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Committee on the Environment, Public Health and Food Safety

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AMENDMENTS
3 - 43

Draft report
Dimitris Tsiodras
(PE763.253v01-00)

Re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals

Proposal for a regulation
(COM(2023)0783 – C9-0447/2023 – 2023/0455(COD))

Amendment 3
Beatrice Timgren

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(2) In order to achieve this objective, a part of the scientific and technical work on chemicals performed at Union level in support of Union legislation needs to be consolidated in the relevant Union agencies, while obligations on Union agencies to cooperate for the development of assessment methodologies and exchange of data and information should be introduced. This would simplify the current set-up, improve quality and coherence of safety assessments across Union legislation and ensure more efficient use of existing resources.	(2) In order to achieve this objective, a part of the scientific and technical work on chemicals performed at Union level in support of Union legislation needs to be consolidated in the relevant Union agencies, while obligations on Union agencies to cooperate for the development of assessment methodologies and exchange of data and information should be introduced. This would simplify the current set-up, improve quality and coherence of safety assessments across Union legislation***,*** and ensure more efficient use of existing resources ***as well as reduce duplication of efforts across multiple Union agencies***. ***This approach supports the competitiveness of Union industries by reducing compliance costs and administrative burdens on businesses.***

Or. en

Amendment 4
Christophe Clergeau, Estelle Ceulemans, Chloé Ridel, Pierre Jouvet

Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) To improve further the cooperation among Union agencies in the area of chemicals, and to increase coherence and efficiency of assessments related to chemicals across Union legislation, it is necessary to lay the foundation for a common approach to hazard assessment of chemicals across Union legislation. This Regulation should

establish a forum for Agencies to improve sharing and re-use of chemicals data, exchange best practices, and foster cooperation in the hazard assessment of chemicals.

Or. en

Amendment 5
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins, Per Clausen

Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*
(6) To ensure the coherence and efficiency of assessments related to chemicals across Union legislation, it is also important to enable data interoperability and easy exchange of data between the relevant Union agencies, as well as to encourage cooperation on the development of standard formats and controlled vocabularies. Thus, to facilitate data exchange between agencies, any new data formats defined by the European Food Safety Authority or by the European Environmental Agency should be set in cooperation with other relevant Union agencies working on chemicals. To this end, relevant provisions should be introduced in Regulation (EC) No 401/2009 of the European Parliament and of the Council and, in Regulation (EC) No 178/2002 of the European Parliament and of the Council, existing provisions should be strengthened and, where relevant, new ones be introduced. Similar provisions should also be ***considered to be*** proposed for a strengthened mandate of the European Chemicals Agency in its founding regulation.	(6) To ensure the coherence and efficiency of assessments related to chemicals across Union legislation, it is also important to enable data interoperability and easy exchange of data between the relevant Union agencies, as well as to encourage cooperation on the development of standard formats and controlled vocabularies. Thus, to facilitate data exchange between agencies, any new data formats defined by the European Food Safety Authority or by the European Environmental Agency should be set in cooperation with other relevant Union agencies working on chemicals. To this end, relevant provisions should be introduced in Regulation (EC) No 401/2009 of the European Parliament and of the Council and, in Regulation (EC) No 178/2002 of the European Parliament and of the Council, existing provisions should be strengthened and, where relevant, new ones be introduced. Similar provisions should also be proposed for a strengthened mandate of the European Chemicals Agency in its founding regulation***, which should be proposed as soon as possible and no later than 31 December 2025***.

Or. en

Amendment 6
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins, Per Clausen

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(7) To promote the coherence and efficiency of assessments related to chemicals across Union legislation, steps should be taken by the relevant Union agencies to avoid divergent scientific opinions. Existing cases of divergent opinions have lead to increased uncertainty for operators, as well as to declined public trust in the scientific robustness and coherence of scientific decision making. Proposals to address and strengthen procedures for resolving divergence of scientific opinions concerning the European Medicines Agency with other scientific bodies is proposed as part of the revision of Union pharmaceutical legislation. Similar provisions should also be ***considered to be*** proposed for a strengthened mandate of the European Chemicals Agency in its founding regulation, whilst such provisions are not relevant and applicable to the European Environmental Agency, since this agency does not issue scientific opinions on individual chemicals such as to be part in divergent outcomes.	(7) To promote the ***transition towards a toxic-free environment and zero pollution, and the robustness,*** coherence and efficiency of assessments related to chemicals across Union legislation, steps should be taken by the relevant Union agencies to avoid divergent scientific opinions. Existing cases of divergent opinions have lead to increased uncertainty for operators, as well as to declined public trust in the scientific robustness and coherence of scientific decision making. Proposals to address and strengthen procedures for resolving divergence of scientific opinions concerning the European Medicines Agency with other scientific bodies is proposed as part of the revision of Union pharmaceutical legislation. Similar provisions should also be 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.

Or. en

Amendment 7
Beatrice Timgren

Proposal for a regulation

Recital 7 a (new)

Text proposed by the Commission	*Amendment*
	(7a) The measures introduced under this Regulation seek to align regulatory requirements and processes across relevant sectors without creating unnecessary administrative burdens or overregulation. By prioritizing proportionality and efficiency, the Regulation ensures that new tasks are effectively integrated into existing systems while maintaining high standards of environmental and public health protection.

Or. en

Amendment 8
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins, Per Clausen

Proposal for a regulation
Recital 8

Text proposed by the Commission	*Amendment*
(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.	(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, ***optimising the protection of health and the environment. Diverging scientific opinions and their causes, including in methodological differences, should be duly explained and clarified. Where***

diverging scientific opinions exist, the most protective opinion from the One Health perspective should be agreed on. Only when they are not able to resolve the divergence, should they refer to risk managers.

Or. en

Amendment 9
Christophe Clergeau, Estelle Ceulemans, Chloé Ridel, Pierre Jouvet

Proposal for a regulation
Recital 8

Text proposed by the Commission	*Amendment*
(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.	(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. ***Differences in assessment methodologies resulting in divergent opinions, particularly with regards to the protection of vulnerable groups, should be duly clarified. In such instances, priority should be given to the most protective opinion to safeguard the most vulnerable populations.***

Or. en

Amendment 10

Beatrice Timgren

Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) A consistent and predictable regulatory framework is essential for fostering innovation and encouraging investment in sustainable chemical technologies. By simplifying assessment methodologies under the 'one substance, one assessment' approach, this Regulation promotes regulatory efficiency and supports the Union's objective of creating a more competitive internal market.

Or. en

Amendment 11
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins, Per Clausen

Proposal for a regulation
Recital 9

Text proposed by the Commission	*Amendment*
(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	(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.

assessment' vision as regards uniformity of hazard assessments of chemicals across the Union***, optimising the protection of health and the environment***. 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.

Or. en

Amendment 12
Christophe Clergeau, Estelle Ceulemans, Chloé Ridel, Pierre Jouvet

Proposal for a regulation
Recital 9

Text proposed by the Commission	*Amendment*
(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.	(9) In the more specific case of scientific divergence pertaining to the hazard identification of chemical substances, a new procedure enabling the resolution of the divergence should be established. This procedure should enable the Commission to request the European Chemicals Agency, as the Union agency most equipped with expertise and capacity in hazard assessment, as well as long-standing experience with the harmonised classification and labelling process, to develop a proposal for harmonised classification and labelling, in accordance ***with*** 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.

Or. en

Amendment 13
Beatrice Timgren

Proposal for a regulation
Recital 10 a (new)

Text proposed by the Commission	*Amendment*
	(10a) Leveraging existing digital tools and data-sharing platforms, this Regulation aims to minimize duplicative reporting obligations, reduce costs for Member States and economic operators, and provide better access to data for stakeholders. This approach strengthens the role of digital solutions in achieving regulatory efficiency and cost savings.

Or. en

Amendment 14
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins, Per Clausen

Proposal for a regulation
Recital 11

Text proposed by the Commission	*Amendment*
(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.	(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 ***or the environment*** and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council.

Or. en

Amendment 15
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins, Per Clausen

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) Taking account of the new hazard classes and criteria for classification, labelling and packaging of substances introduced by Commission Delegated Regulation (EU) 2023/707 of 19 December 2022[7] , reference to endocrine disruptors for human health, of Category 1, should be specified in 10.4.1., point (b) of Annex I of Regulation (EU) 2017/745 in light of the relevance of that hazard class to the type of substances in medical devices.	(13) Taking account of the new hazard classes and criteria for classification, labelling and packaging of substances introduced by Commission Delegated Regulation (EU) 2023/707 of 19 December 2022[7] , reference to endocrine disruptors for human health ***or the environment***, of Category 1, should be specified in 10.4.1., point (b) of Annex I of Regulation (EU) 2017/745 in light of the relevance of that hazard class to the type of substances in medical devices.
[7] Commission Delegated Regulation (EU) 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures (OJ L 93, 31.3.2023, p. 7–39).	[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).

Or. en

Amendment 16
Martin Hojsík

Proposal for a regulation
Recital 14 a (new)

Text proposed by the Commission	*Amendment*
	(14a) The amendment of Regulation (EU) 2019/1021 introduced by this

Regulation expands the tasks, workload and remit of scientific committees of the European Chemicals Agency. In order to provide adequate expertise, support and thorough scientific evaluations, appropriate and stable resources, capacity and governance of the scientific committees should be ensured. In this respect, the European Commission shall regularly monitor the needs of the European Chemicals Agency stemming from this Regulation and provide the Agency with sufficient and stable resources.

Or. en

Amendment 17
Christophe Clergeau, Estelle Ceulemans, Chloé Ridel, Pierre Jouvet

Proposal for a regulation
Article -1 (new)

Text proposed by the Commission	*Amendment*
	Article -1
	Forum on Hazard Assessment
	1. The Commission shall, by means of an implementing decision, establish and manage a Forum on Hazard Assessment ('the Forum') which shall include representatives from each of the Agencies, the Commission, Member states and the European Parliament.
	2. The Forum shall establish a work programme to
	(a) foster cooperation in the area of hazard assessment of chemicals;
	(b) improve the sharing and re-use of data between agencies;
	(c) establish a strategy toward the common hazard assessment of chemicals across Union legislation in the area of chemicals.

	2. The forum shall meet and update its work programme regularly.
	3. The Forum shall draw up an annual report, compiling and analysing the advancement and conclusions of its work programme referred to in paragraph 2. The first report shall be prepared by [OP: please insert date: 1 year after the end of the first calendar year after entry into force of this Regulation]. The Forum shall present this report to the Commission, relevant Union agencies and Member State competent authorities, the European Parliament and the Council for consideration of the need for regulatory or policy action related to the conclusion of this report

Or. en

Amendment 18
Sander Smit

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EC) No 178/2002
Article 23 – paragraph 1 – point m

Text proposed by the Commission	*Amendment*
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.’;	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 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.’;

Or. nl

Justification

Different agencies and committees carry out separate risk assessments, each tailored to the specific objectives of the underlying legislation. It is important that the enhanced cooperation between authorities be designed in such a way that it does not lead to harmonisation of methods and (risk) assessments beyond the intended purpose of the 'one substance, one assessment' approach. In particular, the introduction of formal cooperation requirements may lead to delays, with negative effects on competitiveness.

Amendment 19
Christophe Clergeau, Estelle Ceulemans, Chloé Ridel, Pierre Jouvet

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 178/2002
Article 30 – paragraph 2 – subparagraph 3

Text proposed by the Commission	*Amendment*
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.	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. ***Difference in assessment methodologies resulting in divergent opinions shall be duly justified, especially regarding the protection of vulnerable groups.***

Or. en

Amendment 20
Sander Smit

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 178/2002
Article 30 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*

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.	Where the Authority identifies a potential source of divergence ***that is not associated with the specific nature and requirements of the applicable legal framework***, 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.

Or. nl

Justification

Care should be taken to ensure that legislation-specific and scientifically relevant differences in data requirements and assessment methods are not unduly classified as 'divergence' and, through the application of Article 30, lead to a harmonised risk analysis for legislation with different objectives.

Amendment 21
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins, Per Clausen

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 178/2002
Article 30 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
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.	The Authority and the body concerned shall cooperate to resolve the divergence***, with the aim of optimising the protection of health and the environment, prioritising the most protective opinion***. 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***,*** identify the relevant uncertainties in the data and ***the possible causes for the diverging opinions, including on methodological differences and*** be made publicly available.

Or. en

Amendment 22
Christophe Clergeau, Estelle Ceulemans, Chloé Ridel, Pierre Jouvet

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 178/2002
Article 30 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
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.	The Authority and the body concerned shall cooperate to resolve the divergence***.*** ***Priority shall be given to the opinion that affords the highest level of protection in order to safeguard the most vulnerable groups***. 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.

Or. en

Amendment 23
Martin Hojsík

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 178/2002
Article 30 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
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.	The Authority and the body concerned shall cooperate to resolve the divergence***, with the aim to ensure highest level of protection of health and environment***. 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***, potential***

consequences on health and environment, and be made publicly available.

Or. en

Amendment 24
Jutta Paulus

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 178/2002
Article 30 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
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.	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 ***within six months after the identification of the source of divergence by the Authority***. The report shall clearly outline the contentious scientific issues and identify the relevant uncertainties in the data and be made publicly available.

Or. en

Justification

A deadline should be set for the drawing up of the report to ensure clear procedures.

Amendment 25
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins, Per Clausen

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 178/2002
Article 30 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where relevant, and where the	3. Where relevant, and where the

divergence concerns conflicting scientific opinions of the Authority and another Union body or agency on whether a substance fulfils the criteria laid out in Annex I of Regulation (EC) No 1272/2008 of the European Parliament and of the Council[11] , the Commission may request the European Chemicals Agency to prepare a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof following the procedure laid out in Article 37 of Regulation (EC) No 1272/2008. The Authority and the Union body or agency concerned shall co-operate with the European Chemicals Agency in developing that proposal**.**	divergence concerns conflicting scientific opinions of the Authority and another Union body or agency on whether a substance fulfils the criteria laid out in Annex I of Regulation (EC) No 1272/2008 of the European Parliament and of the Council[11] , the Commission may request the European Chemicals Agency to prepare a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof following the procedure laid out in Article 37 of Regulation (EC) No 1272/2008***, with the aim of optimising the protection of health and the environment***. The Authority and the Union body or agency concerned shall co-operate with the European Chemicals Agency in developing that proposal.
[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.	[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.

Or. en

Amendment 26
Christophe Clergeau, Estelle Ceulemans, Chloé Ridel, Pierre Jouvet

Proposal for a regulation
Article 1 – paragraph 1 – point 2 a (new)
Regulation (EC) No 178/2002
Article 30 – paragraph 3 a (new)

Present text	*Amendment*
	In article 30, the following paragraph is added

	3a. In cases where a divergence is identified, and the Authority requests additional information from the other Union or Member State authority, the period by when the relevant authorities are required to adopt their respective output, or the joint output referred to in paragraph 2, may be extended. After consulting the body concerned, the Authority shall lay down a period within which this information shall be provided and shall inform the Commission of the additional period needed. The Commission shall inform the concerned business operator(s) and the Member States of the extension.

Or. en

Amendment 27
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins, Per Clausen

Proposal for a regulation
Article 2 – paragraph 1 – point 1 a (new)
Regulation (EC) No 401/2009
Article 15 – paragraph 4

Present text	*Amendment*
	(1a) In Article 15, paragraph 4 is amended as follows:
4. The cooperation referred to in paragraphs 1, 2 and 3 must in particular take account of the need to avoid any duplication of effort.	"4. The cooperation referred to in paragraphs 1, 2 and 3 must in particular take account of the need to ***reduce animal testing and to*** avoid any duplication of effort."

Or. en

(32009R0401)

Amendment 28
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding,

Catarina Martins, Per Clausen

Proposal for a regulation
Article 2 – paragraph 1 – point 2
Regulation (EC) No 401/2009
Article 15 – paragraph 5

Text proposed by the Commission	*Amendment*
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..	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. ***This cooperation shall aim to support the development of innovative methods and tools, notably non animal approaches and aim to ensure that animal testing takes place only as last resort***.

Or. en

Amendment 29
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins, Per Clausen

Proposal for a regulation
Article 3 – paragraph 1 – point 1
Regulation (EU) 2017/745
Annex I – Section 10.4.1 – point b

Text proposed by the Commission	*Amendment*
(b) substances which are ***identified as*** endocrine disruptors for human health, of Category 1, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[12] ***and*** substances having endocrine-disrupting properties for which	(b) substances which are endocrine disruptors for human health ***or the environment***, of Category 1, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[12] ***or*** substances having endocrine-disrupting

there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council or substances having endocrine disrupting properties relevant to human health identified in accordance with Regulation (EU) No 528/2012.

properties for which there is scientific evidence of probable serious effects to human health ***or the environment*** and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council or substances having endocrine disrupting properties relevant to human health ***or the environment*** identified in accordance with Regulation (EU) No 528/2012.

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[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).

[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).

Or. en

Amendment 30
Christophe Clergeau, Estelle Ceulemans, Chloé Ridel, Pierre Jouvet

Proposal for a regulation
Article 3 – paragraph 1 – point 1
Regulation (EU) 2017/745
Annex I – Section 10.4.1 – point b

Text proposed by the Commission

(b) substances which are ***identified*** as endocrine disruptors for human health, of Category 1, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[12] ***and*** substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council or

Amendment

(b) substances which are ***classified*** as endocrine disruptors for human health, of Category 1, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[12] ***or*** substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council or

substances having endocrine disrupting properties relevant to human health identified in accordance with Regulation (EU) No 528/2012.	substances having endocrine disrupting properties relevant to human health identified in accordance with Regulation (EU) No 528/2012.
[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).	[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).

Or. en

Amendment 31
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins, Per Clausen

Proposal for a regulation
Article 3 – paragraph 1 – point 3
Regulation (EU) 2017/745
Annex I – Section 10.4.3

Text proposed by the Commission	*Amendment*
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 deemed appropriate based on the latest scientific evidence, but at least every ***3*** 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

Or. en

Amendment 32
Martin Hojsík

Proposal for a regulation
Article 4 – paragraph 1 – point 2
Regulation (EU) 2019/1021
Article 8 – paragraph 1a – point a

Text proposed by the Commission	*Amendment*
(a) ***as appropriate,*** information on human health and environmental impacts of waste consisting of, containing or contaminated with POPs, including impacts on waste management;	(a) information on human health and environmental impacts of waste consisting of, containing or contaminated with POPs, including impacts on waste management;

Or. en

Amendment 33
Christophe Clergeau, Estelle Ceulemans, Chloé Ridel, Pierre Jouvet

Proposal for a regulation
Article 4 – paragraph 1 – point 2
Regulation (EU) 2019/1021
Article 8 – paragraph 1a – point a

Text proposed by the Commission	*Amendment*
(a) ***as appropriate,*** information on human health and environmental impacts of waste consisting of, containing or contaminated with POPs, including impacts on waste management;	(a) information on human health and environmental impacts of waste consisting of, containing or contaminated with POPs, including impacts on waste management;

Or. en

Amendment 34
Christophe Clergeau, Estelle Ceulemans, Chloé Ridel, Pierre Jouvet

Proposal for a regulation
Article 4 – paragraph 1 – point 2
Regulation (EU) 2019/1021
Article 8 – paragraph 1a – subparagraph 2

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

Or. en

Amendment 35
Christophe Clergeau, Estelle Ceulemans, Chloé Ridel, Pierre Jouvet

Proposal for a regulation
Article 4 – paragraph 1 – point 2
Regulation (EU) 2019/1021
Article 8 – paragraph 1a – subparagraph 3

Text proposed by the Commission	*Amendment*
At the latest 9 months following the submission of that report, 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.	At the latest 9 months following the submission of that 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.

Or. en

Amendment 36
Christophe Clergeau, Estelle Ceulemans, Chloé Ridel, Pierre Jouvet

Proposal for a regulation
Article 4 – paragraph 1 – point 4

Regulation (EU) 2019/1021
Article 15 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission is empowered to adopt delegated acts in accordance with Article 18, to amend Annexes IV and V to adapt them to the changes to the list of substances set out in the Annexes to the Convention or the Protocol or to adapt them to scientific and technical progress.	2. The Commission is empowered to adopt delegated acts in accordance with Article 18, to amend Annexes IV and V to adapt them to the changes to the list of substances set out in the Annexes ***I, II or III to Regulation(EU) 2019/1021, or the Annexes*** to the Convention or the Protocol or to adapt them to scientific and technical progress.

Or. en

Amendment 37
Martin Hojsík

Proposal for a regulation
Article 4 – paragraph 1 – point 4 a (new)
Regulation (EU) 2019/1021
Article 16 – paragraph 2 a (new)

Present text	*Amendment*
	(4a) In Article 16 following paragraph is added
	2a. The Commission shall monitor the situation regarding the resources of the European Chemicals Agency and tasks, workload and remit of the scientific committees of the European Chemicals Agency and present, where necessary, a legislative proposal to reflect any needs of the European Chemicals Agency stemming from tasks introduced by this Regulation and to improve governance of its scientific committees."

Or. en

(32019R1021)

Amendment 38
Christophe Clergeau, Estelle Ceulemans, Chloé Ridel, Pierre Jouvet

Proposal for a regulation
Article 4 – paragraph 1 – point 5 – point c
Regulation (EU) 2019/1021
Article 18 – paragraph 6

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

Or. en

Amendment 39
Christophe Clergeau, Estelle Ceulemans, Chloé Ridel, Pierre Jouvet

Proposal for a regulation
Article 4 – paragraph 1 – point 5 – point c
Regulation (EU) 2019/1021
Annex IV – Table 1 – Row 5

Present text			
Alkanes C10-C13, chloro (short-chain chlorinated paraffins) (SCCPs)	85535-84-8	287-476-5	1 500 mg/kg ***The*** Commission shall review that concentration limit and shall, where appropriate, adopt a legislative proposal to lower that value ***no later than 30 December 2027***.

Amendment			
Alkanes C10-C13,	85535-84-8	287-476-5	1 500 mg/kg

chloro (short-chain chlorinated paraffins) (SCCPs)			***By 30 December 2027, the*** Commission shall review that concentration limit and shall, where appropriate, adopt a ***delegated act in accordance with Article 15(2)*** to lower that value.

Or. en

Amendment 40
Christophe Clergeau, Estelle Ceulemans, Chloé Ridel, Pierre Jouvet

Proposal for a regulation
Article 4 – paragraph 1 – point 5 – point c
Regulation (EU) 2019/1021
Annex IV – Table 1 – Row 12

Present text			
Polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF) and dioxin-like polychlorinated biphenyls (dl-PCBs)			5 µg/kg (2) ***The*** Commission shall review that concentration limit and shall, where appropriate, adopt a ***legislative proposal*** to lower that value***, where such lowering is feasible in accordance with scientific and technical progress, no later than 30 December 2027***.

Amendment			
Polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF) and dioxin-like polychlorinated biphenyls (dl-PCBs)			5 µg/kg (2) ***By 30 December 2027, the*** Commission shall review that concentration limit and shall, where appropriate, adopt a ***delegated act in accordance with Article 15(2)*** to lower that value.

Or. en

Amendment 41

Christophe Clergeau, Estelle Ceulemans, Chloé Ridel, Pierre Jouvet

Proposal for a regulation
Article 4 – paragraph 1 – point 5 – point c
Regulation (EU) 2019/1021
Annex IV – Table 1 – Row 30

Present text			
Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds, as set out in Annex I	335-67-1 and others	206-397-9 and others	1 mg/kg (PFOA and its salts), 40 mg/kg (sum of PFOA-related compounds) ***The*** Commission shall review that concentration limit and shall, where appropriate, adopt a ***legislative proposal*** to lower that value***, where such lowering is feasible in accordance with scientific and technical progress, no later than 30 December 2027***.

Amendment			
Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds, as set out in Annex I	335-67-1 and others	206-397-9 and others	1 mg/kg (PFOA and its salts), 40 mg/kg (sum of PFOA-related compounds) ***By 30 December 2027, the*** Commission shall review that concentration limit and shall, where appropriate, adopt a ***delegated act in accordance with Article 15(2)*** to lower that value.

Or. en

Amendment 42
Christophe Clergeau, Estelle Ceulemans, Chloé Ridel, Pierre Jouvet

Proposal for a regulation
Article 4 – paragraph 1 – point 5 – point c

Regulation (EU) 2019/1021
Annex IV – Table 1 – Row 27

Present text			
Hexabromocyclododecane (4)	25637-99-4, 3194-55-6, 134237-50-6, 134237-51-7, 134237-52-8	247-148-4 221-695-9	500 mg/kg ***The*** Commission shall review that concentration limit and shall, where appropriate, adopt a ***legislative proposal*** to lower that value to not higher than 200 mg/kg ***no later than 30 December 2027***.
(4) For the purpose of emission inventories, the following four compound indicators shall be used: benzo(a)pyrene, benzo(b) fluoranthene, benzo(k)fluoranthene and indeno(1,2,3-cd)pyrene			

Amendment			
Hexabromocyclododecane (4)	25637-99-4, 3194-55-6, 134237-50-6, 134237-51-7, 134237-52-8	247-148-4 221-695-9	500 mg/kg ***By 30 December 2027, the*** Commission shall review that concentration limit and shall, where appropriate, adopt a ***delegated act in accordance with Article 15(2)*** to lower that value to not higher than 200 mg/kg.
(4) For the purpose of emission inventories, the following four compound indicators shall be used: benzo(a)pyrene, benzo(b) fluoranthene, benzo(k)fluoranthene and indeno(1,2,3-cd)pyrene			

Or. en

Amendment 43
Christophe Clergeau, Estelle Ceulemans, Chloé Ridel, Pierre Jouvet

Proposal for a regulation
Article 4 – paragraph 1 – point 5 – point c
Regulation (EU) 2019/1021

Annex IV – Table 1 – Row 31

Present text			
Perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds	355-46-4 and others	206-587-1 and others	1 mg/kg (PFHxS and its salts), 40 mg/kg (sum of PFHxS-related compounds) ***The*** Commission shall review that concentration limit and shall, where appropriate, adopt a ***legislative proposal*** to lower that value***, where such lowering is feasible in accordance with scientific and technical progress, no later than 30 December 2027***.

Amendment			
Perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds	355-46-4 and others	206-587-1 and others	1 mg/kg (PFHxS and its salts), 40 mg/kg (sum of PFHxS-related compounds) ***By 30 December 2027, the*** Commission shall review that concentration limit and shall, where appropriate, adopt a ***delegated act in accordance with Article 15(2)*** to lower that value.

Or. en