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LIMITE

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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Ad hoc Working Party on One Substance One Assessment
N° Cion doc.:	ST 16973/23
Subject:	OSOA Package: Ad Hoc Working Party on One Substance One Assessment on 12 April 2024: Regulation on Union agencies in the area of chemicals - Presidency compromise text

With a view to the above AHWP, delegations will find attached the Presidency compromise text concerning the Union Agencies Regulation, changes to the Commission proposal (...) are set out in **bold underlines**, while ~~strikethrough~~ indicates deletions.

PRESIDENCY REVISED PROPOSAL

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 43, 114, 168(4)(c), 192(1) and 207 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments, Having regard to the opinion of the European Economic and Social Committee, Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure, Whereas:

- (1) The European Green Deal¹ sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability² ('the Strategy') is a crucial delivery of the zero-pollution ambition and introduces the 'one substance, one assessment' approach, which aims to improve the efficiency, effectiveness, coherence, and transparency of safety assessments of chemicals across Union legislation.
- (2) In order to achieve this objective, a part of the scientific and technical work on chemicals performed at Union level in support of Union legislation needs to be

¹ Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal. [COM \(2019\) 640 final](#).

² Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment. [COM \(2020\) 667 final](#)

consolidated in the relevant Union agencies, while obligations on Union agencies to cooperate for the development of assessment methodologies and exchange of data and information should be introduced. This would simplify the current set-up, improve quality and coherence of safety assessments across Union legislation and ensure more efficient use of existing resources.

- (3) The reattribution of certain existing scientific and technical tasks to the European Chemicals Agency, as well as the attribution of new tasks, were proposed as part of

Commented [A1]: PRES notes that some delegations still raised concerns regarding budget, resources, expertise, ... for ECHA and its committees.

PRES notes that the ECHA founding regulation is under preparation and will be made available as soon as ready. The ECHA founding regulation will strive to ensure adequate capacity and expertise of the ECHA's committees to deal with the increased tasks. Reference: COM answers provided in document WK 3719/2024 INIT (delegates portal).

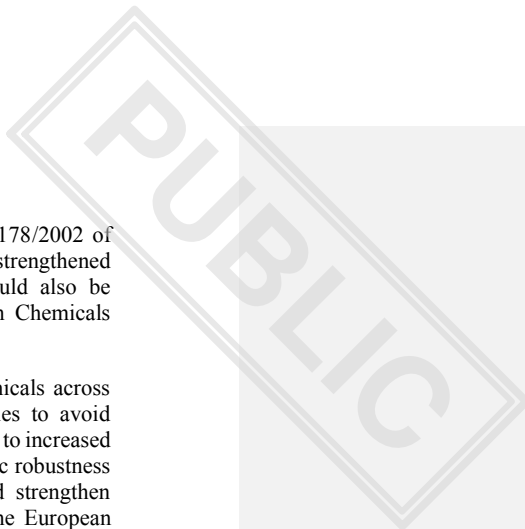
PRES asks whether the resource concerns raised by MSs would prevent agreement to this proposal (given that the ECHA founding regulation is not available at this moment) or whether delegations need further information from the Commission on this element.

ongoing revisions of Union acts. This horizontal proposal aims to provide for further attribution of tasks in respect of those Union acts which are not in the process of being revised and is necessary in order to ensure that the European Chemicals Agency is involved in tasks pertaining to its expertise and developed capacities on chemicals. This is in line with the 'one substance, one assessment' aim to ensure that technical and scientific work is performed by the appropriate Union agency, benefiting from demonstrated experience and established tools in its field. The proposal for a Regulation is accompanied by a proposal for a Directive for the amendment of Directive 2011/65/EU of the European Parliament and of the Council³, aiming to achieve the same objectives.

- (4) As part of the coordinated consolidation and attribution of tasks under the 'one substance, one assessment' approach, provisions to allocate a mandate to the European Medicines Agency to develop and cooperate on the development of assessment methodologies, standard formats and controlled vocabularies and exchange of data and information on chemicals have been introduced in Article 138(1), subparagraphs (zd) and (ze), as well as new procedures for ensuring the coherence between scientific opinions in Article 139 of the proposal for a Regulation amending Union pharmaceutical legislation.⁴
- (5) To ensure the coherence of methodologies for assessments related to chemicals at Union level, all relevant Union agencies should have an equal mandate to develop such methodologies in the areas falling within their respective missions and should be subject to the same obligations to cooperate amongst each other to develop such methodologies.
- (6) To ensure the coherence and efficiency of assessments related to chemicals across Union legislation, it is also important to enable data interoperability and easy exchange of data between the relevant Union agencies, as well as to encourage cooperation on the development of standard formats and controlled vocabularies. Thus, to facilitate data exchange between agencies, any new data formats defined by the European Food Safety Authority or by the European Environmental Agency should be set in cooperation with other relevant Union agencies working on chemicals. To this end, relevant provisions should be introduced in Regulation (EC) No 401/2009

³ Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency.

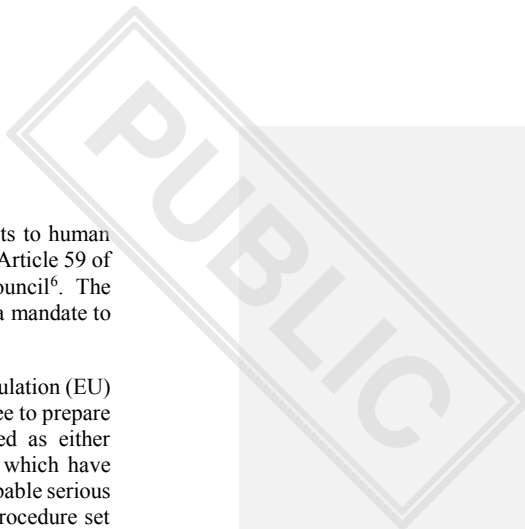
⁴ Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006, [COM\(2023\) 193 final](#). [OJ: Please insert correct reference once the Regulation is adopted].



of the European Parliament and of the Council and, in Regulation (EC) No 178/2002 of the European Parliament and of the Council, existing provisions should be strengthened and, where relevant, new ones be introduced. Similar provisions should also be considered to be proposed for a strengthened mandate of the European Chemicals Agency in its founding regulation.

- (7) To promote the coherence and efficiency of assessments related to chemicals across Union legislation, steps should be taken by the relevant Union agencies to avoid divergent scientific opinions. Existing cases of divergent opinions have led to increased uncertainty for operators, as well as to declined public trust in the scientific robustness and coherence of scientific decision making. Proposals to address and strengthen procedures for resolving divergence of scientific opinions concerning the European Medicines Agency with other scientific bodies is proposed as part of the revision of Union pharmaceutical legislation. Similar provisions should also be considered to be proposed for a strengthened mandate of the European Chemicals Agency in its founding regulation, whilst such provisions are not relevant and applicable to the European Environmental Agency, since this agency does not issue scientific opinions on individual chemicals such as to be part in divergent outcomes.
- (8) Correspondingly, this Regulation aims to address the eventual divergence between scientific opinions of the European Food Safety Authority and those of other Union agencies. Regulation (EC) No 178/2002 of the European Parliament and Council already contains provisions establishing a procedure to solve divergent scientific opinions. Those resolution procedures should be reinforced, in that the European Food Safety Authority and the other dissenting agency should be bound to make their best effort to resolve the divergence on general scientific issues, and only when they are not able to resolve the divergence, should they refer to risk managers.
- (9) In the more specific case of scientific divergence pertaining to the hazard identification of chemical substances, a new procedure enabling the resolution of the divergence should be established. This procedure should enable the Commission to request the European Chemicals Agency, as the Union agency most equipped with expertise and capacity in hazard assessment, as well as long-standing experience with the harmonised classification and labelling process, to develop a proposal for harmonised classification and labelling, in accordance the Regulation (EC) No 1272/2008 of the European Parliament and Council, moving closer to the 'one substance, one assessment' vision as regards uniformity of hazard assessments of chemicals across the Union. This possibility should be reflected in the relevant provision providing for the resolution of diverging scientific opinions laid down in Regulation (EC) No 178/2002.
- (10) To comply with the obligation laid down in Section 10.4.3 of Annex I to Regulation (EU) 2017/745 of the European Parliament and of the Council⁵, the Commission has provided the Scientific Committee on Health, Environmental and Emerging Risks ('SCHEER') with a mandate to prepare guidelines on the benefit-risk assessment of the presence of phthalates which are classified as either carcinogenic, mutagenic or toxic to reproduction category 1A or 1B, or which have endocrine disrupting

⁵ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC ([OJ L 117, 5.5.2017, p. 1](#)).



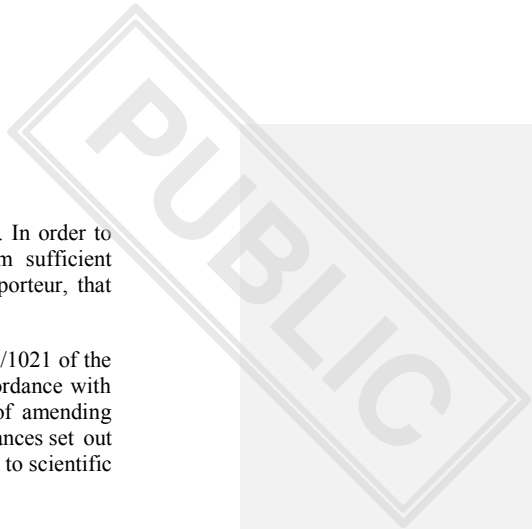
properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁶. The SCHEER issued those guidelines in 2019 and the Commission has issued a mandate to the SCHEER to perform a first update of those guidelines.

- (11) To comply with the obligation laid out in Section 10.4.4. of Annex I to Regulation (EU) 2017/745, the Commission should mandate the relevant scientific committee to prepare guidelines for substances other than phthalates and which are classified as either carcinogenic, mutagenic or toxic to reproduction category 1A or 1B, or which have endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council.
- (12) The European Chemicals Agency already provides scientific advice on chemical substances, including on phthalates, endocrine disruptors and carcinogens, mutagens and reproductive toxicants under Regulation (EC) No 1907/2006. Several key capacities of the agency can be reused, including hazard, risk, exposure and socio- economic assessment capacities, the Committee opinion development and IT capabilities for stakeholder consultation and dissemination. To enable timely future updates on the presence of phthalates and to ensure that the appropriate Union agency develops new guidelines on other substances on the basis of the latest scientific evidence, these tasks should be attributed to the European Chemicals Agency.
- (13) Taking account of the new hazard classes and criteria for classification, labelling and packaging of substances introduced by Commission Delegated Regulation (EU) 2023/707 of 19 December 2022⁷, reference to endocrine disruptors for human health, of Category 1, should be specified in 10.4.1., point (b) of Annex I of Regulation (EU) 2017/745 in light of the relevance of that hazard class to the type of substances in medical devices.
- (14) To make best use of the European Chemicals Agency's knowledge and expertise gained through its involvement in the nomination and assessment processes under the Stockholm Convention on Persistent Organic Pollutants, the European Chemicals Agency should, upon request, assist the Commission in complying with its obligation to amend Annexes IV and V to Regulation (EU) 2019/1021⁸. Where the opinion of the Committee for Socio-Economic analysis is required, and in order to allow for the necessary capacity and resources for the effective functioning of that committee, Member States should be given the opportunity to cover for the specific expertise

⁶ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC ([OJ L 396, 30.12.2006, p. 1–849](#)).

⁷ Commission Delegated Regulation (EU) 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures ([OJ L 93, 31.3.2023, p. 7–39](#)).

⁸ Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants ([OJ L 169, 25.6.2019, p. 45](#)).



required for the effective performance of the task by nominating experts. In order to ensure that the Committee for Socio-Economic analysis benefits from sufficient resources, when the committee appoints one of their members as a rapporteur, that person, or his employer should be remunerated.

- (15) In order to amend certain non-essential elements of Regulation (EU) 2019/1021 of the European Parliament and of the Council, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending Annexes IV and V in order to adapt them to the changes to the list of substances set out in the Annexes to the Stockholm Convention or the Protocol or adapt them to scientific and technical progress.
- (16) As part of their reporting obligations under the Regulation (EU) 2019/1021 of the European Parliament and of the Council, Member States must report to the European Chemicals Agency information on the presence of substances listed in Part A of Annex III in the environment. The use of the Information Platform for Chemical Monitoring ('IPCHEM') is encouraged as a means for Member States to comply with their obligations to report that chemical occurrence data and to simplify and reduce their reporting obligations. Where Member States make data available through IPCHEM, they no longer need to report it to the European Chemicals Agency, as the agency may retrieve it from the platform.
- (17) The revision of the Directive (EU) 2020/2184 of the European Parliament and of the Council⁹ requires Member States to share with European Environmental Agency all chemical occurrence or monitoring data in water. Additionally, the monitoring data on the presence of POPs in air are already being reported by Member States to the EEA as part of the Union air quality legislation. The proposal for a Regulation of the European Parliament and the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable, and reusable and establishing a monitoring and outlook framework for chemicals¹⁰ will require all chemical occurrence data to be held by the EEA. As a result, chemical occurrence data provided to and held in IPCHEM by the Commission will thus be collected and held by the EEA, instead of by the Commission. Therefore, it is necessary to simplify the reporting obligations for Member States to ensure that, where Member States have already submitted that information to the EEA as part of fulfilling obligations required by the provisions of other pieces of Union environmental legislation, Member States should be considered to have fulfilled their reporting obligations under Regulation (EU) 2019/1021.
- (18) Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 should therefore be amended accordingly,

⁹ Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast), ([OJ L 435, 23.12.2020, p. 1–62](#)).

¹⁰ [*OJ Please insert reference once proposal is adopted*]



HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 178/2002

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

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

‘(m) to cooperate with the competent bodies in the Member States that carry out similar tasks to those of the Authority and to cooperate with other scientific bodies established under Union law, notably the European Chemicals Agency, the European Medicines Agency, and the European Environment Agency on the provision of relevant scientific opinions, on the exchange of data and information, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and on the development of scientific methodologies for the assessment of chemicals.’;

(2) Article 30 is replaced by the following:

Article 30

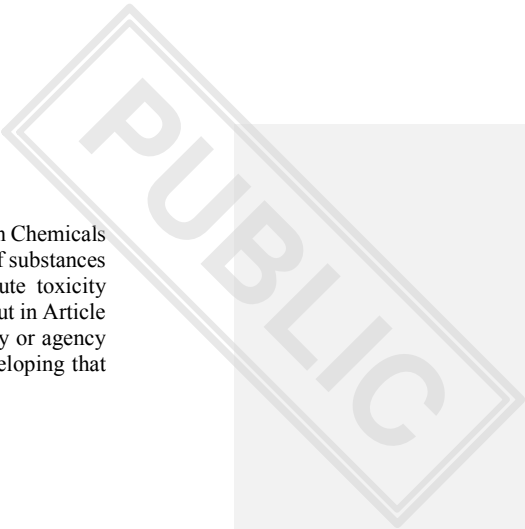
Diverging scientific opinions

1. The Authority shall take the necessary and appropriate measures to monitor and identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks.
2. Where the Authority identifies a potential source of divergence, it shall contact the body concerned in order to ensure that all relevant scientific or technical information is shared and in order to identify the potentially contentious scientific or technical issues.

The Authority and the body concerned shall cooperate to resolve the divergence. If the Authority and the body concerned are not able to resolve the divergence, they shall draw up a joint report. The report shall clearly outline the contentious scientific issues and identify the relevant uncertainties in the data and be made publicly available.

Where the body concerned is a Union agency or a scientific committee, the Authority shall present the joint report to the Commission.
3. Where relevant, and where the divergence concerns conflicting scientific opinions of the Authority and another Union body or agency on whether a substance fulfils the criteria laid out in Annex I of Regulation (EC) No 1272/2008 of the European

Commented [A2]: PRES understands that a typical example where harmonised classification would be used to solve a divergent opinion is a chemical assessed by two agencies and where a divergent opinion in risk assessment would be due to the difference in hazard identification and where the harmonised classification would be able to solve the divergence.
Reference COM answers provided in document WK 3719/2024 INIT (delegates portal).



Parliament and of the Council¹¹, the Commission may request the European Chemicals Agency to prepare a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof following the procedure laid out in Article 37 of Regulation (EC) No 1272/2008. The Authority and the Union body or agency concerned shall co-operate with the European Chemicals Agency in developing that proposal.’.

Article 2

Amendments to Regulation (EC) No 401/2009

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

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

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

- (2) in Article 15, the following paragraph 5 is added:

‘5. The Agency shall cooperate with other scientific bodies established under Union law, notably the European Chemicals Agency, the European Food Safety Authority, and the European Medicines Agency, on the exchange of data and information on chemicals, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and on the development of scientific methodologies for the assessment of chemicals.’.

Commented [A3]: PRES understands that Article 15 of the EEA founding Regulation as a whole relates to various aspects of cooperation of that agency with other bodies. A new paragraph 5 was proposed to minimize changes to the existing Article 15. Reference: COM answers provided in document WK 3719/2024 INIT (delegates portal).

Article 3

Amendments to Regulation (EU) 2017/745

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

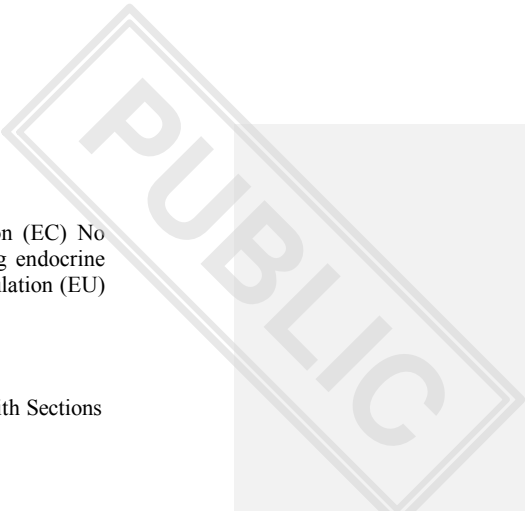
- (1) in Section 10.4.1, point (b) is replaced by the following:

‘(b) substances which are identified as endocrine disruptors for human health, of **Category 1**, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council¹² and substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are

Commented [A4]: PRES notes that in Section 10.4.1, point (a) only CMRs or category 1A or 1B are mentioned and not category 2. ED category 1 would be in line with what is in the text for CMRs.

¹¹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. [OJ L 353 31.12.2008, p. 1 – 1355](#).

¹² Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006([OJ L 353 31.12.2008, p. 1](#)).



identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council or substances having endocrine disrupting properties relevant to human health identified in accordance with Regulation (EU) No 528/2012.’

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

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

(3) Section 10.4.3 is replaced by the following:

‘10.4.3. **Guidelines on phthalates**

When deemed appropriate based on the latest scientific evidence, but at least every 5 years, the Commission shall request the European Chemicals Agency (ECHA) to update guidelines on the benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in Section 10.4.1., points (a) and (b). The benefit-risk assessment shall consider the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments

When appropriate or when requested by the Commission, ECHA shall consult the Committee for Risk Assessment and the Committee for Socio-economic Analysis.’;

(4) Section 10.4.4 is replaced by the following:

‘10.4.4. **Guidelines on other CMR and endocrine-disrupting substances**

The Commission shall request ECHA to prepare guidelines as referred to in Section 10.4.3. and following the process described therein also for other substances referred to in Section 10.4.1., points (a) and (b), where appropriate.’.

Article 4

Amendments to Regulation (EU) 2019/1021

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

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

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

‘(i) upon request from the Commission, and within 12 months from that request, draw up and provide **submit** a report on the human health, environmental and socio-economic impacts of introducing or modifying concentration limit values specified in Annex IV or V.’

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

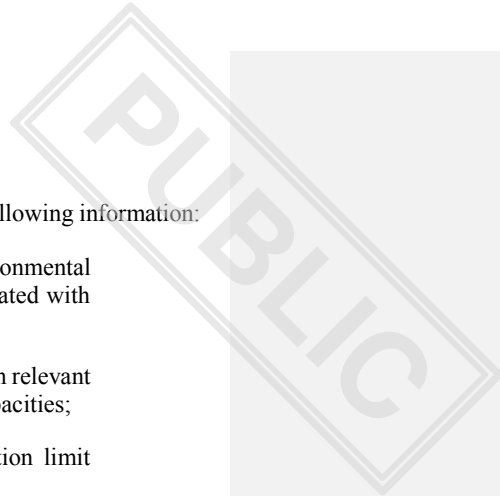
Commented [A5]: PRES understands that the task for ECHA requires to regularly update the existing guideline on the benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates which are carcinogenic, mutagenic, toxic to reproduction (CMR) or have endocrine-disrupting (ED) properties and on the request of the Commission to develop a new guideline for other CMR or ED substances. These guidelines describe the methodology on how to perform a benefit risk assessment of the justification of the presence of CMR 1A or 1B and/or ED phthalates in medical devices. They also describe the evaluation of possible alternatives for these phthalates used in medical devices, including alternative materials or designs. These guidelines apply only to those medical devices and components thereof indicated in Annex I section 10.4.1. of the MDR. They do not provide information for the benefit risk assessment of the use of a medical device itself.

ECHA has the existing competence in assessing the risks of chemicals, the existence of alternatives and the socio-economic benefits of substance use. This will be sufficient and adequate. It might require to gain some expertise in the design of parts of medical devices but this is similar with any work ECHA does on presence of chemicals in articles. Before proposing the reattribution, ECHA was consulted on whether they will be able to perform such task.

The Regulation (EU) 2012/746 for in vitro diagnostic medical devices does not include specific provisions as regards risk benefit assessment of chemicals and is not included in the amendment.

Reference: COM answers provided in document WK 3719/2024 INIT (delegates portal).

PRES: Are there further clarifications needed?



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

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

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

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

The Agency shall submit the report and the opinion of the Committee for the Socio-economic Analysis on the concentration limit values to the Commission without delay.’;

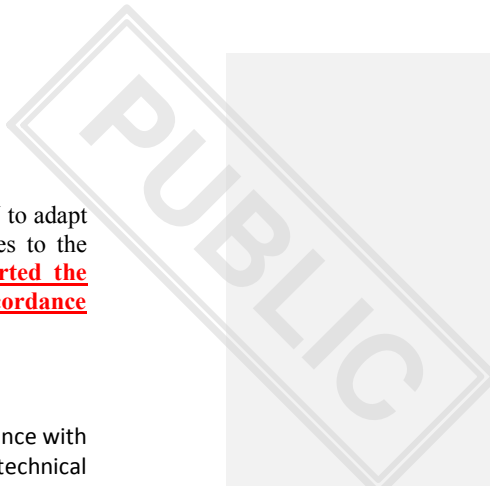
(3) in Article 13, paragraph 2 is replaced by the following:

‘2. Where a Member State shares the information referred to in paragraph 1, point (e), with the European Environmental Agency, that Member State shall indicate that in the report and the Member State shall be considered to have fulfilled its reporting obligations under that point.

Where the information referred to in paragraph 1, point (e), is contained in the report of a Member State provided to the Agency, the Agency shall transmit the information to the European Environmental Agency for compiling, storing and sharing that information’;

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

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



Article 18 of this Regulation in order to amend its Annexes IV and V to adapt them to the changes to the list of substances set out in the Annexes to the Convention or the Protocol, provided that the Union has supported the changes concerned by means of a Council decision adopted in accordance with Article 218(9) TFEU.

(4a) in Article 15, the following paragraph 2a is added:

‘2a. The Commission is empowered to adopt delegated acts in accordance with Article 18 of this Regulation in order to adapt them to scientific and technical progress. **Before adopting such delegated acts, the Commission shall carry out an impact assessment analysing the impacts expected due to amendments to Annexes IV and V, including an assessment of the availability of adequate waste management infrastructure and the need to provide where appropriate for a sufficient transitional period.**

(5) Article 18 is amended as follows:

(a) The first sentence of paragraph 2 is replaced by the following:

‘2. The power to adopt delegated acts referred to in Articles 4(3), 10(2) and 15 shall be conferred on the Commission for a period of five seven years from ... **[OP : Please insert the date of the entry into force of this Regulation] 15 July 2019.** **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the seven-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

Commented [A6]: PRES: Several delegations proposed to extend this period.

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

‘3. The delegation of power referred to in Articles 4(3), 10(2) and 15 may be revoked at any time by the European Parliament or by the Council.’.

(c) Paragraph 6 is replaced by the following:

‘6. A delegated act adopted pursuant to Articles 4(3), 10(2) and 15 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object.’.

Article ~~5~~ 6

Entry into force

Commented [A7]: PRES: There was no article 5, so the error in numbering was corrected.

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President

