([REDACTED] , [REDACTED])

and environment@consilium.europa.eu) at the latest by **Friday 22 March 2024 at 13h00**. On the basis of which the Presidency will decide on the topics to be discussed at the next Ad Hoc Working Party meeting, scheduled for the 12th of April 2024.

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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)

Presidency Steering note
Ad Hoc Working Party on One Substance One Assessment (WP2) – 8 March 2024

On 7 December 2023, the Commission launched proposal 2023_783_1 as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals. At the meeting of the Ad Hoc Working Party on One Substance One Assessment on 23 January 2024, the Commission presented its proposal. Delegations had the opportunity to ask questions and to express their initial views on the text. Afterwards, delegations were invited to send in written comments by Friday, 23 February cob. **The comments received from the Delegations can be found in Annex I to this steering note.**

On 08 March 2024, the Ad Hoc Working Party on One Substance One Assessment will examine the proposal in more detail. **The discussion will be structured into three blocks of debate:**

1. Resources: ECHA's capacity (budget, workload, committees, expertise on waste, medical devices, ...); impact of the proposal on Member States (Amendments to Regulation (EC) No 401/2009; impact of Eionet involvement. This point will be handled transversally over the three OSOA proposals.
2. Diverging scientific opinions between Agencies (Amendments to Regulation (EC) No 178/2002, Article 30)
3. POP regulation (Amendments to Regulation (EU) 2019/1021):
 - a. Changes to the POP Regulation , including questions regarding potential changes to article 4 of the POP Regulation and a request for ECHA to also be given the task to determine limit values amending Annex I and not only Annexes IV and V
 - b. Participation of Member States in the processes described in the proposal and the choice and implementation of delegated acts. (Articles 15,18 of POP Regulation)

Based on the MS comments received after WP1, Presidency presents in **ANNEX II**, for MS and COM consideration, a **table indicating article per article the proposals for amendment, requests for further written comments, and points for discussion at the 2nd WP.**

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)



Annex I to the Steering note:
WRITTEN COMMENTS FROM THE MS AFTER THE 1st WP for
consideration at the OSOA AHWP
8/3/2024

Line nr.		Original COM text	Questions/Comments
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:	Welcomes the proposal: • SI: welcomes all three legislative proposals introduced by the European Commission for ensuring "One Substance, One Assessment" approach. With that, more efficient consolidation of technical and scientific work in the area of chemicals will be ensured. • AT: generally welcomes the overarching aim of the OSOA package to achieve a more efficient use of data and synergies in the work of the various EU agencies. • NL: We welcome the implementation of the one substance, one assessment approach of the Chemicals Strategy for Sustainability. We think that improving the cooperation among EU agencies can contribute to the goals of the one substance, one assessment approach. • DE: We support the Commission's goal of improving the coherence, consistency and efficiency of chemicals assessment. • FR: The French authorities thank the European Commission for the presentation of its proposals during the last group and wish to reiterate their support for this initiative aimed at rationalising the work between the European agencies involved in the evaluation of chemicals. • PT: We support the initiative of this legislative package, considering it as an important step towards the objectives set up in the "Strategy for the Sustainability of Chemical Products" (CSS) such as the simplification and consolidation of the EU's comprehensive and complex chemical products regulatory framework. • PT: We also believe that this initiative will contribute to improve overall coherence, quality, efficiency and transparency of the safety assessment of chemicals across the legislation, as well as to strength confidence in the scientific basis of the EU decision-making process in the field of chemicals.

			• IE : We support that the legislative proposal needs to provide for the Agency to provide the Member States and the institutions of the Community with the scientific/technical advice relating to chemicals. However, we are not convinced that the proposal to assign this responsibility to its RAC and SEAC, which were established initially for the purpose of REACH, is the right approach. • SI: commend the Commission's attempt to enhance scientific reliability and ensure coordinated procedures based on methodologies defined by the REACH regulation, managed by the ECHA agency. We believe it reflects ECHA and EU aspirations and strategy to become and remain a centre of knowledge and data on chemicals. These data should be utilized across a wide spectrum of EU chemical management. The proposal is an important step towards improving the efficiency and functioning of the EU in all fields of chemicals management. Scrutiny reservations: • SI,AT,DE + DK general parliamentary scrutiny General comments: • SI: However, we emphasize the need to ensure favourable working conditions for ECHA, especially regarding its long-term, independent, and sustainable funding. • DE: Most of the proposed task allocations relate to the European Chemicals Agency (ECHA). In addition to the OSOA package, other tasks have been transferred to ECHA over the last years (e.g. under the Batteries Regulation, Waste Framework Directive and the Drinking Water Directive). We are concerned if ECHA will be able to fully accomplish all its already existing tasks and its new tasks which will also at least partly require new expertise at ECHA. We are particularly concerned about
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			the expected additional workload for ECHA's scientific committees, namely the Committee for Risk Assessment (RAC) and the Committee for socioeconomic analysis (SEAC). • ES: Just like other member states already expressed in the past meeting on January 23rd, the Spanish delegation has the following concerns regarding the necessary expertise and financial capacities for ECHA to absorb the new tasks assigned to it. We would like to know if the Agencies to which more tasks will be assigned will have sufficient budget to carry out these modifications. This should include not only the training of existing personnel but also the possible hiring of new expert staff to meet the new demands, the ability to fill future positions with the necessary specialized personnel, and financially assuming the training of this new staff are critical considerations. It is essential to evaluate the financial viability of the adaptation and training process within the agreed budget framework. Additionally, efficient strategies must be considered to ensure that agencies and entities in the industrial sector can effectively and sustainably cope with these changes, thus ensuring the continuity and improvement of their functions in the scientific and technical field in the chemical sector. Regarding the budgetary aspect, another fundamental issue would be the adequacy of financial resources to carry out the technical modifications, infrastructure changes, and information technology required to implement the proposed change. It is imperative to evaluate whether the allocated budget will comprehensively cover the costs associated with the required technical transformations.
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			In this context, it is necessary to consider expenses related to updating or acquiring information technologies, as well as the costs associated with improving or implementing infrastructure relevant for the effective execution of the new work dynamics. Additionally, potential additional costs arising from personnel training in the handling of new technologies and processes must be taken into account. The detailed evaluation of technical and infrastructure requirements, along with the corresponding budget allocation, is essential to ensure that the transition process is efficient and successful. This involves analyzing the available financial capacity and ensuring that funds are allocated appropriately for each critical component of the proposed change, thereby mitigating potential economic challenges during implementation. • IE : The reattribution of tasks will directly affect different EU agencies. We note the re-attribution of tasks to ECHA and its Committees, and in particular to RAC and SEAC, in this legislative proposal. While we acknowledge the Commission's thinking on possible benefits of the proposal, we are mindful of the consequences of it, particularly on the ECHA committees, which is a consequence for the Member States and their resources. While there are consequences for ECHA, the greatest and most significant impacts on ECHA's Committees will fall on the RAC and SEAC members nominated by Member States. The impact of assigning tasks directly to the ECHA Committees results in the tasks actually being re-attributed to the Member States to complete, as it is the Member States who nominate experts to the committees and supports those experts with advisors. The mandate of the RAC was extended in 2008 to include opinions on harmonised classification and that classification
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			workload has now been further extended with the introduction of new hazard classes in CLP in 2022/3. The RACs mandate was further expanded again to occupational exposure limits under occupational health and safety legislation and limits for drinking water, despite the REACH legislation only providing for two expert nominations per Member State. We acknowledge that the Committee membership is not at full capacity. However, the assigning of additional tasks to the Committee may in fact discourage further uptake by new members of the existing vacant positions, as experts do not have the technical competence in the newly assigned areas. We feel membership would be encouraged by allowing a greater number of experts to cover different aspects of ECHA's opinion making tasks. In some instances, we believe it would be more appropriate to assign the task(s) to prepare 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 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. • IE: It is our preference 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. We note from the presentation given by the Commission on January 23rd that the expected impact of the reattribution of tasks on the ECHA committees is that RAC will need to deliver 79.7 opinions per year, with SEAC delivering 50.2. This is a very large number of opinions expected to be delivered from the two committees, especially given the extremely high workload of those committees presently, combined with the expectation that RAC may get even busier with CLH work in light of the new CLP hazard classes.
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			• IE : We recall a presentation given by the RAC chair to the CARACAL meeting in November 2023, in which it was indicated that the RAC meeting days have increased from about 30 meetings days per year in 2015 to about 50 per year currently, also noting that with the current members, committee production cannot be increased. It was a similar story from the SEAC chair, who noted a falling number of regular members since the peak in 2015 and difficulties in filling co-opted members slots. Like the RAC chair, the SEAC chair indicated that with current membership, it is not possible for the SEAC to increase capacity. Request • IE : Like other Member States our concern is with the capacity of the individual members to deliver on this expected workload, even if both Committees were at full capacity. Therefore, we 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 request from the Executive Director. Finally, the inclusion of remuneration for Committee rapporteurs for all tasks needs to be provided for. • IE : We also recommend the OSOA legislation package amends Article 85 & 87 of REACH to provide for additional experts to cover the additional work and its associated remuneration. Some possible changes are suggested below (see IE document) Questions: • NL: The establishment of a central data platform and re-attribution of tasks to EU-agencies do require the necessary infrastructure and resources. We request if the Commission can elaborate on how they will ensure that the EU-agencies are adequately equipped for the new tasks. • NL: Can the Commission confirm that the initial and the operational costs for all three proposals will be covered by already existing funding or does the Commission foresee that additional budgetary claims will follow?
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			• DE: How can it be ensured that ECHA and its Committees remain fully operational and can deliver the necessary high-quality scientific output in its existing and its new tasks? • DE: In that respect, does the Commission consider the proposed additional resources to be sufficient or which further measures could become necessary?
2	Recital 1	The European Green Deal¹ sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability² ('the Strategy') is a crucial delivery of the zero-pollution ambition and introduces the 'one substance, one assessment' approach, which aims to improve the efficiency, effectiveness, coherence, and transparency of safety assessments of chemicals across Union legislation. ¹Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal. COM (2019) 640 final. ²Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment. COM (2020) 667 final	
3	Recital 2	In order to achieve this objective, a part of the scientific and technical work on chemicals performed at Union level in support of Union legislation needs to be consolidated in the relevant Union agencies, while obligations on Union agencies to cooperate for the development of assessment methodologies and exchange of data and information should be introduced. This would	

		simplify the current set-up, improve quality and coherence of safety assessments across Union legislation and ensure more efficient use of existing resources.	
4	Recital 3	The reattribution of certain existing scientific and technical tasks to the European Chemicals Agency, as well as the attribution of new tasks, were proposed as part of ongoing revisions of Union acts. This horizontal proposal aims to provide for further attribution of tasks in respect of those Union acts which are not in the process of being revised and is necessary in order to ensure that the European Chemicals Agency is involved in tasks pertaining to its expertise and developed capacities on chemicals. This is in line with the ‘one substance, one assessment’ aim to ensure that technical and scientific work is performed by the appropriate Union agency, benefiting from demonstrated experience and established tools in its field. The proposal for a Regulation is accompanied by a proposal for a Directive for the amendment of Directive 2011/65/EU of the European Parliament and of the Council³, aiming to achieve the same objectives. ³Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency	
5	Recital 4	As part of the coordinated consolidation and attribution of tasks under the ‘one substance, one assessment’ approach, provisions to allocate a mandate to the European Medicines Agency to develop and cooperate on the development of	

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

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

		founding regulation, whilst such provisions are not relevant and applicable to the European Environmental Agency, since this agency does not issue scientific opinions on individual chemicals such as to be part in divergent outcomes.	
9	Recital 8	Correspondingly, this Regulation aims to address the eventual divergence between scientific opinions of the European Food Safety Authority and those of other Union agencies. Regulation (EC) No 178/2002 of the European Parliament and Council already contains provisions establishing a procedure to solve divergent scientific opinions. Those resolution procedures should be reinforced, in that the European Food Safety Authority and the other dissenting agency should be bound to make their best effort to resolve the divergence on general scientific issues, and only when they are not able to resolve the divergence, should they refer to risk managers.	
10	Recital 9	In the more specific case of scientific divergence pertaining to the hazard identification of chemical substances, a new procedure enabling the resolution of the divergence should be established. This procedure should enable the Commission to request the European Chemicals Agency, as the Union agency most equipped with expertise and capacity in hazard assessment, as well as long-standing experience with the harmonised classification and labelling process, to develop a proposal for harmonised classification and labelling, in accordance the Regulation (EC) No	

		1272/2008 of the European Parliament and Council, moving closer to the ‘one substance, one assessment’ vision as regards uniformity of hazard assessments of chemicals across the Union. This possibility should be reflected in the relevant provision providing for the resolution of diverging scientific opinions laid down in Regulation (EC) No 178/2002.	
11	Recital 10	To comply with the obligation laid down in Section 10.4.3 of Annex I to Regulation (EU) 2017/745 of the European Parliament and of the Council⁵, the Commission has provided the Scientific Committee on Health, Environmental and Emerging Risks (‘SCHEER’) with a mandate to prepare guidelines on the benefit-risk assessment of the presence of phthalates which are classified as either carcinogenic, mutagenic or toxic to reproduction category 1A or 1B, or which have endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁶. The SCHEER issued those guidelines in 2019 and the Commission has issued a mandate to the SCHEER to perform a first update of those guidelines. ⁵ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).	

		⁶ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1–849).	
12	Recital 11	To comply with the obligation laid out in Section 10.4.4. of Annex I to Regulation (EU) 2017/745, the Commission should mandate the relevant scientific committee to prepare guidelines for substances other than phthalates and which are classified as either carcinogenic, mutagenic or toxic to reproduction category 1A or 1B, or which have endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council.	
13	Recital 12	The European Chemicals Agency already provides scientific advice on chemical substances, including on phthalates, endocrine disruptors and carcinogens, mutagens and reproductive toxicants under Regulation (EC) No 1907/2006. Several key capacities of the agency can be reused, including hazard, risk, exposure and socio-economic assessment capacities, the Committee opinion development and IT capabilities for stakeholder consultation and dissemination. To enable timely	

		future updates on the presence of phthalates and to ensure that the appropriate Union agency develops new guidelines on other substances on the basis of the latest scientific evidence, these tasks should be attributed to the European Chemicals Agency.	
14	Recital 13	Taking account of the new hazard classes and criteria for classification, labelling and packaging of substances introduced by Commission Delegated Regulation (EU) 2023/707 of 19 December 2022⁷, reference to endocrine disruptors for human health, of Category 1, should be specified in 10.4.1., point (b) of Annex I of Regulation (EU) 2017/745 in light of the relevance of that hazard class to the type of substances in medical devices. ⁷ Commission Delegated Regulation (EU) 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures (OJ L 93, 31.3.2023, p. 7–39).	
15	Recital 14	To make best use of the European Chemicals Agency's knowledge and expertise gained through its involvement in the nomination and assessment processes under the Stockholm Convention on Persistent Organic Pollutants, the European Chemicals Agency should, upon request, assist the Commission in complying with its obligation to amend Annexes IV and V to Regulation (EU) 2019/1021 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 Council⁹ requires Member States to share with European Environmental Agency all chemical occurrence or monitoring data in water. Additionally, the monitoring data on the presence of POPs in air are already being reported by Member States to the EEA as part of the Union air quality legislation. The proposal for a Regulation of the European Parliament and the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable, and reusable and establishing a monitoring and outlook framework for chemicals¹⁰ will require all chemical occurrence data to be held by the EEA. As a result, chemical occurrence data provided to and held in IPCHEM by the Commission will thus be collected and held by the EEA, instead of by the Commission. Therefore, it is necessary to simplify the reporting obligations for Member States to ensure that, where Member States have already submitted that information to the EEA as part of fulfilling obligations required by the provisions of other pieces of Union environmental legislation, Member States should be considered to have fulfilled their reporting obligations under Regulation (EU) 2019/1021. ⁹ Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of	

		water intended for human consumption (recast), (OJ L 435, 23.12.2020, p. 1–62). ¹⁰ [OJ Please insert reference once proposal is adopted]	
19	Recital 18	Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 should therefore be amended accordingly,	
20	Articles	HAVE ADOPTED THIS REGULATION:	
21	1	Amendments to Regulation (EC) No 178/2002	
22		Regulation (EC) No 178/2002 is amended as follows:	
23	(1)	in Article 23, the following point (m) is added:	
24		‘(m) to cooperate with the competent bodies in the Member States that carry out similar tasks to those of the Authority and to cooperate with other scientific bodies established under Union law, notably the European Chemicals Agency, the European Medicines Agency, and the European Environment Agency on the provision of relevant scientific opinions, on the exchange of data and information, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and on the development of scientific methodologies for the assessment of chemicals.’;	
25	(2)	Article 30 is replaced by the following:	Comments: DE: It would be important to receive confirmation from the commission that the amendments of Article 30 are intended to steer the process of coordinating a uniform

			assessment. The actual EFSA procedure for risk assessments must not be changed as a result. Questions: • DE: It must be ensured that the assessments 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?
26		‘Article 30 Diverging scientific opinions	Questions: • DE: Could an example be given what would be considered diverging scientific opinion in the light of the intended new mechanism to resolve divergence?
27		1. The Authority shall take the necessary and appropriate measures to monitor and identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks.	
28		2. Where the Authority identifies a potential source of divergence, it shall contact the body concerned in order to ensure that all relevant scientific or technical information is shared and in order to identify the potentially contentious scientific or technical issues. The Authority and the body concerned shall cooperate to resolve the divergence. If the Authority and the body concerned are not able to resolve the divergence, they shall draw up a joint report. The report shall clearly outline the contentious scientific issues and identify the relevant uncertainties in the data and be made publicly available.	

		Where the body concerned is a Union agency or a scientific committee, the Authority shall present the joint report to the Commission.	
29		3. Where relevant, and where the divergence concerns conflicting scientific opinions of the Authority and another Union body or agency on whether a substance fulfils the criteria laid out in Annex I of Regulation (EC) No 1272/2008 of the European Parliament and of the Council ¹¹ , the Commission may request the European Chemicals Agency to prepare a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof following the procedure laid out in Article 37 of Regulation (EC) No 1272/2008. The Authority and the Union body or agency concerned shall co-operate with the European Chemicals Agency in developing that proposal.'.	
30		¹¹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353 31.12.2008, p. 1 – 1355.	
31	2	Amendments to Regulation (EC) No 401/2009	Questions: DE asks for clarification why the EEA's cooperation with the ECHA is supposed to be regulated in Article 15(5) of the EEA Regulation. Systematically, Paragraph 1 with a new letter c seems much closer. In addition, it would be clear that paragraph 4 also refers to this cooperation. Comments:

			• PT: The proposal amends Articles 2 and 15 of 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 (EIONET). The reason for this amendment stems, according to COM, from the fact that the current provisions do not give the EEA an explicit mandate or obligation to cooperate with ECHA, EMA and EFSA, and that it is necessary to strengthen the cooperation provisions in order to realise the ambition of one substance, one assessment. • PT: According to the explanatory memorandum, page 14, on collection and use of expertise – have been taken into account the contributions provided by the EU agencies concerned when assessing which tasks deserve to be re-attributed to EU agencies, how they should be assigned, as well as the potential effects on these agencies. In this context, we see as positive the strengthening of the co-operation between the Agencies, however, doubts remain about the impact of the Eionet Network's involvement in this cooperation.
32		Regulation (EC) No 401/2009 is amended as follows:	
33	(1)	in Article 2, the following point (p) is added:	
34		‘(p) to develop assessment methodologies related to chemicals in the fields falling within its mission.’;	
35	(2)	in Article 15, the following paragraph 5 is added:	
36		‘5. The Agency shall cooperate with other scientific bodies established under Union law, notably the European Chemicals Agency, the European Food Safety Authority, and the European Medicines	

		Agency, on the exchange of data and information on chemicals, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and on the development of scientific methodologies for the assessment of chemicals.’.	
37	3	Amendments to Regulation (EU) 2017/745	Questions: DE: It is intended that ECHA is given the task to prepare or update guidance on risk-benefit assessments in accordance with section 10.4.3. and 10.4.4. of Annex I to regulation (EU) 2017/745. How can be ensured that ECHA has the required medical device-specific expertise to fulfill this task?
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	Support: • PT: We support, in particular, the change of POP monitoring reporting to the EEA, thus allow for better organization and consolidation of information, as well as a more efficient distribution of tasks. • PT: Regarding the amendments to annexes IV and V of the POP Regulation, we agree in principle with the possibility given to COM to amend these annexes through a delegated act, once it is embodied in an impact assessment report, subject to consultation of interested parties and a SEAC opinion. We can also agree, in principle, with the attribution of the additional tasks on this matter to ECHA, as we believe that the procedures established at this level will ensure greater robustness in the decision-making process, being also aligned with the procedures adopted in other Regulations such as REACH and CLP. Request for amendments: • FI: It is proposed that the Article 4 of the POP-regulation ((EU) 2019/1021) 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. Comments:

			• NL: Regarding the Persistent Organic Pollutants Regulation we have the following remarks. With the new proposal, the Commission can request ECHA to prepare a report on the impact on human health, the environment, and social and economic impact of the introduction and modification of limit values for concentrations of POPs in Annexes IV and V to the Regulation. This new task also requires special expertise regarding the waste and recycling phase. The staff Commission document states that ECHA does not have this expertise at this moment. Could the Commission elaborate how ECHA will be equipped to enable sufficient knowledge on the impact of adjusting Annex IV values on the waste and recycling phase? • NL: We noticed that ECHA has been given the task to do the scientific assessment for determining the concentration limit values for substances in Annexes IV and V to the POP regulation, but not for determining the limit values in Annex I. Our suggestion is that in the spirit of 'one-substance-one-assessment' - assessments for amending Annex I should also be done by ECHA. • FI: While FI finds useful the utilisation of the expertise of the agency's Committee for Socio-Economic Analysis (SEAC), we express our reservations about whether the committee has enough expertise on waste management. Questions: •
49		Regulation (EU) 2019/1021 is amended as follows:	
50	(1)	Article 8(1) is amended as follows:	
51	(a)	the following point (i) is added:	

52		‘(i) upon request from the Commission, and within 12 months from that request, draw up and provide a report on the human health, environmental and socio-economic impacts of introducing or modifying concentration limit values specified in Annex IV or V.’	Proposed amendments: SE: draw up and ~~provide~~ submit a report. Comment: In this article the word ‘provide’ is used but in Article 8(1a) subparagraph three the word ‘submission’ is used. SE propose using the same word as in Article 8(1a) subparagraph three, since it refers to the same event.
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, point (i), publish on its website a notice that a report on a possible amendment of Annex IV or V will be prepared inviting all interested parties, including waste operators and users of recycled materials, to submit comments within 8 weeks. The Agency shall publish those comments on its website.	Proposed amendments: SE: referred to in Article 8(1) ~~the first subparagraph~~, point (i) Comment: Editorial proposal to change the reference, to clarify and to use the same kind of reference as is used in the paragraph above.
60		At the latest 9 months following the submission of that report, the Committee for Socio-economic	Proposed amendments:

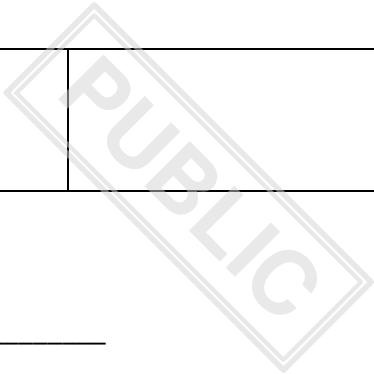
		Analysis of the Agency, set up pursuant to Article 76(1), point (d), of Regulation (EC) No 1907/2006 shall adopt an opinion on the report and on the concentration limit values proposed therein. For the purpose of adopting an opinion on the report, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.	SE: following the submission of ~~that the~~ report <u>referred to in Article 8(1), point (i)</u>, Comment: Proposal 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'
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:	Amendment request: FI: 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 a delegated act.
63		'2. Where a Member State shares the information referred to in paragraph 1, point (e), with the European Environmental Agency, that Member State shall indicate that in the report and the Member State shall be considered to have fulfilled its reporting obligations under that point.	
64		Where the information referred to in paragraph 1, point (e), is contained in the report of a Member State provided to the Agency, the Agency shall transmit the information to the European Environmental Agency for compiling, storing and sharing that information';	
65	(4)	in Article 15, paragraph 2 is replaced by the following:	
66		'2. The Commission is empowered to adopt delegated acts in accordance with Article 18, to	Proposed amendments:

		amend Annexes IV and V to adapt them to the changes to the list of substances set out in the Annexes to the Convention or the Protocol or to adapt them to scientific and technical progress.’	- SE: to amend Annexes IV and V <u>to this Regulation</u> to adapt Comment: Proposed amendment in order to clarify that the reference is to the annexes in this Regulation. Questions: - FR: The French authorities are in favour of Article 4(4) of the proposal allowing the Commission to adopt delegated acts to amend Annexes IV and V of the Regulation on persistent organic pollutants. The French authorities would like confirmation of the Commission's obligation to consult Member State experts before adopting such delegated acts, as appears to be provided in Article 18(4) of the POP Regulation. Discussions on the interpretation and implementation of these annexes should also be encouraged within this consultation body. - ES: Spain acknowledges the merits of maximising synergies and making best use of available expertise and resources in EU agencies. Nevertheless, regarding the proposal change for the procedure for amendment of Annexes IV and V (article 15) from ordinary legislative procedure to delegated act, Spain considers of high importance to preserve the expertise of the Meeting of the Competent Authorities for Regulation (EU) 2019/1021 on Persistent Organic Pollutants. We would like to know in which stage of the future amendments of the annexes the experts from the competent authorities will be consulted. Also, if additional POP experts from Members States will be incorporated to the SEAC and/or the RAC. Comments: - FI: While FI generally supports the one substance, one assessment policy target, we believe that the delegation
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			of legislative powers to the Commission in POP-regulation Article 15 needs further consideration. • FI: sees the role of the POP-CA (competent authorities) very important in preparation of the delegated acts. In case the above described amendments [BE PRESIDENCY: see FI proposed amendments for art.4 and 13.2 of POP regulation] would be accepted, what would be the role of the POP-CA in the future? Would the Commission still consult the experts designated by each Member State and closely collaborate with POP-CA before adopting a delegated act?
67	(5)	Article 18 is amended as follows:	Request for amendments: <i>DK: Concerning the proposed amendments of Regulation (EU) 2019/1021, article 18, we do not agree to the proposed text, and suggest no changes are made concerning article 18.</i> It is important that the procedure for amending Annexes IV and V on the limit values for POP-substances in waste remains subject to the general legislative procedure. These amendments will have a significant influence on the regulation of the most dangerous environmental pollutants, including balancing the promotion of circular economy and the need to phase out particularly dangerous environmental toxins from material flows for recovery. We recognize that the use of delegated acts is likely to benefit the speed at which limit values will be updated. However, we maintain that speed in the process cannot compensate for the fact that this is an important provision, and that it is of particular importance that EU citizens are directly involved in the EU decision-making procedure and we do not wish to delegate this regulatory authority to the Commission.
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	Comments:

		the Commission for a period of five years from 15 July 2019.’.	NL: We notice that the authority delegated to the ECHA in art. 18 part 2 is delegated for aa period of five years, starting on the 15th of July 2019. This five-year term is very likely to have passed before the proposed delegation of authority takes effect. Therefore, we suggest adjusting the period in order to have effect in practice.
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	
75		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	



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)



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

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

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

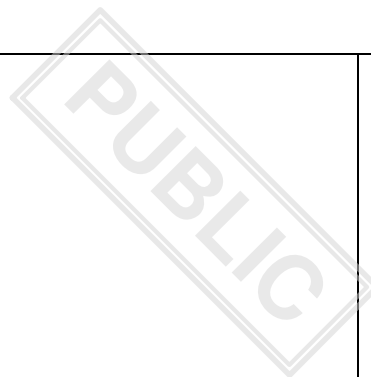
		proposed as part of ongoing revisions of Union acts. This horizontal proposal aims to provide for further attribution of tasks in respect of those Union acts which are not in the process of being revised and is necessary in order to ensure that the European Chemicals Agency is involved in tasks pertaining to its expertise and developed capacities on chemicals. This is in line with the ‘one substance, one assessment’ aim to ensure that technical and scientific work is performed by the appropriate Union agency, benefiting from demonstrated experience and established tools in its field. The proposal for a Regulation is accompanied by a proposal for a Directive for the amendment of Directive 2011/65/EU of the European Parliament and of the Council³, aiming to achieve the same objectives. ³Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency	infrastructure requirements and training), workload, committees, expertise to take on the extra tasks. This relates amongst others to the expertise of committee members (and not only the number of experts), potential establishment of technical expert groups (and how they relate to the Committees’ role), what is to be left for the founding regulation, potential targeted REACH amendments, ECHA and committees expertise in medical devices and in POP-waste. Some specific elements for discussion: IE proposes 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. IE prefers that the legislative package makes provisions for ECHA to prepare opinions in some circumstances without	
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			the explicit need for those opinions to be drafted by RAC and SEAC. IE 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 proposes a discussion on the elements raised above.	
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 Council⁵, the Commission has provided the Scientific Committee on Health, Environmental and Emerging Risks (‘SCHEER’) with a mandate to prepare guidelines on the benefit-risk assessment		

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

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

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

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

		Council, Member States must report to the European Chemicals Agency information on the presence of substances listed in Part A of Annex III in the environment. The use of the Information Platform for Chemical Monitoring ('IPCHEM') is encouraged as a means for Member States to comply with their obligations to report that chemical occurrence data and to simplify and reduce their reporting obligations. Where Member States make data available through IPCHEM, they no longer need to report it to the European Chemicals Agency, as the agency may retrieve it from the platform.		
18	Recital 17	The revision of the Directive (EU) 2020/2184 of the European Parliament and of the Council⁹ requires Member States to share with European Environmental Agency all chemical occurrence or monitoring data in water. Additionally, the monitoring data on the presence of POPs in air are already being reported by Member States to the EEA as part of the Union air quality legislation. The proposal for a Regulation of the European Parliament and the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable, and reusable and establishing a monitoring and outlook framework for chemicals¹⁰ will		

		require all chemical occurrence data to be held by the EEA. As a result, chemical occurrence data provided to and held in IPCHEM by the Commission will thus be collected and held by the EEA, instead of by the Commission. Therefore, it is necessary to simplify the reporting obligations for Member States to ensure that, where Member States have already submitted that information to the EEA as part of fulfilling obligations required by the provisions of other pieces of Union environmental legislation, Member States should be considered to have fulfilled their reporting obligations under Regulation (EU) 2019/1021. ⁹ Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast), (OJ L 435, 23.12.2020, p. 1–62). ¹⁰ [OJ Please insert reference once proposal is adopted]		
19	Recital 18	Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 should therefore be amended accordingly,		
20	Articles	HAVE ADOPTED THIS REGULATION:		
21	1	Amendments to Regulation (EC) No 178/2002		

22		Regulation (EC) No 178/2002 is amended as follows:		
23	(1)	in Article 23, the following point (m) is added:		
24		‘(m) to cooperate with the competent bodies in the Member States that carry out similar tasks to those of the Authority and to cooperate with other scientific bodies established under Union law, notably the European Chemicals Agency, the European Medicines Agency, and the European Environment Agency on the provision of relevant scientific opinions, on the exchange of data and information, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and on the development of scientific methodologies for the assessment of chemicals.’;		
25	(2)	Article 30 is replaced by the following:	Question were raised by DE 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 proposes a discussion on this issue	
26		‘Article 30 Diverging scientific opinions	DE requests an example of what could be considered diverging scientific opinions.	

			PRES proposes a discussion on examples.	
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	DE asks 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. PT has doubts about the impact of the Eionet Network's involvement in this cooperation.	
32		Regulation (EC) No 401/2009 is amended as follows:		
33	(1)	in Article 2, the following point (p) is added:		
34		‘(p) to develop assessment methodologies related to chemicals in the fields falling within its mission.’;		
35	(2)	in Article 15, the following paragraph 5 is added:		
36		‘5. The Agency shall cooperate with other scientific bodies established under Union law, notably the European Chemicals Agency, the European Food Safety Authority, and the European Medicines Agency, on the exchange of data and information on chemicals, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and on the development of scientific methodologies for the assessment of chemicals.’.		
37	3	Amendments to Regulation (EU) 2017/745	DE questions ECHA's expertise regarding medical devices.	
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	FI proposes 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 FI sees the role of the POP-CA (competent authorities) very important in preparation of the delegated acts. In case the above described amendments would be accepted, what would be the role of the POP-CA in the future? Would the Commission still consult the experts designated by each Member State and closely collaborate with POP-CA before adopting a delegated act? NL 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. NL also ask whether ECHA will have the knowledge on the impact of adjusting	
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			Annex IV values on the waste and recycling phase, while FI questions the knowledge of SEAC on waste management. PRES proposes amendments to be made to the proposal. Will ask the Commission if a change in the POP regulation (Article 8, "Tasks of the Agency and the Forum") is needed to assign ECHA to conduct scientific assessments or whether this is already covered by Article 8, points 1a or 1b.	
49		Regulation (EU) 2019/1021 is amended as follows:		
50	(1)	Article 8(1) is amended as follows:		
51	(a)	the following point (i) is added:		
52		‘(i) upon request from the Commission, and within 12 months from that request, draw up and ~~provide-submit~~ a report on the human health, environmental and socio-economic impacts of introducing or modifying concentration limit values specified in Annex IV or V.’	SE proposes to change ‘draw up and provide a report’ to ‘draw up and submit a report.’ PRES proposed a change to the text.	
53	(2)	Article 8(1a) is added:		
54		‘1a. The report referred to in Article 8(1), point (i), shall contain the following information:		
55		(a) as appropriate, information on human health and environmental impacts of		

		waste consisting of, containing or contaminated with POPs, including impacts on waste management;		
56		(b) information on concentrations and mass flows of POPs in relevant waste streams and on waste treatment and treatment capacities;		
57		(c) an analysis of the impacts of the different concentration limit values considered;		
58		(d) a duly motivated proposal for concentration limit values to be introduced in Annex IV and, as appropriate, in Annex V.		
59		The Agency shall, as soon as it receives the request referred to ~~in the first subparagraph~~ Article 8(1) , point (i), publish on its website a notice that a report on a possible amendment of Annex IV or V will be prepared inviting all interested parties, including waste operators and users of recycled materials, to submit comments within 8 weeks. The Agency shall publish those comments on its website.	SE proposed to change the reference, to clarify and to use the same kind of reference as is used in the paragraph above. PRES proposed change accordingly	
60		At the latest 9 months following the submission of ~~the~~ report referred to in Article (8(1), point (i)) , the Committee for Socio-economic Analysis of the Agency, set up pursuant to Article 76(1), point (d), of Regulation (EC) No 1907/2006 shall adopt an opinion on the report and on the concentration limit	SE 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'	

		values proposed therein. For the purpose of adopting an opinion on the report, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.		
61		The Agency shall submit the report and the opinion of the Committee for the Socio-economic Analysis on the concentration limit values to the Commission without delay.’;		
62	(3)	in Article 13, paragraph 2 is replaced by the following:	FI further proposed (Article 13 paragraph 2) that this provision would also introduce the adoption of amendments to Annexes IV and V by means of delegated acts. PRES requires further clarification from FI (potential text proposal).	
63		‘2. Where a Member State shares the information referred to in paragraph 1, point (e), with the European Environmental Agency, that Member State shall indicate that in the report and the Member State shall be considered to have fulfilled its reporting obligations under that point.		
64		Where the information referred to in paragraph 1, point (e), is contained in the report of a Member State provided to the Agency, the Agency shall transmit the information to the European Environmental Agency for compiling, storing and sharing that information’;		

65	(4)	in Article 15, paragraph 2 is replaced by the following:		
66		‘2. The Commission is empowered to adopt delegated acts in accordance with Article 18, to amend Annexes IV and V to this Regulation to adapt them to the changes to the list of substances set out in the Annexes to the Convention or the Protocol or to adapt them to scientific and technical progress.’	SE proposed the amendment in order to clarify that the reference is to the Annexes in this Regulation. PRES changed the text. FR 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. ES considers it of high importance to preserve the expertise of the Meeting of the Competent Authorities for Regulation (EU) 2019/1021 on POPs and would like to know in which stage of the future amendments of the annexes the experts from the CAs will be consulted and whether additional POP experts will be incorporated to SEAC and/or RAC. FI ask for the delegation of legislative powers to the COM in POP regulation article 15 to be further considered. FI sees the role of the POP-CA very important in the preparation of the delegated acts.	
67	(5)	Article 18 is amended as follows:	DK suggests no changes to be made to Article 18, they don’t want to delegate this regulatory authority to the COM.	

			PRES proposes to discuss this during WP2.	
68	(a)	The first sentence of paragraph 2 is replaced by the following:		
69		‘2. The power to adopt delegated acts referred to in Articles 4(3), 10(2) and 15 shall be conferred on the Commission for a period of five years from 15 July 2019.’.	DK 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 proposed to discuss this during WP2	
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.’.		

[illegible]