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DIRECTIVE (EU) 2025/2456 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 26 November 2025

amending Directive 2011/65/EU as regards the reattribution of scientific and technical tasks to the European Chemicals Agency

(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 Article 114 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 ([1]),

Acting in accordance with the ordinary legislative procedure ([2]),

Whereas:

(1) The communication of the Commission of 11 December 2019 on the European Green Deal sets as an objective that chemical safety assessments should move towards a 'one substance, one assessment' approach, calling for more transparent and simpler risk assessment processes in order to reduce the burden on all stakeholders, accelerate decision-making and increase consistency and predictability of scientific decisions and opinions. The communication of the Commission of 14 October 2020 entitled 'Chemicals Strategy for Sustainability Towards a Toxic-Free Environment' concludes that, in order to achieve that objective, part of the scientific and technical work on chemicals performed at Union level in support of Union law needs to be reattributed to the most suitable Union agencies. This would simplify the current set-up, improve the quality and coherence of safety assessments across Union law, and ensure more efficient use of existing resources. This approach is also expected to promote cost-effectiveness and competitiveness by simplifying regulatory procedures and reducing the administrative burden, thereby ensuring that businesses can adapt efficiently to evolving regulatory frameworks.

(2) The reattribution of certain scientific and technical tasks to the European Chemicals Agency (the 'Agency') is necessary in order to align processes and levels of scientific scrutiny and digitalisation with the current standards and processes of the Agency. The reattribution of such tasks is also necessary in order to ensure a consistent standard of scientific quality, transparency, data searchability and interoperability, in line with the 'one substance, one assessment' approach. Moreover, digitalisation and streamlining of processes will reduce the duplication of efforts and administrative delays, providing significant cost savings and efficiency gains for both Member States and economic operators.

(3) The amendment of Directive 2011/65/EU of the European Parliament and of the Council ([3]) aims to expand the tasks, workload and remit of scientific committees of the Agency. In order to provide adequate expertise and support, and thorough scientific evaluations, appropriate and stable resources and governance of the scientific committees should be ensured. In this respect, it is appropriate to provide for a review clause to ensure that the Commission take account of any future regulatory developments relating to the governance of the scientific committees of the Agency in order, if necessary, to revise Directive 2011/65/EU accordingly.

([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 (not yet published in the Official Journal) and decision of the Council of 13 November 2025.
([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).

(4) Directive 2011/65/EU contains two procedures relating to the assessment of chemicals: the evaluation of economic operators' applications for granting, renewing or revoking an exemption from the substance restrictions and the review of substances to be added to the list of restricted substances. There is a need to increase transparency by setting detailed procedural steps for the process of reviewing substances for potential inclusion in the list of restricted substances.

(5) Data and information held by the Agency in the context of regulatory processes under Titles VII and VIII of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([4]) can be usefully deployed for the assessment of potential substance restrictions and for the assessment of applications for exemption under Directive 2011/65/EU. Established structures and procedures can help to build on the existing knowledge base, maximise synergies and make the best use of available expertise and resources.

(6) To ensure consistency between the evaluation of economic operators' applications for granting, renewing or revoking an exemption pursuant to Article 5 of the Directive 2011/65/EU, and to make the best use of existing chemicals-related expertise, the technical evaluation to assess the justification of such exemption applications should be carried out by the Agency and its committees in close coordination with the Commission.

(7) The information submitted in the confidential version of an exemption application should be subject to an assessment by the Agency. Such assessment should comply with Union law concerning confidential data and protection of personal data, in particular regarding dissemination and confidentiality criteria established under Regulation (EC) No 1907/2006.

(8) Most exemption applications are expected to require the expertise of the Committee for Socioeconomic Analysis set up pursuant to Regulation (EC) No 1907/2006. The Commission should consult Members States' representatives when adopting guidelines on the involvement of the Committee for Risk Assessment.

(9) To ensure that the restriction process of Directive 2011/65/EU is consistent with the restriction processes under other legal acts related to chemicals, and in particular the substance restriction process laid down in Regulation (EC) No 1907/2006, Directive 2011/65/EU should be amended in order to formally assign the Agency a role in the restriction process. In light of experience gained while carrying out substance reviews, it is essential for the quality of the related technical assessment and for enabling synergies, to make use of information and tools being used in the context of assessments for chemical restrictions under Regulation (EC) No 1907/2006.

(10) The list of restricted substances referred to in Directive 2011/65/EU should be periodically reviewed to ensure a high level of protection of human health, the environment and consumer safety. It is appropriate for such reviews to take place at least every 4 years, taking into account market developments, technical and scientific progress, that restriction dossiers can be submitted by Member States at any time and that horizontal restriction measures can be initiated and adopted under Regulation (EC) No 1907/2006, Regulation (EU) 2019/1021 of the European Parliament and of the Council ([5]) or other Union law concerning sustainability criteria for hazardous substances and chemicals.

(11) The Agency can develop guidance concerning the Annex to Directive 2011/65/EU introduced by this Directive. In addition, where relevant, reference can be made to the existing guidance concerning Annex XV to Regulation (EC) No 1907/2006 in respect of the specific aim of Directive 2011/65/EU and the criteria laid down in Article 6(1) of that Directive.

([4]) 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).

([5]) 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).

(12) The two procedures described under Article 5 and Article 6 of Directive 2011/65/EU are applicable at Union level. National provisions should not deviate from those Articles.

(13) In order to ensure that this Directive is consistent with any future amendment of Regulation (EC) No 1907/2006, and with other future Union legal acts concerning sustainability criteria for hazardous substances and chemicals, the Commission should assess whether further amendments of Directive 2011/65/EU are necessary in order to amend the rules concerning the adaptation of the Annexes to that Directive to scientific and technical progress and the rules concerning the amendment of the list of restricted substances in Annex II to that Directive. Where appropriate, the Commission should propose amendments to Directive 2011/65/EU in future proposals concerning sustainability criteria for hazardous substances and chemicals or in other future Union legal acts concerning sustainability criteria for hazardous substances and chemicals.

(14) For amending procedural provisions under Directive 2011/65/EU, it is necessary to provide for a transitional period of 20 months to allow for appropriate resource allocation and task assignment in respect of the Agency. That timeframe is considered sufficient to allow potential applicants or Member States to adjust to the modified procedural steps under that Directive.

(15) Directive 2011/65/EU should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Amendments to Directive 2011/65/EU

Directive 2011/65/EU is amended as follows:

(1) Article 5 is amended as follows:

(a) paragraphs 3 and 4 are replaced by the following:

‘3. An application for granting, renewing or revoking an exemption shall be made to the European Chemicals Agency set up pursuant to Article 75(1) of Regulation (EC) No 1907/2006 (the “Agency”) in accordance with Annex V.

4. The Agency shall:

(a) acknowledge receipt of an application within 15 days of its receipt, stating the date of receipt of the application;

(b) upon receipt of an application, notify the Commission of the application and keep it informed of any of the procedural steps under points (c) to (g) and the second, third and fourth subparagraphs;

(c) verify that the application contains all the elements set out in Annex V;

(d) if necessary and within 45 days of receipt of the application:

(i) request the applicant to complete the application; and

(ii) set an appropriate time limit of maximum 60 days for completion of the application.

(e) make the application and any supplementary information supplied by the applicant available to Member States;

(f) make available to the public a summary and a non-confidential version of the application on the Agency’s website, as well as the date on which it considers the application to be complete;

(g) invite interested parties to submit information within 3 months of making the application available in accordance with point (f).

If the volume and the complexity of the application is such that the Agency cannot comply with the 45 day time limit referred to in the first subparagraph, point (d), the Agency shall inform the applicant of any extension of the time limit and of the reasons therefor, as soon as possible, and in any case before the end of that time limit.

The Agency may extend the 60 day time limit referred to in the first subparagraph, point (d)(ii), if the volume and the complexity of the application is such that that time limit cannot be complied with and provided that the applicant submits a reasoned request for an extension before the expiry of the 60 day time limit. The Agency shall decide on such extension within 5 working days of the request.

If the applicant does not complete the application, in accordance with Annex V, with the elements identified as missing by the Agency, within the time limit set in accordance with the first subparagraph, point (d)(ii), and the second and third subparagraphs, of this Article, the Agency shall reject the application. The Agency shall establish and communicate to the applicant without delay the date when the application is considered complete.';

(b) the following paragraph is inserted:

'4a. Once the Agency considers the application to be complete, it shall request the opinion of the Committee for Socioeconomic Analysis, set up pursuant to Article 76(1), point (d), of Regulation (EC) No 1907/2006 (the "Committee for Socioeconomic Analysis"). The Agency shall also request the opinion of the Committee for Risk Assessment, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006 (the "Committee for Risk Assessment"), in the case of an application for a new exemption, or where otherwise considered appropriate.

The Committee for Socioeconomic Analysis and, where relevant, the Committee for Risk Assessment:

(a) shall draw up draft opinions within 9 months of the date the application is considered complete by the Agency;

(b) shall assess whether the criteria in Article 5(1), point (a), are met;

(c) shall provide clear guidance to the Commission on granting, renewing or revoking an exemption;

(d) may request the applicant or third parties to submit, within a specified period, additional information;

(e) upon adopting the draft opinions, shall communicate those draft opinions to the applicant and allow the applicant the opportunity to comment within 4 weeks of that communication;

(f) shall adopt their final opinions, taking into account the comments from the applicant.

Each Committee shall take into account any information submitted by third parties in accordance with the second subparagraph, point (d).

The Agency shall send the final opinions of the Committees to the Commission within 12 months of the date on which the Agency considers the application to be complete.

The Agency shall identify which parts of those opinions, including any attachments thereto are to be made publicly available on its website. The Agency shall make those parts, and any requests made in accordance with the second subparagraph, point (d), available to the public on its website.

For the purpose of adopting opinions pursuant to this paragraph, Article 87 of Regulation (EC) No 1907/2006 shall apply *mutatis mutandis*.';

(c) paragraph 5 is replaced by the following:

‘5. An application for renewal of an exemption shall be made no later than 18 months before the exemption expires. The Commission shall adopt the decision on the application within 9 months of receipt of the opinions from the Agency pursuant to paragraph 4a, fourth subparagraph. The existing exemption shall remain valid until a decision on the application for renewal is adopted by the Commission.’;

(d) paragraph 8 is replaced by the following:

‘8. The Agency shall, in agreement with the Commission, establish a harmonised format for the applications as referred to in paragraph 3 as well as comprehensive guidelines for such applications, taking into account the situation of SMEs. Any application to the Agency shall be made using that harmonised format and submission tools made available by the Agency.’;

(e) the following paragraph is added:

‘9. The Commission shall publish guidelines to facilitate the harmonised application of this Article.’;

(2) Article 6 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) the first subparagraph is replaced by the following:

‘With a view to achieving the objectives set out in Article 1 and taking account of the precautionary principle, a review, based on a thorough assessment, and an amendment of the list of restricted substances in Annex II shall be considered by the Commission periodically and at least every 4 years on its own initiative or following the submission of a restriction dossier prepared by a Member State containing the information referred to in paragraph 2.’;

(ii) the fourth subparagraph is deleted.

(b) paragraph 2 is replaced by the following:

‘2. The review and amendment of the list of restricted substances, or a group of similar substances, in Annex II shall be based on restriction dossiers prepared by the Agency at the request of the Commission or prepared by a Member State.

In preparing restriction dossiers, the Agency or a Member State shall take into account any available information and any relevant assessment submitted for the purposes of other Union legal acts covering any part of the life cycle of the substance used in EEE, in particular the waste phase. To that end, other bodies established under Union law and carrying out similar tasks shall, on request, provide information to the Agency or Member State concerned.

Restriction dossiers shall comply with the requirements set out in paragraph 1 of this Article, and shall, in addition, contain the information set out in Annex Va.’;

(3) the following Articles are inserted:

‘*Article 6a*

Initiation of a procedure for review and amendment of the list of restricted substances

1. Within 12 months of receipt of the request from the Commission as referred to in Article 6(2), first subparagraph, the Agency shall prepare a restriction dossier in accordance with Article 6(2), and shall propose restrictions in order to initiate the procedure for review and amendment of the list of restricted substances (the “restriction process”).

2. Where a Member State intends to prepare a restriction dossier, it shall notify the Agency at least 12 months in advance of the submission of that restriction dossier. If the restriction dossier demonstrates that action on a Union-wide basis is necessary, beyond any measures already in place, the Member State shall submit it to the Agency in order to initiate the restriction process.

3. The Agency shall, without delay, make available to the public on its website the intention of the Commission or the Member State to initiate the restriction process.

4. The Agency shall establish and maintain a list of substances for which a restriction dossier is intended or is being prepared by either the Agency or a Member State for the purposes of a proposed restriction.

5. The Agency shall consult the Committee for Risk Assessment and the Committee for Socioeconomic Analysis. The Committees shall verify whether the restriction dossier submitted meets requirements referred to in Article 6(2).

Within 30 days of receipt of the restriction dossier, the Committees shall inform the Agency or the Member State proposing restrictions whether the dossier meets the requirements referred to in Article 6(2). If the dossier does not meet those requirements, the Committees shall provide the Agency or the Member State with the reasons therefor, in writing, within 45 days of receipt of that dossier. The Agency or the Member State shall bring the dossier into conformity within 60 days of the date of receipt of the reasons from the Committees, otherwise the procedure under this Article shall be terminated.

6. Where the restriction dossier meets the requirements referred to in Article 6(2), the Agency shall make it publicly available without delay, clearly indicating the date of publication. The Agency shall invite all interested parties, including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations to submit, individually or jointly, within 4 months of the date of the publication of the dossier, the following:

(a) comments on the restriction dossier and the proposed restrictions;

(b) a socioeconomic analysis, including an analysis of possible substitutes and other alternatives, or information relevant to the examination of the advantages and disadvantages of one of the proposed restrictions.

The socioeconomic analysis referred to in the first subparagraph, point (b), shall meet the requirements set out in Annex XVI to Regulation (EC) No 1907/2006 that relate to the criteria set out in Article 6(1) of this Directive.

Article 6b

Opinion of the Agency's Committees

1. Within 12 months of the date of publication referred to in Article 6a(6), the Committee for Risk Assessment shall adopt an opinion as to whether the restriction is appropriate in reducing the detrimental effects and exposure referred to in Article 6(1). That opinion shall take account of the restriction dossier prepared by the Agency, at the request of the Commission, or by the Member State, and the comments of interested parties submitted pursuant to Article 6a(6), point (a).

2. Within 15 months of the date of publication referred to in Article 6a(6), the Committee for Socioeconomic Analysis shall adopt an opinion on the proposed restrictions, based on its consideration of the relevant parts of the dossier and the of socioeconomic impact of the proposed restrictions, taking account of any existing analysis or information submitted pursuant to Article 6a(6), point (b).

Prior to adopting its opinion, the Committee for Socioeconomic Analysis shall prepare a draft of that opinion and shall submit it to the Agency.

3. The Agency shall publish the draft opinion of the Committee for Socioeconomic Analysis on its website without delay and invite interested parties to provide their comments on the draft opinion no later than 60 days from its publication.

4. The Committee for Socioeconomic Analysis shall adopt its opinion without delay, taking into account the comments of interested parties submitted in accordance with Article 6a(6), point (a), and paragraph 3 of this Article.

5. Where the opinion of the Committee for Risk Assessment diverges significantly from the restrictions proposed, the Agency shall postpone the deadline for the opinion of the Committee for Socioeconomic Analysis by a maximum of 90 days.

6. For the purpose of adopting opinions pursuant to this Article, Article 87 of Regulation (EC) No 1907/2006 shall apply *mutatis mutandis*.

Article 6c

Submission of an opinion to the Commission

1. The Agency shall submit to the Commission, without delay, the opinions of the Committees for Risk Assessment and Socioeconomic Analysis adopted pursuant to Article 6b. Where the opinions of the Committees for Risk Assessment and Socioeconomic Analysis diverge significantly from the proposed restrictions, the Agency shall submit an explanatory note to the Commission providing a detailed explanation of the reasons for those divergences. If one or both of the Committees do not adopt an opinion by the deadlines set in Article 6b(1) and (2), the Agency shall inform the Commission accordingly, stating the reasons.

2. The Agency shall publish the opinions of the Committees for Risk Assessment and Socioeconomic Analysis on its website without delay.

3. The Agency shall, on request, provide the Commission or Member State with all documents and evidence submitted to or considered by it.';

(4) Article 20 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. The power to adopt the delegated acts referred to in Article 4(2), Article 5(1) and Article 6 shall be conferred on the Commission for a period of 5 years from 21 July 2011. The Commission shall draw up a report in respect of delegated powers at the latest 6 months before the end of the 5-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 21.';

(b) the following paragraph is inserted:

'1a. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making (*).

(*) OJ L 123, 12.5.2016, p. 1, ELI: http://data.europa.eu/eli/agree_interinstit/2016/512/oj.';

(5) In Article 24, the following paragraph is added:

'3. Taking due account of any regulatory developments concerning the status of the resources and of the governance of the scientific committees of the 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 this Directive accordingly.';

(6) In Annex V, the following paragraph is added:

'In cases referred to in the first paragraph, point (h), the applicant shall submit a non-confidential version of the application.';

(7) The text set out in the Annex to this Directive is added as Annex Va.

Article 2

Application

This Directive shall apply from 13 August 2027.

Article 3

Entry into force

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

Article 4

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 26 November 2025.

For the European Parliament	*For the Council*
The President	*The President*
R. METSOLA	M. BJERRE

ANNEX

'ANNEX Va

Dossiers for restriction proposals

The proposals to review and amend the list of restricted substances, or a group of similar substances, in Annex II shall contain at least the following information:

(1) the identity of the substance or substances;

(2) a precise and clear wording of the entry of the proposed restriction in Annex II;

(3) references and scientific evidence for such restriction;

(4) information on the use of the substance or the group of similar substances in the EEE;

(5) information on detrimental effects and exposure in particular during waste EEE management operations;

(6) information on possible substitutes and other alternatives, their availability and reliability;

(7) a justification for considering a Union-wide restriction to be the most appropriate measure;

(8) a socioeconomic assessment.'.