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CONTRIBUTION

From:	General Secretariat of the Council
To:	Ad hoc Working Party on One Substance One Assessment
N° prev. doc.:	WK 1604/2024
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Subject:	OSOA Package: Follow-up to Ad Hoc Working Party on One Substance One Assessment on 23 January 2024 - comments from delegations

Following the call for comments on the above set out with WK 1604/2024, delegations will find attached comments from DK, DE, IE, ES, FR, HU, NL, AT, PT, SI, FI and SE.

DENMARK

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

Questions

Thank you for giving us the possibility to submit comments on the proposal for a Regulation establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals.

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

Questions regarding Article 4 Implementation plan and governance of common data platform

DKQ1:
In the light of our wish to make better use of the Common Data Platform in the future for the purpose to use data to make better assessments on chemicals across sectors, DK suggests the following text proposal to Article 4:

5a. The Commission shall prepare a recommendation no later than 24 months after the Common Data Platform is established on how to amend legislation listed in the Annexes to this regulation for the purpose to use all data in the Common Data Platform to improve assessments on chemicals across sectors.
5b. 5c. By [Month, YEAR], the Commission shall present its recommendation referred to in paragraph 5a, accompanied, if necessary, by appropriate legislative proposals.

Questions regarding Article 10 Information on regulatory processes on chemicals

DK Q2:
Denmark notes that it is not clear whether regulatory processes mentioned in Article 10, paragraph 1, refers to national law processes, EU law processes, e.g. a submission of a dossier under REACH, or both? Could the Commission please specify/explain?

DK Q3:
As also stated January AHWP during Q&A, regarding the proposed obligation in Article 10, paragraph 2, we are keen to understand which voluntary notifications the Commissions referred to in its explanation on the obligation. Could be Commission please provide examples?

As Denmark understands the Commission, Article 10, paragraph 2, does in fact introduce a new obligation for the Member States to inform about information on regulatory processes of individual substances or substance groups in addition to the obligations that already exist in the different EU legislations, the information directive and the treaty.

The Commission explained during the first ADWP that the new obligation reflects a transition from voluntary notifications that already exist in the different EU legislations listed in Annex III towards an actual obligation where these voluntary notifications exist under EU legislations listed in Annex III. Denmark is aware of the existing ACT-PACT.

In general, DK is keen to understand the reference to voluntary notifications under EU legislation listed in Annex III.

Questions regarding Article 17 Use of chemicals data contained in the common data platform

DK Q4:
It is our understanding that *development or implementation of chemicals legislation and policy* in Article 17, paragraph 1, refers to both national and EU chemicals legislation and policy.

In the light of our understanding, we suggest the following text amendment to Article 17, paragraph 1:

Article 17, paragraph 1: The Authorities may use the chemicals data contained in the common data platform in the performance of any of their activities, where those activities support the development **of both national and EU chemicals legislation and policy** or implementation of **both national and EU** chemicals legislation and policy.

DK Q5:
Has the Commission reached clarity on the possibility to add an overview available in the Common Data Platform across the different pieces of legislation on confidential data with respect to existing provisions on confidentiality? And if the Commission did reach clarity, would the Commission share its insights?

We first raised this question at the January AHWP during Q&A by asking wether the Commission could consider to make an overview available in the platform across the different pieces of legislation on confidential data with respect to existing provisions on confidentiality, so that any duty holder will be aware that confidential data exists and possibly take advantage of that knowledge providing that confidentiality, ownership and formal rules on data sharing within each relevant legislation are duly respected.

The suggestion to add an overview on confidential data with respect to existing provisions on confidentiality reflects Danish Information Act. By way of illustration, the Danish Information Act shows how confidential data held by the national authorities cannot be shared with the general public, but a disclosure of an overview of the confidential held by the authorities is mandatory, when the general public apply for disclosure of information.

Denmark welcomes the requirements set in Article 17 regarding when Member States competent authorities may use and share of information on chemical data contained in the Common Data Platform. We do also believe it to be important to raise the question on how to best make use of the Common Data Platform introduced in the proposed regulation.

DKQ6:
During the January AHWP, DK suggested an overview available in the platform across the different pieces of legislation on confidential data with respect to existing provisions on confidentiality.

As Denmark understands, the Commission did consider the legal consequences in terms of confidential data generated as part of chemical products already placed on the internal market oppose to confidential data generated in connection to chemical products not yet placed on the market.

In the light of the Commission's considerations, Denmark is keen to understand, that was meant by *chemical products* in the Commission's consideration. Is to be understood as mixtures, articles or substances? Could be Commission please provide examples?

Questions regarding chapter V Monitoring and outlook framework for chemicals

DK Q7:
Could the Commission consider to adopt and publish the list of selected chemicals referred to in Article 20, paragraph 2, by means of an implementing decision and in accordance with the advisory procedure in article 4 in Regulation (EU) No 182/2011 of the European Parliament and the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers?'

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

Furthermore, as Denmark understands the Commission, the referred implementing decision in Article 4, paragraphs 1 and 2, and Article 13, paragraph 4, is in fact an internal decision prepared only by the Commission. We find that the word *implementing* may be misleading, in the sense that *implementing* in the context of EU regulation often refers to implementing acts and the procedures following.

DK Q8:
Could the Commission clarify what is meant by *scientific studies* introduced in Article 21? What types of studies are covered and are there some types of studies, that will not be covered?

DK Q9:
Can we assume that animal studies commissioned will be notified in the Database of Study Notification introduced in Article 9 and in accordance with Article 22 of the proposal?

DKQ10:
DK suggests the following addition to Article 21, paragraph 5:
5a.
The ECHA shall consult Member States prior to commission of scientific studies.

DENMARK

Remarks from Denmark

Ad hoc Working Party on One Substance One Assessment

Dear Presidency,

Thank you for giving us the possibility to submit comments on the proposal for amending Directive 2011/65/EU. As mentioned at the first Ad hoc Working Party (AHWP) on One Substance One Assessment, Denmark has a general parliamentary scrutiny reservation on the proposal. We have presented our comments in a systematic way using a table with the current text of the Directive 2011/65/EU, the Amendments to Directive 2011/65/EU as proposed by the Commission in COM (2023)781 final, Proposal by Denmark on the basis of the amendments proposed by the Commission and the explanation for our text proposals. We may come back with additional comments on Annex II, in the directive.

Amendments to Directive 2011/65/EU

Directive 2011/65/EU	**Amendments to Directive 2011/65/EU as proposed by the Commission in COM (2023)781 final**	**Proposal by Denmark on the basis of the amendments proposed by the Commission**	**Explanation to the Proposal by Denmark**
Article 5(4) 4. The Commission shall:	*Article 5(4)* 4. The ~~Commission~~ **Agency** shall:	*Article 5(4)*	*Article 5(4)*
(a) acknowledge receipt of an application in writing within 15 days of its receipt. The acknowledgement shall state the date of receipt of the application;	(a) acknowledge receipt of an application ~~in writing~~ within 15 days of its receipt~~. The acknowledgement shall state~~**, stating** the date of receipt of the application;		
(b) inform the Member States of the application without delay and make the application and any supplementary information supplied by the applicant available to them;	(b) ~~inform the Member States of the application without delay and make the application and any supplementary information supplied by the applicant available to them;~~ **verify that the application contains all the elements laid out in Annex V;**		
ba) within 1 month of receipt of an application, provide to the applicant, the Member States and the European Parliament a timeline for the adoption of its decision on the application;			
(c) make a summary of the application available to the public;	(c) ~~make a summary of the application available to the public;~~ **if necessary, request the applicant to complete the application, and provide an appropriate deadline;**	(c) if necessary, request the applicant to complete the application **within 45 days of receipt of the application**, and provide an appropriate deadline **of maximum 60 days**;	The applicant should be given a deadline within which the application should be completed, since the exemption continue to apply during the process of evaluation of the application. The 45 days and 60 days are proposed based on the deadlines given in REACH Article 69 (4) for restrictions proposals, as there are no similar deadlines under the authorisation scheme in REACH.
(d) evaluate the application and its justification			

	(d) ~~evaluate the application and its justification~~ **make the application and any supplementary information supplied by the applicant available to Member State**s; **(e) make a summary of the application and a non-confidential version of the application as submitted by the applicant, as well as the date when the application is considered complete, available to the public on the Agency's website;** **(f) invite interested parties to submit information within 3 months of its publication on the Agency's website.** **Where the applicant does not complete the application with the missing elements identified by the Agency in compliance with Annex V within the deadline provided in accordance with the first subparagraph, point (c), the Agency may reject such application. The Agency shall establish and communicate to the applicant without undue delay the date when the application is considered complete.** **Upon receipt of an application, the Agency shall notify the Commission of the application and keep it informed of any of the procedural steps under points (b) to (f).';**		
New 4a paragraph inserted after paragraph 4	*Article 5(4a)* 4a. The Agency shall, after verifying the completeness of the application, request the opinion of the Committee for Socio-economic Analysis, set up pursuant to Article 76(1), point (d) of Regulation (EC) No 1907/2006. It shall request the opinion of the Committee for Risk Assessment, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006, in the case of an application for a new exemption, or where otherwise considered appropriate.	*Article 5(4a)* 4a. The Agency shall, after verifying the completeness of the application, request the opinion of the Committee for Socio-economic Analysis, set up pursuant to Article 76(1), point (d) of Regulation (EC) No 1907/2006. It shall request the opinion of the Committee for Risk Assessment, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006, in the case of an application for a new exemption, or where otherwise considered appropriate.	*Article 5(4a)* It is our understanding that RAC are only to be involved where appropriate regarding renewal requests to save resources and that it is foreseen that RAC to only be involved in 10% of all exemption request assessments constituting on average 3 of 30 requests per year as set out in the Staff Working Document (p. 117-120). In light of the fact that renewal requests must meet the exact same criterions as requests for new exemptions, the technical development concerning products encompassed by the RoHS Directive is oftentimes very swift. The number and complexity of exemptions requests are

	The Committee for Socio-economic Analysis and, where relevant, the Committee for Risk Assessment: (a) shall draw up draft opinions within 9 months of the date the application has been considered complete by the Agency under paragraph 4, point (b); (b) shall assess whether the criteria in Article 5(1), point (a), are met and shall provide clear guidance to the Commission on granting, renewing or revoking an exemption; (c) may request the applicant or third parties to submit, within a specified period, additional information; (d) upon adopting the draft opinions, shall communicate those draft opinions to the applicant and shall allow the applicant the opportunity to comment within 4 weeks of the communication of the draft opinions to the applicant; (e) shall adopt their final opinions, taking into account the comments from the applicant. Each Committee shall take into account any information submitted by third parties in accordance with the second subparagraph, point (c) The Agency shall send the final opinion(s) of the Committees to the Commission within 12 months from the date an application has been considered complete by the Agency. The Agency shall identify which parts of its opinions and of any attachments thereto should be made publicly available on its website and shall make those parts publicly available on its website.	The Committee for Socio-economic Analysis and, where relevant, the Committee for Risk Assessment: (a) shall draw up draft opinions within **10** ~~9~~ months of the date the application has been considered complete by the Agency under paragraph 4, point (b); The Agency shall send the final opinion(s) of the Committees to the Commission within 1~~4~~2 months from the date an application has been considered complete by the Agency.	foreseen to continue to increase in the coming years, we therefore find it necessary either for RAC to be involved in the assessment of all exemption request alongside SEAC or for the legal text to clarify when it is not necessary to involve RAC. In the latter, the foreseen 10% of cases should not not end up acting as a hindrance to involving RAC. If RAC is not to be involved in all application, it is relevant that the legal text should request the development of guidance for when to involve RAC and that this guidance is adopted by the expert group (see proposal for article 20). In order to align the deadline for RAC and SEAC for the assessment of exemptions with the authorisation scheme and assessment of authorisation under the REACH-Regulation, the deadline for the draft opinion should be set to 10 months. This corresponds to the deadlines in REACH, Article 64 (1). In order to align the deadline for RAC and SEAC for the assessment of exemptions with the authorisation scheme and assessment of authorisation under the REACH-Regulation, the deadline for sending the final opinion to the Commission should be set to 14 months. This will assure that ECHA will have at least the same time period as is given under Article 64 (5) in REACH, where the Committees shall adopt their final opinion within two

	For the purpose of adopting opinions pursuant to this paragraph, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.’;		months after receiving the comments from the applicant and send it to the Commission within 15 days after this.
Article 5(5) An application for renewal of an exemption shall be made no later than 18 months before the exemption expires.	*Article 5(5)* An application for renewal of an exemption shall be made no later than 18 months before the exemption expires.	*Article 5(5)* An application for renewal of an exemption shall be made no later than ~~18~~ **24** months before the exemption expires.	When aligning the exemptions assessment process with REACH, the Commission will be phased with the issue of expediting delegated directives before the expiration of the concerned exemption. In order to alleviate this issue we suggest to leave more room for the assessment procedure.
Article 5(8) 8. The Commission shall adopt a harmonised format for applications referred to in paragraph 3 of this Article as well as comprehensive guidelines for such applications, taking into account the situation of SMEs. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(2).	*Article 5(8)* 8. The ~~Commission~~ **Agency** shall ~~adopt~~, **in agreement with the Commission, provide** a harmonized format for the applications referred to in paragraph 3 of this Article as well as comprehensive guidelines for such applications, taking into account the situation of SMEs. ~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(2).~~ **Any submission to the Agency shall be made using the format and the submission tools made available by the Agency.’**;	*Article 5(8)* The Agency shall, in agreement with the Commission **and the committee set up according to article 20** provide a harmonised format for the applications referred to in paragraph 3 of this Article as well as comprehensive guidelines for such applications **including the criteria described under paragraph 1,** taking into account the situation of SMEs. Any submission to the Agency shall be made using the format and submission tool made available by the Agency.	Clarification is needed in relation to criterion no. 3 in art. 5 pieces. 1, letter a; *the total negative environmental, health and consumer protection impact as a result of the substitution is likely to be greater than the total environmental, health and consumer protection benefits thereof.* Many exemptions are granted or renewed with reference to this criterion, not infrequently, where the other criterions do not apply i.e. where substitution is possible or reliable alternatives are available, in spite of the weight of substation in RoHS as reflected in recital 8 *the most effective way of ensuring a significant reduction of risks to health and the environment relating to those substances, in order to achieve the chosen level of protection in the Union, is the substitution of those substances in EEE by safe or safer materials.* The criterion is often applied based on energy considerations. It is unclear if this was the intention of this criteria and, which weight to assign energy considerations compared to chemicals considerations within the frame of RoHS. In light of the experienced difficulty concerning collection of information from applicants as identified during the RoHS review process, priority should be given to clarifying the applicability of this criterion. Therefore, there is a need to clarify the applicability of this criteria and it is important that ECHA does so through following this re-attribution of tasks. ECHA

			should revise this guidance and that the guidance should be adopted by the expert committee (see proposal for reference to this committee in under article 20).
Article 6(1), subparagraph 1 1. With a view to achieving the objectives set out in Article 1 and taking account of the precautionary principle, a review, based on a thorough assessment, and amendment of the list of restricted substances in Annex II shall be considered by the Commission before 22 July 2014, and periodically thereafter on its own initiative or following the submission of a proposal by a Member State containing the information referred to in paragraph 2.	*Article 6(1), subparagraph 1* 1. With a view to achieving the objectives set out in Article 1 and taking account of the precautionary principle, a review, based on a thorough assessment, and an amendment of the list of restricted substances in Annex II shall be considered by the Commission ~~before 22 July 2014,~~ periodically ~~thereafter~~ on its own initiative or following the submission of a restriction dossier prepared by a Member State containing the information referred to in paragraph 2.	*Article 6(1), subparagraph 1* 1. With a view to achieving the objectives set out in Article 1 and taking account of the precautionary principle, a review, based on a thorough assessment, and an amendment of the list of restricted substances in Annex II shall be considered by the Commission **every five year** ~~periodically~~ on its own initiative or following the submission of a restriction dossier prepared by a Member State containing the information referred to in paragraph 2. **1a. The assessment referred to in paragraph 1 shall include relevant substances on Annex II of Regulation 2019/1021 of the European Parliament and the Council of 20 June 2019, which are exempted from EEE.**	The list of substances restricted under the ROHS directive should be evaluated on a more regular basis. Here a 5-year period is suggested. It is not paramount that it should be a 5-year period, however, a timeline is needed. Furthermore, substances restricted in the POP-regulation, and where the use in EEE is exempted, should be considered for Annex II in the RoHS-Directive. Staff working document p. 119 assesses the impact for ECHA. Here it says: *As the assessments are to be done ca. every 5 years*. Therefore, a time limit of 5 years is considered appropriate. eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52023SC0850
Article 6(1), subparagraph 4 During that review, the Commission shall consult interested parties, including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations	*Article 6(1), subparagraph 4* ~~During that review, the Commission shall consult interested parties, including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations.~~		It is unclear, why this subparagraph is suggested to be deleted, when Article 5(7) in the RoHS-directive not deleted. Could the Commission please clarify.
Article 6(2) 2. The proposals to review and amend the list of restricted substances, or a group of similar substances, in Annex II shall contain at least the following information: (a) precise and clear wording of the proposed restriction; (b) references and scientific evidence for the restriction; (c) information on the use of the substance or the group of similar substances in EEE;	*Article 6(2)* 2. The ~~proposals to review and amend~~ **review and amendment of** the list of restricted substances in Annex II shall ~~contain at least the following information:~~ ~~(a) precise and clear wording of the proposed restriction;~~ ~~(b) references and scientific evidence for the restriction;~~ **be based on restriction dossiers prepared by the Agency at the request of the Commission or prepared by a Member State.** **The Agency or a Member State shall take into account any available information and**	*Article 6(2)* The review and amendment of the list of restricted substances, **or a group of similar substances,** in Annex II shall be based on restriction dossiers prepared by the Agency at the request of the Commission or prepared by a Member State. The Agency or a Member State shall take into account any available information and any	The reference to the assessment of groups of substances should not be deleted.

(d) information on detrimental effects and exposure in particular during waste EEE management operations; (e) information on possible substitutes and other alternatives, their availability and reliability; (f) justification for considering a Union-wide restriction as the most appropriate measure; (g) socioeconomic assessment.	**any relevant risk assessment submitted for the purposes of other Union legislation covering the life cycle of the substance used in EEE, in particular the waste phase. To this end, other bodies established under Union law and carrying out a similar task shall, on request, provide information to the Agency or Member State concerned.** **The restriction dossier shall comply with the requirements set out in Part II, point 3, of Annex XV to Regulation (EC) No 1907/2006 and shall, in addition, contain the following information:** (~~e~~ **a**) information on the use of the substance or the group of similar substances in EEE; (b) information on detrimental effects and exposure in particular during waste EEE management operations.' ~~(f) justification for considering a Union-wide restriction as the most appropriate measure;~~ ~~(g) socioeconomic assessment.~~	relevant ~~risk~~ assessment submitted for the purposes of other Union legislation covering the life cycle of the substance used in EEE, in particular the waste phase. To this end, other bodies established under Union law and carrying out a similar task shall, on request, provide information to the Agency or Member State concerned. The restriction dossier shall ~~comply with the requirements set out in Part II, point 3, of Annex XV to Regulation (EC) No 1907/2006 and shall, in addition,~~ contain the following information: (a) information on the use of the substance or the group of similar substances in EEE; (b) information on detrimental effects and exposure in particular during waste EEE management operations.' The restriction dossier shall comply with the requirements set out in Part II, point 3, of Annex XV to Regulation (EC) No 1907/2006 **with respect to the proposal, information on hazard, information on alternatives, justification for restriction at community level, socioeconomic assessment and information on stakeholder consultation.**	Any relevant assessment should be included, including assessments of waste handling, therefore "risk" should be deleted from the text. Annex XV require an assessment of risk, which is the central part of the assessment. This will point the focus away from the essential part of the assessment required under the RoHS namely information on the use of the substance or the group of similar substances in EEE and information on detrimental effects and exposure in particular during waste EEE management operations. We therefore suggest to exclude the requirement in relation to assessing the risk.
New article inserted after article 6	*Article 6b* **Opinion of the Agency's Committees** 1. Within 12 months from the date of publication referred to in Article 6a(6), the Committee for Risk Assessment shall adopt an opinion as to whether the restriction is appropriate in reducing the risk to human health or the environment, specifically by reference to the risks set out in Article 6(1), third subparagraph, based on its consideration of the relevant parts of the dossier. This opinion shall take account of the restriction dossier prepared by the Agency at the request of the Commission or by the Member State,	*Article 6b* **Opinion of the Agency's Committees** 1. Within 12 months from the date of publication referred to in Article 6a(6), the Committee for Risk Assessment shall adopt an opinion as to whether the restriction is appropriate in ~~reducing~~ the **protection** ~~risk to~~ of human health or the environment, specifically by reference to the **concerns** ~~risks~~ set out in Article 6(1), third subparagraph, based on its consideration of the relevant parts of the dossier. This opinion shall take account of the restriction dossier prepared by the Agency at the request of the Commission or by	The aim of the RoHS directive as described in article 1 of that directive is not to reduce the risk from hazardous substances in EEE, but to "*contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE*". Requesting the Agency's Committees to evaluate the reduction of risk would therefore be misleading. Furthermore, article 6.1 does not specifically refer to "risk". Rather, it centralizes the above mentioned objectives of article 1 at the forefront of the review process.

	and the views of interested parties referred to in Article 6a(6), point (a). 2. Within 15 months from the date of publication referred to in Article 6a(6), the Committee for Socio-economic Analysis, shall adopt an opinion on the proposed restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. Prior to that, it shall prepare a draft opinion on the suggested restrictions and on the related socio-economic impact, taking account any existing analysis or information according to Article 6a(6), point (b). 3. The Agency shall publish the draft opinion of the Committee for Socio-economic Analysis on its website without delay and invite interested parties to provide their comments on the draft opinion no later than 60 days from its publication. 4. The Committee for Socio-economic Analysis shall without delay adopt its opinion, taking into account where appropriate further comments received by the deadline set in paragraph 3. This opinion shall take into account the comments of interested parties submitted under Article 6a(6), point (a), and paragraph 3 of this Article. 5. Where the opinion of the Committee for Risk Assessment diverges significantly from the restrictions proposed, the Agency shall postpone the deadline for the opinion of the Committee responsible for Socio-economic Analysis by a maximum of 90 days. 6. For the purpose of adopting opinions pursuant to this article, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.	the Member State, and the views of interested parties referred to in Article 6a(6), point (a). 2. Within 15 months from the date of publication referred to in Article 6a(6), the Committee for Socio-economic Analysis, shall adopt an opinion on the proposed restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. Prior to that, it shall prepare a draft opinion on the suggested restrictions and on the related socio-economic impact, taking account any existing analysis or information according to Article 6a(6), point (b). 3. The Agency shall publish the draft opinion of the Committee for Socio-economic Analysis on its website without delay and invite interested parties to provide their comments on the draft opinion no later than 60 days from its publication. 4. The Committee for Socio-economic Analysis shall without delay adopt its opinion, taking into account where appropriate further comments received by the deadline set in paragraph 3. This opinion shall take into account the comments of interested parties submitted under Article 6a(6), point (a), and paragraph 3 of this Article. 5. Where the opinion of the Committee for Risk Assessment diverges significantly from the restrictions proposed, the Agency shall postpone the deadline for the opinion of the Committee responsible for Socio-economic Analysis by a maximum of 90 days. 6. For the purpose of adopting opinions pursuant to this article, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.	

Article 20 **Exercise of the delegation** 1. The powers to adopt the delegated acts referred to in Article 4(2), Article 5(1) and Article 6 shall be conferred on the Commission for a period of 5 years from 21 July 2011. The Commission shall draw up a report in respect of delegated powers at the latest 6 months before the end of the 5 year period. The delegation of power shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 21. 2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council. 3. The powers to adopt delegated acts are conferred on the Commission subject to the conditions laid down in Articles 21 and 22.	*No proposal for change*	*Article 20* **Exercise of the delegation** 1. The powers to adopt the delegated acts referred to in Article 4(2), Article 5(1) and Article 6 shall be conferred on the Commission for a period of 5 years from 21 July 2011. The Commission shall draw up a report in respect of delegated powers at the latest 6 months before the end of the 5-year period. The delegation of power shall be ~~automatically~~ **tacitly** extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 21. **1a. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.** 2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council. 3. The powers to adopt delegated acts are conferred on the Commission subject to the conditions laid down in Articles 21 and 22.	Update of language. Exercising the power of delegated act, the consultation of an expert group with member state representation should be specified.

DENMARK

Remarks from Denmark to COM(2023) 783 concerning the POP-regulation

Dear Presidency,

Thank you for giving us the possibility to submit comments.

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

Concerning the proposed amendments of Regulation (EU) 2019/1021, article 18, we do not agree to the proposed text, and suggest no changes are made concerning article 18.

It is important that the procedure for amending Annexes IV and V on the limit values for POP-substances in waste remains subject to the general legislative procedure. These amendments will have a significant influence on the regulation of the most dangerous environmental pollutants, including balancing the promotion of circular economy and the need to phase out particularly dangerous environmental toxins from material flows for recovery. We recognize that the use of delegated acts is likely to benefit the speed at which limit values will be updated. However, we maintain that speed in the process cannot compensate for the fact that this is an important provision, and that it is of particular importance that EU citizens are directly involved in the EU decision-making procedure and we do not wish to delegate this regulatory authority to the Commission.

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GERMANY

OSOA Package

Follow-up to ad-hoc Working Party on One Substance One Assessment on 23 January 2024

Written comments

A) General remarks

DE would like to thank the Commission for presenting the three legislative proposals as part of the *One Substance One Assessment package* (OSOA package) in the ad-hoc Working Party on 23 January 2024. We support the Commission's goal of improving the coherence, consistency and efficiency of chemicals assessment. A detailed examination of the three proposals is still ongoing. The DE comments below do not yet represent a final position, but rather focus on questions of understanding and preliminary comments. DE reserves its right to provide additional comments later on.

Most of the proposed task allocations relate to the European Chemicals Agency (ECHA). In addition to the OSOA package, other tasks have been transferred to ECHA over the last years (e.g. under the Batteries Regulation, Waste Framework Directive and the Drinking Water Directive). We are concerned if ECHA will be able to fully accomplish all its already existing tasks and its new tasks which will also at least partly require new expertise at ECHA. We are particularly concerned about the expected additional workload for ECHA‘s scientific committees, namely the Committee for Risk Assessment (RAC) and the Committee for socioeconomic analysis (SEAC).

Therefore, we ask the Commission:

- How can it be ensured that ECHA and its Committees remain fully operational and can deliver the necessary high-quality scientific output in its existing and its new tasks?

- In that respect, does the Commission consider the proposed additional resources to be sufficient or which further measures could become necessary?

B) Proposal on a directive amending the RoHS Directive as regards the re-attribution of scientific and technical tasks to ECHA

DE welcomes in principle the proposal for a Directive amending Directive 2011/65/EU (RoHS Directive), which aims to consolidate the exemption and the substance restrictions procedures at ECHA.

In particular, DE welcomes the fact that the proposed measures should lead to more legal certainty and clarity for manufacturers and Member States with regard to the evaluation of temporary exemptions and substance restrictions. The provisions in Art. 5 and Art. 6 form in principle a good basis for ensuring stricter, more efficient, harmonised procedures and improve overall transparency.

DE considers that the proposal supports the European Green Deal commitment to move towards a process of "one substance, one assessment'". Coherence and effectiveness will be increased by taking into account interactions with other legislation on chemical substances (e.g. REACH).

Art. 1 (1) (a) of the COM proposal (Art. 5 (4) (c) and (e) of Directive 2011/65/EU)

DE would like the Commission to clarify the term "appropriate" in Art. 5 (4) (c). In past assessments, significant delays in the exemption process were introduced by waiting for applicants to provide supportive documentation. DE would therefore suggest replacing the word "appropriate" with a specific deadline in order to improve legal certainty for the actors concerned. This would also ensure that current applications are published on the Agency's website in a timely manner.

Further DE would like the Commission to assess if applications should be published on the Agency's website on reservation once at least the documents listed in Annex V a-e are available. Early publication of applications will lead to reduced bureaucracy and ensure transparency for manufacturers. Other manufacturers may then decide not to submit an application.

Art. 1 (1) (c) of the COM proposal (Art. 5 (8) of Directive 2011/65/EU)

DE supports a harmonised format for the applications and clear guidelines for applicants. Further, DE welcomes the introduction of online submissions tools for applications and finds this to be a good improvement. DE would ask for further clarification, how this process will exactly function in practice. Further, DE would like to ask if the harmonised application under RoHS will be streamlined with other exemption processes. This would be encouraged.

Art. 1 (3) of the COM proposal (Art. 6a (3) of Directive 2011/65/EU)

The provisions are not clear where the intention to review and amend the list of restricted substances will be published. Whereas in Art. 5 it is clearly stated that the applications will be published on the Agency's website, the provisions only refer to "publish". DE would like to suggest to clarify the wording in this Article.

Art. 2 of the COM proposal

DE would like to understand better how long it will take to build up the necessary resources and expert knowledge at ECHA, as the planned transitional period of 12 months seems very ambitious.

In view of the increasing complexity and volume of applications for exemptions under Art. 5 of Directive 2011/65/EU, DE has further concerns if the Committee for Socio-economic Analysis and, where relevant, the Committee for Risk Assessment, can manage the increase in work load. Well-functioning and staffed Committees will be central to ensure a real increase in efficiency with regard to the processing of requests for exemptions and substance restrictions. Otherwise, it is doubtful whether all the objectives of the OSOA initiative can be achieved.

C) 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

DE has the following preliminary comments and questions:

Concerning the amending of Regulation (EC) 178/2002

It would be important to receive confirmation from the commission that the amendments of Article 30 are intended to steer the process of coordinating a uniform assessment. The actual EFSA procedure for risk assessments must not be changed as a result.

It must be ensured that the assessments of EFSA and, if applicable, other EU authorities are properly and appropriately taken into account by ECHA. How is this ensured by the provisions in Article 30?

Could an example be given what would be considered diverging scientific opinion in the light of the intended new mechanism to resolve divergence?

Concerning the amending of Regulation (EC) 401/2009

DE asks for clarification why the EEA's cooperation with the ECHA is supposed to be regulated in Article 15(5) of the EEA Regulation. Systematically, Paragraph 1 with a new letter c seems much closer. In addition, it would be clear that paragraph 4 also refers to this cooperation.

Concerning the amending of Regulation (EU) 2017/745

It is intended that ECHA is given the task to prepare or update guidance on risk-benefit assessments in accordance with section 10.4.3. and 10.4.4. of Annex I to regulation (EU) 2017/745. How can be ensured that ECHA has the required medical device-specific expertise to fulfill this task?

Concerning the amending of Regulation (EU) 2019/1021

At COP11 three new POPs (Methoxychlor, Dechlorane Plus and UV-328) were listed in Annex A of the Stockholm Convention. According to Article 15 (2) of the POP Regulation, the Commission shall make legislative proposals to amend Annexes IV and V in order to adapt them to the changes to the list of substances in the Annexes to the Convention. When does the Commission plan to amend Annexes IV and V of the POP Regulation to include these new POPs in these Annexes?

ECHA has so far been seen by waste management stakeholders as an agency within European chemicals legislation. How can it be ensured that ECHA’s request for comments reaches all relevant waste management stakeholders so they can provide useful information?

Information on POP contents in waste, the various fractions from the treatment of waste and recyclates is often only available to a very limited extent. In the past, for example, DE has carried out studies on POPs in waste and recyclates. Are the Commission and ECHA considering how this information gap could be improved?

In accordance with Article 18(4) of the POPs Regulation, the Commission consults the experts appointed by the individual Member States. How does the Commission intend to ensure that the Member States' waste experts are consulted on amendments to Annexes IV and V?

D) 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

DE considers in general the common data platform on chemicals as an important tool for achieving the goals of OSOA. DE has the following preliminary comments and questions:

Concerning data platform elements

Will member states and the public be consulted during implementation of the platform, e.g. on formats or vocabulary?

Article 17 (2) of the proposal states that data in the platform shall not be used to fulfill the duty holder's obligations. Could the Commission elaborate more about the practical use of the data under a specific regulation under which the duty holder has to provide the data? (i.e. can it only be used to check plausibility of the data provided by the duty holder?).

Will data that are not already in the possession of the Agencies and the Commission be included or utilised within this platform?

Concerning data generation mechanism

Is it planned to implement a cross-check with industry expertise/stakeholders on a draft testing proposal?

Concerning updating of information

The Commission proposal does not specify how often agencies are expected to update information provided for the common data platform on chemicals. How does Commission plan to organize this? Did Commission assess the problem that the platform's information could become outdated?

Concerning contradictions or ambiguities of information

It is planned to bring together data about substances from different legislations. It can be expected that contradictions or ambiguities will arise, for example because studies in different regulatory areas are carried out differently or evaluated differently. Such contradictions/ambiguities might lead to public debate. Who will resolve these contradictions and ambiguities and with what resources? In the explanatory memorandum the Commission mentions the solving of divergences in scientific output. We ask Commission to illustrate that mechanism with relevant examples.

Furthermore, the different vocabulary used in different legislations so far might lead to inconsistencies and ambiguities when combining existing data pools. How does the Commission intend to deal with such problems?

Concerning the description of substance identity

It is known that substance identity is defined and handled inconsistently in different regulatory areas. Which mechanism could be used to solve this problem, for example if two pieces of information about a substance differ because the definition of the substance identity is different?

Concerning the common data platform and the use for scientific bodies

Will it be possible to use the information in the common data platform for scientific purposes? Did Commission assess whether and how it could be made possible that scientific bodies also feed data into the platform? How could that be organized?

Concerning the notification of studies

Laboratories and business operators are expected to notify studies on the properties of substances before they are carried out. Can Commission explain this system further? For example, how does Commission want to deal with studies conducted outside the EU without notification that are submitted afterwards?

Is reference made to any definition of the term "study" in other legislation (or how will it be implemented)? Is it intended to target specific cases/study endpoints by the notification requirement?

Is a mechanism analogous to Art. 32b of the EFSA transparency regulation foreseen for late notifications?

Can the Commission provide more details, which studies/data are potentially affected by the notification requirement related to regulations listed in annex I?

Concerning the early warning action system

Are Member States going to be involved in the development of the indicators (Art. 18)?

What is the relation between indicators (Article 18) and the early warning signals (Article 19)? Is it planned to employ scientific expertise of the Member States and the Agency's committees (i.e. ECHA Committee for Risk Assessment) in identifying the early warning signals?

Does the Commission target specific chemical risks under Article 20 or should all possible risks be covered under this mechanism? If so, could the Commission elaborate a bit more on the interplay with existing chemicals legislation?

Concerning human-biomonitoring data

The Commission proposal describes some purposes that require the use of personal data. These purposes are not sufficiently defined and require further specification.

In some cases harmonization and communication of individual data requires unequivocal consent from study participants. Such consent cannot be obtained retrospectively. Did the Commission consider this issue and if so, how will this be addressed?

Concerning indoor air quality data

Does the Commission pursue plans for systematic or regular surveys of indoor air quality data?

Concerning Pharmaceuticals

Recital 8 & 9 contain statements that can be interpreted as a strong limitation of the data to be included in the common data platform. Could you please specify "relevant substances" with regard to medicinal active substances? Is it intended that other active substances whose data were submitted to the European Medicines Agency (EMA) before the regulation came into force will also be included in the database?

As part of the current revision of the EU's general pharmaceutical legislation, i.a. the setting up of an active substance monograph system on environmental data is being considered. Are there plans to integrate these pharmaceutical substances monographs into the central database? If not, how would the two systems work together?

Concerning technical interoperability

The creation and maintenance of the platform requires complex data flows for both the collection and distribution of data. Does the Commission intend to promote the use of advanced programming interfaces (API) to organise and facilitate data flows?

IRELAND

Comments on One Substance One Assessment Legislative Package
16th February 2024

We thank the Commission for the presentation provided at the meeting on January 23rd and for the opportunity to provide written comments.

Please find below comments on the elements of the One Substance, One Assessment Legislative Package below.

(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

The reattribution of tasks will directly affect different EU agencies. Our observations here concern the re-attribution of tasks to ECHA.

We note the re-attribution of tasks to ECHA and its Committees, and in particular to RAC and SEAC, in this legislative proposal. While we acknowledge the Commission's thinking on possible benefits of the proposal, we are mindful of the consequences of it, particularly on the ECHA committees, which is a consequence for the Member States and their resources. While there are consequences for ECHA, the greatest and most significant impacts on ECHA's Committees will fall on the RAC and SEAC members nominated by Member States.

The impact of assigning tasks directly to the ECHA Committees results in the tasks actually being re-attributed to the Member States to complete, as it is the Member States who nominate experts to the committees and supports those experts with advisors.

We support that the legislative proposal needs to provide for the Agency to provide the Member States and the institutions of the Community with the scientific/technical advice relating to chemicals. However, we are not convinced that the proposal to assign this responsibility to its RAC and SEAC, which were established initially for the purpose of REACH, is the right approach.

The mandate of the RAC was extended in 2008 to include opinions on harmonised classification and that classification workload has now been further extended with the introduction of new hazard classes in CLP in 2022/3. The RACs mandate was further expanded again to occupational exposure limits under occupational health and safety legislation and limits for drinking water, despite the REACH legislation only providing for two expert nominations per Member State. We acknowledge that the Committee membership is not at full capacity. However, the assigning of additional tasks to the Committee may in fact discourage further uptake by new members of the existing vacant positions, as experts do not have the technical competence in the newly assigned areas. We feel membership would be encouraged by allowing a greater number of experts to cover different aspects of ECHA's opinion making tasks.

In some instances, we believe it would be more appropriate to assign the task(s) to prepare opinions to ECHA, and allow ECHA to best determine the most efficient and appropriate way to deliver a robust opinion. For example, ECHA's technical experts could draft opinions and establish technical expert working groups to consult with in order for scientific opinions to be delivered. In certain cases, the Executive Director can still use their powers under Article 77 (3) to issue a request to RAC and SEAC, thus negating the need for all tasks to have a RAC and/or SEAC opinion.

It is our preference that the legislative package makes provisions for ECHA to prepare opinions in some circumstances without the explicit need for those opinions to be drafted by RAC and SEAC.

We note from the presentation given by the Commission on January 23rd that the expected impact of the reattribution of tasks on the ECHA committees is that RAC will need to deliver 79.7 opinions per year, with SEAC delivering 50.2. This is a very large number of opinions expected to be delivered from the two committees, especially given the extremely high workload of those committees presently, combined with the expectation that RAC may get even busier with CLH work in light of the new CLP hazard classes.

We recall a presentation given by the RAC chair to the CARACAL meeting in November 2023, in which it was indicated that the RAC meeting days have increased from about 30 meetings days per year in 2015 to about 50 per year currently, also noting that with the current members, committee production cannot be increased. It was a similar story from the SEAC chair, who noted a falling number of regular members since the peak in 2015 and difficulties in filling co-opted members slots. Like the RAC chair, the SEAC chair indicated that with current membership, it is not possible for the SEAC to increase capacity.

Like other Member States our concern is with the capacity of the individual members to deliver on this expected workload, even if both Committees were at full capacity. Therefore, we see a need for provisions to be included to allow for amending the composition of the current ECHA's committees to cover also any ad-hoc Article 77 (3) requests in light of request from the Executive Director.

Finally, the inclusion of remuneration for Committee rapporteurs for all tasks needs to be provided for.

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

Ireland is supportive of measures that will lead to greater efficiency in assessing exemptions under the ROHS Directive, but has concerns in relation to the capacity of the Committee for Socio-Economic Analysis (SEAC), or of the Committee for Risk Assessment (RAC). We particularly note the expected impact on the SEAC with the delivery of 31 opinions on the RoHS Directive per year and are of the opinion that this impact needs careful consideration before it is assigned to RAC or SEAC. Currently, the technical experts Ireland provides to RAC and SEAC do not have expertise in ROHS, the Drinking Water Directive, etc. Their expertise does not go beyond the tasks in REACH, CLP and Occupational Exposure limits. Additional technical experts from other government departments or agencies would be needed however the current cap on membership restrictions will not allow this to happen. It will be important to clearly demonstrate the way in which the ECHA capacity will be increased in order to ensure the operability of this proposal.

The following is an example of some suggested changes to Directive 2011/65/EU to allow the tasks to be assigned to ECHA rather than directly to RAC and SEAC. These changes would not preclude the Executive Directive from requesting the assistance of the Committees on a case by case basis for example.

Article 1

Amendments to Directive 2011/65/EU

Directive 2011/65/EU is amended as follows:

(1) Article 5 is amended as follows:

(a) paragraphs 3 and 4 are replaced by the following:

'3. An application for granting, renewing or revoking an exemption shall be made to the European Chemicals Agency set up pursuant to Article 75(1) of Regulation (EC) No 1907/2006 ('the Agency') in accordance with Annex V.

4. The Agency shall:

(a) acknowledge receipt of an application within 15 days of its receipt, stating the date of receipt of the application;

(b) verify that the application contains all the elements laid out in Annex V;

(c) if necessary, request the applicant to complete the application, and provide an appropriate deadline;

(d) make the application and any supplementary information supplied by the applicant available to Member States;

(e) make a summary of the application and a non-confidential version of the application as submitted by the applicant, as well as the date when the application is considered complete, available to the public on the Agency's website;

(f) invite interested parties to submit information within 3 months of its publication on the Agency's website.

Where the applicant does not complete the application with the missing elements identified by the Agency in compliance with Annex V within the deadline provided in accordance with the first subparagraph, point (c), the Agency may reject such application. The Agency shall establish and communicate to the applicant without undue delay the date when the application is considered complete.

Upon receipt of an application, the Agency shall notify the Commission of the application and keep it informed of any of the procedural steps under points (b) to (f).';

(b) the following paragraph 4a is inserted after paragraph 4:

'4a. The Agency shall, after verifying the completeness of the application, prepare ~~request~~ a scientific and technical ~~the opinion of the Committee for Socio-economic Analysis, set up pursuant to Article 76(1), point (d) of Regulation (EC) No 1907/2006. It shall request the opinion of the Committee for Risk Assessment, set up pursuant to Article 76(1), point ©, of~~

~~Regulation (EC) No 1907/2006, in the case of an application for a new exemption, or where otherwise considered appropriate.~~

The Agency ~~Committee for Socio-economic Analysis and, where relevant, the Committee for Risk Assessment~~:

(a) shall draw up draft scientific and technical opinions within 9 months of the date the application has been considered complete by the Agency under paragraph 4, point (b);

(b) shall assess whether the criteria in Article 5(1), point (a), are met and shall provide clear guidance to the Commission on granting, renewing or revoking an exemption;

(c) may request the applicant or third parties to submit, within a specified period, additional information;

(d) ~~upon adopting the draft opinions~~, shall communicate those draft scientific and technical opinions to the applicant and shall allow the applicant the opportunity to comment within 4 weeks of the communication of the draft scientific and technical opinions to the applicant;

(e) shall adopt their final opinions, taking into account the comments from the applicant.

~~Each Committee~~ The Agency shall take into account any information submitted by third parties in accordance with the second subparagraph, point (c).

The Agency shall send the final scientific and technical opinion(s) ~~of the Committees~~ to the Commission within 12 months from the date an application has been considered complete by the Agency.

The Agency shall identify which parts of its scientific and technical opinions and of any attachments thereto should be made publicly available on its website and shall make those parts publicly available on its website.

~~For the purpose of adopting opinions pursuant to this paragraph, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.'~~;

We suggest the addition of a provisions to cover Executive Director Requests is also provided for.

"The Agency at the Executive Directors request, may consult with or request its Committees or relevant Committee experts to provide technical and scientific support on technical and scientific issues relating to the preparation of its scientific and technical opinions (or advices could be used instead of opinion if the Commission want to distinguish between an Agency opinion by the Committee versus an opinion by its technical staff) for Member States and the institutions of the Community."

"The Agency at the Executive Directors request, may establish expert working groups following a call for nominations from Member States to assist it in drafting technical and scientific support on technical and scientific issues relating to the preparation of technical advice(s)/opinions for Member States and the institutions of the Community."

(c) paragraph 8 is replaced by the following:
'8. The Agency shall, in agreement with the Commission, provide a harmonised format for the applications referred to in paragraph 3 of this Article as well as comprehensive guidelines for such applications, taking into account the situation of SMEs. Any submission to the Agency shall be made using the format and the submission tools made available by the Agency.';

(2) in Annex V, the following paragraph is added:
'In cases referred to in the first paragraph, point (h), the applicant shall submit a non-confidential version of the application.'.

(3) Article 6 is amended as follows:
(a) in paragraph 1, the first subparagraph is replaced by the following:
'With a view to achieving the objectives set out in Article 1 and taking account of the precautionary principle, a review, based on a thorough assessment, and an amendment of the list of restricted substances in Annex II shall be considered by the Commission periodically on its own initiative or following the submission of a restriction dossier prepared by a Member State containing the information referred to in paragraph 2.';
(b) in paragraph 1, the fourth subparagraph is deleted.
(c) paragraph 2 is replaced by the following:

'2. The review and amendment of the list of restricted substances in Annex II shall be based on restriction dossiers prepared by the Agency at the request of the Commission or prepared by a Member State.
The Agency or a Member State shall take into account any available information and any relevant risk assessment submitted for the purposes of other Union legislation covering the life cycle of the substance used in EEE, in particular the waste phase. To this end, other bodies established under Union law and carrying out a similar task shall, on request, provide information to the Agency or Member State concerned.
The restriction dossier shall comply with the requirements set out in Part II, point 3, of Annex XV to Regulation (EC) No 1907/2006 and shall, in addition, contain the following information:
(a) information on the use of the substance or the group of similar substances in EEE;
(b) information on detrimental effects and exposure in particular during waste EEE management operations.'

(4) the following Articles 6a, 6b and 6c are inserted:

'Article 6a

Initiation of procedure for review and amendment of the list of restricted substances

1. Within 12 months of receipt of the request from the Commission referred to in Article 6(2), first subparagraph, the Agency shall prepare a restriction dossier conforming to the requirements referred to in Article 6(2), third subparagraph, and suggest restrictions in order to initiate the restriction process.

2. A Member State shall notify the Agency that it proposes to prepare a restriction dossier which conforms to the requirements referred to in Article 6(2), third subparagraph, within 12 months. If that dossier demonstrates that action on a Union- wide basis is necessary, beyond

any measures already in place, the Member State shall submit it to the Agency in order to initiate the restriction process.

3. The Agency shall publish without delay the intention of the Commission or the Member State to initiate the process to review and amend the list of restricted substances in Annex II.

4. The Agency shall establish and maintain a list of substances for which a restriction dossier conforming to the requirements of Article 6(2) is planned or underway by either the Agency or a Member State for the purposes of a proposed restriction.

5. The Agency shall consult the Committee for Risk Assessment, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006, and the Committee for Socio-economic Analysis, set up pursuant to Article 76(1), point (d), of that Regulation. The Committees shall verify whether the restriction dossier submitted conforms to the requirements referred to in Article 6(2), third subparagraph.

Within 30 days of receipt of the restriction dossier, the respective Committee shall inform the Agency or the Member State proposing restrictions whether the dossier conforms to the requirements referred to in Article 6(2), third subparagraph. If the dossier does not conform to those requirements, the reasons shall be given to the Agency or the Member State in writing within 45 days of receipt of that dossier. The Agency or the Member State shall bring the dossier into conformity within 60 days of the date of receipt of the reasons from the Committees, otherwise the procedure under this Article shall be terminated.

6. Where the dossier meets the requirements referred to in Article 6(2), third subparagraph, the Agency shall make it publicly available without delay, clearly indicating the date of publication. The Agency shall invite all interested parties, including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations to submit, individually or jointly, within 4 months from the date of the publication of the dossier, the following:

(a) comments on dossiers and the suggested restrictions;

(b) a socio-economic analysis including an analysis of alternatives, or information which can contribute to one of the suggested restrictions, examining the advantages and drawbacks of the proposed restrictions.

The analysis referred to in the first subparagraph, point (b), shall conform to the requirements in Annex XVI to Regulation (EC) No 1907/2006.

Article 6b

Opinion of the Agency's Committees

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

2. Within 15 months from the date of publication referred to in Article 6a(6), the Committee for Socio-economic Analysis, shall adopt an opinion on the proposed restrictions, based on its

consideration of the relevant parts of the dossier and the socio-economic impact. Prior to that, it shall prepare a draft opinion on the suggested restrictions and on the related socio-economic impact, taking account any existing analysis or information according to Article 6a(6), point (b).

3. The Agency shall publish the draft opinion of the Committee for Socio-economic Analysis on its website without delay and invite interested parties to provide their comments on the draft opinion no later than 60 days from its publication.
4. The Committee for Socio-economic Analysis shall without delay adopt its opinion, taking into account where appropriate further comments received by the deadline set in paragraph 3. This opinion shall take into account the comments of interested parties submitted under Article 6a(6), point (a), and paragraph 3 of this Article.
5. Where the opinion of the Committee for Risk Assessment diverges significantly from the restrictions proposed, the Agency shall postpone the deadline for the opinion of the Committee responsible for Socio-economic Analysis by a maximum of 90 days.
6. For the purpose of adopting opinions pursuant to this article, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.

Additional suggestions to provide for legislative provisions for the remuneration of tasks by Rapporteurs within the OSOA Package.

Where, in accordance with Article 6b, a Committee is required to provide an opinion or consider whether a Member State dossier conforms with the requirements insert relevant article/Annex, it shall appoint one of its members as a rapporteur.

The Committee concerned may appoint additional member(s) or their advisor(s) to act as co-rapporteur(s). For each case, rapporteurs and co-rapporteurs shall undertake to act in the interests of the Community and shall make a declaration of commitment to fulfil their duties and a declaration of interests in writing.

A member of a Committee shall not be appointed rapporteur for a particular case if he indicates any interest that might be prejudicial to the independent consideration of that case. The Committee concerned may replace the rapporteur or co-rapporteur by another one of its members at any time, if, for example, they are unable to fulfil their duties within the prescribed time limits, or if a potentially prejudicial interest comes to light.

Member States shall transmit to the Agency the names of experts with proven experience in the tasks required by Article 6b who would be available to serve on working groups of the Committees, together with an indication of their qualifications and specific areas of expertise.

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

The provision of services by Committee members as rapporteurs/co rapporteurs or any expert serving on a working group established by ECHA, its Committees or Forum, or performing any other task for the Agency shall be governed by a written contract between the Agency and the person concerned, or where appropriate between the Agency and the employer of the person concerned.

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

Article 6c

Submission of an opinion to the Commission

1. The Agency shall submit to the Commission, without delay, the opinions of the Committees for Risk Assessment and Socio-economic Analysis on the restrictions suggested pursuant to Article 6b. Where the opinions of the Committees for Risk Assessment and Socio-economic Analysis diverge significantly from the restrictions suggested by the dossier, the Agency shall submit an explanatory note to the Commission providing a detailed explanation of the reasons for such differences. If one or both of the Committees do not adopt an opinion by the deadlines set in Article 6b(1) and (2) the Agency shall inform the Commission accordingly, stating the reasons.
2. The Agency shall publish the opinions of both Committees on its website without delay.
3. The Agency shall, on request, provide the Commission or Member State with all documents and evidence submitted to or considered by it.';

Article 2

The provisions under this Directive shall be applicable from [OJ: 12 months after the publication of this Directive].

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament *For the Council*
The President *The*

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

Each Member State may nominate candidates to membership of the Committee for Risk Assessment and or expert working groups established by ECHA. The Executive Director shall establish a list of the nominees, which shall be published on the Agency's website, without prejudice to Article 88(1). The Management Board shall appoint the members of the Committee from this list, including at least one member but not more than three or four ~~two~~ from the nominees of each Member State that has

nominated candidates. Members shall be appointed to the Committee or to an expert working group for their role and experience in performing the tasks specified in Article 77(3) (insert relevant Articles from other legislation that assigns ECHA tasks here).

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

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

Article 87

Rapporteurs of Committees and use of experts

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

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

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

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

The person concerned, or his employer, shall be remunerated by the Agency in accordance with a scale of fees to be included in the financial arrangements established by the Management Board.

Where the person concerned fails to fulfil his duties, the Executive Director has the right to terminate or suspend the contract or withhold remuneration.

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

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

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

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

(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

Overall, we welcome the proposal for a regulation to establish a common data platform on chemicals. We have the following observations:

- Article 1. There is no specific reference to the promotion of data from non-animal methods, perhaps a reference could be included in the subject matter and scope or the recitals.
- Article 2(4): we suggest to use ‘economic operators’ instead of ‘business operators’ to ensure alignment with other relevant legislation
- Article 6(4): we propose to add 6(4)(f) supporting regulatory risk management
- Article 7(1): we query as to what is envisaged to be covered by the term ‘products’ here
- Article 16(2); Will MSs access the platform in a similar manner as to how they access REACH IT and ECHA MSCA applications and so be required to have similar security requirements in place?
- We query as to how the provision of information in the common data platform will align itself with article 25(3) of REACH and the 12 year rule on access to data?

In addition, we have the following comments in relation to the overlap with ESPR:

- We note that Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products will soon be repealed and replaced by the ESPR Regulation. Political agreement has been reached and we are awaiting a final draft for proofreading before it is adopted and published in the OJ.
- It is essential that the common data platform for chemicals is aligned to the greatest extent possible with plans for a digital product passport under ESPR. One of the sustainability criteria likely to be included in many ecodesign measures under ESPR will be presence of substances of concern in the product being regulated. It is essential that the economic operators will be able to easily access this information and share it with consumers, authorities and other actors in the supply chain via the DPP.

IRELAND

IE Queries on proposal COM (2023) 799:

On cosmetics:

1. We also note that the data listed in COM 779 may come into scope under the European Health Data Space (EHDS), and we would welcome further details on how the governance structures developed under COM 23 (779) would link to those within the EHDS.
2. Regarding streamlining standard formats and vocabularies: for cosmetics the INCI name is that which is established and used on the labelling. Can we get confirmation that the proposed regulation (e.g. Articles 14 and 15) will not impact cosmetic substance identification and product labelling?
3. Regarding the use of the database for trending, and also emerging risks to health: caution is needed in relation to administrative burden on authorities and clarity in relation to the data sought. For example, will undesirable effects from cosmetic products where a specific substance has been confirmed to be the culprit be expected to be notified to the database (in addition to the current notification to the Communication System for Market Surveillance (ICSMS) Art 23 Reg 1223/2009) and will there be scope to justify the continued use of such a product in particular, critical circumstances?
4. While the collation of data on a substance is welcomed, data used to demonstrate the safety of a cosmetic ingredient cannot have been generated via animal testing. Determining how these sets of data can be distinguished in practice in the database will be something to bear in mind for those planning to use data for carrying out safety assessments of cosmetics.

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SPAIN

OSOA PROPOSALS: COMMENTS

TASK REASSIGNMENT ECHA (DOCUMENT 781). ROHS DIRECTIVE

Regarding the implementation of procedures for the European Chemicals Agency (ECHA) to analyse extension requests and possible modifications to Annex II of the RoHS Directive, which details prohibited substances and allowable limits, the proposed structure for these procedures is considered appropriate and more transparent than the previous one.

However, a procedural question arises. Article 5 of the RoHS Directive addresses how operators can request exemptions.

All these aspects are already transposed in our National Regulation, in Royal Decree 219/2013, of March 22, on restrictions on the use of certain hazardous substances in electrical and electronic equipment.

However, the proposed amendment to the Directive, in its Article 2, does not use the same formulation as other Directives to indicate to Member States (MS) that they must transpose it. It is necessary to set whether this proposal requires transposition since the directive is addressed to MS and imposes obligations on them.

If so, should Article 1 of the proposal be modified to include that the MS will adopt and publish legal, regulatory, and administrative measures, as well as the transposition deadline?

CHEMICAL AGENCIES REGULATION (DOCUMENT 783)

Just like other member states already expressed in the past meeting on January 23rd, the Spanish delegation has the following concerns regarding the necessary expertise and financial capacities for ECHA to absorb the new tasks assigned to it.

- We would like to know if the Agencies to which more tasks will be assigned will have sufficient budget to carry out these modifications. This should include not only the training of existing personnel but also the possible hiring of new expert staff to meet the new demands, the ability to fill future positions with the necessary specialized personnel, and financially assuming the training of this new staff are critical considerations.

  It is essential to evaluate the financial viability of the adaptation and training process within the agreed budget framework. Additionally, efficient strategies must be considered to ensure that agencies and entities in the industrial sector can effectively and sustainably cope with these changes, thus ensuring the continuity and improvement of their functions in the scientific and technical field in the chemical sector.

- Regarding the budgetary aspect, another fundamental issue would be the adequacy of financial resources to carry out the technical modifications, infrastructure changes, and information technology required to implement the proposed change. It is imperative to evaluate whether the allocated budget will comprehensively cover the costs associated with the required technical transformations.

- In this context, it is necessary to consider expenses related to updating or acquiring information technologies, as well as the costs associated with improving or implementing infrastructure relevant for the effective execution of the new work dynamics. Additionally, potential additional costs arising from personnel training in the handling of new technologies and processes must be taken into account.

- The detailed evaluation of technical and infrastructure requirements, along with the corresponding budget allocation, is essential to ensure that the transition process is efficient and successful. This involves analyzing the available financial capacity and ensuring that funds are allocated appropriately for each critical component of the proposed change, thereby mitigating potential economic challenges during implementation.

- As for the amendment of the Regulation (EU) 2019/1021 on persistent organic pollutants (POPs):

Spain acknowledges the merits of maximising synergies and making best use of available expertise and resources in EU agencies. Nevertheless, regarding the proposal change for the procedure for amendment of Annexes IV and V (article 15) from ordinary legislative procedure to delegated act, Spain considers of high importance to preserve the expertise of the Meeting of the Competent Authorities for Regulation (EU) 2019/1021 on Persistent Organic Pollutants. We would like to know in which stage of the future amendments of the annexes the experts from the competent authorities will be consulted. Also, if additional POP experts from Members States will be incorporated to the SEAC and/or the RAC.

COMMON DATA PLATFORM ON CHEMICALS REGULATION (DOCUMENT 779)

The Spanish delegation appreciates the proposal from the COM for the legislative creation of a common data platform, where all information related to chemicals will be hosted.

We think that this is a very necessary proposal, it is also a very ambitious text and should be implemented cautiously due to the involvement of numerous regulations, agencies, authorities, and stakeholders. The concerns and doubts arising from a preliminary analysis of the proposal are:

- As mentioned by the Swedish delegation in the meeting held on January 23rd, we believe that everything related to data confidentiality should be carefully considered when developing this instrument, and we should be equipped with the necessary tools to ensure this principle.

- In line with the concern expressed by Germany at the last meeting regarding the classification and grouping of data, we would like to add that we believe data evaluated by authorities or agencies should prevail or be more visible. This would help prevent the platform from becoming a conglomerate of data that complicates finding reliable data for regulatory decision-making.

- The proposal, as it is written, does not distinguish between substances and mixtures. Therefore, if data on mixtures are also going to be available, a more in-depth analysis of their implications on the data generated in the evaluations for the authorizations of plant protection products at national level will be necessary.

  Regarding Article 3.4, the initiative states that documents relating to Authorities' internal work or decision-making processes not need to be included in the common data platform, but there may be situations where it is possible. What kind of situations are these? Has it been assessed how this could impact the work carried out by the Authorities?

- Regarding Article 6, are MS required to submit biomonitoring data carried out in their respective territories under national programs?

- Is there a specific communication channel foreseen for competent Authorities evaluating substances to convey information on the stage of the evaluation, as indicated in Article 10? Some regulations listed in the Annex already do so; would they need to be adapted in case of a new communication channel, or would the existing one be sufficient?

- Regarding Article 21, will MS be able to use the Data Generation mechanism by requesting it through ECHA, for example, or will it be restricted to only the Commission and Agencies? Furthermore, we would like to insist that this mechanism should only be used in exceptional cases and always keeping the burden of proof on the industry. The procedure and the responsible parties for the requests and financing of required studies should be clearly established.

- With regard to Article 22 and the notification of studies, does the Commission consider that not having a transitional period for the entry into force of this Regulation could negatively affect obliged companies, potentially leading to non-compliance with Article

22 and therefore subjecting them to penalties under Article 26? Furthermore, can this method of notification be made available to companies prior to the adoption of the Regulation so that they can familiarise themselves with it?

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FRANCE

Objet : Commentaires des autorités françaises suite à la réunion du groupe de travail du 23 janvier 2024 sur le paquet législatif « Une substance une évaluation »

Les autorités françaises remercient la Commission européenne pour la présentation de ses propositions lors du dernier groupe et souhaitent rappeler leur soutien à cette initiative visant à rationaliser les travaux entre les agences européennes impliquées dans l'évaluation des produits chimiques.

Les autorités françaises remercient également la Présidence belge pour l'animation de ce premier groupe et l'octroi d'un délai conséquent pour la transmission des commentaires sur ces trois propositions législatives.

- Règlement modifiant les règlements (CE) n°178/2002, (CE) n°401/2009, (UE) 2017/745 et (UE) 2019/1021 du Parlement européen et du Conseil en ce qui concerne la réattribution des tâches scientifiques et techniques et améliorant la coopération entre les agences de l'Union dans le domaine des produits chimiques

Les autorités françaises sont favorables à l'article 4 (4) de la proposition permettant à la Commission d'adopter des actes délégués pour modifier les annexes IV et V du règlement sur les polluants organiques persistants. Les autorités françaises souhaiteraient avoir confirmation de l'obligation pour la Commission de consulter les experts des Etats membres avant l'adoption de tels actes délégués comme il semble prévu au paragraphe 4 de l'article 18 du règlement POP. Il conviendrait également de favoriser les échanges sur l'interprétation et la mise en œuvre de ces annexes dans cette instance de consultation.

- Directive modifiant la directive 2011/65/UE du Parlement européen et du Conseil en ce qui concerne la réattribution de tâches scientifiques et techniques à l'Agence européenne des produits chimiques

Les autorités françaises sont favorables aux modifications proposées de la directive 2011/65/UE relative à la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques.

- Règlement établissant une plateforme de données commune sur les produits chimiques fixant des règles visant à garantir que les données qu'elle contient sont faciles à trouver, accessibles, interopérables et réutilisables et définissant un cadre de surveillance et de prospective pour les produits chimiques

Chapitre I – Objet, champ d'application et définitions

Les autorités françaises considèrent qu'il est difficile à ce stade de vérifier l'exhaustivité des réglementations listées aux annexes I et III de la proposition et donc de l'exhaustivité des données qui seront prises en compte dans la plateforme. Les autorités françaises saluent toutefois la possibilité offerte par la Commission de modifier ses annexes par actes délégués via l'article 23 de la proposition.

Les autorités françaises reconnaissent par ailleurs la spécificité d'un certain nombre de substances actives pour les médicaments, spécificité amenée à croître dans les prochaines années avec les immunothérapies. Toutefois, il serait utile de disposer d'une analyse de l'impact de la limitation des données relatives à ces substances prévue à l'annexe II.

De plus, les autorités françaises s'interrogent sur l'approche différenciée entre les médicaments et les produits biocides et phytopharmaceutiques pour lesquels il n'y a pas de limitation prévue par rapport aux données d'efficacité. Il existe des usages parfois proches entre les médicaments vétérinaires et les produits biocides, par exemple les TP3 sur l'hygiène vétérinaire.

Pour ce qui concerne l'exclusion des informations relatives à la composition des mélanges dangereux et des produits cosmétiques de la plateforme, les autorités françaises approuvent cette disposition du fait de la sensibilité des informations. Elles s'interrogent néanmoins sur l'opportunité de mettre à disposition ces données aux autorités seulement afin de pouvoir collecter des informations sur les usages des substances et ainsi améliorer les évaluations des risques des substances menées par les autorités.

Chapitre II – Systèmes et plateformes d'information

A l'article 3 paragraphe 11 de la proposition, les autorités françaises s'interrogent sur la mention « sauf indication contraire » en ce qui concerne le délai d'établissement de la plateforme de données commune et ses services spécialisés. Les autorités françaises comprennent de la lecture de la proposition que seul le service de notification des études dispose d'un délai différent fixé à 2 ans suivant la date d'entrée en vigueur du texte. Elles souhaiteraient avoir une confirmation de cette lecture par la Commission. Le cas échéant, la mention « sauf indication contraire » pourrait être remplacée par « sauf pour le service de notification des études » afin de faciliter la compréhension du texte.

Dans ce même paragraphe, la Commission propose que les jeux de données soient progressivement intégrés dans la plateforme conformément au plan de mise en œuvre visé à l'article 4 (1) première phrase. Les autorités françaises s'interrogent sur cette dernière mention « première phrase » alors que la deuxième phrase de l'article 4 (1) fait référence aux plans de mise en œuvre glissants et qu'il semblerait cohérent de tenir compte également des mises à jour du plan de mise en œuvre pour l'intégration des données.

A l'article 4 paragraphe 1 de la proposition, il est proposé que la Commission adopte un plan de mise en œuvre établissant l'ensemble des données à inclure dans la plateforme ainsi que le calendrier correspondant pour leur inclusion. Les autorités françaises s'interrogent sur la procédure d'adoption d'un tel plan notamment en termes de consultation. Les autorités françaises souhaiteraient avoir la confirmation de la Commission que cette procédure sera définie dans le système de gouvernance défini à l'article 4 (5). Elles s'interrogent par ailleurs sur l'intention de la Commission pour ce qui concerne l'implication des Etats membres dans cette procédure.

Plus généralement, les autorités françaises s'interrogent sur les modalités de consultation, en particulier des Etats membres, avant l'adoption par la Commission des décisions d'exécution prévues dans le projet de règlement aux articles 4, 13 et 20.

Pour ce qui concerne le répertoire des valeurs de référence introduit à l'article 8 de la proposition, les autorités françaises souhaitent indiquer qu'il existe une base de données similaire aux Etats-Unis intitulée CompTox/ToxValDB. Il serait intéressant de bénéficier de l'expérience des autorités américaines pour construire un tel répertoire.

A l'article 10 paragraphe 3 de la proposition, les autorités françaises considèrent que le point e) relatif au résultat du processus réglementaire ne pourra être systématiquement indiqué en fonction de l'état d'avancement du processus et proposent d'ajouter la mention « le cas échéant ».

Les autorités françaises souhaitent indiquer que l'utilisation de l'intelligence artificielle pourrait permettre de faciliter la mise en œuvre et d'enrichir la base de données introduite à l'article 11 sur les dispositions et obligations juridiques applicables aux produits chimiques.

Chapitre III – Formats de données et vocabulaires contrôlés

Les autorités françaises considèrent nécessaire qu'il soit prévu à terme que les données concernant le danger des substances chimiques soient fournies sous forme de rapport d'études et de données brutes et non sous forme de résumé d'études. Ce format est nécessaire pour permettre l'utilisation d'outils performants d'exploitation des données.

Chapitre IV – Confidentialité et utilisation des données relatives aux produits chimiques

Les autorités françaises ont bien pris note des dispositions relatives à la gestion de la confidentialité des données diffusées sur la plateforme. Elles s'interrogent toutefois sur la gestion de la propriété intellectuelle de ces données dans le cadre de leur réutilisation.

Chapitre V – Cadre de surveillance et de prospective pour les produits chimiques

Les autorités françaises s'interrogent sur les délais d'établissement du cadre d'indicateurs pour la surveillance des facteurs et des incidences de l'exposition aux produits chimiques mentionné à l'article 18 de la proposition.

A l'article 19 paragraphe 4 de la proposition est prévu un rapport annuel de l'Agence européenne pour l'environnement permettant de compiler et analyser les données relatives aux signaux d'alerte collectées afin d'examiner la nécessité de mesures réglementaires ou de stratégies d'action. Les autorités françaises s'interrogent sur l'opportunité et la pertinence de demander que l'Agence européenne pour l'environnement mette en avant, dans le rapport, les domaines sur lesquels focaliser l'attention afin que les différentes parties concernées se saisissent du sujet.

Chapitre VII – Notification des études

Les autorités françaises soutiennent la mise en place d'un système de notification des études mais s'interrogent sur plusieurs aspects du système.

Les autorités françaises s'interrogent sur l'articulation prévue entre les notifications des opérateurs économiques et celles des laboratoires pour les mêmes études. Il conviendra d'avoir un système permettant de regrouper les notifications d'une même étude pour éviter les doublons.

La proposition prévoit que les notifications d'études ne soient mises à disposition sur la plateforme qu'une fois les dossiers réglementaires tenant compte de ces études soumis. Les autorités françaises ont bien pris connaissance des justifications de la Commission dans le considérant 30 de la proposition. Elles se questionnent néanmoins sur l'intérêt de mettre en place un tel système si l'information n'est pas mise à disposition dès le début du lancement d'une étude. Cette stratégie ne permet pas aux opérateurs et autorités

d'optimiser la conduite des études et donc de limiter l'expérimentation animale. *A minima* les autorités françaises considèrent que les autorités des Etats membres devraient avoir accès à la base de données sur les notifications d'études avant la diffusion sur la plateforme de données commune.

Enfin, les autorités françaises regrettent l'absence de moyen de coercition défini dans la législation européenne pour ce qui est de l'obligation de notification des études. L'expérience montre que l'existence de sanctions à l'échelle nationale comme il est proposé de définir dans le projet de texte de la Commission n'est pas toujours assez incitative pour qu'une réglementation soit correctement appliquée (exemple de l'enregistrement dans REACH où le retrait du numéro d'enregistrement n'est pas prévu en cas de non-conformité manifeste et persistante).

Potentielles corrections de forme

Par ailleurs, les autorités françaises ont identifié des potentielles corrections de forme à apporter dans la proposition de la Commission notamment dans les paragraphes suivants :

- Article 2 paragraphe 12 sur les « données à caractère personnel » : cette définition est précisée à l'article 3, **point 1)** du règlement **2018/1725** et non l'article 3, point 16) du règlement 2018/175. Le règlement **2018/1725** doit également être corrigé aux paragraphes 13 et 14 de ce même article.

- Article 5 paragraphe 2 : il est fait référence aux données contextuelles pertinentes, ces données sont visées à l'article 4 **paragraphe 5** (et non paragraphe 4) point c).

- Article 6 paragraphe 6 : l'Agence européenne pour l'environnement procède au traitement des données de biosurveillance humaine aux fins visées au **paragraphe 4** (et non paragraphe 2).

- Article 20 paragraphe 2 deuxième phrase : il manque le mot de liaison « et » avant la proposition « adopte toute révision selon les mêmes modalités ».

- Annexe I de la proposition : le règlement 108/2008 relatif à l'adjonction de vitamines, de minéraux et de certaines autres substances aux denrées alimentaires est listé au point 28 de l'annexe I alors que ce règlement semble être déjà pris en compte via le règlement 1925/2006 mentionné au point 26 de l'annexe I.

- Annexe III de la proposition : le règlement 1331/2008 établissant une procédure d'autorisation uniforme pour les additifs, enzymes et arômes alimentaires est listé deux fois à l'annexe III aux points 17 et 21.

COURTESY TRANSLATION

This is a courtesy translation and in the event there are any differences between the French and English texts, the French text governs.

Subject: Comments following the working group meeting of 23 January 2024 on the "One substance, one assessment" legislative package

The French authorities thank the European Commission for the presentation of its proposals during the last group and wish to reiterate their support for this initiative aimed at rationalising the work between the European agencies involved in the evaluation of chemicals.

The French authorities would also like to thank the Belgian Presidency for its leadership of this first group and for allowing a substantial period of time for comments on these three legislative proposals.

- Regulation 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 French authorities are in favour of Article 4(4) of the proposal allowing the Commission to adopt delegated acts to amend Annexes IV and V of the Regulation on persistent organic pollutants. The French authorities would like confirmation of the Commission's obligation to consult Member State experts before adopting such delegated acts, as appears to be provided in Article 18(4) of the POP Regulation. Discussions on the interpretation and implementation of these annexes should also be encouraged within this consultation body.

- Directive amending Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency

The French authorities are in favour of the proposed amendments to Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

- 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

Chapter I – Subject matter, scope and definitions

The French authorities consider that it is difficult at this stage to verify the exhaustiveness of the regulations listed in Annexes I and III of the proposal and therefore the exhaustiveness of the data that will be taken into account in the platform. However, the French authorities welcome the possibility offered by the Commission to amend its annexes by delegated acts via Article 23 of the proposal.

The French authorities also recognise the specificity of a certain number of active substances for medicinal products, a specificity that is set to increase in the coming years with immunotherapies. However, it would be useful to have an analysis of the impact of the limitation on data relating to these substances set out in Annex II.

In addition, the French authorities question the differentiated approach between medicinal products and biocidal and phytopharmaceutical products for which there are no restrictions on access to efficacy data. Veterinary medicinal products and biocidal products sometimes have similar uses, for example in TP3 on veterinary hygiene.

As regards the exclusion of information on the composition of hazardous mixtures and cosmetic products from the platform, the French authorities approve this provision due to the sensitivity of the information. However, they question the appropriateness of making these data only available to the authorities to be able to collect information on the uses of substances and thus improve the risk assessments of substances carried out by the authorities.

Chapter II – Information systems and platforms

In Article 3(11) of the proposal, the French authorities question the mention "unless specified otherwise" with regard to the deadline for establishing the common data platform and its dedicated services. The French authorities understand from reading the proposal that only the study notification service has a different deadline set at 2 years following the date of entry into force of the text. They would like the Commission to confirm this interpretation. Where applicable, the mention "unless specified otherwise" could be replaced by "except for the study notification service" to make the text easier to understand.

In the same paragraph, the Commission proposes that datasets shall be integrated progressively into the platform in accordance with the implementation plan referred to in Article 4(1), first sentence. The French authorities question this reference to the "first sentence" when the second sentence of Article 4(1) refers to rolling implementation plans and it would seem consistent to also take account of updates to the implementation plan for data integration.

Article 4(1) proposes that the Commission adopt an implementation plan identifying datasets for inclusion in the platform together with a timeline for their inclusion. The French authorities question the procedure for adopting such a plan, particularly in terms of consultation. The French authorities would like confirmation from the Commission that this procedure will be defined in the governance scheme defined in Article 4(5). They also question the Commission's intention regarding the involvement of Member States in this procedure.

More generally, the French authorities question the consultation modalities, in particular for the Member States, before the Commission adopts the implementing decisions provided in Articles 4, 13 and 20 of the draft regulation.

With regard to the repository of reference values introduced in Article 8 of the proposal, the French authorities would like to point out that a similar database exists in the United States entitled CompTox/ToxValDB. It would be interesting to benefit from the experience of the American authorities in building such a repository.

In Article 10(3) of the proposal, the French authorities consider that point e) relating to the outcome of the regulatory process cannot be systematically indicated according to the state of play of the process and propose adding the mention "where appropriate".

The French authorities would like to point out that the use of artificial intelligence could facilitate implementation and enhance the database introduced in Article 11 on the legal provisions and obligations applicable to chemicals.

Chapter III – Data formats and controlled vocabularies

The French authorities consider it necessary that data related to the hazard of chemical substances should eventually be provided in the form of study reports and raw data and not in the form of study summaries. This format is necessary to enable the use of high-performance data processing tools.

Chapter IV – Chemicals data confidentiality and use

The French authorities have taken note of the provisions for managing the confidentiality of the data published on the platform. However, they are concerned about the management of the intellectual property of this data in the context of its re-use.

Chapter V – Monitoring and outlook framework for chemicals

The French authorities are concerned about the timescales for establishing the framework of indicators for monitoring the drivers and impacts of exposure to chemicals referred to in Article 18 of the proposal.

Article 19(4) of the proposal provides for an annual report by the European Environment Agency to compile and analyse the data collected on early warning signals in order to examine the need for regulatory measures or action strategies. The French authorities question the appropriateness and relevance of requesting that the European Environment Agency highlight, in the report, the areas on which to focus attention to enable the various parties concerned to take up the issue.

Chapter VII – Notifications of studies

The French authorities support the introduction of a study notification system but have questions about several aspects of the system.

The French authorities are concerned about the planned interaction between notifications from economic operators and those from laboratories for the same studies. A system will be needed to group together notifications for the same study in order to avoid duplication.

The proposal states that notifications of studies will only be made available on the platform once the regulatory dossiers taking account of these studies have been submitted. The French authorities have taken due note of the Commission's justifications in recital 30 of the proposal. However, they question the point of setting up such a system if the information is not made available as soon as a study is launched. This strategy does not enable operators and authorities to optimise the conduct of studies and therefore limit animal experimentation. At the very least, the French authorities consider that the authorities of the Member States should have access to the database on study notifications before it is published on the common data platform.

Finally, the French authorities regret the absence of means of coercion defined at European level with regard to the obligation to notify studies. Experience shows that the existence of sanctions at national level, as proposed in the Commission's draft text, is not always enough of an incentive for regulations to be properly applied (for example, in the case of REACH registration, where there is no provision for withdrawal of the registration number in the event of manifest and persistent non-compliance).

Potential formal corrections

In addition, the French authorities have identified potential formal corrections to be made to the Commission's proposal, particularly in the following paragraphs:

- Article 2(12) on "personal data": this definition is specified in **article 3(1)** of Regulation **2018/1725** and not article 3(16) of Regulation 2018/175. Regulation **2018/1725** also needs to be corrected in paragraphs 13 and 14 of the same article.

- Article 5(2): reference is made to relevant context data, these data are referred to in **article 4(5)(c)** and not article 4(4)(c).

- Article 6(6): the European Environment Agency shall process human biomonitoring data for the purposes referred to in **paragraph 4** (and not paragraph 2).

- Article 20(2), second sentence: the linking word "**and**" is missing before the proposal "shall adopt any revision in accordance with the same procedures".

- Annex I to the proposal: Regulation 108/2008 on the addition of vitamins and minerals and of certain other substances to foods is listed in point 28 of Annex I, whereas this regulation appears to be already covered by Regulation 1925/2006 mentioned in point 26 of Annex I.

- Annex III of the proposal: Regulation 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings is listed twice in Annex III, in points 17 and 21.

HUNGARY

Comment on the OSOA legislative package

After the first meeting of the Ad hoc Working Party on One Substance One Assessment, Hungary wishes to share some further remarks and to ask for further clarifications regarding certain elements of the OSOA package:

In general, in view of the expected significant increase in the workload of ECHA's scientific committees, we would like to emphasise the importance to have the draft of ECHA basic regulation available as soon as possible, to have a sound basis for decisions on certain issues related to this legislative package.

Re-attribution of scientific and technical tasks and improving the cooperation among Union agencies in the area of chemicals (COM(2023) 783 final)

Article 1(2): In order to make the process more transparent and plannable and to avoid backlogs, we suggest to consider the possibility of establishing reasonable deadlines for the procedural steps.

Establishing a common data platform on chemicals (COM(2023) 779 final)

General remarks:

- ECHA launched its new database on 30 January. Will this be the basis for the common data platform?
- Will the Common Data Platform exist in parallel with other (already existing) data platforms (e.g. ECHA's dissemination site, substance info cards, brief profiles etc.) or will it replace them? In the former case, data consistency would be a critical issue.
- What level of security would be required from authorities accessing confidential data in the Common Data Platform? Something similar to S-CIRCABC or a more stringent one, e.g. accessing ECHA's IT tools (regular full scope audits, physical security recommendations, recommendations for the Organisation's IT-systems)?

Specific remarks:

- Article 9: We suggest to explicitly mention in the text that information in the Database of Study Notifications are confidential (taking into account future ATD requests). Furthermore, will Member States have access to the Database of Study Notifications? As ECHA will integrate the notifications once the corresponding registration, application, notification or other relevant regulatory dossier has been submitted, concerned parties will not be aware of the ongoing studies.
- Article 10(2): In our view, it is more transparent to set a deadline for submitting information on intentions, e.g. 6 months before the actual submission (or in case of ongoing and completed processes after this regulation enters into force). Thus, the procedures would be more predictable for the concerned parties than the application of the term 'undue delay'.
- Article 22: How will the system manage the duplication of notifications, if business operators and laboratories will notify the same study?

- Article 22(1): We are of the opinion that the text 'prior placing on the market' narrows down the scope of the obligation. We are concerned that studies conducted after the chemicals are placed on the market will not be notified.
- Article 22(3): We suggest requiring business operators to indicate to the laboratories that the study will support a regulatory dossier; otherwise laboratories cannot notify this kind of information. Furthermore, do we understand it correctly that, if a study does not support application, notification or regulatory dossiers, it will not be notified at all?
- Article 22(5). We have concerns regarding the enforcement of obligations on laboratories and testing facilities located in third countries. We wonder what kind of enforcement measures could be taken, if any?
- Article 24(4). Does the Commission have an idea about the kind of platform that will be used for the consultations? (e.g. CARACAL, or a new forum will be established?)

<u>Amending Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency (COM(2023) 781 final)</u>

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

THE NETHERLANDS

Contribution regarding the Commission proposals on one substance, one assessment

We thank the Commission for the proposals regarding the re-attribution of scientific and technical tasks and improving the cooperation among Union agencies in the area of chemicals and the proposal to establish a common data platform.

We welcome the implementation of the one substance, one assessment approach of the Chemicals Strategy for Sustainability. We think that improving the cooperation among EU agencies can contribute to the goals of the one substance, one assessment approach.

The establishment of a central data platform and re-attribution of tasks to EU-agencies do require the necessary infrastructure and resources. We request if the Commission can elaborate on how they will ensure that the EU-agencies are adequately equipped for the new tasks.

Can the Commission confirm that the initial and the operational costs for all three proposals will be covered by already existing funding or does the Commission foresee that additional budgetary claims will follow?

We note that ECHA will have a new task regarding the RoHS directive, which is to advise on the restriction of chemicals. This new task requires expertise regarding the life cycle of the substance in particular the refurbishment, and the waste and recycling phase. The staff Commission document states that ECHA does not currently have this expertise. Could the Commission elaborate how ECHA will be equipped to enable sufficient knowledge on assessing the impact of a restriction on refurbishment, and the waste and recycling phase?

Regarding the Persistent Organic Pollutants Regulation we have the following remarks. With the new proposal, the Commission can request ECHA to prepare a report on the impact on human health, the environment, and social and economic impact of the introduction and modification of limit values for concentrations of POPs in Annexes IV and V to the Regulation. This new task also requires special expertise regarding the waste and recycling phase. The staff Commission document states that ECHA does not have this expertise at this moment. Could the Commission elaborate how ECHA will be equipped to enable sufficient knowledge on the impact of adjusting Annex IV values on the waste and recycling phase?

We noticed that ECHA has been given the task to do the scientific assessment for determining the concentration limit values for substances in Annexes IV and V to the POP regulation, but **not** for determining the limit values in Annex I. Our suggestion is that in the spirit of 'one-substance-one-assessment' - assessments for amending Annex I should also be done by ECHA.

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

Regarding the central data platform, it is noted that both public data and confidential data will come together in one database. We kindly ask the Commission to elaborate on how it will be ensured that the confidentiality of data as currently laid down in the existing regulations will not change.

With the new proposal on the central data platform, ECHA will be given the mandate to generate data or studies on chemicals. Although in general we can support such a mandate, we would like to emphasize that this should not be at the expense of the responsibility of companies that import or produce a chemical substance to guarantee its safety . Can the Commission confirm that this principle will remain the central principle of the EU chemicals legislation? Furthermore, we suggest to frame the new mandate accordingly in the proposed decision.

We agree with the Commission that the data platform can function also as an early warning tool on chemicals. We propose that the database also plays a role in Safe and Sustainable-by-Design, the concept in which chemical substances are already assessed at the design table for safety for people and the environment and sustainability. Could the Commission consider adding this to the role of the data platform in the decision?

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AUSTRIA

WRITTEN COMMENTS: 'One substance, one assessment' (OSOA) Legislative Package (WK 1064/2024)

The following comments only constitute initial reactions and comments and do not constitute an official AT position. We maintain our general scrutiny reservation and reserve the right to make further comments at a later stage.

In general:
AT generally welcomes the overarching aim of the OSOA package to achieve a more efficient use of data and synergies in the work of the various EU agencies. However, several issues will need to be further clarified and concretised, in particular regarding the common data platform.

In detail (COM(2023) 779 final):
Art. 2(6) in conjunction with Art. 8 and Art. 14
For reference values without a toxicological threshold "*below which risks related to the adverse effects [...] are considered acceptable or tolerable*", the statistical (cancer) risk that is associated with these values should be specified as well. The statistical (cancer) risk should be stated in Art. 8 (Repository of reference values) and a data format should be specified in Art. 14 accordingly.

Art. 2 para. 11 and Art. 13
The term "*environmental sustainability related data*" is very vague and comprehensive. We believe that this term should be clarified and concretised, since the concrete data content will only be defined at EU level in the coming years (e.g. via "*eco-design requirements*" as part of the Eco-design Regulation). Therefore, we suggest adding a reference to an Annex (e.g. in Art. 13) which can be updated on a regular basis by means of Delegated Acts. This annex should contain the respective legal acts as well as the associated sustainability information.

Art. 5 (1)
The wording "*chemicals data generated as part of [...] national [...] legislation*" potentially also includes, for example, requirements regarding the emission of chemicals in individual notifications by the authorities of the Member States. This would be a disproportionate effort that should be limited.

Art. 9 (3)
AT considers that the concept of Article 9 (3) needs further discussion, as it seems to prevent Member States authorities from getting relevant information on notified studies in time.

Art. 22(1)
It is unclear to us whether the term "*products*" also includes mixtures and articles (within the meaning of the REACH Regulation). In order to clarify this, the term "*products*" should be included in the definitions within Art. 2.

Annex III
We are wondering why Reg. (EC) No 1331/2008 is mentioned twice (No. 17 and No. 21). Maybe this is a an editorial mistake/error.

PORTUGAL

"One Substance One Assessment" Package

Follow-up to the ad-hoc WP meeting of 23rd January 2024

(WK 1064/2024)

MAAC Comments

Reference documents:

- doc. ST 16956/23 and ST 16956/23 add1, of 19th December 2023;
- doc ST 16961/23 and ST 16961/23 add1, of 18th December 2023;
- doc. ST 16972/23 and ST 16972/23 add1, of 19th December 2023;
- doc. ST 16973/23 and ST 16973/23 add1, of 19th December 2023.

"One Substance One Assessment" Package - general comments

We support the initiative of this legislative package, considering it as an important step towards the objectives set up in the "Strategy for the Sustainability of Chemical Products" (CSS) such as the simplification and consolidation of the EU's comprehensive and complex chemical products regulatory framework.

We also believe that this initiative will contribute to improve overall coherence, quality, efficiency and transparency of the safety assessment of chemicals across the legislation, as well as to strength confidence in the scientific basis of the EU decision-making process in the field of chemicals.

"One Substance One Assessment" Package - general comments to the re-attribution of scientific and technical tasks and improving cooperation among union agencies in the area of chemicals (**Omnibus proposal)**

- *Omnibus Regulation*

The proposal amends Articles 2 and 15 of Regulation (EC) No 401/2009 of the European Parliament and of the Council of 23 April 2009 on the European Environment Agency and the European Environment Information and Observation Network (EIONET). The reason for this amendment stems, according to COM, from the fact that the current provisions do not give the EEA an explicit mandate or obligation to cooperate with ECHA, EMA and EFSA, and that it is necessary to strengthen the cooperation provisions in order to realise the ambition of one substance, one assessment.

According to the explanatory memorandum, page 14, on collection and use of expertise – have been taken into account the contributions provided by the EU agencies concerned when assessing which tasks deserve to be re-attributed to EU agencies, how they should be assigned, as well as the potential effects on these agencies. In this context, **we see as positive the strengthening of the co-operation between the Agencies, however, doubts remain about the impact of the Eionet Network's involvement in this cooperation.**

"One Substance One Assessment" Package - general comments to the specific legislation proposals

- *Amending the POPs Regulation*

We support, in particular, the change of POP monitoring reporting to the EEA, thus allow for better organization and consolidation of information, as well as a more efficient distribution of tasks.

Regarding the amendments to annexes IV and V of the POP Regulation, we agree in principle with the possibility given to COM to amend these annexes through a delegated act, once it is embodied in an impact assessment report, subject to consultation of interested parties and a SEAC opinion. We can also agree, in principle, with the attribution of the additional tasks on this matter to ECHA, as we believe that the procedures established at this level will ensure greater robustness in the decision-making process, being also aligned with the procedures adopted in other Regulations such as REACH and CLP.

- *Amending the RoHS Directive*

We agree in general with the proposal for amending the RoHS Directive, taking into consideration the following aspects:

- the substances regulated under RoHS Directive are the same or similar to those regulated under REACH Regulation and therefore similar data, scientific methodologies and ECHA procedures can be used/applied for the development of exemption restriction dossiers and subsequent formulation of the RoHS Directive opinions; this will assure the optimization of the processes.
- the procedures established at ECHA level, which are aligned with the procedures adopted in pieces of legislation such as REACH, CLP and POP Regulations, will ensure greater coherence and alignment between the risk management measures laid down in these Regulations and the RoHS Directive.
- this will take advantage of ECHA's extensive knowledge and experience on risk assessment and socio-economic assessment and will therefore ensure greater robustness in the RoHS Directive decision-making process.

In addition, we welcome the COM's additional information provided in the meeting regarding the steps that are foreseen in order to assure the allocation to ECHA of the adequate expertise as well as the human and financial resources aiming at responding to these new tasks.

Our concern is only about the confidentiality of the request of the companies regarding the substance requirements

- *Common Data Platform on Chemicals*

We support in general the development of a common data platform in alignment with the CSS, which allows the collection of relevant information on chemicals and early warning signs of chemical risks, ensuring interoperability between the databases and thus facilitating the sharing, access and re-use of information on chemicals coming from all sources.

It is considered that this measure is an important step towards assuring that data meets the FAIR guiding principles and building greater trust in the scientific highlighting of the EU decision-making process for chemicals.

In addition, we have some observations/concerns that we would like to mention, namely:

- **We have concerns related to Art. 6 - Human Biomonitoring data** – such a task will involve allocating additional resources to the EEA, however, it is mentioned no significant impact on the EEA network. The network may be asked to assist in the collection of human biomonitoring data and early warning signals from the activities of EEA member countries and "providing assistance" means carrying out new/increased tasks, which raises the question of why COM considers there to be an impact on the EEA - providing financial and human resources for this purpose - but not a similar impact on the Eionet Network. **The table "Future workload and resource needs" (SWD, p. 184) identifies a series of tasks in this area which, due to their number and content, corroborate what we consider to be a greater impact on the Eionet Network**. **There´s a need to further develop what this competence entails for the Eionet Network.**
- **As part of the provision of regulatory information (Art. 10), it is not clear what it refers to, as far as the EEA is concerned, since it does not have competences about regulatory processes on chemical products.**
- **Regarding the database on information related to environmental sustainability (Art. 13) it is not clear whether the Eionet network will be utilised (taking into account that the EEA does not currently have any relevant data for this database).**
- **We are concerned that the aim of interoperability is not fully achieved if data treatment is not foreseen**. We are aware that assuring the interoperability of such a platform will be quite challenging, as we are dealing with a significant amount of data coming from different sources and using different terminologies and formats (Art. 14 and 15). **Additionally, we also have concerns relating to conflicting results and analyses of data from studies (art. 3(2)) and not only with harmonisation of vocabularies and formats**.
- **Although the reuse/sharing of data was considered by the authorities as one of the important parameters to be taken into consideration in the OSOA Package, it seems that this issue did not receive attention within the scope of the proposal**. **The reason behind this option could be related to data ownership aspects, we would ask the COM to better clarify this issue**. **The possibility in art. 17(1) for Authorities to use the data will not override the ownership and use of data.**
- **Regarding the confidentiality of data (art. 16 and 17), we still have some doubts on the procedure that will be applied when the same study is submitted under different legislative instruments with different levels of confidentiality. We would like to confirm if the level of confidentiality in the origin is going to be maintained.**
- **The framework of indicators established in article 18, we would like to clarify how these indicators will be related to the existent statistics systems as we believe that they can be a relevant added value in this process. In addition, under the monitoring framework of the 8EAP, resources (human and financial) were allocated to the EEA, but no resources were allocated to the Eionet network, which raises the question of whether the impact for the Eionet network will be the same (low) as for the EEA**.

- **The early warning system is to be based on a framework of indicators that will monitor the chemical pollution. In this sense, we would like to be informed about the level of ambition of this process taking into consideration those situations where: pollution is not directly detected; the cause-effect relationship is difficult to claim; the risk is becoming more systemic (e.g. considering climate related risks).**
- **We would also like to underline the importance of the inclusion of the item "prevention of emerging risks related to chemicals", which we also consider very challenging.**
- **As other MS mentioned in the meeting, we also have some concerns on which will be the involvement of MS in the early warning and action system (art. 19), since details on the operation of the early warning and action system are lacking, as MS hold data which EEA needs to consider, as this is a new task for EEA (with allocation of resources)**. **We believe that there is a need for better clarification of what is considered to be the process of collecting this data from the MS and the involvement of the Eionet Network for this purpose.**
- Regarding the notification of studies (art. 22), we welcome the inclusion of the item "to prevent withholding of specific study results" related to the notification of studies, **although we have some concerns on how ECHA will manage to merge all the information that will be notified to "Database of Study Notifications" by business operators, the laboratories and testing facilities, especially those that are established in third countries (art. 22(5)). We have also some concerns on how the enforcement of this notification can be guaranteed if commissioned to third countries**.

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SLOVENIA

Comments in accordance with the Presidency note (WK 1064/2024 INIT) on »One Substance One assessment« - OSOA legislative package:

SI welcomes all three legislative proposals introduced by the European Commission for ensuring "One Substance, One Assessment" approach. With that, more efficient consolidation of technical and scientific work in the area of chemicals will be ensured.

For the moment, we are still under general scrutiny for all three proposals and we raise the scrutiny reservation in this respect.

Regarding the Regulation establishing a common data platform on chemicals to assess the feasibility of consolidating the data on chemicals collected by EU institutions, bodies and agencies (ST 16961/23) we welcome the proposal. SI agrees that having a uniform platform collecting various data related to chemicals will be beneficial to all.

Nonetheless, we would like to provide some comments on human biomonitoring. In Slovenia, we have already collected a substantial amount of data on human biomonitoring, which to a lesser extent has already been forwarded to the IPCHEM database. In our opinion, this proposal would need the following clarifications of the provisions in order to be better understood:

- The role and processes of the European Chemicals Agency regarding the new platform on chemicals;
- Different entities providing personal data to which the platfom provides access;
- The reference to paragraphs 3, 4, and 5 in Article 6(6) instead of the reference to paragraph 2 and to include the same reference to Articles 6(3) and 6(4);
- In Article 6(4) processing of biomonitoring data constituting personal data (at EEA) shall not entail sharing of such data with third parties;
- Third parties shall be defined in Article 2;
- Sources of the received human biomonitoring data from sources other then the Commission or researchers;
- to inform providers of human biomonitoring data about the proper type of data needed;
- compliance with Article 89 of GDPR and with Article 13 of EUDPR regarding the processing of personal data for scientific research and statistics;
- the rights to access to personal data by Authorities and the general public in Article 16 should be limited according to the purposes claimed

Generally, we can also support changes to the RoHS regulation. We welcome the improved and refined process for restricting new substances, which will enhance transparency and legal certainty. Additionally, we appreciate the alignment of the RoHS directive with REACH, addressing an issue that has been open since the adoption of the current RoHS directive.

Finally, we commend the Commission's attempt to enhance scientific reliability and ensure coordinated procedures based on methodologies defined by the REACH regulation, managed by the ECHA agency. We believe it reflects ECHA and EU aspirations and strategy to become and remain a centre of knowledge and data on chemicals. These data should be utilized across a wide spectrum of EU chemical management. The proposal is an important step towards improving the efficiency and functioning of the EU in all fields of chemicals management.

However, we emphasize the need to ensure favourable working conditions for ECHA, especially regarding its long-term, independent, and sustainable funding.

FINLAND

Initial comments on OSOA-package

Streamlining work and reducing overlapping work is very important. We support the strengthening of ECHA's role as long as sufficient resources are ensured.

It is proposed that the Article 4 of the POP-regulation ((EU) 2019/1021) would be amended to give the Commission the possibility to request ECHA to carry out the assessment required to amend the concentration limit values in the Annexes IV and V to the POP-regulation. While FI finds useful the utilisation of the expertise of the agency's Committee for Socio-Economic Analysis (SEAC), we express our reservations about whether the committee has enough expertise on waste management.

It is further proposed (Article 13 paragraph 2) that this provision would also introduce the adoption of amendments to Annexes IV and V by means of a delegated act. While FI generally supports the one substance, one assessment policy target, we believe that the delegation of legislative powers to the Commission in POP-regulation Article 15 needs further consideration.

FI sees the role of the POP-CA (competent authorities) very important in preparation of the delegated acts. In case the above described amendments would be accepted, what would be the role of the POP-CA in the future? Would the Commission still consult the experts designated by each Member State and closely collaborate with POP-CA before adopting a delegated act?

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SWEDEN

Questions and comments on the One Substance, OneAssessment legislative package

Sweden thanks the BE PRES for the opportunity to ask questions and make general comments regarding the One substance, One assessment legislative package in this early stage of negotiations. In general, Sweden welcomes the Commission proposal of OSOA and sees it as a part of the implementation of the Green Deal and the EU's chemicals strategy for sustainability towards a toxic-free environment.

Comments and questions of particular priority can be found in article 3(2), 5, 16 and 17 of the Common Data Platform, and in article 1(3) (c) regarding amendments of the second paragraph of Article 6 under RoHS. The rest of our input can be found in order of appearance.

Attached you may also find text proposals on the proposal for revising the RoHS directive and on the omnibus regulation. SE is not presenting any text proposal on the Common Data Platform at this moment as we see a need to understand the proposal more closely before we can propose any changes.

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

General comments and questions

Regarding resources, we wonder how the Commission has taken into account the increased need for resources for work under the Medical Devices Regulation? Could the Commission also clarify how it has derived the resources ECHA will need for the Water Framework Directive?

Under which procedures shall the Commission consult experts before adopting implementation decisions?

Article 2(3) and (4)
Could the Commission elaborate the need of the term 'duty holders' given the lack of obligations for these actors?

Article 2(12-14)
In the reference to Regulation (EU) 2018/1725, the number 2 is missing in '1725'.

Article 3
Given the wide range of legislation and the different regulatory systems from which data will be gathered in the platform, how will the Commission ensure the quality of data that is included? Will the quality of data be reviewed periodically, for example that studies to redundant guidelines or standards are removed?

Article 3(2)(a)
For legislation such as the Water Framework Directive and its daughter directives, more complex data is generated compared to the derived data that is submitted to Commission. Will requirements of inclusion in the data platform cover data that has reporting requirements or will original data also be included?

Article 3(2)(c)
Sweden considers that environmental risk assessments and information on where medicinal active substances and products are produced should be made available. It is proposed that some data regarding medicinal active substances are not to be included in the common data platform. Could the Commission explain the purpose of excluding some data that could be relevant for the development of EU legislation on chemicals, for example, within the Water Framework Directive?

Article 3(11)
Could the Commission clarify what is meant by 'relevant datasets' in Article 3(11)? Is the intention to include data that was submitted before the date of entry into force of the Regulation?

Article 4

There are product sectors that don't have a specified EU Agency responsible, such as medical devices and cosmetic products. Has the Commission considered how, and if, these will have a sufficient level of participation and influence of governance in the platform?

Article 5(2)
Article 5(2) second sentence is based on the assumption that all the regulations listed in Annex I include provisions on a procedure of making non-confidential information available to the public. We wonder whether all regulations in Annex I include such a procedure? How should the confidentiality assessment be done and by whom in the absence of such procedure, for the purpose of the data platform?

We also ask the Commission to clarify how confidentiality will be ensured for data submitted outside of an approval process?

Article 8
Where there are multiple reference values for a substance submitted to the repository, we wonder who will decide which of them shall be used in future assessments in order to achieve a harmonized approach?

Article 8(4)
When a regulatory dossier is submitted to an Agency by MS, no EU decision has yet been taken on the reference values. The proposed provision, however, suggests that values adopted by individual MS or even proposed by individual evaluators will be included in the platform. Could the Commission elaborate on this and whether the provision may contradict Article 8(2) where it is stated that the values will be agreed at EU level?

Article 10
Could the Commission explain further what MS competent authorities have to submit in accordance with Article 10(2)?

Article 16(2)
How do these requirements relate to obligations under the Aarhus Regulation to give access to environmental information?

Article 16(3)
The proposed provision addresses actively making data available to the public. Could the Commission clarify how individual requests for access to data in the data platform should be handled under the Regulation, by special request to the national authorities?

Article 17 (1)
We want to ask the Commission if we have correctly understood that studies owned by companies shall not be included in the scope of data that can be reused? Or does the Commission mean that only studies where their regulatory use is protected ('data protection' or intellectual property rights) shall be excluded? How might this affect the drive for more closely harmonized assessments if not all studies owned by companies are available beyond the original legislation within which it was submitted?

Could the Commission explain how Article 17(1) will be applied in practice? For example, will it be applied even to evaluations for product authorisations?

Article 17(2)
Is it possible to use data to the <u>disadvantage</u> of a duty holder in assessment procedures?

If an authority has used data to the disadvantage of a duty holder, is that duty holder included in the term 'the public' in Article 17(3)? If the duty holder is included in 'the public' then how is 'access to justice' guaranteed? If it is not included, how can the confidentiality be maintained?

Article 17(3) and Article 5(2), second subparagraph
Shall data which is not made public always be considered as confidential, even if publication cannot lead to any harm (and regarding the Regulation (EC) No 1367/2006 on the application of the provisions of the Aarhus Convention)? How will it be ensured that the provisions on data protection[1] and intellectual property rights will be upheld?

[1] As applied in Regulations (EU) 528/2012 and (EU) 1107/2009, not GDPR.

Article 19 and 20
According to the articles indicators and compiled data will be uploaded into the platform in order to facilitate informed societal discussion and increase public awareness. Could the Commission comment on whether there are plans for development of procedures or legislation so that regulatory action can be taken to address identified emerging risks?

Article 21(3)
Has the Commission considered including wording to avoid, wherever possible, the commissioning of vertebrate studies?

Article 22
Will studies that ECHA has commissioned in accordance with Article 21 be notified to the Database of Study Notifications?

Article 25
We wonder how the compliance of business operators and laboratories will be checked regarding the obligation to notify studies, is it MS or ECHA?

Annex II, Part 1
Sweden considers that environmental risk assessment data from medicinal active substances should be included within the scope of the regulation together with information on where medicinal active substances and products are manufactured. Could the Commission explain why Articles 10, 11, 15 and 21 will not apply for environmental risk data for medical active substances?

We also see the need for some further definitions and clarifications in this part, including a definitions of 'relevant active substances', which we will come back to at a later stage.

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

Article 3
How will it be ensured that ECHA will have the competence for the evaluation of medical devices?

Could the Commission confirm if Regulation (EU) 2012/746 for in vitro diagnostic medical devices (IVDR) also shall be included in this initiative?

Article 4
Regarding the empowerment to the Commission in Article 15(2) in Regulation (EU) 2019/1021 to adapt the Annexes IV and V to scientific and technical progress, we wonder how the empowerment relates to the empowerment in Article 15(1) that is limited to 'modify existing entries or provisions'? In our opinion the empowerment is broader in Article 15(2) then in Article 15(1), and we wonder why they differ?

Article 4(1)(a), point (i)
We wonder how the Commission sees the possibility for ECHA to provide technical and scientific support for proposals for additions to and changes to Annexes I-III?

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

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

Article 1(1)(a) on Article 5(4)(e) in the RoHS Directive
According to what criteria should confidentiality be assessed?

Article 1(1)(b) on addition of Article 4a to the RoHS Directive
Could the Commission explain why the opinion of the Committee for Risk Assessment is only requested for new applications or situations otherwise considered appropriate?

Article 1(3)(a) regarding Article 6 of the RoHS Directive
Could the Commission clarify when a review of the list of restrictions should be conducted? We note that new adoptions of restrictions have still not been made as a follow up the last review which started 2018.

Article 1(3)(c) regarding Article 6(2) of the RoHS Directive
We wonder how ECHA and Member States will know when they have collected all relevant and available information?

Article 1(3) (c), regarding amendments of the second paragraph of Article 6 under RoHS
We wonder whether the reference to Annex XV in REACH could be interpreted as a substantial amendment and not just a procedural amendment considering that restrictions and exemptions in RoHS are separate processes while they are combined in REACH?

Have you considered including, in a restriction proposal, when a substance restriction shall begin to apply for the different categories in RoHS?

Article 1(4) regarding addition of Article 6a(4) under RoHS
Does this article refer to a workplan of a review of restricted substances? Where is it supposed to be published? When are new substance restrictions supposed to be added to the list, for example in relation to the publication according to Article 6a(3)?

Article 1(4) regarding addition of Article 6b(3) under RoHS
What is the second consultation supposed to deal with in this part of the process when there is a separate exemption process in it? Could this information be handled in the first consultation according to Article 6a(6) of the proposal?

SWEDEN

Initial amendment proposals to OSOA legislative package

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

Article 4

Text proposal:

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.'

Comment: In this article the word 'provide' is used but in Article 8(1a) subparagraph three the word 'submission' is used. SE propose using the same word as in Article 8(1a) subparagraph three, since is it refers to the same event.

Text proposal:

The Agency shall, as soon as it receives the request referred to in **Article 8(1)**~~the first subparagraph~~, point (i), publish on its website a notice that a report on a possible amendment of Annex IV or V will be prepared inviting all interested parties, including waste operators and users of recycled materials, to submit comments within 8 weeks. The Agency shall publish those comments on its website.

Comment: Editorial proposal to change the reference, to clarify and to use the same kind of reference as is used in the paragraph above.

Text proposal:

At the latest 9 months following the submission of ~~that~~ **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.

Comment: Proposal to claify which submission it is referred to given that it is mentioned in several paragraphs earlier in the text. The proposed change would help to clarify this together with a consequential amendment in Article 8(1) point (i) to change the word 'provide' to 'submit'.

Text proposal:

(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, to amend Annexes IV and V **to this Regulation** to adapt them to the changes to the list of substances set out in the Annexes to the Convention or the Protocol or to adapt them to scientific and technical progress.'

Comment: Proposed amendment in order to clarify that the reference is to the annexes in this Regulation.

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

Article 1, on the inclusion of paragraph 4a

"4a. The Agency shall, after verifying the completeness of the application, request the opinion of the Committee for Socio-economic Analysis, set up pursuant to Article 76(1), point (d) of Regulation (EC) No 1907/2006. It

shall request the opinion of the Committee for Risk Assessment, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006, in the case of an application for a new **exemption or an application for a renewal of an** exemption **submitted to the Agency for the first time**, or where **there are amendments in an exemption that RAC has not evaluated** before ~~otherwise considered appropriate~~. "

Comment: SE suggests that it needs to be clearer when RAC shall evaluate an application for exemption. Therefore, it may be good to clarify that RAC shall evaluate applications for renewal of exemptions that have previously been evaluated by external consultants or where there are amendments in the exemption that have not been evaluated before. This would have the effect of increasing consistency between the evaluations.

Article 1(4) on the inclusion of Article 6a, 6b and 6c, last paragraph

~~"a~~ socio-economic **information** ~~analysis~~ including ~~an analysis of~~ **information on** alternatives, or information which can contribute to ~~one of~~ the suggested **restriction** ~~restrictions~~, examining the advantages and drawbacks of the proposed **restriction** ~~restrictions~~.

~~The analysis referred to in the first subparagraph, point (b), shall conform to the requirements in Annex XVI to Regulation (EC) No 1907/2006."~~

Comment: SE considers that the restriction process in RoHS may be too extensive compared to the restriction process in REACH, and with the delay of the REACH revision it is unclear how the restriction process in REACH will look like in the future.