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# Re-attribution of scientific and technical tasks to the European Chemicals Agency

**Amendments adopted by the European Parliament on 1 April 2025 on the 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 (COM(2023)0781 – C9-0448/2023 – 2023/0454(COD))** [1]

**(Ordinary legislative procedure: first reading)**

(C/2025/4377)

**Amendment 1**

**Proposal for a directive**

**Recital 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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. | (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] 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). | [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). |

[1] The matter was referred back for interinstitutional negotiations to the committee responsible, pursuant to Rule 60(4), fourth subparagraph (A10-0019/2025).

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| ([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). | ([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). |

**Amendment 2**

**Proposal for a directive**

**Recital 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (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. | (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.*** |

**Amendment 3**

**Proposal for a directive**

**Recital 6 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(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 36 months, 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.*** |

**Amendment 4**

**Proposal for a directive**

**Recital 8**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (8) For amending procedural provisions under Directive 2011/65/EU, a transitional period of ***12*** 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. | (8) For amending procedural provisions under Directive 2011/65/EU, a transitional period of ***18*** 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. |

**Amendment 5**

**Proposal for a directive**

**Article 1 – paragraph 1 – point 1 – point a**

Directive 2011/65/EU

Article 5 – paragraph 4 – subparagraph 2

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 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 ***may*** reject such application. The Agency shall establish and communicate to the applicant without undue delay the date when the application is considered complete. | 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. |

**Amendment 6**

**Proposal for a directive**

**Article 1 – paragraph 1 – point 1 – point b**

Directive 2011/65/EU

Article 5 – paragraph 4a – subparagraph 5

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 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. | 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***. |

**Amendment 7**

**Proposal for a directive**

**Article 1 – paragraph 1 – point 1 – point b a (new)**

Directive 2011/65/EU

Article 5 – paragraph 5

| *Present text* | *Amendment* |
|---|---|
| | ***(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 existing exemption shall remain valid until a decision on the renewal application is taken by the Commission. | '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 six 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.***'*** |

**Amendment 8**

**Proposal for a directive**

**Article 1 – paragraph 1 – point 3 – point a**

Directive 2011/65/EU

Article 6 – paragraph 1 – subparagraph 1

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 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 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.; | 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 36 months*** 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.; |

**Amendment 9**

**Proposal for a directive**

**Article 1 – paragraph 1 – point 3 – point c**

Directive 2011/65/EU

Article 6 – paragraph 2 – subparagraph 1

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| The review and amendment of the list of restricted 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 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. |

**Amendment 10**

**Proposal for a directive**

**Article 1 – paragraph 1 – point 3 – point c**

Directive 2011/65/EU

Article 6 – paragraph 2 – subparagraph 2

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| The Agency or a Member State shall take into account any available information and any relevant ***risk*** assessment submitted for the purposes of other Union legislation covering 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 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. |

**Amendment 11**

**Proposal for a directive**

**Article 1 – paragraph 1 – point 3 – point c**

Directive 2011/65/EU

Article 6 – paragraph 2 – subparagraph 3 – point -a (new)

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(-a) the identity of the substance;*** |

**Amendment 12**

**Proposal for a directive**

**Article 1 – paragraph 1 – point 3 – point c**

Directive 2011/65/EU

Article 6 – paragraph 2 – subparagraph 3 – point -a a (new)

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(-aa) a precise and clear wording for the entry of the proposed restriction in Annex II;*** |

**Amendment 13**

**Proposal for a directive**

**Article 1 – paragraph 1 – point 3 – point c**

Directive 2011/65/EU

Article 6 – paragraph 2 – subparagraph 3 – point -a b (new)

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(-ab) references and scientific evidence for the restriction;*** |

**Amendment 14**

**Proposal for a directive**

**Article 1 – paragraph 1 – point 3 – point c**

Directive 2011/65/EU

Article 6 – paragraph 2 – subparagraph 3 – point b a (new)

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(ba) information on possible alternatives, their availability and suitability;*** |

**Amendment 15**

**Proposal for a directive**

**Article 1 – paragraph 1 – point 3 – point c**

Directive 2011/65/EU

Article 6 – paragraph 2 – subparagraph 3 – point b b (new)

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(bb) justification for considering a Union-wide restriction as the most appropriate measure.*** |

**Amendment 16**

**Proposal for a directive**

**Article 1 – paragraph 1 – point 3 – point c**

Directive 2011/65/EU

Article 6 – paragraph 2 – subparagraph 3 – point b c (new)

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(bc) a socio-economic assessment.*** |

**Amendment 17**

**Proposal for a directive**

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

Directive 2011/65/EU

Article 20 – paragraph 1 a (new)

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(4a) In Article 20, the following paragraph is inserted:*** <br> ***'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.'*** |

**Amendment 18**

**Proposal for a directive**

**Article 1 – paragraph 1 – point 4 b (new)**

Directive 2011/65/EU

Article 24 – paragraph 2 a (new)

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(4b) In Article 24, the following paragraph is added:*** <br> ***'2a. The Commission shall monitor the situation regarding the resources of the European Chemicals Agency and the tasks, workload and remit of the scientific committees of the European Chemicals Agency and present, where necessary, a legislative proposal to reflect any needs of the European Chemicals Agency stemming from tasks introduced by this Regulation and to improve the governance of its scientific committees.'*** |

**Amendment 19**

**Proposal for a directive**

**Article 2 – paragraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| The provisions under this Directive shall be applicable from [OJ: ***12*** months after the publication of this Directive]. | The provisions under this Directive shall be applicable from [OJ: ***18*** months after the publication of this Directive]. |