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Brussels, 16 May 2024

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**Interinstitutional files:**

**2023/0453 (COD)**

**2023/0454 (COD)**

**2023/0455 (COD)**

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**WK 7049/2024 INIT**

**LIMITE**

**ENV**

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## **CONTRIBUTION**

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From:	General Secretariat of the Council
To:	Ad hoc Working Party on One Substance One Assessment
N° prev. doc.:	WK 6848/2024
N° Cion doc.:	ST 16973/23, 16972/23, 16961/23 + ADD 1
Subject:	OSOA Package: comments from delegations

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Following the call for comments on the above set out with WK 6848/2024, delegations will find attached comments from DK, DE, EE, IE, IT, AT, SI, SE and the Commission.

## **DENMARK**

### **Ad hoc Working Party on One Substance One Assessment - The common data platform on chemicals**

Thank you for giving us the possibility to submit comments on the proposal for a regulation establishing a common data platform on chemicals. We appreciate the careful presentation of our comments.

Denmark will send further remarks on the issue regarding medicinal products.

#### **Confidentiality and data access/use**

In light of the previous discussions on Art. 17(3), Denmark suggests to delete article 17(3) to avoid any confusing regarding confidentiality rules of the respective underlying legislations.

#### **Involvement of the MS, delegated and implementing acts**

##### **Article 4 – implementation plan and governance and Article 13 - environmental sustainability**

Denmark still questions the added value of an implementing act in line 116, line 119 and line 190. These decisions are rather technical and does not benefit from an implementing act adopted in accordance with the procedure referred to in article 24a.

##### **Article 20 - observatory list**

In line 258, Denmark suggests to adopt the implementing acts in according to paragraph 2 of Article 24a, the advisory procedure, instead of paragraph 3, the examination procedure.

## **DENMARK**

### **Ad hoc Working Party on One Substance One Assessment**

#### **Remarks from Denmark to the revision of the RoHS Directive (2011/65/EU)**

Dear Presidency,

Thank you for giving us the possibility to submit comments again on the proposal for amending the RoHS Directive (2011/65/EU).

There has been developed a large number of guidance documents for REACH Annex XV and some of these could be relevant when assessing new substances under RoHS. We therefore suggest that in the preamble it should be noted that:

“ECHA can develop guidance to the new Annex IX under RoHS and, when applicable in this regard, reference can be made to the already available guidance for REACH Annex XV in respect of the specific aim of the RoHS Directive and the criteria given in article 6.1.”

This text will further assure the balance between the OSOA approach - as the guidance applied under the REACH-regulation will also be applied in relation to RoHS – and the aim of the RoHS directive to address hazardous substances in waste for electric and electronic equipment.

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## **GERMANY**

### **OSOA Package**

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

**15 May 2024**

#### **Written comments by Germany**

#### **RoHS Directive (ST 16972/23)**

#### **Re-attribution of Tasks (ST 16973/23)**

#### **Common data platform Regulation (ST 16961/23)**

DE thanks the presidency for the further opportunity to submit written comments. We have the following comments on the amendments of the RoHS directive, the Re-attribution of Tasks Regulation and the Common Data Platform Regulation which were partly already addressed in the ad hoc Working Party “One Substance One Assessment” on 13 May 2024.

#### **A) Proposal on a directive amending the RoHS Directive as regards the re-attribution of scientific and technical tasks to ECHA (comments refer to the PRES compromise text, WK 6525/2024 ADD 1)**

DE supports in principle the compromise text presented by the Presidency on 6 May 2024. We have the following comments:

#### **Review clause in recital (2a) and Article 1(5)**

DE is concerned about the increasing workload for ECHA and especially for ECHA’s scientific committees. Transferring more and more tasks to ECHA might lead to the situation that ECHA is no longer able to fulfill its core tasks. A proposal for the ECHA basic regulation is urgently needed. DE is still of the opinion that the problem is not addressed in the right way by adding this review clause. In our view the relevant aspects concerning workload, capacities and structures of committees go far beyond the tasks which are assigned to ECHA as part of the „One Substance One Assessment“. These aspects should be discussed more widely in the context of the ECHA basic regulation.

In addition, DE would also like to refer once again to the written comments of March 18, 2024 and April 19, 2024 regarding the proposals on **Article 1(1), point (b), regarding inclusion of article 4a (c), Article 5(6) and Article 6.**

- DE suggests inserting the following addition in **Article 1(1), point (b), regarding inclusion of article 4a (c):**

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

This would help to avoid misinterpretations, especially if contradictory information is received from interested parties during the consultations.

- Furthermore, DE asks to examine whether, in view of the complex and long supply chains, an extension of the transitional period in the event of rejection of extension requests could be useful (**Article 5(6)**).

- With regard to **Article 6**, DE advocates that the principle of "repair as produced" is guaranteed in general and in particular for new substance restrictions in order to ensure the availability of original spare parts for durable products even after further changes to the exemptions or substance restrictions granted.

**B) 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 (comments refer to the PRES compromise text, WK 6525/2024 ADD 2)**

DE thanks the Presidency for the compromise text submitted. We have the following comments on the Presidency's proposed amendments:

**Inserting a review clause regarding the Agency's governance and expanded workload to the Committees (recital 14A and Art. 21b):** see our comment above in the context of the RoHS directive.

**Article 15 of Regulation (EC) No 401/2009, not adding a new paragraph 5 but instead put this text in Article 15 par. 1(c). In addition some further clarifications were added to Article 15 of Regulation (EC) No 401/2009 (Article 2):** DE agrees and thanks for this amendment. From our point of view, this amendment regulates the cooperation between ECHA and EMA more clearly than in the original COM proposal.

**Article 8(1)(i) of Regulation (EU) 2019/1021 change the word provide to submit (Article 4 (1)(a)):** DE agrees.

**Article 8(1a) of Regulation (EU) 2019/1021 delete 'as appropriate' in point (a) (contrary to WP3 not in point (d)) (Article 4(2)):** DE agrees.

**Article 8(1a) of Regulation (EU) 2019/1021 change the reference from in ‘the first subparagraph’ to ‘article 8(1)’ (Article 4(2)):** DE agrees.

**Article 8(1a) of Regulation (EU) 2019/1021 change the reference from in ‘the report’ to ‘that report referred to in Article (8(1), point (i) (Article 4(2)):** DE agrees.

**Article 15, paragraph 2 of Regulation (EU) 2019/1021 was amended to clarify the delegated acts’(Article 4(4)). Please note that the impact assessment as discussed during WP3 is no longer in the text after discussion and commenting received. Delegations are invited to indicate whether they consider it appropriate to specify the framework for the delegation of powers to the Commission (part into brackets at the end of the Article):**

DE supports the deletion of the impact assessment.

In our view, the current state of science and technology should always be taken into account when adapting the POP limit values in Annex IV. We ask PRES to explain how the wording "on the basis of new scientific information indicating that the hazards and risks associated to a substance in waste have been underestimated" is to be understood. The substances in question are classified as POPs and must be disposed of in accordance with the provisions of Article 7 of the POPs Regulation. From our point of view, this wording is not absolutely necessary.

**Article 18 (paragraph 2) of Regulation (EU) 2019/1021 change of the starting date to the date of entry into force (contrary to WP3, the period is no longer prolonged from 5 to 7 years). Some additions were made to this paragraph (Article 4(5)):** DE agrees.

**Article 18 paragraph 6 of Regulation (EU) 2019/1021 the original last sentence is added to the paragraph (Article 4 (5c)):** DE agrees.

**C) 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 (comments refer to the PRES amendments in document WK 6525/2024 ADD 3)**

DE has the following comments:

**1) Personal Data Protection:**

DE supports the approach of presenting the purposes of the processing of personal data more specifically. This applies in particular to the changes in Article 6. In general, DE could support the block.

**2) Confidentiality and data access/use:**

DE thanks for the inclusion of the reference in Art. 17 (3) to the confidentiality rules of Art. 5 (3) and can support this wording.

### **3) Involvement of the MS, delegated and implementing acts:**

For implementation plan and governance scheme (Art. 4), DE is in favour of option b (i.e. the involvement of the MS via the advisory procedure under Art. 4 of Regulation 182/2011). DE supports the proposed reference to the examination procedure in the PRES compromise for the list of identified chemicals (Art. 20).

For Article 4, lines 116 and 119, DE prefers the text in square brackets (i.e. implementing decision through the advisory procedure).

### **4) Medicinal products data: scope and structure of the text:**

#### **Recital 8:**

DE does not agree to the statements in recital 8. We would like to point out that the assessment of environmental risks and hazards of active pharmaceutical substances is in our view comparable to that of other substances. In addition, active pharmaceutical ingredients can be environmental pollutants of particular concern. Several active pharmaceutical ingredients are relatively persistent and are therefore found in various environmental compartments. We do not agree with the restriction to "relevant" active substances and the definition of "relevant" in recital 8. In this context also Article 3 No 2a(b) should be deleted. The term "known high level of residues in the environment" is in our view too restrictive and ambiguous.

The listing of P-B-T properties is also insufficient in our view, as relevant hazardous properties such as vPvB, PMT, vPvM are missing.

#### **Article 3 No. 2a (c)**

It is unclear to us why medicinal products for human use should be treated slightly differently from veterinary medicinal products.

#### **Article 4 (2)**

For the pharmaceutical sector, it is essential to ensure that ISO IDMP (Identification of medicinal products) compatibility for the data platform and that the terms and IDs of the EU SRS (Substance Registration System) for pharmaceutical substances are used.

The Platform Steering Committee is responsible for establishing and managing the platform and also covers the topics of data management and standard formats.

At least, these important technical details should be defined by the Platform Steering Committee provided for in Art. 4 (2) (Implementation plan and governance of the common data platform) of the draft Regulation, with representatives of the authorities (ECHA, EEA, EFSA, EMA, EU-OSHA and the Commission) as a suitable body for detailed technical issues.

### **Article 26a**

We would like to reiterate that most medicinal products are not authorized through centralized procedures and therefore relevant data may only be available at the national competent authorities and not at the EMA. For this reason, we welcome the review in accordance with Article 26a. In order to take full account of the concerns raised in recital 8a concerning the presence of relevant data at national authorities only, it should be clarified in the review clause that the review should include all regulatory regimes listed in annex I.

Concerning medicinal products, established reporting channels via the national authorities to the EMA should be maintained as far as possible.

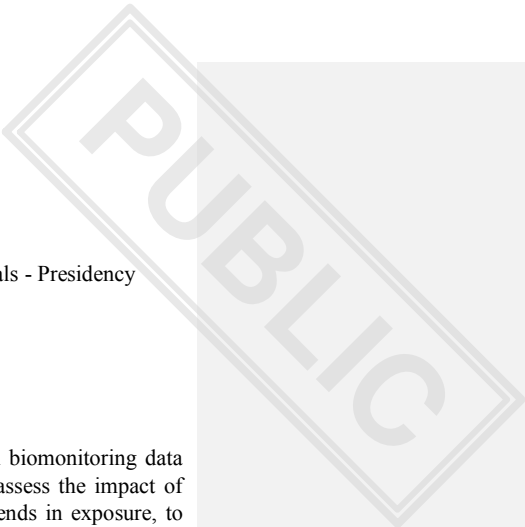
### **Article 3 No. 2a (a)**

The restriction to "relevant" procedures should be deleted for the submission of data from EMA to ECHA

### **5) Studies notifications and enforcement:**

DE can support the approach of the PRES in line 275, as the studies to be notified are adequately described there.

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**ESTONIA**

**Comments**

OSOA Package: Regulation establishing a common data platform on chemicals - Presidency compromise text  
WK 6525/2024 ADD 3

**Rec 32.c. new (24b)**

The EEA, ECHA, EFSA and the Commission should be able to process human biomonitoring data constituting personal data. The EEA should be allowed to process 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, risk management and policy making. The Commission should be allowed to ~~act as a processor for process~~ human biomonitoring data constituting personal data for policy making, for monitoring and assessing the effectiveness of measures by analysing, for example, co-exposure to multiple chemicals for which data on co-occurrence of various chemicals per individual is necessary to observe common patterns and draw conclusions for populations, and for research purposes supporting policy making. The ECHA should also be allowed to ~~act as a data processor for process~~ human biomonitoring data constituting personal data for the performance of assessments on chemicals, such as risk and safety assessments. Individual measurements of chemicals in human matrices may assist regulatory exposure and risk assessment, such as in the formulation of an opinion of the Risk Assessment Committee, and lead to recommendations of risk management measures. The EFSA should also be allowed to ~~act as a data processor for process~~ human biomonitoring data constituting personal data, notably to support the prioritisation of regulatory actions. Such data are also useful for EFSA when conducting assessments of chemicals in food and for understanding the effectiveness of existing measures in preventing human contamination through the food and feed chains. The Commission should also be allowed to process human biomonitoring data, notably to assess the impact of chemicals on human health and the environment, to support regularity risk assessment and risk management, and to support policy making. When processing human biomonitoring data constituting personal data, the EEA, the ECHA, the EFSA and the Commission should pay particular attention to compliance with Article 13 of Regulation (EU) No 2018/1725. *Personal data for human biomonitoring processed by the Commission and the Agencies shall not be stored and made available through the common data platform on chemicals.*

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**EE comment:**

We propose to add a sentence to make it clear that personal data is not processed on the common data platform. Furthermore, it needs to be clarified whether the Commission and the Agencies are acting as processors or controllers within the meaning of GDPR. If they are processing personal data independently for the purposes set in this Regulation (as defined in Art 6), they are to be considered as controllers. If they are processing data on behalf of another actor as processors, the controller for the personal data should be specified as well. Currently, there is a contradiction between this recital and Article 5(10) and Article 6 (9), which designates the Commission and the Agencies as controllers.

GDPR Art 4: (7) ‘controller’ means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided for by Union or Member State law; (8) ‘processor’ means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller;

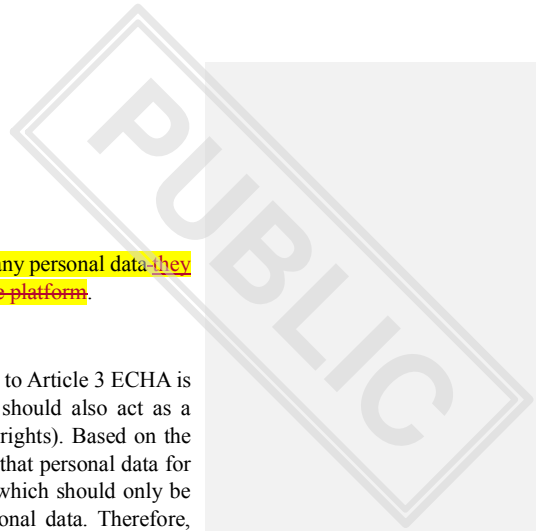
**Art 5 (10)**

136. a.new 10. The Commission and the Agencies shall act as data controllers for **any personal data they process for the purposes of human biomonitoring defined in Article 6 stored in the platform.**

**EE comment:**

It is not clear what kind of personal data is referred to in Article 5 (10). According to Article 3 ECHA is responsible for setting up and managing the common data platform and thus should also act as a controller for personal data necessary for these purposes (e.g to manage access rights). Based on the explanations given at the ad-hoc working party meetings, it is our understanding that personal data for human biomonitoring **is not processed and stored on the common platform**, which should only be used for making available anonymised data and not for processing HBM personal data. Therefore, reference to personal data stored in the platform should be deleted. According to Article 6(5) in the Commission proposal, the EEA shall make human biomonitoring data they hold or host publicly available in **anonymised form** through the Information Platform for Chemical Monitoring. The same should be specified also for the Commission and other Agencies processing personal data for human biomonitoring.

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## IRELAND

### Comments on One Substance One Assessment Legislative Package 15 May 2024

We thank the Commission for the opportunity to provide written comments.

Please find below IE comments on each of the 3 elements of the One Substance, One Assessment Legislative Package following the AHWP on 13 May 2024.

- (i) **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 and**
- (ii) **Proposal on a Directive amending the RoHS Directive as regards the re-attribution of scientific and technical tasks to ECHA**

IE notes the discussions at the meeting on 13 May on the horizontal issue relating to resources and governance of ECHA, and specifically the allocation of tasks to RAC and SEAC in these legislative proposals. While our preference remains to remove reference to specific ECHA committees in the legislative proposals, and instead to explore an alternative approach for ECHA to establish an expert group to peer review the opinions, we acknowledge the difficulties in implementing such an approach in the context of the legislative proposals, as discussed at the meeting. However, we support further exploring these issues in the context of the development of ECHA's Founding Regulation.

With respect to the introduction of a review clause (recital 2A and Article 24(3) of RoHS Directive and recital 14A and Article 21b for Re-attribution of tasks Regulation), we appreciate that the introduction of a review clause will provide the opportunity to review when ECHA has practical experience of managing all newly allocated tasks, in addition to existing tasks. However, it is not clear whether a review is triggered based only on tasks covered by this Directive/ Regulation or all tasks assigned to ECHA collectively across all legislation. We also consider that the review clause could be strengthened by being time bound, for example, that any review would be triggered 5 years after entry into force of both pieces of legislation. In addition we would suggest the review clause include provision for consideration of the members state resourcing of its Committees because the resourcing of ECHA is a separate matter to the resourcing by member states of ECHA's committees.

*"Taking due account of any regulatory developments concerning the status of the resources and the governance of the European Chemicals Agency and the resourcing of the ECHA Committees, the Commission shall monitor the situation regarding the tasks, workload and remit of the Agency and its scientific committees, and where necessary present a legislative proposal to amend accordingly this regulation."*

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

#### **Involvement of the MS, delegated and implementing acts**

With respect to the different options provided for in the PRES steering note for the 13 May meeting, we are generally in support of an Implementing Act with comitology. We are of the opinion that this could be the best option, at least in the initial few years of the implementation of this Regulation. A

review period after a certain period of time (e.g. 5 years) may be useful to determine the optimal operation of the procedures and if the comitology procedure is warranted.

We appreciate that where the proposal refers to an Implementing Act with comitology, it differentiates between the OSOA Expert Group and a Member State Committee (the latter having a different mandate to the OSOA Expert Group). We are of the view that if it is decided to proceed with comitology, then the roles of the 2 groups/committees will need to be very clear and opportunities to streamline the different groups as much as possible should be explored. This is also important seeing as it will likely be the same experts/representatives from Member States on these two groups regardless of the name of the group/committee or its mandate.

### **Medicinal Products Data**

IE acknowledges the amendments which seek to address previous input with the following specific observations:

Amendments to Recital 8 - certain aspects of the wording of the recital remain unclear (e.g. 'medicinal products with a known added value', 'a known high level of residues in the environment', 'active substances of concern').

Article 3(3):

- Interpretation of 'a known high level of residues in the environment' may be challenging.
- Article 3(3)a requires that the platform provide access to data submitted before entry into force of the Regulation. The relationship of this Article to the new Article 2a should be clarified as bullet point (a) of that article indicates that the common data platform shall provide access to data "that are held by EMA and submitted to EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation". This text would seem to be consistent with the revised text proposed for recital 9 and would limit the retrospective application of the common data platform with respect to active substances or medicinal products at least until a later stage. Clarity is needed in this regard.
- Article 3(11) states "...The relevant chemicals data, according to paragraphs 2, 2a, 3 and 3a, shall be integrated progressively into the common data platform, ...". Paragraph 3 lists information not to be included in the platform, therefore should be deleted from the text of Article 3(11).

We remain supportive in principle of the one substance one assessment approach, subject to appropriate consideration of the need appropriate assessment depending on the type of product in which the substance is to be incorporated. In principle we believe that it is important to ensure that the extent of data related to medicinal products to be included in the common data platform, does not go significantly beyond that originally proposed by the Commission.

### **Data generation and animal testing**

IE previously suggested alternative wording for this recital to remove reference specifically to data generated for 'human toxicity', since the principle of animal testing as a last resort, and the promotion of alternative methods, should apply to all types of data. We note the revised wording in the compromise proposal which in general we can support.

We suggest removing the final part of the added text however, since we consider it to be redundant:

“Where relevant and whenever possible, information generated through studies commissioned by the ECHA should be generated by means other than vertebrate animal tests, ~~through the use of alternative methods~~”

### **Studies notifications and enforcement**

IE previously suggested deleting the definition of “studies to be notified”. Therefore, we can support the removal of the definition from Article 2. We note the revised wording of Article 22(1), which we can support.

We previously proposed a revision to recital 28 to reflect the need for the development of guidance on the type of studies which require notification. We note that this suggestion was not taken up in the revised proposal. As there is now no definition of “studies to be notified”, the provision of guidance will be important for the successful implementation of this provision.

We therefore repeat our suggestion to amend recital 28 as follows:

“...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. **The ECHA should also develop guidance as to the type of studies requiring notification.** 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.”

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## ITALY

### OSOA Package

#### **1) Proposal for a Directive amending Directive 2011/65/EU as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency - Presidency compromise text.**

List of Italy's New Comments and Proposals for amendments, referred to the latest version of the proposals (ref. WK 06525)

Article 1(3a)(b) →: We propose to replace "experts" with "a group of experts designated by each Member States".

Article 1(4) → we support the proposed amendment.

Italy expresses: Positive scrutiny reservation

#### **2) Proposal for a Regulation on Union agencies in the area of chemicals.**

List of Italy's New Comments and Proposals for amendments, referred to the latest version of the proposals (ref. WK 06525)

Article 3(1) →: We propose to replace the word "identified" with "classified", as this is more consistent with CLP Regulation. Riteniamo importante allineare il linguaggio al regolamento CLP che ha individuato le nuove classi di pericolo sugli interferenti endocrini

Article 4(4) → We propose to delete the part in brackets at the end of the article, as the generic reference could be more inclusive. Motivation: it is considered more appropriate not to have the part of the text in brackets as this could potentially limit the field of action

About the delegation power to amend Annexes IV and V (ii) we wait for the new compromise's text.

Italy expresses: Positive scrutiny reservation

#### **3) Proposal for a Regulation establishing common platform on chemicals.**

List of Italy's New Comments and Proposals for amendments, referred to the latest version of the proposals (ref. WK 06525/2024 ADD 4)

#### **BLOCK 1) Personal data protection**

We support the lines 20, 23.a.new,32.a.new,32.b.new, 32.d.new, 88.b.new, 132, 136.a.new, 146.b.new, 146.c.new, 146.d.new, 146.e.new, 146.f.new, 148

**Line 32.c.new:** we would like to have an explicit indication on the kind of "common pattern", consequently we propose to rephrase "*common patterns and draw conclusion*" with "*common patterns of effect on human health and draw conclusion*".

**Line 148.b:** we suggest to substitute "*Article 6*" with "*this Article*" and to substitute "*article 6(9)*" with "*paragraph 9*".

## **BLOCK 2) Confidentiality and data access/use**

We support the lines 22,109, 113, 129, 233, 234, 235, 237,238,

Line 239 (Article 17). Taking into account that the article 17 regards the use of chemicals data contained in the common data platform, it should not mixed with the request to access data because this last one is already managed into article 3.10 that recall the reg. 1049/2011 (its article 4 “expectation to allow the access to the data” is relevant in order to decide what kind of data can be disclosed to satisfy the access request). Consequently, in order to balance the target to allow information to the public and the need to protect confidential information strategic for the company, we prefer the original formulation of the article 17 (“*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.*”).

*When making data used by the Authorities available to the public, information or data marked by the originator as confidential shall not be disclosed without prior consultation with the originator.”)*

## **BLOCK 3) Involvement of the MS, delegated and implementing acts**

Concerning the two options a) or b) about the scheme of governance we are flexible, anyway the Option a) provides a procedure that is certainly more streamlined than that provided for by option b), which involves a passage for the Committee of Member States

## **BLOCK 4) Medicinal products data: scope and structure of the text.**

We support the lines 16 (p.8), 17, 96a news

We support the deletion of Annex II and transfer of the regulations relating to medicinal products to Annex I

Concerning line 99 news : we express reserve to examination

## **BLOCK 5) Definitions and scope**

We support the lines 26, 27, 50, 88b.new, 89a, 114, 116, 164, 190, 249, 260

Line 99. We thank the Commission for the answering to our proposal on the modification 99 during the 4th meeting. Anyway we put under the attention that extract in aggregated form the information (by EUPCS category) where substances are used could support the implementation of chemical legislation (coherently with the article 17 and with the choice of indicative indicator under the article 18 to monitor the drivers of exposure to chemicals) that is a scope of the common platform.

About the possible annex IV we wait the new compromise text .

In this block 5) we deem opportune to put your attention also other lines where we prefer some modifications:

Line 14 (recital 6), in particular we propose the following modification

*“This increases the likelihood of inconsistency between various **sectorial risk** 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.”*

Motivation: The risk assessment of the various legislations should remain diversified, in relation to the different contexts in which is carried out, while the hazard assessment should be common and based on the whole shared data for all the European legislation.

Line 35 (recital 27), in particular we propose the following modification:

*“In order to ~~promote the use and harmonization~~ **increase transparency** 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” .*

Motivation: This suggested amendment intends to keep sectors-specific risk assessments (especially considering the animal testing ban in force for cosmetics).

Line 65 (**article 1.2**) - we propose the following modification : (a)bring together data and information on chemicals and ensure that data and information are easily findable, accessible, interoperable and re-usable **to a common hazard assessment;**

Motivation: the hazard assessment should be common and based on the whole shared data for all the European legislation while the risk assessment of the various legislations should remain diversified, in relation to the different contexts in which is carried out.

Line 82, article 2(11) - we propose the following modification: *“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.” .*

Motivation: This suggested amendment aims at keeping the focus on chemicals since this is the object of the Common Data Platform.

Line 189 (article 13.3) - Coherently with the previous proposal on line 82, article 2(11), we add the proposal: *” 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.”*

Line 212 (article 14.6) – we propose the following modification: *“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. **They shall also consult stakeholders.***

Line 228 (article 15.6) – we propose the following modification: “*The Commission and the Agencies shall cooperate with each other in setting the controlled vocabularies. **They shall also consult stakeholders.***”

Motivation for two previous proposals: Standard data formats and controlled vocabularies must be developed in consultation with stakeholders and especially the industry, as the expectation is that in the longer term the formats and vocabularies set by the Agencies will be used also for the submission of data by the duty holders under the individual pieces of legislation.

#### **Block 6) Data generation and Animal testing**

We support the lines 56 and 35

Line 270 (article 21.5) we suggest the following modification “5. The ECHA shall commission these scientific studies in an open and transparent manner including **a consultation of stakeholders and the public**”

Motivation: Before undertaking new scientific studies, it is important that all relevant information is taken into consideration, including on the methodologies of the study and to avoid potential duplication of work (include at global level). The industry has vast experience in designing scientific studies and with other stakeholders could share specific expertise on studies to be commissioned under the data generation mechanism

#### **Block 7) Studies notifications and enforcement**

Line 275: we agree with the deletion definition in article 2 and clarified in article 22(1) the kind of studies to be notified in relation to chemicals data anyway it would be helpful if it were possible to further identify which studies will be subject to the notification process (eg. a guidance or other kind of communication).

In addition, we think it might be useful to set a time limit for notifications. We suggest replacing “without undue delay” with “within one month” (or even more), where it appears in the article 22(1). Motivation a established time helps also the enforcement activity

Line 165 (art 9.3) we suggest the following modification “*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 **summary** in accordance with the applicable rules on confidentiality.*”

Motivation: Since not all sectorial legislations listed in Annex I have provisions on confidentiality or on access of the public to studies, this suggested amendment aims at limiting the disclosing of studies to ‘study summary’, to avoid free-riding and protect intellectual property rights of studies.

#### **“OTHER BLOCK” Early warning and action system for emerging chemical risks**

Line 255 (article 19.5) We would like to suggest an other modification “ **5. The EEA shall make all relevant **confirmed** 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. **To avoid confusion, data that is not a positive identification of an emerging risk as described in article 19.3 will not be included in the common data platform.**”**

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## **SLOVENIA**

**Comments on OSOA package (ST 16973/23, 16972/23, 16961/23 + ADD 1) as stated in a BE presidency document WK 6848/2024 INIT from May 13th, 2024**

### **1) Directive amending Directive 2011/65/EU as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency**

SI would prefer to have text without safeguard clause as we do not see real need for it.

In Article 6 we would prefer text without setting a defined timeline, i.e. »at least every five years«, instead word »occasionally« would be acceptable to us.

The reasoning behind is simple, as it can be that in ten years nothing happens or the frequency of events might be more regular to five year. We see no need in setting a time limit, which will also present additional administrative burden to the COM.

In the spirit of compromise we can support text from the Presidency.

### **2) Regulation on Union agencies in the area of chemicals**

SI is most concerned with regard to Annexes IV and V of POPs Regulation (replacement of second paragraph of Article 15). We understand the reasoning of the COM on changing those annexes with delegated acts and thus making the procedure faster.

However, in our view this is an essential element of EU POPs regulation with a political element and we see this as more than just a technical amendment. We would like to stress to approach this matter with more caution. In a current procedure concentration limits in Annex IV are adopted through ordinary procedure and not with delegated acts.

We believe that this proposed change goes beyond of what we are supposed to regulate with this regulation on Union Agencies.

Nonetheless, this is not a red line for us and we can support any compromise text from the Presidency.

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**Data platform**

	<b>PRES proposal</b>	<b>Sweden comments</b>
113	10. The Commission or Agencies <del>y</del> under whose authority chemicals data is included in the common data platform on chemicals shall remain responsible for handling any requests for access to documents made under Regulation (EC) No 1049/2001 <b><u>of the European Parliament and of the Council</u></b> <sup>2</sup> . 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).	10. The Commission or Agencies <del>y</del> under whose authority chemicals data is included in the common data platform on chemicals shall remain responsible for handling any <del>fr</del> requests for access to documents <b><u>shall be handled made under in accordance with</u></b> Regulation (EC) No 1049/2001 of the European Parliament and of the Council <sup>52</sup> .  Justification: The handling of requests of access to documents is regulated in Regulation (EC) No 1049/2001 and concerns both the institutions and the Member States. Sweden therefore proposes to include a general reference to the Regulation.
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 <del>referred to in Article 4(4), point (c).</del> <b><u>referred to in Article 4(5), point (c)</u></b> . <del>2a. The Commission and the Agencies shall indicate whether that data or information is made available to the public under the originating Union act shall not be made available to the public in accordance with provisions on confidentiality under the originating Union act.</del> <b><u>is confidential in accordance with provisions on confidentiality under the originating Union act.</u></b>	Sweden supports the proposed amendments.
232	Article 16 Access rights and transparency	
232.a.new	<b><u>XXX. The public shall have access to all the chemicals data contained in the common data platform, except data which is deemed to be confidential under Article 5(2), second sentence. To help the public understand the content of the data, the Commission can provide references to scientific publications and outreach.</u></b>	
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 a), <b><u>second sentence</u></b> .	
234	2. The Authorities shall take the necessary <b><u>security</u></b> measures to ensure that information contained in the common data platform marked as confidential in accordance with 5(2a), <b><u>second sentence</u></b> is not made <b><u>available to the</u></b> public.	Sweden welcomes the addition.
235	<del>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.</del> All chemicals data contained in the common data platform, excluding data which is deemed to be confidential under Article 5(2a), shall be made <b><u>available to the public</u></b> .	
236	Article 17 Use of chemicals data contained in the common data platform	
237	1. The Authorities may use the chemicals data contained in the common data platform in the	

	<p>performance of any of their activities, where those activities support the development, <del>or</del> implementation <b>or enforcement</b> of chemicals legislation and policy.</p>	
238	<p>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.</p>	
239	<p><del>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.</del></p> <p><del>When making data used by the Authorities available to the public, information or data marked by the originator as confidential shall not be disclosed without prior consultation with the originator.</del></p> <p><b><u>Where an Authority receives a request for data or information marked as confidential under Article 5(2) that the Authority is using, unless it is clear that the data or information shall not be disclosed, the Authority shall consult with the originator in order to take a decision that does not jeopardise the confidentiality of the data or information.</u></b></p>	<p>Sweden considers that the handling of requests of access to documents, originating from an EU institution and held by a Member State, is already regulated by Article 5 in Regulation (EC) No 1049/2001. Sweden can also conclude that the proposed Article 17(3) is more restrictive in comparison to Regulation (EC) No 1049/2001.</p> <p>In Article 5 of Regulation (EC) No 1049/2001 it states that: <i>Where a Member State receives a request for a document in its possession, originating from an institution, unless it is clear that the document shall or shall not be disclosed, the Member State shall consult with the institution concerned in order to take a decision that does not jeopardise the attainment of the objectives of this Regulation. The Member State may instead refer the request to the institution.</i></p> <p>Sweden therefore proposes to delete Article 17(3).</p> <p>However, Sweden consider that it should be clarified how the confidentiality of data which is used according to Article 17(1) shall be handled, and propose the following provision:</p> <p>When <b>an Authority is</b> using chemicals data contained in the common data platform that is deemed confidential under Article 5(2), second sentence, the Authorities <b>shall respect the confidentiality of information or data as marked by the originator, and</b> shall not disclose that data to the public without the consent <b>consulting</b> of the originator <b>in order to determine whether the information shall be considered confidential.</b></p>

## **COMMISSION**

### **Common data platform on chemicals – explanation on medicinal products data provided at the WP meeting on 13 May 2024**

COM understands the PRES proposal as follows:

- The original scope is maintained
- The scope is however presented in a different manner – by moving everything in Article 3 and Annex I and by removing the text in Annex II.
- A review clause was added to see whether the scope should be expanded in the future

#### **1. On scope**

COM welcomes the intention of the PRES to maintain the scope as in the original proposal. This is very important for us.

COM understands that it was not always clear to MS what scope exactly we proposed to cover and why. Therefore, we would like to provide some explanations.

When COM concluded on the scope for the original proposal, it took into account the following considerations:

- The application and use of hazard and risk assessments performed on them under Union acts on medicinal products is different from the application and use of hazard and risk assessments performed under the main Union acts on chemicals.
- Some data provided on pharmaceuticals are not useful for reuse by other agencies (e.g. efficacy data, pharmacovigilance data, etc).
- Medicinal data are not machine readable and are stored in PDFs, and their digitalisation requires a significant effort.

Because on this and in order to achieve the best possible balance between the administrative burden for the European Medicines Agency and the added value for Authorities of including chemicals data related to medicinal products in the common data platform, only chemicals data with the highest added value related to relevant active substances contained in medicinal products should be included.

When prioritising medicinal data for inclusion in the common data platform, the following aspects were considered:

- Only centrally authorised vs. all authorisations
- Human pharmaceuticals vs. veterinary medicines - revision of human pharma legislation is ongoing in parallel envisaging digitalisation of new submissions on human medicinal products
- Only those which are chemicals/substances vs. All (i.e. including vaccines)
- Legacy data vs. new data (i.e. submitted before vs. after entry into force)
- All data vs only some data - those with the highest added value for use by other agencies and authorities (i.e. environmental risk assessment data, non-clinical data and MRL data)
- Relevant substances - 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

This resulted in the following scope:

- New relevant non-clinical safety studies for human health medicines including environmental risk assessment data
- New relevant Environmental risk assessment data for veterinary medicine
- New relevant MRL underlying data - those pharmaceuticals that can end up in the humans
- New PNECs derived as part of the ERA for human and veterinary medicines

COM would like to emphasise that environmental risk assessment data are included both for veterinary and human medicinal active substances.

## 2. On presentation

**COM is not convinced that the PRES proposal is clearer than the original proposal.**

In fact, the PRES proposal may cause more confusion as the text becomes quite lengthy. In addition, moving some parts of the Annex II to the main legal text will distort the structure of the proposal, where the details of the scope are defined in the Annexes, which does not improve the clarity. In addition, defining the scope in the legal text has a consequence that if any changes to the scope need to be made in the future, this will (most likely) need to be done through OLP. COM prefers using a delegated act procedure, should any changes to the scope of medicinal data be necessary. This will allow us to act much more swiftly and operationally.

COM understands that there were some unclarities in the original proposal, and that these were mostly linked to inconsistent use of words. For example, the original proposal referred to medicinal products in one place and to active substances in another.

COM therefore proposes to maintain Annex II as was originally proposed and to **improve the recitals** explaining the reasons for treating medicinal data differently, to make the **wording in Article 3(2)(c) consistent with the wording in Article 3(2)(a)** and to consistently use the terminology on medicinal products vs. medicinal active substances as appropriate. Below, COM's text proposal is given.

## 3. On review clause

**COM is not in favor of the review clause.** The review is already envisaged by proposing the delegated powers for the Commission to amend Annex II, with particular focus on the legacy data (i.e. data obtained before the entry into force).

## 4. Additionally

COM notes that PRES has added **line 99.a.new**, which adds the clause: 'The common data platform shall also provide access to data submitted before the entry into force of this Regulation'.

- First of all, COM does not see a specific need for this, as the obligation for Agencies is to provide all the chemicals data that they have or hold. This will include legacy data. But if there is a strong desire to have this text explicitly included, COM is flexible on this.
- However, COM wonders how this provision relates to line 96.a.new, and point (a) thereunder, which describes the scope of medicinal data, and states that the scope is limited to data that is submitted after entry into force of this Regulation.

## COM text proposals:

### Recitals:

(8) While some medicinal products are also chemicals, the application and use of hazard and risk assessments performed on them under Union acts on medicinal products is different from the application and use of hazard and risk assessments performed under the main Union acts on chemicals. Because of this and in order to [achieve the best possible balance] [optimise the trade-off] between the administrative burden for the European Medicines Agency ('EMA') and the added value for Authorities of including chemicals data related to medicinal products in the common data platform, only chemicals data with the highest added value related to relevant active substances contained in medicinal products should be included. Relevant active substances 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. The specific chemicals data to be included for those relevant active substances should cover chemicals data related to environmental risk assessments carried out under Union legislation on medicinal products for human and veterinary use, non-clinical studies carried out under Union legislation on medicinal products for human use and maximum residue limit values the EMA holds, as well as specific reference values.

(9) **(this one is also taken up in PRES proposal)** Considering the format these data are in and the effort it would require to transform them into an appropriate format, for efficiency reasons, only data that is submitted to the EMA in the context of the relevant procedures that are finalised or submitted after the entry into force of this Regulation should be included in the common data platform. 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.

### Article 3(2):

The common data platform shall provide access to all chemicals data:

(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;

(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;

~~(c) listed in Annex II and held by the EMA;~~

**(c) generated or submitted for medicinal products as part of the implementation of the Union acts listed in Annex II to this Regulation and as specified in that Annex, Part 1, and held by the EMA;**

## ANNEX II

### UNION ACTS REFERRED TO IN ARTICLES 2, 3, 12, 17 AND 23 AND REFERENCE VALUES REFERRED TO IN ARTICLE 8

**Part 1** - Specific data on relevant active substances **contained in medicinal products and to be identified in accordance with Article 4(5)(b) falling under the scope of this Regulation to be included in the common data platform as referred to in for the purposes of Article 3(2)(c) for human and veterinary medicinal products**

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<sup>1</sup> and Regulation (EC) No 726/2004 of the European Parliament and of the Council;
2. Data related to environmental risk assessments, compiled pursuant to Regulation (EU) 2019/6 of the European Parliament and of the Council; and
3. Maximum residue levels data compiled pursuant to Regulation (EC) No 470/2009 of the European Parliament and of the Council.

These data shall be limited to data submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation. Where relevant, ~~the~~ data held by the EMA resulting from procedures concluded before the entry into force of this Regulation may also be considered for inclusion into the common data platform.

**Part 2** - Reference values to be included in the repository of reference values following Article 8(3)

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.

These data shall be limited to data submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation. Where relevant, data held by the EMA resulting from procedures concluded before the date of entry into force of this Regulation shall also be considered for inclusion into the common data platform.

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**COMMISSION**

PRESIDENCY REVISED COMPROMISE TEXT

**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**

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,

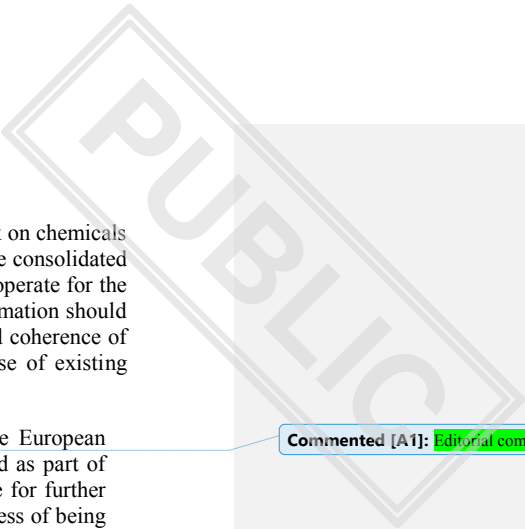
Whereas:

- (1) The European Green Deal<sup>1</sup> sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability<sup>2</sup> ('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.

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<sup>1</sup> 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](#).

<sup>2</sup> 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](#)



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- (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.
- (3) The re-attribution 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 Council<sup>3</sup>, aiming to achieve the same objectives.
- (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.<sup>4</sup>
- (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.
- (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

<sup>3</sup> 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.

<sup>4</sup> 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].

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.

- (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 led~~ 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.
- (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.
- (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 ~~with~~ 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.
- (10) To comply with the obligation laid down in Section 10.4.3<sup>5</sup> of Annex I to Regulation (EU) 2017/745 of the European Parliament and of the Council<sup>5</sup>, 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

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<sup>5</sup> 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](#)).

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<sup>6</sup>. 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.

- (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.
- (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.
- (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<sup>7</sup>, 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.
- (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<sup>8</sup>. 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

<sup>6</sup> 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](#)).

<sup>7</sup> 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](#)).

<sup>8</sup> 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](#)).

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.

**(14a) The amendment of Regulation (EU) 2019/1021 introduced by this Regulation expands the tasks, workload and remit of scientific committees of the European Chemicals Agency (ECHA), in particular of its Committee for Socio-economic Analysis. In order to provide adequate expertise, support and thorough scientific evaluations, appropriate and stable resources, capacity and governance of the scientific committees should be ensured. In this respect, it is appropriate to provide for a review clause to ensure that the Commission takes account of any future regulatory developments to the Agency's governance in order to revise, if necessary Article 8 of Regulation (EU) 2019/1021.**

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Commented [A7]: The COM prefers no review clause as it is not necessary. If the provisions governing the functioning of the committees are changed via new ECHA's basic act, then that act will also amend the other pieces of legislation (if necessary). For that reason we would propose to replace this text as follows:

**For that purpose, Regulation (EU) 2019/1021 should remain coherent with any future revision of provisions governing the functioning of the committees of the European Chemicals Agency. In accordance with any such revision, the Commission should assess whether an amendment of Article 8 of Regulation (EU) 2019/1021 is required.**

(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.

(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.

(17) The revision of the Directive (EU) 2020/2184 of the European Parliament and of the Council<sup>9</sup> 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 **European Environmental Agency (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<sup>10</sup> will require all chemical occurrence data to be held by the **European Environmental Agency (EEA)**. As a result, chemical occurrence data provided to and held in IPCHEM by the Commission will thus be collected and held by the **European Environmental Agency (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 **European Environmental Agency (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.

Commented [A8]: Editorial comment for consistency in green

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(18) Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU)

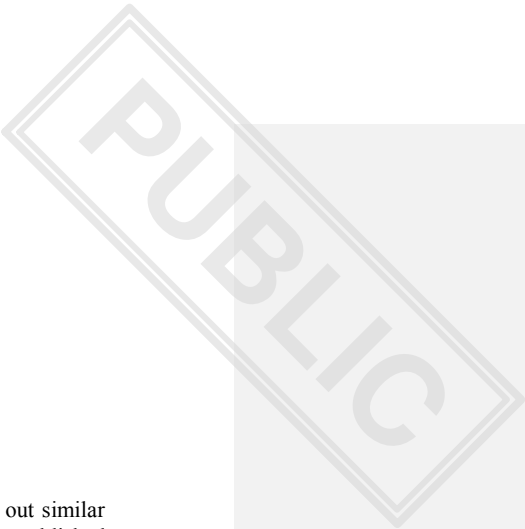
2019/1021 should therefore be amended accordingly,

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<sup>9</sup> 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](#)).

<sup>10</sup> [*OJ Please insert reference once proposal is adopted*]





HAVE ADOPTED THIS REGULATION:

*Article 1*

**Amendments to Regulation (EC) No 178/2002**

Regulation (EC) No 178/2002 is amended as follows:

(1) in Article 23, the following point (m) is added:

‘(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.’;

(2) Article 30 is replaced by the following:

*Article 30*

**Diverging scientific opinions**

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.
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.

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<sup>11</sup>, 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.’

## Article 2

### Amendments to Regulation (EC) No 401/2009

Regulation (EC) No 401/2009 is amended as follows:

- (1) in Article 2, the following point (p) is added:

‘(p) to develop assessment methodologies related to chemicals in the fields falling within its mission.’;

- (2) ~~in Article 15, paragraph 1 is amended as follows; the following paragraph 5 is added:~~

~~‘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.’~~

1. The Agency shall actively seek the cooperation of ~~the Commission and~~ other ~~Union Community~~ bodies and programmes, and notably the Joint Research Centre, the Statistical Office of the ~~Union European Communities~~ (Eurostat), ~~the European Chemicals Agency, the European Food Safety Authority, and the European Medicines Agency,~~ and the ~~Union’s Community’s~~ environmental research and development programmes. In particular:

- a. cooperation with the Joint Research Centre shall include the tasks set out in Annex I under A;
- b. Coordination with Eurostat and the statistical programme of the ~~Union European Communities~~ shall follow the guidelines outlined in Annex I under B;
- c. ~~cooperation with the European Chemicals Agency, the European Food Safety Authority, and the European Medicines Agency shall relate to 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 to on the development of scientific methodologies for the assessment of chemicals.~~

~~2. The Agency shall also cooperate actively with other bodies such as the European Space Agency, the Organisation for Economic Cooperation and Development (OECD), the Council of Europe and the International Energy Agency as well as the United Nations and its specialised~~

agencies, particularly the United Nations Environment Programme, the World Meteorological Organisation and the International Atomic Energy Authority.

3. The Agency may cooperate in areas of common interest with those institutions in countries which are not members of the Community which can provide data, information and expertise, methodologies of data collection, analysis and assessment which are of mutual interest and which are necessary for the successful completion of the Agency's work.

**(3) in Article 15, paragraph 4 is amended as follows:**

4. The cooperation referred to in paragraphs 1, 2 and 3 must ~~in particular~~ take account, amongst others, of the need to enhance coherence, synergies and to avoid any duplication of effort.

*Article 3*

**Amendments to Regulation (EU) 2017/745**

Annex I to Regulation (EU) 2017/745 is amended as follows:

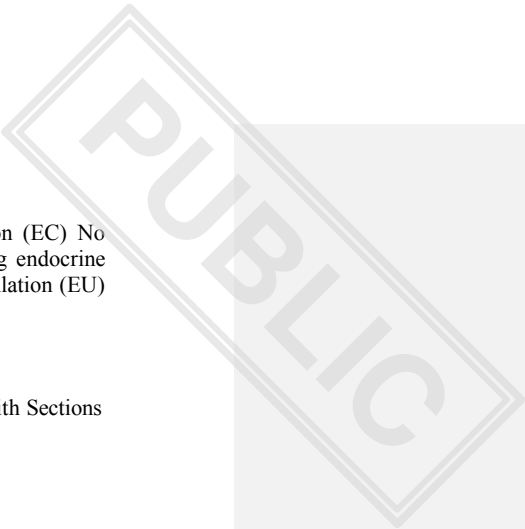
(1) in Section 10.4.1, point (b) is replaced by the following:

‘(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<sup>12</sup> and substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are

<sup>11</sup> 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](#).

<sup>12</sup> 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](#)

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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.’

(2) in Section 10.4.2, point (d) is replaced by the following:

‘(d) where applicable and available, the latest relevant guidelines in accordance with Sections 10.4.3. and 10.4.4.’;

(3) Section 10.4.3 is replaced by the following:

‘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.’;

(4) Section 10.4.4 is replaced by the following:

‘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.’.

*Article 4*

**Amendments to Regulation (EU) 2019/1021**

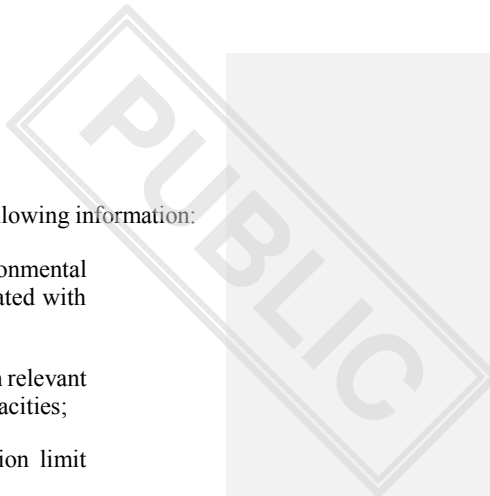
Regulation (EU) 2019/1021 is amended as follows:

(1) Article 8(1) is amended as follows:

(a) the following point (i) is added:

‘(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.’

(2) Article 8(1a) is added:



‘1a. The report referred to in Article 8(1), point (i), shall contain the following information:

- (a) **as appropriate**, information on human health and environmental impacts of waste consisting of, containing or contaminated with POPs, including impacts on waste management;
- (b) information on concentrations and mass flows of POPs in relevant waste streams and on waste treatment and treatment capacities;
- (c) an analysis of the impacts of the different concentration limit values considered;
- (d) a duly motivated proposal for concentration limit values to be introduced in Annex IV and, as appropriate, in Annex V.

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.

At the latest 9 months following the submission of ~~the~~ report **referred to in Article (8(1), point (i))**, the Committee for Socio- economic Analysis of the Agency, set up pursuant to Article 76(1), point (d), of Regulation (EC) No 1907/2006 shall adopt an opinion on the report and on the concentration limit values proposed therein. For the purpose of adopting an opinion on the report, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.

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.’;

(3) in Article 13, paragraph 2 is replaced by the following:

‘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.

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’;

(4) in Article 15, paragraph 2 is replaced by the following:

‘2. The Commission is empowered to adopt delegated acts in accordance with

Article 18, in order to amend Annexes IV and V ~~to this Regulation to mirror the addition of new substances in~~ **adapt them to changes to the list of substances set out in the Annexes I, II or III to this Regulation to the Convention or the Protocol** or ~~to modify entries in Annex IV to comply with the obligation laid out therein to review and lower the concentration values, or to modify existing entries in Annexes IV and V to this Regulation to~~ **adapt them to scientific and technical progress, including developments in waste treatment and decontamination technologies and on the basis of new scientific information indicating that the hazards and risks associated to a substance in waste have been underestimated.**

(5) Article 18 is amended as follows:

(a) ~~The first sentence of~~ **The first sentence of** Paragraph 2 is replaced by the following:

‘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 ... **[OP : Please insert the date of the entry into force of this Regulation] 15 July 2019.** ~~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 period.~~

(b) The first sentence of paragraph 3 is replaced by the following:

‘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.’.

(c) Paragraph 6 is replaced by the following:

‘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. **That period shall be extended by two months at the initiative of the European Parliament or of the Council.**

**(6) the following article is inserted:**

**Article 21b**

**Review**

**Taking due account of any regulatory developments concerning the status of the**

**Commented [A12]:** This change is proposed to keep the consistency of the text in this para with the para 1 as much as possible. We also do not think the word 'mirror' is the most appropriate, because the annexes IV and V are different from Annexes I, II or III.

**Commented [A13]:** This part is added to make sure that the COM can use delegated powers to comply with the review clauses in the Annex IV.

**Commented [A14]:** COM would prefer to have no further specification of the 'scientific and technical progress'. As we argued at the meeting, this is a standard phrasing in the chemical legislation, including in the POPs regulation in another paragraph. Such wording is needed to ensure the flexibility to adapt the values to any possible technical and scientific progress.

Should there be a desire to better indicate what scientific and technical progress means, we prefer to describe this in the associated recital.

If there would be a desire to better indicate what scientific and technical progress means directly in the legal text, then we prefer to make non-exclusive list of main identified examples, as provided in green.

**Commented [A15]:** As we are now in practice amending only the first sentence of paragraph 2 of Article 18 of the POPs regulation, the heading of article 4(5)(a) of the proposal could be modified to reintroduce words 'the first sentence' and the part of the paragraph which is not changed can be deleted.

**Commented [A16]:** The COM prefers no review clause as it is not necessary. If the provisions governing the functioning of the committees are changed via new ECHA's basic act, then that act will also amend the other pieces of legislation (if necessary).

Should the review clause remain, we propose a small drafting suggestions (on 2 places) for the review clause. It is indicated in green.

This is to make it clear that the focus of the review is on the functioning, resourcing and the governance of the committees and not on resourcing of ECHA, as ECHA is receiving a significant and sufficient reinforcement of resources via the financial legislative statement.

The proposed drafting suggestions make it also coherent with the new recital 14a.

resources and the governance of the scientific committees of the European Chemicals Agency, the Commission shall monitor the situation regarding the tasks, workload and remit of the Agency and its scientific committees, and where necessary present a legislative proposal to amend accordingly this regulation.';

Article 56

**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*

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