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INFORMATION NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
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 - Outcome of the European Parliament's first reading (Strasbourg, 20 to 23 October 2025)

I. INTRODUCTION

In accordance with the provisions of Article 294 of the TFEU and the Joint declaration on practical arrangements for the codecision procedure¹, a number of informal contacts have taken place between the Council, the European Parliament and the Commission with a view to reaching an agreement on this proposal at first reading.

¹ OJ C 145, 30.6.2007, p. 5.

In this context, the Chair of the Committee on the Environment, Climate and Food Safety (ENVI), Antonio DECARO (S&D, IT), presented on behalf of ENVI a compromise amendment (amendment number 20) to the abovementioned proposal for a Regulation, for which Dimitris TSIODRAS (EPP, EL) had prepared a draft report. This amendment had been agreed during the informal contacts referred to above. No other amendments were tabled.

II. VOTE

When it voted on 21 October 2025, the plenary adopted the compromise amendment (amendment number 20) to the abovementioned proposal for a Regulation. The Commission's proposal as thus amended constitutes the European Parliament's first-reading position which is contained in its legislative resolution as set out in the Annex hereto².

The European Parliament's position reflects what had been previously agreed between the institutions. The Council should therefore be in a position to approve the Parliament's position.

The act would then be adopted in the wording which corresponds to the European Parliament's position.

² The version of the Parliament's position in the legislative resolution has been marked up to indicate the changes made by the amendments to the Commission's proposal. Additions to the Commission's text are highlighted in ***bold and italics***. The symbol "■" indicates deleted text.

P10_TA(2025)0237**Re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals**

European Parliament legislative resolution of 21 October 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) No 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))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2023)0783),
 - having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0447/2023),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 20 March 2024¹,
 - having regard to the provisional agreement approved by the committee responsible under Rule 75(4) of its Rules of Procedure and the undertaking given by the Council representative by letter of 25 June 2025 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rules 60 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Climate and Food Safety (A10-0020/2025),
1. Adopts its position at first reading hereinafter set out²;

¹ OJ C, C/2024/3381, 31.5.2024, ELI: <http://data.europa.eu/eli/C/2024/3381/oj>.

² This position replaces the amendments adopted on 1 April 2025 (Texts adopted, P10_TA(2025)0047).

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Position of the European Parliament adopted at first reading on 21 October 2025 with a view to the adoption of Regulation (EU) 2025/... 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 as regards the reattribution 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), point (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 Committee¹,

Acting in accordance with the ordinary legislative procedure²,

¹ OJ C, C/2024/3381, 31.5.2024, ELI: <http://data.europa.eu/eli/C/2024/3381/oj>.

² Position of the European Parliament of 21 October 2025.

Whereas:

- (1) The communication of the Commission of 11 December 2019 on the European Green Deal sets high ambitions for enabling the transition towards a toxic-free environment and zero pollution. The strategy set out in the communication of the Commission of 14 October 2020 entitled ‘Chemicals Strategy for Sustainability Towards a Toxic-Free Environment’ is a crucial step towards achieving zero pollution 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 legal acts.
- (2) To achieve these objectives, scientific and technical work on chemicals performed at Union level in support of Union legal acts in this field needs to be consolidated in the relevant Union agencies and obligations on Union agencies to cooperate in developing assessment methodologies and exchanging data and information should be introduced. This would simplify the current framework, improve the quality and coherence of safety assessments across Union legal acts and ensure that existing resources are used more efficiently.

- (3) The reattribution of certain existing scientific and technical tasks to the appropriate Union agency, as well as the attribution of entirely new tasks, were proposed as part of ongoing revision of Union legal acts. This Regulation provides for other tasks, which are provided for under Union legal acts which are not in the process of being revised, to be reallocated to the European Chemicals Agency in order to benefit from its expertise and capabilities in the assessment of chemicals. This is in line with the ‘one substance, one assessment’ approach to ensure that technical and scientific work is performed by the appropriate Union agency, benefiting from demonstrated experience and established tools in its field. This Regulation should be adopted at the same time as a Directive amending Directive 2011/65/EU of the European Parliament and of the Council³, aiming to achieve the same objectives.
- (4) As part of the implementation of the ‘one substance, one assessment’ approach, provisions have been introduced in a proposal for a Regulation amending Union pharmaceutical legislation in order to give the European Medicines Agency a mandate to develop and cooperate on the development of assessment methodologies, standard formats and controlled vocabularies and to exchange data and information on chemicals, as well as to provide for new procedures to ensure consistency between scientific opinions.

³ Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88, ELI: <http://data.europa.eu/eli/dir/2011/65/oj>).

- (5) To ensure the consistency of methodologies for assessments related to chemicals at Union level, all relevant Union agencies should have an equivalent mandate to develop such methodologies in the areas falling within their respective mandates and should be subject to the same obligations to cooperate amongst each other to develop such methodologies.
- (6) To ensure the consistency and efficiency of assessments related to chemicals provided for in Union legal acts, it is also important for data to be interoperable and for the exchange of data between the relevant Union agencies to be easy, 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 developed by the European Food Safety Authority (the 'EFSA') or by the European Environmental Agency (the 'EEA') should be established in cooperation with other relevant Union agencies working on chemicals. To that end, relevant new provisions should be introduced in Regulations (EC) No 401/2009⁴ and (EC) No 178/2002⁵ of the European Parliament and of the Council and existing provisions should be strengthened. The proposal of similar provisions in the Regulation on the European Chemicals Agency should also be considered, in order to ensure that provisions on cooperation among all relevant Union agencies are consistent.
- (7) To ensure consistency and efficiency of assessments related to chemicals provided for in Union legal acts, the relevant Union agencies should take measures to avoid divergent scientific opinions. Instances of divergent scientific opinions have **led** to increased uncertainty for operators, as well as to a decrease in public trust in the robustness and consistency of scientific decision making. Proposals to address and strengthen procedures for resolving divergences of scientific opinion between the European Medicines Agency and other scientific bodies have been made as part of the revision of Union pharmaceutical legislation. The proposal of similar provisions in the Regulation on the European Chemicals Agency could also be considered, in order to ensure that provisions for solving

⁴ Regulation (EC) No 401/2009 of the European Parliament and of the Council of 23 April 2009 on the European Environment Agency and the European Environment Information and Observation Network (OJ L 126, 21.5.2009, p. 13, ELI: <http://data.europa.eu/eli/reg/2009/401/oj>).

⁵ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1, ELI: <http://data.europa.eu/eli/reg/2002/178/oj>).

divergent scientific opinions between all relevant Union agencies are consistent. No such additional provisions would be necessary as regards the EEA, since the EEA does not issue scientific opinions on individual chemicals.

- (8) This Regulation aims to address potential divergences between scientific opinions given by the EFSA and those given by other bodies, ***taking into account the objective of ensuring a high level of protection of the environment and human health, including that of vulnerable groups***. Regulation (EC) No 178/2002 already provides for procedures whereby ***divergences between*** scientific opinions can be resolved. Those procedures should be strengthened. The EFSA and the other body involved should be required to make their best efforts to resolve any divergence between scientific opinions or over scientific issues. They should only refer the matter to risk managers where they are unable to resolve the divergence of opinion themselves. ***In addition, when referring the matter to risk managers, they should give the reasons underlying the divergence , including any methodological differences.***

- (9) In the specific case of a divergence of scientific opinion relating to the hazard identification of chemical substances, a new procedure enabling the resolution of the divergence of opinion should be established. Under that procedure, the Commission should be able to request the European Chemicals Agency, as the Union agency best equipped with expertise and capacity in hazard assessment, and having much 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 Council⁶. This would represent a step 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 incorporated in the provision on the resolution of diverging scientific opinions in Regulation (EC) No 178/2002.

⁶ 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, <http://data.europa.eu/eli/reg/2008/1272/oj>).

- (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 Council⁷, 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 Council⁸. The SCHEER issued those guidelines in 2019 and the Commission has mandated the SCHEER to carry out 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 provide the relevant scientific committee with a mandate 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 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.

⁷ 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, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>).

⁸ 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, ELI: <http://data.europa.eu/eli/reg/2006/1907/oj>).

- (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, development of those guidelines should be allocated to the European Chemicals Agency. ***For the preparation and update of the guidelines , the European Chemicals Agency should involve the relevant experts in the field of medical devices.***

- (13) Given the new hazard classes and criteria for classification, labelling and packaging of substances introduced by Commission Delegated Regulation (EU) 2023/707⁹, a reference to endocrine disruptors for human health, of Category 1, should be made in Section 10.4.1., point (b) of Annex I to Regulation (EU) 2017/745 in light of the relevance of that hazard class to the types of substances in medical devices.
- (14) To make the best use of the European Chemicals Agency's knowledge and expertise acquired through its involvement in the nomination and assessment processes under the Stockholm Convention on Persistent Organic Pollutants (the 'Stockholm Convention'), 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 of the European Parliament and of the Council¹⁰. Member States should be able to nominate experts to serve on working groups of the Committee for Socio-economic Analysis to ensure that that committee has the capacity and resources necessary for it to function effectively and to provide its opinion when required. In order to facilitate the functioning of the Committee for Socio-economic Analysis, when the Committee appoints one of its members as a rapporteur, that person, or that person's employer, should be remunerated.

⁹ 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, ELI: http://data.europa.eu/eli/reg_del/2023/707/oj).

¹⁰ 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, ELI: <http://data.europa.eu/eli/reg/2019/1021/oj>).

- (15) *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 particular of the Committee for Socio-economic Analysis. In order to provide adequate expertise and support, thorough scientific evaluations, and appropriate and stable resources, the capacity and governance of the scientific committees should be ensured. For that purpose, it may be appropriate to adapt Regulation (EU) 2019/1021 to reflect any future revision of the provisions governing the functioning of the committees of the European Chemicals Agency. In the light of such revision, the Commission should assess whether Regulation (EU) 2019/1021 needs to be amended.*
- (16) In order to amend certain non-essential elements of Regulation (EU) 2019/1021, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union 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 to the Convention on Long Range Transboundary Air Pollution on Persistent Organic Pollutants or adapt them to scientific and technical progress.

- (17) As part of their reporting obligations under Regulation (EU) 2019/1021, Member States have a duty to report information on the presence of substances listed in Part A of Annex III to that Regulation in the environment to the European Chemicals Agency. 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 such 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 such data to the European Chemicals Agency, as the agency will be able to retrieve them from the platform.

- (18) The revision of Directive (EU) 2020/2184 of the European Parliament and of the Council¹¹ requires Member States to share with the EEA all data on chemical occurrences in water and on the monitoring of such chemical occurrences. Additionally, Member States are already required to report monitoring data to the EEA regarding the presence of persistent organic pollutants (‘POPs’) in air under Union air quality legislation. Regulation (EU) 2025/... of the European Parliament and the Council¹²⁺ requires the EEA to hold all chemical occurrence data. Consequently, the EEA is to collect and hold any chemical occurrence data provided to and held by the Commission in IPCHEM. It is therefore necessary to simplify the reporting obligations for Member States to ensure that, where information has already been submitted to the EEA voluntarily or pursuant to obligations under other pieces of Union environmental legislation, Member States should be considered to have fulfilled their reporting obligations under Regulation (EU) 2019/1021.
- (19) 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:

¹¹ 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 (OJ L 435, 23.12.2020, p. 1, ELI: <http://data.europa.eu/eli/dir/2020/2184/oj>).

¹² Regulation (EU) 2025/...of the European Parliament and of the Council of... 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 (OJ ..., ELI: ...).

⁺ OJ: please insert in the text the number of the Regulation contained in the document PE xx/24 (2023/0453(COD)) and complete the corresponding footnote.

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 is added:

‘(m) to cooperate with the competent bodies in the Member States that carry out similar tasks to those of the Authority and with other scientific bodies established under Union law, in particular 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 potential establishment of related data formats and controlled vocabularies to facilitate such an exchange, and on the development of scientific methodologies for the assessment of chemicals.’;

(2) *in Article 27 (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;*’;

- (3) 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 as referred to in paragraph 1, it shall contact the other body in order to ensure that all relevant scientific or technical information is shared and to identify potentially contentious scientific or technical issues.

The Authority and the other body shall cooperate to resolve any divergence , ***taking into consideration the objective of a high level of protection of health and the environment.*** If the Authority and the other body are not able to resolve the divergence, they shall draw up a joint report. The report shall clearly outline the contentious scientific issues, identify any relevant uncertainties in the data ***and give the underlying reasons for the divergence of opinions, including reasons related to methodological differences.*** ***The report shall*** be made publicly available.

Where the other body is a Union agency or a scientific committee, the Authority shall also 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 on whether a substance fulfils the criteria laid out in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council*, the Commission may request the European Chemicals Agency to prepare a proposal for the harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for the revision of such classification and labelling of substances, and, where appropriate, for the revision of such limits, factors or estimates in accordance with the procedure laid down in Article 37 of Regulation (EC) No 1272/2008. The Authority and the other Union body shall co-operate with the European Chemicals Agency in preparing that proposal.

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- * 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, ELI: <http://data.europa.eu/eli/reg/2008/1272/oj>).’.

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 is added:

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

(2) Article 15 ■ *is amended as follows:*

(a) paragraph 1 is replaced by the following:

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

Cooperation with the Joint Research Centre shall include in particular the tasks set out in Annex I, Part A.

Coordination with Eurostat and the statistical programme of the Union shall follow in particular the guidelines outlined in Annex I, Part B.

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.’;

(b) paragraph 4 is replaced by the following:

‘4. The cooperation referred to in paragraphs 1, 2 and 3 shall take account , inter alia, of the need to enhance coherence and 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 of the European Parliament and the Council***.

* 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).

** 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, ELI: <http://data.europa.eu/eli/reg/2006/1907/oj>).

*** Regulation (EU) No 528/2012 of the European Parliament and the Council of 22 May 2012 concerning the making available on the market of and use of biocidal products (OJ L 167, 27.6.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/528/oj>).’;

(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 prepare and 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, the 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

In addition to the guidelines referred to in Section 10.4.3., the Commission shall request the ECHA to prepare such guidelines for other substances referred to in Section 10.4.1., points (a) and (b), where appropriate. Such guidelines shall be prepared in accordance with the process described in Section 10.4.3. ■’.

Article 4

Amendments to Regulation (EU) 2019/1021

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

- (1) Article 8 is amended as follows:

- (a) in paragraph 1, the following point is added:

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

(b) the following paragraph is inserted:

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

- (a) ■ information on the impacts on human health and on the environment 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 in drawing up the report;
- (d) a reasoned 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 *paragraph 1*, point (i), publish on its website a notice that a report on a possible amendment of Annex IV or V will be prepared. The notice shall also invite 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 paragraph 1, point (i)*, of this Article, 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 that purpose Article 87 of Regulation (EC) No 1907/2006 shall apply *mutatis mutandis*.

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

(2) 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 (the ‘EEA’), that Member State shall indicate that in the report and, in doing so, shall be deemed 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 EEA for compiling, storing and sharing that information.’;

(3) 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 adapt them to the changes to the list of substances set out in ■ Annexes ***I, II or III or to modify existing entries in Annex IV and V*** 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 the presence of a substance in waste.***’;

(4) Article 18 is amended as follows:

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

‘The power to adopt delegated acts referred to in Article 4(3), Article 10(2) and Article 15 shall be conferred on the Commission for a period of five years from ... ***[date of the entry into force of this amending act]***.’;

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

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

(c) Paragraph 6 is replaced by the following:

‘A delegated act adopted pursuant to Article 4(3), Article 10(2) or Article 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.***’;

(5) *the following article is inserted:*

‘Article 21b

Review

Taking due account of any regulatory developments concerning the status of the resources and of 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 appropriate, present a legislative proposal to amend this Regulation accordingly.’;

(6) *Annex IV, table 1, is amended as follows:*

(a) *in 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 ■ .’;

(b) *in 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 ■ .’;

(c) *in 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 ■ .’;

(d) *in 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 ■ .’;

(e) *in 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*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at ...

For the European Parliament

For the Council

The President

The President

P10_TA(2025)0237

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

European Parliament legislative resolution of 21 October 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) No 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))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2023)0783),
 - having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0447/2023),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 20 March 2024¹³,
 - having regard to the provisional agreement approved by the committee responsible under Rule 75(4) of its Rules of Procedure and the undertaking given by the Council representative by letter of 25 June 2025 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rules 60 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Climate and Food Safety (A10-0020/2025),
1. Adopts its position at first reading hereinafter set out¹⁴;
 2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

¹³ OJ C, C/2024/3381, 31.5.2024, ELI: <http://data.europa.eu/eli/C/2024/3381/oj>.

¹⁴ This position replaces the amendments adopted on 1 April 2025 (Texts adopted, P10_TA(2025)0047).

Position of the European Parliament adopted at first reading on 21 October 2025 with a view to the adoption of Regulation (EU) 2025/... 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 as regards the reattribution 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), point (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 Committee¹,

Acting in accordance with the ordinary legislative procedure²,

¹ OJ C, C/2024/3381, 31.5.2024, ELI: <http://data.europa.eu/eli/C/2024/3381/oj>.

² Position of the European Parliament of 21 October 2025.

Whereas:

- (1) The communication of the Commission of 11 December 2019 on the European Green Deal sets high ambitions for enabling the transition towards a toxic-free environment and zero pollution. The strategy set out in the communication of the Commission of 14 October 2020 entitled ‘Chemicals Strategy for Sustainability Towards a Toxic-Free Environment’ is a crucial step towards achieving zero pollution 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 legal acts.
- (2) To achieve these objectives, scientific and technical work on chemicals performed at Union level in support of Union legal acts in this field needs to be consolidated in the relevant Union agencies and obligations on Union agencies to cooperate in developing assessment methodologies and exchanging data and information should be introduced. This would simplify the current framework, improve the quality and coherence of safety assessments across Union legal acts and ensure that existing resources are used more efficiently.

- (3) The reattribution of certain existing scientific and technical tasks to the appropriate Union agency, as well as the attribution of entirely new tasks, were proposed as part of ongoing revision of Union legal acts. This Regulation provides for other tasks, which are provided for under Union legal acts which are not in the process of being revised, to be reallocated to the European Chemicals Agency in order to benefit from its expertise and capabilities in the assessment of chemicals. This is in line with the ‘one substance, one assessment’ approach to ensure that technical and scientific work is performed by the appropriate Union agency, benefiting from demonstrated experience and established tools in its field. This Regulation should be adopted at the same time as a Directive amending Directive 2011/65/EU of the European Parliament and of the Council³, aiming to achieve the same objectives.
- (4) As part of the implementation of the ‘one substance, one assessment’ approach, provisions have been introduced in a proposal for a Regulation amending Union pharmaceutical legislation in order to give the European Medicines Agency a mandate to develop and cooperate on the development of assessment methodologies, standard formats and controlled vocabularies and to exchange data and information on chemicals, as well as to provide for new procedures to ensure consistency between scientific opinions.

³ Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88, ELI: <http://data.europa.eu/eli/dir/2011/65/oj>).

- (5) To ensure the consistency of methodologies for assessments related to chemicals at Union level, all relevant Union agencies should have an equivalent mandate to develop such methodologies in the areas falling within their respective mandates and should be subject to the same obligations to cooperate amongst each other to develop such methodologies.
- (6) To ensure the consistency and efficiency of assessments related to chemicals provided for in Union legal acts, it is also important for data to be interoperable and for the exchange of data between the relevant Union agencies to be easy, 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 developed by the European Food Safety Authority (the 'EFSA') or by the European Environmental Agency (the 'EEA') should be established in cooperation with other relevant Union agencies working on chemicals. To that end, relevant new provisions should be introduced in Regulations (EC) No 401/2009⁴ and (EC) No 178/2002⁵ of the European Parliament and of the Council and existing provisions should be strengthened. The proposal of similar provisions in the Regulation on the European Chemicals Agency should also be considered, in order to ensure that provisions on cooperation among all relevant Union agencies are consistent.
- (7) To ensure consistency and efficiency of assessments related to chemicals provided for in Union legal acts, the relevant Union agencies should take measures to avoid divergent scientific opinions. Instances of divergent scientific opinions have **led** to increased uncertainty for operators, as well as to a decrease in public trust in the robustness and consistency of scientific decision making. Proposals to address and strengthen procedures for resolving divergences of scientific opinion between the European Medicines Agency and other scientific bodies have been made as part of the revision of Union pharmaceutical legislation. The proposal of similar provisions in the Regulation on the European Chemicals Agency could also be considered, in order to ensure that provisions for solving

⁴ Regulation (EC) No 401/2009 of the European Parliament and of the Council of 23 April 2009 on the European Environment Agency and the European Environment Information and Observation Network (OJ L 126, 21.5.2009, p. 13, ELI: <http://data.europa.eu/eli/reg/2009/401/oj>).

⁵ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1, ELI: <http://data.europa.eu/eli/reg/2002/178/oj>).

divergent scientific opinions between all relevant Union agencies are consistent. No such additional provisions would be necessary as regards the EEA, since the EEA does not issue scientific opinions on individual chemicals.

- (8) This Regulation aims to address potential divergences between scientific opinions given by the EFSA and those given by other bodies, ***taking into account the objective of ensuring a high level of protection of the environment and human health, including that of vulnerable groups***. Regulation (EC) No 178/2002 already provides for procedures whereby ***divergences between*** scientific opinions can be resolved. Those procedures should be strengthened. The EFSA and the other body involved should be required to make their best efforts to resolve any divergence between scientific opinions or over scientific issues. They should only refer the matter to risk managers where they are unable to resolve the divergence of opinion themselves. ***In addition, when referring the matter to risk managers, they should give the reasons underlying the divergence , including any methodological differences.***

- (9) In the specific case of a divergence of scientific opinion relating to the hazard identification of chemical substances, a new procedure enabling the resolution of the divergence of opinion should be established. Under that procedure, the Commission should be able to request the European Chemicals Agency, as the Union agency best equipped with expertise and capacity in hazard assessment, and having much 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 Council⁶. This would represent a step 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 incorporated in the provision on the resolution of diverging scientific opinions in Regulation (EC) No 178/2002.

⁶ 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, <http://data.europa.eu/eli/reg/2008/1272/oj>).

- (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 Council⁷, 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 Council⁸. The SCHEER issued those guidelines in 2019 and the Commission has mandated the SCHEER to carry out 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 provide the relevant scientific committee with a mandate 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 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.

⁷ 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, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>).

⁸ 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, ELI: <http://data.europa.eu/eli/reg/2006/1907/oj>).

- (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, development of those guidelines should be allocated to the European Chemicals Agency. ***For the preparation and update of the guidelines , the European Chemicals Agency should involve the relevant experts in the field of medical devices.***

- (13) Given the new hazard classes and criteria for classification, labelling and packaging of substances introduced by Commission Delegated Regulation (EU) 2023/707⁹, a reference to endocrine disruptors for human health, of Category 1, should be made in Section 10.4.1., point (b) of Annex I to Regulation (EU) 2017/745 in light of the relevance of that hazard class to the types of substances in medical devices.
- (14) To make the best use of the European Chemicals Agency's knowledge and expertise acquired through its involvement in the nomination and assessment processes under the Stockholm Convention on Persistent Organic Pollutants (the 'Stockholm Convention'), 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 of the European Parliament and of the Council¹⁰. Member States should be able to nominate experts to serve on working groups of the Committee for Socio-economic Analysis to ensure that that committee has the capacity and resources necessary for it to function effectively and to provide its opinion when required. In order to facilitate the functioning of the Committee for Socio-economic Analysis, when the Committee appoints one of its members as a rapporteur, that person, or that person's employer, should be remunerated.

⁹ 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, ELI: http://data.europa.eu/eli/reg_del/2023/707/oj).

¹⁰ 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, ELI: <http://data.europa.eu/eli/reg/2019/1021/oj>).

- (15) *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 particular of the Committee for Socio-economic Analysis. In order to provide adequate expertise and support, thorough scientific evaluations, and appropriate and stable resources, the capacity and governance of the scientific committees should be ensured. For that purpose, it may be appropriate to adapt Regulation (EU) 2019/1021 to reflect any future revision of the provisions governing the functioning of the committees of the European Chemicals Agency. In the light of such revision, the Commission should assess whether Regulation (EU) 2019/1021 needs to be amended.*
- (16) In order to amend certain non-essential elements of Regulation (EU) 2019/1021, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union 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 to the Convention on Long Range Transboundary Air Pollution on Persistent Organic Pollutants or adapt them to scientific and technical progress.

- (17) As part of their reporting obligations under Regulation (EU) 2019/1021, Member States have a duty to report information on the presence of substances listed in Part A of Annex III to that Regulation in the environment to the European Chemicals Agency. 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 such 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 such data to the European Chemicals Agency, as the agency will be able to retrieve them from the platform.

- (18) The revision of Directive (EU) 2020/2184 of the European Parliament and of the Council¹¹ requires Member States to share with the EEA all data on chemical occurrences in water and on the monitoring of such chemical occurrences. Additionally, Member States are already required to report monitoring data to the EEA regarding the presence of persistent organic pollutants (‘POPs’) in air under Union air quality legislation. Regulation (EU) 2025/... of the European Parliament and the Council¹²⁺ requires the EEA to hold all chemical occurrence data. Consequently, the EEA is to collect and hold any chemical occurrence data provided to and held by the Commission in IPCHEM. It is therefore necessary to simplify the reporting obligations for Member States to ensure that, where information has already been submitted to the EEA voluntarily or pursuant to obligations under other pieces of Union environmental legislation, Member States should be considered to have fulfilled their reporting obligations under Regulation (EU) 2019/1021.
- (19) 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:

¹¹ 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 (OJ L 435, 23.12.2020, p. 1, ELI: <http://data.europa.eu/eli/dir/2020/2184/oj>).

¹² Regulation (EU) 2025/...of the European Parliament and of the Council of... 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 (OJ ..., ELI: ...).

⁺ OJ: please insert in the text the number of the Regulation contained in the document PE xx/24 (2023/0453(COD)) and complete the corresponding footnote.

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 is added:

‘(m) to cooperate with the competent bodies in the Member States that carry out similar tasks to those of the Authority and with other scientific bodies established under Union law, in particular 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 potential establishment of related data formats and controlled vocabularies to facilitate such an exchange, and on the development of scientific methodologies for the assessment of chemicals.’;

(2) *in Article 27 (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;*’;

- (3) 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 as referred to in paragraph 1, it shall contact the other body in order to ensure that all relevant scientific or technical information is shared and to identify potentially contentious scientific or technical issues.

The Authority and the other body shall cooperate to resolve any divergence , ***taking into consideration the objective of a high level of protection of health and the environment.*** If the Authority and the other body are not able to resolve the divergence, they shall draw up a joint report. The report shall clearly outline the contentious scientific issues, identify any relevant uncertainties in the data ***and give the underlying reasons for the divergence of opinions, including reasons related to methodological differences.*** ***The report shall*** be made publicly available.

Where the other body is a Union agency or a scientific committee, the Authority shall also 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 on whether a substance fulfils the criteria laid out in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council*, the Commission may request the European Chemicals Agency to prepare a proposal for the harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for the revision of such classification and labelling of substances, and, where appropriate, for the revision of such limits, factors or estimates in accordance with the procedure laid down in Article 37 of Regulation (EC) No 1272/2008. The Authority and the other Union body shall co-operate with the European Chemicals Agency in preparing that proposal.

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- * 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, ELI: <http://data.europa.eu/eli/reg/2008/1272/oj>).’.

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 is added:

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

(2) Article 15 ■ *is amended as follows:*

(a) paragraph 1 is replaced by the following:

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

Cooperation with the Joint Research Centre shall include in particular the tasks set out in Annex I, Part A.

Coordination with Eurostat and the statistical programme of the Union shall follow in particular the guidelines outlined in Annex I, Part B.

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.’;

(b) paragraph 4 is replaced by the following:

‘4. The cooperation referred to in paragraphs 1, 2 and 3 shall take account , inter alia, of the need to enhance coherence and 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 of the European Parliament and the Council***.

* 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).

** 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, ELI: <http://data.europa.eu/eli/reg/2006/1907/oj>).

*** Regulation (EU) No 528/2012 of the European Parliament and the Council of 22 May 2012 concerning the making available on the market of and use of biocidal products (OJ L 167, 27.6.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/528/oj>).’;

(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 prepare and 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, the 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

In addition to the guidelines referred to in Section 10.4.3., the Commission shall request the ECHA to prepare such guidelines for other substances referred to in Section 10.4.1., points (a) and (b), where appropriate. Such guidelines shall be prepared in accordance with the process described in Section 10.4.3. ■’.

Article 4

Amendments to Regulation (EU) 2019/1021

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

- (1) Article 8 is amended as follows:

- (a) in paragraph 1, the following point is added:

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

(b) the following paragraph is inserted:

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

- (a) ■ information on the impacts on human health and on the environment 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 in drawing up the report;
- (d) a reasoned 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 *paragraph 1*, point (i), publish on its website a notice that a report on a possible amendment of Annex IV or V will be prepared. The notice shall also invite 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 paragraph 1, point (i)*, of this Article, 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 that purpose Article 87 of Regulation (EC) No 1907/2006 shall apply *mutatis mutandis*.

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

(2) 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 (the ‘EEA’), that Member State shall indicate that in the report and, in doing so, shall be deemed 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 EEA for compiling, storing and sharing that information.’;

(3) 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 adapt them to the changes to the list of substances set out in ■ Annexes ***I, II or III or to modify existing entries in Annex IV and V*** 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 the presence of a substance in waste.***’;

(4) Article 18 is amended as follows:

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

‘The power to adopt delegated acts referred to in Article 4(3), Article 10(2) and Article 15 shall be conferred on the Commission for a period of five years from ... ***[date of the entry into force of this amending act]***.’;

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

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

(c) Paragraph 6 is replaced by the following:

‘A delegated act adopted pursuant to Article 4(3), Article 10(2) or Article 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.***’;

(5) *the following article is inserted:*

‘Article 21b

Review

Taking due account of any regulatory developments concerning the status of the resources and of 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 appropriate, present a legislative proposal to amend this Regulation accordingly.’;

(6) *Annex IV, table 1, is amended as follows:*

(a) *in 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 ■ .’;

(b) *in 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 ■ .’;

(c) *in 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 ■ .’;

(d) *in 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 ■ .’;

(e) *in 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*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at ...

For the European Parliament

For the Council

The President

The President
