C/2025/4378

9.9.2025

P10_TA(2025)0047

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

Amendments adopted by the European Parliament on 1 April 2025 on the 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 (COM(2023)0783 – C9-0447/2023 – 2023/0455(COD)) [1]

(Ordinary legislative procedure: first reading)

(C/2025/4378)

Amendment 1

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***. Differences in assessment methodologies resulting in divergent opinions, particularly with regard to the protection of vulnerable groups, should be duly justified. In such instances, priority should be given to the most protective opinion to safeguard vulnerable groups.*** Only when they are not able to resolve the divergence, should they refer to risk managers.

[1] The matter was referred back for interinstitutional negotiations to the committee responsible, pursuant to Rule 60(4), fourth subparagraph (A10-0020/2025).

Amendment 2

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***, enhancing 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.

Amendment 3

Proposal for a regulation

Recital 14 a (new)

Text proposed by the Commission	*Amendment*
	(14a) This Regulation expands the tasks, workload and remit of the 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 should regularly monitor the needs of the European Chemicals Agency stemming from this Regulation, and provide the Agency with sufficient and stable resources.

Amendment 4

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, 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. ***Differences in assessment methodologies resulting in divergent opinions shall be duly justified, especially regarding the protection of vulnerable groups.***

Amendment 5

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 ensuring the highest level of protection of health and the environment. 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***,*** identify the relevant uncertainties in the data and ***the possible causes for the diverging opinions, including on methodological differences, and*** be made publicly available.

Amendment 6

Proposal for a regulation

Article 1 – paragraph 1 – point 2

Regulation (EC) No 178/2002

Article 30 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Where a substantive divergence over scientific issues has been identified and the body in question is a Member State body, the Authority and the national body shall be obliged to cooperate with a view to either resolving the divergence or preparing a joint document clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. That document shall be made public.

Amendment 7

Proposal for a regulation

Article 1 – paragraph 1 – point 2

Regulation (EC) No 178/2002

Article 3 – paragraph 3 b (new)

Text proposed by the Commission	*Amendment*
	3b. In cases where a divergence is identified, and the Authority requests additional information from the other Union or Member State authority, the period within which 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 that information is to be provided and shall inform the Commission of the additional period needed. The Commission shall inform the business operators and the Member States concerned of the extension.

Amendment 8

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

Amendment 9

Proposal for a regulation

Article 4 – paragraph 1 – point 2

Regulation (EU) 2019/1021

Article 8 – paragraph 1a – subparagraph 1 – 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;

Amendment 10

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.

Amendment 11

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 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.

Amendment 12

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 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.

Amendment 13

Proposal for a regulation

Article 4 – paragraph 1 – point 4 a (new)

Regulation (EU) 2019/1021

Article 16 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	(4a) In Article 16, the 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 the governance of its scientific committees.'

Amendment 14

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'***.

Amendment 15

Proposal for a regulation

Article 4 – paragraph 1 – point 5 – point c a (new)

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			
(ca) in Annex IV, table 1, row 5 is replaced by the following:			
Alkanes C10-C13, chloro (short-chain chlorinated paraffins) (SCCPs)	85535-84-8	287-476-5	1 500 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.

Amendment 16

Proposal for a regulation

Article 4 – paragraph 1 – point 5 – point c b (new)

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 ***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			
(cb) in Annex IV, table 1, row 12 is replaced by the following:			
Polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF) and dioxin-like polychlorinated biphenyls (dl-PCBs)			5 µg/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.

Amendment 17

Proposal for a regulation

Article 4 – paragraph 1 – point 5 – point c c (new)

Regulation (EU) 2019/1021

Annex IV – Table 1 – Row 27

Present text			
Hexabromocyclododecane ([1])	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***.

([1]) 'Hexabromocyclododecane' means hexabromocyclododecane, 1,2,5,6,9,10-hexabromocyclododecane and its main diastereoisomers: alpha-hexabromocyclododecane, beta-hexabromocyclododecane and gamma-hexabromocyclododecane.

Amendment			
(cc) in Annex IV, table 1, row 27 is replaced by the following:			
Hexabromocyclododecane ([1])	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.

([1]) 'Hexabromocyclododecane' means hexabromocyclododecane, 1,2,5,6,9,10-hexabromocyclododecane and its main diastereoisomers: alpha-hexabromocyclododecane, beta-hexabromocyclododecane and gamma-hexabromocyclododecane.

Amendment 18

Proposal for a regulation

Article 4 – paragraph 1 – point 5 – point c d (new)

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			
(cd) in Annex IV, table 1, row 30 is replaced by the following:			
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.

Amendment 19

Proposal for a regulation

Article 4 – paragraph 1 – point 5 – point c e (new)

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			
(ce) in Annex IV, table 1, row 31 is replaced by the following:			
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.