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From:	General Secretariat of the Council
To:	Delegations
Subject:	Proposal for a Directive of the European Parliament and of the Council amending Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency

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

ANNEX

2023/0454 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency

(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],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure,

[1] OJ C […], […], p. […].

Whereas:

(1) The Commission has, in its Communication 'European Green Deal'[2], set an objective that chemical safety assessments should move towards a process of 'one-substance, one-assessment', calling for more transparent and simpler risk assessment processes in order to reduce the burden on all stakeholders, accelerate decision-making, as well as to increase consistency and predictability of scientific decisions and opinions. The Commission, in its Communication on Chemicals Strategy for Sustainability[3] 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 legislation needs to be reattributed to the most suitable Union agencies. This would simplify the current set-up, improve quality and coherence of safety assessments across Union legislation, and ensure more efficient use of existing resources. ***This approach is also expected to promote cost-effectiveness and competitiveness by simplifying regulatory procedures and reducing administrative burdens, ensuring that businesses can adapt efficiently to evolving regulatory frameworks.***

(2) The reattribution of certain scientific and technical tasks to the European Chemicals Agency is necessary in order to align processes and levels of scientific scrutiny and digitalisation with current standards and processes of the European Chemicals Agency. This 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' ambition. ***Moreover, digitalisation and streamlined processes will reduce duplicative efforts and administrative delays, providing significant cost savings and efficiency gains for both Member States and economic operators.***

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[2] Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal (COM (2019) 640 final of 11 December 2019).

[3] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment (COM (2020) 667 final of 14 October 2020).

(2a) The amendment of Directive 2011/65/EU introduced by this Directive expands the tasks, workload and remit of scientific committees of the European Chemicals Agency (ECHA). In order to provide adequate expertise, 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 takes account of any future regulatory developments relating to the governance of the scientific committees of the European Chemicals Agency in order to revise, if necessary, Directive 2011/65/EU on the relevant points.

(3) Directive 2011/65/EU of the European Parliament and of the Council[4] contains two procedures related to the assessment of chemicals: the evaluation of economic operators' applications for granting, renewing or revoking an exemption from the substance restrictions pursuant to Article 5 of that Directive and the review of substances to be added to the list of restricted substances pursuant to Article 6 of that Directive. There is a need to increase transparency by setting detailed procedural steps for the process to review substances for a potential inclusion in the list of restricted substances.

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[4] 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.

(4) Data and information held by the European Chemicals 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[5] can be usefully deployed for the assessment of potential substance restrictions and for assessing 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.

(5) 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, as well as to make the best use of existing chemicals-related expertise, the technical evaluation to assess the justification of such exemption requests should be carried out by the European Chemicals Agency and its committees in close coordination with the Commission.

(5a) The submitted information within the confidential version of an exemption application should be subject to an assessment by the European Chemicals 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.

(5b) Most exemption requests are expected to require the expertise of the Committee for Socio-economic Analysis set up pursuant to Article 76(1), point (d) of Regulation (EC) No 1907/2006. The Members States' representatives should be consulted by the Commission when adopting guidelines on the involvement of the Committee for Risk Assessment.

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[5] 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.

(6) To ensure that the restriction process referred to Article 6 in Directive 2011/65/EU is consistent with the restriction processes under other legislation related to chemicals, in particular with the substance restriction process laid down in Articles 69 to 73 of Regulation (EC) No 1907/2006, it is necessary to amend Directive 2011/65/EU to formally task the European Chemicals Agency with a role in the restriction process. In the light of experience obtained when 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.

(6a) 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 to set a review period of at least 4 years, taking into account market developments and technical and scientific progress, and the fact that restriction dossiers can be submitted by Member States at any time and horizontal restriction measures can be initiated and adopted under Regulation (EC) No 1907/2006, Regulation (EU) 2019/1021 or other Union law concerning sustainability criteria for hazardous substances and chemicals.

▌

(6c) The European Chemicals Agency can develop guidance to the new Annex IX under Directive 2011/65/EU and, when applicable in this regard, reference can be made to the already available guidance for Annex XV to Regulation (EC) No 1907/2006 in respect of the specific aim of the Directive 2011/65/EU and the criteria given in Article 6(1).

(7) The two procedures described under Article 5 and Article 6 are applicable at the EU level. National provisions should not deviate from these Articles set in Directive 2011/65/EU.

(8) In order to ensure that this Directive is coherent with any future amendment of Regulation (EC) No 1907/2006, or of other future Union law concerning sustainability criteria for hazardous substances and chemicals, the Commission should assess whether an amendment of Articles 5 and 6 of this Directive is required. Where appropriate, the Commission should propose amendments to this Directive in a future regulation amending Regulation (EC) No 1907/2006 or in other future Union law concerning sustainably criteria for hazardous substances and chemicals.

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

(9) 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) verify that the application contains all the elements laid out in Annex V;

(c) if necessary ***and within 45 days of receipt of the application***, request the applicant to complete the application ▌ and provide an appropriate deadline ***of maximum 60 days to do so. If the volume and the complexity of the application is such that the Agency cannot comply with the 45 days period, the Agency shall inform the applicant of any extension and of the reasons for it, as soon as possible, and in any case before the end of that period. Upon duly justified request of the applicant introduced within the period provided for completing the application and where the volume and the complexity of the application is such that the 60 days period cannot be complied with, the Agency may extend that period. The Agency shall decide on such extension within 5 working days of the request***;

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

(e) make a summary of the application and a non-confidential version of the application as submitted by the applicant, as well as the date when the application is considered complete, available to the public on the Agency's website;

(f) invite interested parties to submit information within 3 months of its publication on the Agency's website.

Where the applicant does not complete the application with the missing elements identified by the Agency in compliance with Annex V within the deadline provided in accordance with the first subparagraph, point (c), the Agency ***shall*** reject such application. The Agency shall establish and communicate to the applicant without undue delay the date when the application is considered complete.

Upon receipt of an application, the Agency shall notify the Commission of the application and keep it informed of any of the procedural steps under points (b) to (f).**'**;'

(b) the following paragraph 4a is inserted after paragraph 4:

'4a. The Agency shall, after verifying the completeness of the application, request the opinion of the Committee for Socio-economic Analysis, set up pursuant to Article 76(1), point (d) of Regulation (EC) No 1907/2006. It shall request the opinion of the Committee for Risk Assessment, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006, in the case of an application for a new exemption, or where otherwise considered appropriate.

The Committee for Socio-economic Analysis and, where relevant, the Committee for Risk Assessment:

(a) shall draw up draft opinions within 9 months of the date the application has been considered complete by the Agency under paragraph 4, point (b);

(b) shall assess whether the criteria in Article 5(1), point (a), are met and shall provide clear guidance to the Commission on granting, renewing or revoking an exemption;

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

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

(e) 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 (c).

The Agency shall send the final opinion(s) of the Committees to the Commission within 12 months from the date an application has been considered complete by the Agency.

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

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

(ba) 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. The existing exemption shall remain valid until a decision on the renewal application is taken by the Commission.''

(c) paragraph 8 is replaced by the following:

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

(d) the following paragraph 9 is added:

'9. The Commission shall publish guidelines to facilitate the harmonised application of this Article.''

(2) 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. '

(3) Article 6 is amended as follows:

(a) in paragraph 1, 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 four 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.;'

(b) in paragraph 1, the fourth subparagraph is deleted.

(c) paragraph 2 is replaced by the following:

‘2. The review and amendment of the list of restricted substances***, or a group of 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.

The Agency or a Member State shall take into account any available information and any relevant ▌ assessment submitted for the purposes of other Union legislation covering ***any part of*** the life cycle of the substance used in EEE, in particular the waste phase. To this end, other bodies established under Union law and carrying out a similar task shall, on request, provide information to the Agency or Member State concerned.

The restriction dossier shall comply with the requirements set out in ***Article 6(1)***, ▌ and shall, in addition, contain the information ***contained in Annex IX.***

(4) the following Articles 6a, 6b and 6c are inserted:

‘Article 6a

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

1. Within 12 months of receipt of the request from the Commission referred to in Article 6(2), first subparagraph, the Agency shall prepare a restriction dossier conforming to the requirements referred to in Article 6(2), third subparagraph, and suggest restrictions in order to initiate the restriction process.

2. A Member State shall notify the Agency that it proposes to prepare a restriction dossier which conforms to the requirements referred to in Article 6(2), third subparagraph, within 12 months. If that 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 publish without delay the intention of the Commission or the Member State to initiate the process to review and amend the list of restricted substances in Annex II ***on the Agency's website***.

4. The Agency shall establish and maintain a list of substances for which a restriction dossier conforming to the requirements of Article 6(2) is planned or underway 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, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006, and the Committee for Socio-economic Analysis, set up pursuant to Article 76(1), point (d), of that Regulation. The Committees shall verify whether the restriction dossier submitted conforms to the requirements referred to in Article 6(2), third subparagraph.

   Within 30 days of receipt of the restriction dossier, the respective Committee shall inform the Agency or the Member State proposing restrictions whether the dossier conforms to the requirements referred to in Article 6(2), third subparagraph. If the dossier does not conform to those requirements, the reasons shall be given to the Agency or the Member State 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 dossier meets the requirements referred to in Article 6(2), third subparagraph, 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 from the date of the publication of the dossier, the following:

   (a) comments on dossiers and the suggested restrictions;

(b) a socio-economic analysis including an analysis of alternatives, or information which can contribute to one of the suggested restrictions, examining the advantages and drawbacks of the proposed restrictions.

The analysis referred to in the first subparagraph, point (b), shall conform to the requirements in Annex XVI to Regulation (EC) ***No 1907/2006 for those requirements that relate to the criteria set out in Article 6(1).***

Article 6b

Opinion of the Agency's Committees

1. Within 12 months from the date of publication referred to in Article 6a(6), the Committee for Risk Assessment shall adopt an opinion as to whether the restriction ***according to Annex IX,*** is appropriate in reducing the ***detrimental effects and exposure described in*** Article 6(1) ▌ . This 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 views of interested parties referred to in Article 6a(6), point (a).

2. Within 15 months from the date of publication referred to in Article 6a(6), the Committee for Socio-economic Analysis, shall adopt an opinion on the proposed restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. Prior to that, it shall prepare a draft opinion on the suggested restrictions and on the related socio-economic impact, taking account any existing analysis or information according to Article 6a(6), point (b).

3. The Agency shall publish the draft opinion of the Committee for Socio-economic 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 Socio-economic Analysis shall without delay adopt its opinion, taking into account where appropriate further comments received by the deadline set in paragraph 3. This opinion shall take into account the comments of interested parties submitted under 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 responsible for Socio-economic 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 Socio-economic Analysis on the restrictions suggested pursuant to Article 6b. Where the opinions of the Committees for Risk Assessment and Socio-economic Analysis diverge significantly from the restrictions suggested by the dossier, the Agency shall submit an explanatory note to the Commission providing a detailed explanation of the reasons for such differences. 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 both Committees 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.;’

(4a) 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 1a is inserted after paragraph 1:

'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.''

▌

(5) In Article 24, the following paragraph 3 is added:

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

(6) The following Annex IX is added:

'ANNEX IX

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 the restriction;

(4) information on the use of the substance or the group of similar substances in 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) justification for considering a Union-wide restriction as the most appropriate measure;

(8) socioeconomic assessment.'

Article 2

The provisions under this Directive shall be applicable from [OJ: ***20*** months after the publication of this Directive].

Article 3

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

This Directive is addressed to the Member States.

Done at Brussels,

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