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Committee on the Environment, Public Health and Food Safety

2023/0454(COD)

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AMENDMENTS
3 - 41

Draft report
Dimitris Tsiodras
(PE763.254v02-00)

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

Proposal for a directive
(COM(2023)0781 – C9-0448/2023 – 2023/0454(COD))

Amendment 3
Beatrice Timgren

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).
[3] Communication from the Commission to	[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).	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).

Or. en

Amendment 4
Beatrice Timgren

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, digitalization and streamlined processes will reduce duplicative efforts and administrative delays, providing significant cost savings and efficiency gains for both Member States and economic operators.***

Or. en

Amendment 5
Beatrice Timgren

Proposal for a directive
Recital 4

Text proposed by the Commission	*Amendment*
(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.	(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. ***Utilising these established structures not only enhances efficiency but also reduces compliance costs for businesses, ensuring that regulatory processes support innovation and competitiveness in Union industries.***
[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.	[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.

Or. en

Amendment 6
Beatrice Timgren

Proposal for a directive
Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5a) The information submitted as part of 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.

Or. en

Amendment 7
Beatrice Timgren

Proposal for a directive
Recital 5 b (new)

Text proposed by the Commission	*Amendment*
	(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.

Or. en

Amendment 8
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a directive
Recital 6 a (new)

Text proposed by the Commission	*Amendment*
	(6a) The list of restricted substances

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

Or. en

Amendment 9
Beatrice Timgren

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 ***24*** 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.

Or. en

Amendment 10
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a directive
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) 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.

Or. en

Amendment 11
Sander Smit

Proposal for a directive
Article 1 – paragraph 1 – point 1 – point -a (new)
Directive 2011/65/EU
Article 5 – paragraph 2

Present text	*Amendment*
	(-a) Paragraph 2 is replaced by the following:
2. Measures adopted in accordance with point (a) of paragraph 1 shall, for categories 1 to 7, 10 and 11 of Annex I, have a validity period of up to ***5*** years and, for categories 8 and 9 of Annex I, a validity period of up to ***7*** years. The validity periods are to be decided on a case-by-case basis and may be renewed.	"2. Measures adopted in accordance with point (a) of paragraph 1 shall, for categories 1 to 7, 10 and 11 of Annex I, have a validity period of up to ***6*** years and, for categories 8 and 9 of Annex I, a validity period of up to ***12*** years. The validity periods are to be decided on a case-by-case basis and may be renewed."

Or. en

(02011L0065-20240801)

Justification

The Commission's 2023 review of the RoHS Directive found the 7-year exemption period insufficient for products requiring long development, testing, and validation, such as medical devices (category 8) and monitoring instruments (category 9). It is proposed to extend exemptions for these categories to 12 years, aligning with REACH Authorization and ensuring regulatory consistency. For other categories (1-7, 10, 11), increasing exemptions from 5 to 6 years would streamline reviews, reduce burdens, and support EU goals of legislative simplification.

Amendment 12
Sander Smit

Proposal for a directive
Article 1 – paragraph 1 – point 1 – point a
Directive 2011/65/EU
Article 5 – paragraph 4 – point c

Text proposed by the Commission	*Amendment*
(c) if necessary, request the applicant to complete the application, and provide an appropriate deadline;	(c) if necessary, request the applicant to complete the application, and provide an appropriate deadline; ***and shall, whenever appropriate, set up a meeting of applicants and/or interested parties particularly if contradictory information is received during the procedural step under paragraph 4, point (f)***

Or. en

Justification

It is essential to conduct proper stakeholder consultations throughout the process, including with the affected industry, to ensure the inclusion of sector-specific expertise and technical know-how. This approach is particularly critical for making well-informed policy decisions regarding any exemption request, especially if contradictory information is received during the exemption review process.

Amendment 13
Jutta Paulus

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.

Or. en

Justification

If an applicant does not complete the application after ECHA request, ECHA should be obliged to reject the application. This implements the recent recommendation by the ombudsman to the Commission in case OI/2/2023/MIK in analogy to ECHA (recommendation adopted on 17 October 2024), see https://www.ombudsman.europa.eu/en/recommendation/en/194088

Amendment 14
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a directive
Article 1 – paragraph 1 – point 1 – point b
Directive 2011/65/EU
Article 5 – paragraph 4a – subparagraph 2 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) shall publish the draft opinions referred to in point (a) on its website without delay and invite interested parties to provide their comments on the draft opinion for a period no shorter than 60 days after its publication;

Or. en

Amendment 15
Jutta Paulus

Proposal for a directive
Article 1 – paragraph 1 – point 1 – point b
Directive 2011/65/EU
Article 5 – paragraph 4a – subparagraph 2 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) shall publish the draft opinions 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;

Or. en

Justification

REACH Article 71 foresees that SEAC is to publish the draft opinion for possible comments by interested parties. Given that exemptions under RoHS are applicable for the whole sector and not just for the applicants (contrary to authorisations under REACH), the draft opinion by RAC should also be subject to comments by interested parties. There is sufficient time for this, as the drafts are to be drawn up within nice months and the final opinions are to be sent to the Commission within 12 months.

Amendment 16
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a directive
Article 1 – paragraph 1 – point 1 – point b
Directive 2011/65/EU
Article 5 – paragraph 4a – subparagraph 3

Text proposed by the Commission	*Amendment*
Each Committee shall take into account any information submitted by third parties in accordance with the second subparagraph, point (c).	Each Committee shall take into account any information ***submitted by interested parties in accordance with the second subparagraph, point (aa), and*** submitted by third parties in accordance with the second subparagraph, point (c).

Or. en

Amendment 17

Jutta Paulus

Proposal for a directive
Article 1 – paragraph 1 – point 1 – point b
Directive 2011/65/EU
Article 5 – paragraph 4a – subparagraph 3

Text proposed by the Commission	*Amendment*
Each Committee shall take into account any information submitted ***by third parties*** in accordance with the second subparagraph, point (c).	Each Committee shall take into account any information submitted in accordance with the second subparagraph, point ***(aa) and point*** (c).

Or. en

Justification

Consequential amendment linked to the introduction of a new subparagraph aa) by the same author. Deletion of the reference to third parties as applicants may also be requested to submit additional information, which should obviously also be taken into account.

Amendment 18
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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***, together with any requests made in accordance with the second subparagraph, point (c)***.

Or. en

Amendment 19
Jutta Paulus

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***, including any requests made in accordance with the second subparagraph, point (c)*** .

Or. en

Justification

In the context of RoHS, such requests are usually made public by the consultants. This practice needs to be continued when shifting the assessment to the ECHA committees, all the more that the OSOA package intends to increase transparency about regulatory processes and not to decrease it.

Amendment 20
Sander Smit

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***. If the conditions laid down in Article 5(1), point (a), are fulfilled, the Commission shall prepare a draft amendment to Annex III or Annex IV, within three months of receipt of the opinion of the Agency***. The existing exemption shall remain valid until a decision on the renewal application is taken by the

Commission."

Or. en

(02011L0065-20240801)

Justification

The Commission's plan to shift RoHS exemption evaluations to ECHA improves process predictability but fails to address decision-making delays. Currently, no time limit exists for drafting a delegated act after ECHA's technical assessment. Decision times have risen from 12-18 months in 2006 to over 3 years in 2020, with 60+ requests pending by December 2022. This inefficiency hampers innovation and creates commercial uncertainty. The Commission should finalize and publish amendments within three months, aligning with REACH restrictions. COM(2023)760 and SWD(2023)760

Amendment 21
Jutta Paulus

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 three months of receipt of the opinions from the Agency***."

Or. en

(02011L0065)

Justification

In line with the provisions of REACH, the Commission should have a clear deadline for the adoption of its decision after reception of the opinions by the Agency. That would ensure that applicants have certainty about the Commission decision three months before the expiry date. In any case, in case the application is rejected, according to paragraph 6, the exemption shall expire at the earliest 12 months, and at the latest 18 months, after the date of the decision. Applications should no longer have suspensive effects.

Amendment 22
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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:
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***.	"An application for renewal of an exemption shall be made no later than 18 months before the exemption expires. The ***Commission*** shall ***prepare the*** decision ***within three months of receipt of the opinions from the Agency***."

Or. en

(02011L0065)

Amendment 23
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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 30 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.;

Or. en

Amendment 24
Jutta Paulus

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.

Or. en

Justification

Many of the substances listed in Annex II actually represent whole groups of substances. As such, it is adequate to also refer to groups of substances.

Amendment 25
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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 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.

Or. en

Amendment 26
Martin Hojsík

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 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.

Or. en

Justification

In line with the rest of the text that refers to group of substances.

Amendment 27
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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.

Or. en

Amendment 28
Jutta Paulus

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 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.

Or. en

Justification

Article 6 also foresees consideration of the availability of alternatives. As such, it is not appropriate to refer to "risk" assessments. Instead, all relevant assessments should be considered.

Amendment 29
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a directive
Article 1 – paragraph 1 – point 3 – point c
Directive 2011/65/EU
Article 6 – paragraph 2 – point –a (new)

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

Or. en

Amendment 30

Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a directive
Article 1 – paragraph 1 – point 3 – point c
Directive 2011/65/EU
Article 6 – paragraph 2 – point –a a (new)

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

Or. en

Amendment 31
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a directive
Article 1 – paragraph 1 – point 3 – point c
Directive 2011/65/EU
Article 6 – paragraph 2 – point –a b (new)

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

Or. en

Amendment 32
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a directive
Article 1 – paragraph 1 – point 3 – point c
Directive 2011/65/EU
Article 6 – paragraph 2 – point b a (new)

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

Or. en

Amendment 33
Martin Hojsík, Sigrid Friis

Proposal for a directive
Article 1 – paragraph 1 – point 3 – point c
Directive 2011/65/EU
Article 6 – paragraph 2 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) information on possible suitable alternatives and their availability;

Or. en

Justification

The amendment aims at facilitating information on and uptake of available alternatives.

Amendment 34
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a directive
Article 1 – paragraph 1 – point 3 – point c
Directive 2011/65/EU
Article 6 – paragraph 2 – point b b (new)

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

Or. en

Amendment 35
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a directive
Article 1 – paragraph 1 – point 3 – point c
Directive 2011/65/EU
Article 6 – paragraph 2 – point b c (new)

Text proposed by the Commission	*Amendment*
	(bc) socioeconomic assessment.

Or. en

Amendment 36
Daniel Buda

Proposal for a directive
Article 1 – paragraph 1 – point 4
Directive 2011/65/EU
Article 6a – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The Agency, working in cooperation with the Commission, shall draw up and implement an international cooperation mechanism for the exchange of information and statistics on chemical substances, with a view to increasing the transparency and safety of their use worldwide.

Or. ro

Amendment 37
Daniel Buda

Proposal for a directive
Article 1 – paragraph 1 – point 4
Directive 2011/65/EU
Article 6a – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. The Agency shall facilitate the exchange of information and access to statistics on chemical substances, including by developing links to relevant international databases, so as to ensure a comprehensive analysis of their risks and of alternatives.

Or. ro

Amendment 38
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a directive
Article 1 – paragraph 1 – point 4 a (new)
Directive 2011/65/EU
Article 20 – paragraph 1

Present text	*Amendment*
	(4a) In Article 20, paragraph 1 is replaced by the following:
1. The ***powers*** 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 ***automatically*** extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 21.	"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."

Or. en

(02011L0065)

Amendment 39
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a directive
Article 1 – paragraph 1 – point 4 b (new)
Directive 2011/65/EU
Article 20 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	(4b) In Article 20, the following paragraph 1a 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."

Or. en

Amendment 40
Martin Hojsík, Sigrid Friis

Proposal for a directive
Article 1 – paragraph 1 – point 4 a (new)
Directive 2011/65/EU
Article 24 – paragraph 2a (new)

Text proposed by the Commission	*Amendment*
	(4a) In Article 24 , the following paragraph is added:
	"(2 a). The Commission shall monitor the situation regarding the resources of the European Chemicals Agency and 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 governance of its scientific committees. "

Or. en

Amendment 41
Beatrice Timgren

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: ***24*** months after the publication of this Directive].

Or. en