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From:	General Secretariat of the Council
To:	Delegations
Subject:	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

Delegations will find in the Annex the final consolidated text of the abovementioned proposal endorsed by the Permanent Representatives Committee meeting on 25 June 2025.

ANNEX

PE-CONS No /YY - 2023/0455(COD)

REGULATION (EU) 2025/...
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of...

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure,

Whereas:

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

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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)0640).

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)0667).

(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 ongoing revisions of Union acts. This horizontal proposal aims to provide for further attribution of tasks in respect of those Union acts which are not in the process of being revised and is necessary in order to ensure that the European Chemicals Agency is involved in tasks pertaining to its expertise and developed capacities on chemicals. This is in line with the 'one substance, one assessment' aim to ensure that technical and scientific work is performed by the appropriate Union agency, benefiting from demonstrated experience and established tools in its field. The proposal for a Regulation is accompanied by a proposal for a Directive for the amendment of Directive 2011/65/EU of the European Parliament and of the Council[3], 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]

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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)0193) [*OJ:Please insert correct reference once the Regulation is adopted*].

(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 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***, taking into consideration the objective of ensuring a high level of protection of the environment and human health, including of vulnerable groups***. Regulation (EC) No 178/2002 of the European Parliament and Council already contains provisions establishing a procedure to solve ***divergence in*** 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. ***In addition, when referring to risk managers, they should explain the reasons underlying the divergence in opinions, including potential methodological differences.***

(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 human 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.

(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 Council[5], 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 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[6]. 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.

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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).

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).

(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.

(12a) For the preparation and update of the guidelines referred to in Article 3(2) and 3(3) of this Regulation, the European Chemicals Agency should involve the necessary expertise in the field of 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, of Category 1, should be specified in 10.4.1., point (b) of Annex I of Regulation (EU) 2017/745 in light of the relevance of that hazard class to the type of substances in medical devices.

(14) To make best use of the European Chemicals Agency's knowledge and expertise gained through its involvement in the nomination and assessment processes under the Stockholm Convention on Persistent Organic Pollutants, the European Chemicals Agency should, upon request, assist the Commission in complying with its obligation to amend Annexes IV and V to Regulation (EU) 2019/1021[8]. 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 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.

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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).

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).

(14b) The amendment of the Regulation (EU) 2019/1021 introduced by this Regulation expands the tasks, workload and remit of scientific committees of the European Chemicals Agency, in particular of its Committee for Socio-economic Analysis. In order to provide adequate expertise, support, and thorough scientific evaluations, appropriate and stable resources, capacity and governance of the scientific committees should be ensured. For that purpose, Regulation (EU) 2019/1021 should be adapted to reflect any future revision of the provisions governing the functioning of the committees of the European Chemicals Agency. In line with any such revision, the Commission should assess whether an amendment of Article 8 of Regulation (EU) 2019/1021 is required.

(15) In order to amend certain non-essential elements of Regulation (EU) 2019/1021 of the European Parliament and of the Council, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending Annexes IV and V in order to adapt them to the changes to the list of substances set out in the Annexes to the Stockholm Convention or the Protocol or adapt them to scientific and technical progress.

(16) As part of their reporting obligations under the Regulation (EU) 2019/1021 of the European Parliament and of the Council, Member States must report to the European Chemicals Agency information on the presence of substances listed in Part A of Annex III in the environment. The use of the Information Platform for Chemical Monitoring ('IPCHEM') is encouraged as a means for Member States to comply with their obligations to report that chemical occurrence data and to simplify and reduce their reporting obligations. Where Member States make data available through IPCHEM, they no longer need to report it to the European Chemicals Agency, as the agency may retrieve it from the platform.

(17) The revision of the Directive (EU) 2020/2184 of the European Parliament and of the Council[9] 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 chemicals[10] 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,

HAVE ADOPTED THIS REGULATION:

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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).

10 [OJ Please insert reference once proposal is adopted]

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;’

(1a) in Article 27, paragraph 4, point (b) is replaced by the following:

(b) in those circumstances identified in Article 30(2), where the Authority and a national body are obliged to cooperate;

(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***, taking into consideration the objective of a high level of protection of health and the 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***,*** identify the relevant uncertainties in the data ***and the underlying reasons for the diverging opinions, including on methodological differences, 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[1] of the European Parliament and of the Council, 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.’

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[1] 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.

Article 2

Amendments to Regulation (EC) No 401/2009

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

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

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

(2) in Article 15, ▌ paragraph ***1 is amended as follows***:

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

(a) Cooperation with the Joint Research Centre shall include the tasks set out in Annex ***I under A;***

(b) Coordination with Eurostat and the statistical programme of the Union shall follow the guidelines outlined in Annex I under B;

(c) Cooperation with the European Chemicals Agency, the European Food Safety Authority and the European Medicines Agency shall relate to the exchange of data and information on chemicals, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and to the development of scientific methodologies for the assessment of chemicals.’;

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

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

Article 3

Amendments to Regulation (EU) 2017/745

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

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

'(b) substances which are ***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 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.';

(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 ***submit*** a report on the human health, environmental and socio-economic impacts of introducing or modifying concentration limit values specified in Annex IV or V.’;

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

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

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

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

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

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

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

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

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

‘2. The Commission is empowered to adopt delegated acts in accordance with Article 18, ***in order*** to amend Annexes IV and V ***to this Regulation*** to adapt them to the changes to the list of substances set out in ▌ Annexes ***I, II or III to this Regulation or to modify existing entries in Annex IV and V to this Regulation*** to adapt them to scientific and technical progress***, including developments in waste treatment and decontamination technologies or new scientific information regarding health and environmental impacts associated with a presence of a substance in waste***.’;

(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 years from ***[OP : Please insert the date of the entry into force of this Regulation]***.’;

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

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

(c) Paragraph 6 is replaced by the following:

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

(5a) the following Article 21b is inserted:

‘Article 21b
Review

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

(5b) in Annex IV, table 1, row 4, the text in the fourth column is replaced by the following:

‘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 ▌.’;

(5c) in Annex IV, table 1, row 11, the text in the fourth column is replaced by the following:

‘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 ▌.’;

(5d) in Annex IV, table 1, row 26, the text in the fourth column is replaced by the following:

‘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 ▌.’;

(5e) in Annex IV, table 1, row 29, the text in the fourth column is replaced by the following:

‘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 ▌.’;

(5f) in Annex IV, table 1, row 30, the text in the fourth column is replaced by the following:

‘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 ▌.’.

Article 5

Entry into force

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

Done at Brussels,

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