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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Ad hoc Working Party on One Substance One Assessment
N° Cion doc.:	ST 16972/23
Subject:	OSOA Package: AHWP on 8 March 2024: Proposal for a Directive on the re-attribution of scientific and technical tasks to the European Chemicals Agency - Presidency's steering note - CALL FOR COMMENTS

With a view to the above Ad Hoc Working Party, delegations will find attached the Presidency's steering note together with its Annexes.

Delegations are invited to send written comments, possible text suggestions on all articles and to react on the amendments already proposed to the Presidency ([redacted]) copying the Commission ([redacted]) and the Council Secretariat [redacted] and environment@consilium.europa.eu) at the latest by **Friday 22 March 2024, at 13h00**. On the basis of which the Presidency will decide on the topics to be discussed at the next Ad Hoc Working Party meeting, scheduled for the 12th of April 2024.

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

Presidency Steering note

Ad Hoc Working Party on One Substance One Assessment (WP2) – 8 March 2024

On 7 December 2023, the Commission launched a 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. At the meeting of the Ad Hoc Working Party on One Substance One Assessment on 23 January 2024, the Commission presented its proposal. Delegations had the opportunity to ask questions and to express their initial views on the text. Afterwards, delegations were invited to send in written comments by Friday, 23 February cob.

On 08 March 2024, the Ad Hoc Working Party on One Substance One Assessment will examine the proposal in more detail. The discussion will be structured into five blocks of debate:

1. **REACH/ROHS alignment:**
   Some delegations appreciated the alignment of the ROHS directive with REACH Regulation, while others expressed some concerns related to that alignment (i.e.: restriction and exemptions being separate processes under ROHS while under REACH they are combined). It was also highlighted that Annex XV according to REACH requires an assessment of risk which may point the focus away from the essential part of the assessment required under the RoHS.
   Alignment of deadlines with REACH was suggested and lack of RAC's involvement in the renewal of the exemptions was questioned.
   Article 1(1), point (a), paragraph (4c)
   Article 1(1), point (b), regarding inclusion of article 4a (a)
   Article 1(1), point (b), regarding inclusion of article 4a
   Article 1(3), point (c)
   Article 1(4), regarding insertion of Article 6a

2. **Consultation of the Committee prior delegated act adaptation.**
   One delegation requested the Commission to consult experts designated by each MS before adoption of the delegated act in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making (***additional proposal for amendments of Art. 20*** linked with proposal for amendments of linked with proposal for amendments of ***Article 1(1), point (c), paragraph 8***
   Another delegation asked for clarification regarding application of third criterion in Art. 5(1)(a) of the ROHS Directive and expressed a need for harmonization of its application.
   The Commission will take this opportunity to insist on the legal principle of parallelism of forms regarding the delegated acts.
   Article 1(1), point (c), paragraph 8

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3. **Transposition vs. transitional period**
   Some delegations expressed their concern regarding transitional period of 12 months in case proposed amendments require transposition as the directive is addressed to Member States and imposes obligations on them.
   Feedback from the Council regarding legal advice was requested during Ad Hoc OSOA WP of 23 January 2023.
   Article 2

4. **ECHA's capacity (budget, workload, committees, expertise, …)**
   Delegations expressed their concern regarding the increase of the workload of the ECHA's scientific committees (SEAC and RAC). In their comments delegations therefore recommended the Commission to ensure sufficient resources to ECHA. Some proposed not to put too much emphasis on the ECHA Committees, but rather to re-attribute tasks to ECHA (and its already existing Expert Groups), while other comment underlined the importance to have a draft of ECHA basic regulation available as soon as possible in order to have a sound basis for decisions on certain issues related to this legislative package.
   Lack of in-house expertise for example in the evaluation of the life cycle of the substance in the refurbishment, waste and recycling stage was also highlighted.
   Article 1(1), point (b), regarding inclusion of article 4a
   Article 1(1), point (b), regarding inclusion of article 4a (a)
   Article 1(1), point (b), regarding inclusion of article 4a (d)
   Article 1(4), regarding insertion of Article 6b, point (6)
   Additional proposal concerning amendments of Article 5(5)
   Similar comments regarding ECHA's and Member State capacities, in-house expertise, workload of the Committees and budget were received on the Commission's proposal for Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals. For this reason, this point is going to be discussed with the under re-attribution of scientific and technical tasks proposal.

For each block, the Commission is invited to provide answers to the questions and issues raised in Member States' written comments (received after WP1) and to provide further clarifications on the proposed articles and discussion blocks. Thereafter, delegations will be given the opportunity to ask further questions and clarifications and to express their positions.

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Annex 1

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directive 2011/65/EU pf 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)

Version 1

XX-XX-XXX at XX:XX

Delegations will find attached a **revised** Presidency compromise proposal on the above-mentioned Proposal for a Directive.

Changes in comparison to the previous compromise proposal, document XXXX, are marked in **red bold underline** for additions and in ~~red strikethrough~~ for deletions.

	Commission Proposal	Presidency Justification	Reaction of the Commission
Proposal Title			
1	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMAENT 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)		
Formula			
2	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,		

Citation 1			
3	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,		
Citation 2			
4	Having regard to the proposal from the European Commission,		
Citation 3			
5	After transmission of the draft legislative act to the national parliaments,		
Citation 4			
6	Having regard to the opinion of the European Economic and Social Committee[1]		
Footnote 1			
7	[1] OJ C [...], [...], p. [...].		
Citation 5			
8	After consulting the Committee of the Regions,		
Citation 6			
9	Acting in accordance with the ordinary legislative procedure,		
Formula			
10	Whereas:		
Recital 1			
	(1) The Commission has, in its Communication 'European Green		

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11	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.		
Footnote 2			
12	[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).		

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Footnote 3			
13	[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).		
Recital 2			
14	(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.		
Recital 3			
15	(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		

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	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.		
Footnote 4			
16	[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.		
Recital 4			
17	(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		

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	the best use of available expertise and resources.		
Footnote 5			
18	[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.		
Recital 5			
19	(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		

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	committees in close coordination with the Commission.		
Recital 6			
20	(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.		
Recital 7			
21	(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.		
Recital 8			

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22	(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 ~~F~~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.		
Recital 9			
23	(9) Directive 2011/65/EU should therefore be amended accordingly,		
Formula			
24	HAVE ADOPTED THIS DIRECTIVE:		
Article 1			
25	*Article 1* **Amendments to Directive 2011/65/EU** Directive 2011/65/EU is amended as follows:		
Article 1(1)			
26	(1)Article 5 is amended as follows:		

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Article 1(1), point (a)			
27	(a) paragraphs 3 and 4 are replaced by the following		
Article 1(1), point (a), paragraph 3			
28	'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.		
Article 1(1), point (a), paragraph 4a			
29	4. The Agency shall: (a) acknowledge receipt of an application within 15 days of its receipt, stating the date of receipt of the application;		
Article 1(1), point (a), paragraph 4b			
30	(b) verify that the application contains all the elements laid out in Annex V;		
Article 1(1), point (a), paragraph 4c			
31	(c) if necessary, request the applicant to complete the application **within XX days of receipt of the application**, and provide an appropriate deadline **of maximum XX days**;	Change proposed based on the comments from **DE and DK**. **DE** suggested replacing the word "appropriate" with a specific deadline in order to improve legal certainty for the actors concerned. **DE** motivated that this would also ensure that current applications are published on the Agency's website in a timely manner. Additionally, **DK** motivated that the applicant should be given a deadline within which the application should be completed, since the exemption continue to apply during the process of evaluation of the application. The 45 days and 60	

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		days were proposed based on the deadlines given in REACH Article 69 (4) for restrictions proposals, as there are no similar deadlines under the authorisation scheme in REACH. (see ROHS Directive_comments_FOR WP 2 document, line 31) **BE PRES awaits discussion regarding suitable deadlines.**	
Article 1(1), point (a), paragraph 4d			
32	(d) make the application and any supplementary information supplied by the applicant available to Member States;		
Article 1(1), point (a), paragraph 4e			
33	(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;		
Article 1(1), point (a), paragraph 4f			
34	(f) invite interested parties to submit information within 3 months of its publication on the Agency's website.		
Article 1(1), point (a), paragraph 4			
35	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,		

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	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. 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).'; PUBLIC		
Article 1(1), point (b)			
36	b) the following paragraph 4a is inserted after paragraph 4:		
Article 1(1), point (b), regarding inclusion of article 4a			
37	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	**SE** suggested that it needs to be clearer when RAC shall evaluate an application for exemption. Therefore, they considered that it may be good to clarify that RAC shall evaluate applications for renewal of exemptions that have previously been evaluated by external consultants or where there are amendments in the exemption that have not been evaluated before. This would have the effect of increasing consistency between the evaluations. Alternatively, **IE** proposed in their comments to rather assign the tasks to ECHA (and its Expert Groups) than directly to RAC and SEAC. Their proposal was motivated by a concern related to the capacity of SEAC and RAC to perform the tasks under Art. 5 (lack of expertise in ROHS within the Committees, insufficient staff). In their opinion, the proposed change in the text would not preclude the Executive Director from requesting the assistance of the Committees of ECHA on a case-by-case basis. (see ROHS Directive_comments_FOR WP 2 document, line 37)	

	relevant, the Committee for Risk Assessment:	**BE PRES awaits further discussions during WP2**	
Article 1(1), point (b), regarding inclusion of article 4a (a)			
38	(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);	Change proposed based on the **DK** comment. **DK** proposed to align the deadline for RAC and SEAC for the assessment of exemptions with the authorisation scheme and assessment of authorisation under the REACH-Regulation (Article 64 (1) of the REACH Regulation). **IE** proposed to specify that the opinions drawn shall be scientific and technical. This proposal is a consequence of the IE proposal above (line 37 of this document), where it is considered that tasks should be rather assigned to ECHA (and its Expert Groups) than directly to RAC and SEAC. (see ROHS Directive_comments_FOR WP 2 document, line 38) **BE PRES did not modify the COM's proposal and awaits further discussions during WP2.**	
Article 1(1), point (b), regarding inclusion of article 4a (b)			
39	(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;		
Article 1(1), point (b), regarding inclusion of article 4a (c)			
40	(c) may request the applicant or third parties to submit, within a specified period, additional information;		
Article 1(1), point (b), regarding inclusion of article 4a (d)			
41	(d) upon adopting the draft opinions, shall communicate those draft opinions to the	**IE** proposed to specify that the opinions drawn shall be scientific and technical. This proposal is a consequence of the IE proposal above (line 37 of this document), where it is considered that tasks	

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	applicant and shall allow the applicant the opportunity to comment within 4 weeks of the communication of the draft opinions to the applicant;	should be rather assigned to ECHA (and its Expert Groups) than directly to RAC and SEAC. (see ROHS Directive_comments_FOR WP 2 document, line 41) **BE PRES did not modify the COM's proposal according to the IE comment and awaits further discussions during WP2.**	
Article 1(1), point (b), regarding inclusion of article 4a (e)			
42	(e) shall adopt their final opinions, taking into account the comments from the applicant.		
Article 1(1), point (b), regarding inclusion of article 4a			
43	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. For the purpose of adopting opinions pursuant to this paragraph, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.'	**DK** proposed to align the deadline for RAC and SEAC for the assessment of exemptions with the authorisation scheme and assessment of authorisation under the REACH-Regulation. Therefore, in their view the deadline for sending the final opinion to the Commission should be set to 14 months. This will assure that ECHA will have at least the same time period as is given under Article 64 (5) in REACH, where the Committees shall adopt their final opinion within two months after receiving the comments from the applicant and send it to the Commission within 15 days after this. Additionally, **IE** proposed to specify that the opinions drawn shall be scientific and technical. This proposal is a consequence of the IE proposal above (line 37 of this document), where it is considered that tasks should be rather assigned to ECHA (and its Expert Groups) than directly to RAC and SEAC. (see ROHS Directive_comments_FOR WP 2 document, line 43) **BE PRES did not modify** the COM's proposal according to the IE comment **and awaits further discussions during WP2.**	
Article 1(1), point (c)			

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44	(c) paragraph 8 is replaced by the following:		
Article 1(1), point (c), paragraph 8			
45	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.';	**DK** considered that a clarification is needed in relation to third criterion in Art. 5(1)(a) of the ROHS Directive: '*the total negative environmental, health and consumer protection impact as a result of the substitution is likely to be greater than the total environmental, health and consumer protection benefits thereof'*. In their view many exemptions are granted or renewed with reference to this criterion, not infrequently, where the other criterions do not apply i.e. where substitution is possible or reliable alternatives are available, in spite of the weight of substitution in RoHS as reflected in recital 8 *the most effective way of ensuring a significant reduction of risks to health and the environment relating to those substances, in order to achieve the chosen level of protection in the Union, is the substitution of those substances in EEE by safe or safer materials.* The criterion is often applied based on energy considerations. It is unclear if this was the intention of this criteria and, which weight to assign energy considerations compared to chemicals considerations within the frame of RoHS. In light of the experienced difficulty concerning collection of information from applicants as identified during the RoHS review process, priority should be given to clarifying the applicability of this criterion. Therefore, there is a need to clarify the applicability of this criteria and it is important that ECHA does so through following this re-attribution of tasks. ECHA should revise this guidance and that the guidance should be adopted by the expert committee (see proposal for reference to this committee in under article 20). (see ROHS Directive_comments_FOR WP 2 document, line 45) **BE PRES did not modify** the COM's proposal based on the **DK** comment **and awaits further discussions during WP2.**	

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Article 1(2)			
46	(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.'.		
Article 1(3)			
47	(3) Article 6 is amended as follows:		
Article 1(3), point (a)			
48	(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 **every five years** ~~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.';	Change proposed based on the **DK** comment. **DK** considered that the list of substances restricted under the ROHS directive should be evaluated on a more regular basis. Here a 5-year period is suggested. It is not paramount that it should be a 5-year period, however, a timeline is needed. Staff working document p. 119 assesses the impact for ECHA. Here it says: *As the assessments are to be done ca. every 5 years*. Therefore, a time limit of 5 years is considered appropriate. eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52023SC0850 **DK** proposed also some additional changes (introduction of subparagraph 1a) as they considered that the substances restricted in the POP-regulation, and where the use in EEE is exempted, should be considered for Annex II in the RoHS-Directive. (see ROHS Directive_comments_FOR WP 2 document, line 48) **BE PRES awaits further discussion.**	
Article 1(3), point (b)			
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	(b) in paragraph 1, the fourth subparagraph is deleted.		
Article 1(3), point (c)			
50	(c) 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. 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 restriction dossier shall comply with the requirements set out in Part II, point 3, of Annex XV to Regulation (EC) No 1907/2006 and shall, in addition, contain the following information: (a) information on the use of the substance or	Change proposed based on the **DK** comment. **DK** considered that the reference to the assessment of groups of substances should not be deleted as it is in the current COM's proposal. Additionally, **DK** considered that any relevant assessment, including assessments of waste handling, should be included in a restriction dossier, therefore DK proposed to delete "risk" from the text. Moreover, in **DK**'s view the Annex XV require an assessment of risk, which is the central part of the assessment. This will point the focus away from the essential part of the assessment required under the RoHS namely information on the use of the substance or the group of similar substances in EEE and information on detrimental effects and exposure in particular during waste EEE management operations. Consequently, **DK** suggested to exclude the requirement in relation to assessing the risk, by adding additional text ((see ROHS Directive_comments_FOR WP 2 document, line 50) **BE PRES did not modify the COM's proposal and awaits further discussions during WP2.**	

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	the group of similar substances in EEE; (b) information on detrimental effects and exposure in particular during waste EEE management operations.'		
Article 1(4)			
51	(4) the following Articles 6a, 6b and 6c are inserted:		
Article 1(4), regarding insertion of Article 6a			
52	'Article 6a **Initiation of procedure for review and amendment of the list of restricted substances**		
Article 1(4), regarding insertion of Article 6a, point (1)			
53	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.		
Article 1(4), regarding insertion of Article 6a, point (2)			
54	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,		

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	beyond any measures already in place, the Member State shall submit it to the Agency in order to initiate the restriction process.		
Article 1(4), regarding insertion of Article 6a, point (3)			
55	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**.	Change proposed based on the **DE** comment and in line with the text proposed in Art. 5 (see line 28 of this document). DE considered that it was not clear where the intention to review and amend the list of restricted substances will be published. (see ROHS Directive_comments_FOR WP 2 document, line 55)	
Article 1(4), regarding insertion of Article 6a, point (4)			
56	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.		
Article 1(4), regarding insertion of Article 6a, point (5), paragraph 1			
57	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		

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	to in Article 6(2), third subparagraph.		
Article 1(4), regarding insertion of Article 6a, point (5), paragraph 2			
58	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.		
Article 1(4), regarding insertion of Article 6a, point (6)			
59	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		

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	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:		
Article 1(4), regarding insertion of Article 6a, point (6a)			
60	(a) comments on dossiers and the suggested restrictions;		
Article 1(4), regarding insertion of Article 6a, point (6b)			
61	(b) a socio-economic analysis including an analysis of alternatives, or information which can contribute to ~~one of~~ the suggested restriction~~s~~, examining the advantages and drawbacks of the proposed restriction~~s~~.	Changes partially modified based on the **SE** comment (see ROHS Directive_comments_FOR WP 2 document, line 61)	
Article 1(4), regarding insertion of Article 6a			
62	The analysis referred to in the first subparagraph, point (b), shall conform to the requirements in Annex XVI to Regulation (EC) No 1907/2006.	**SE** suggested to delete this text, as they consider that the restriction process in ROHS may be too extensive compared to the restriction process in REACH. They were also concerned that having in mind future revision of the REACH Regulation, it is not clear how the restriction process will look like in the future. ((see ROHS Directive_comments_FOR WP 2 document, line 62) **BE PRES did not modify the proposal according to the SE comments and awaits further discussions regarding this point during WP2**.	
Article 1(4), regarding insertion of Article 6b			
63	*Article 6b* **Opinion of the Agency's Committees**		
Article 1(4), regarding insertion of Article 6b, point (1)			
	1. Within 12 months from the date of publication referred to	**DK** considered that the aim of the RoHS directive as described in article 1 of that directive is not to reduce the risk from hazardous substances in EEE,	

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64	in Article 6a(6), the Committee for Risk Assessment shall adopt an opinion as to whether the restriction is appropriate in reducing the risk to human health or the environment, specifically by reference to the risks set out in Article 6(1), third subparagraph, based on its consideration of the relevant parts of the dossier. 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).	but to "*contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE*". Therefore, DK is of the opinion that requesting the Agency's Committees to evaluate the reduction of risk would be misleading. Furthermore, they underlined that the article 6.1 does not specifically refer to "risk". Rather, it centralizes the above-mentioned objectives of article 1 at the forefront of the review process. Consequently, **DK** proposed some textual changes. (see ROHS Directive_comments_FOR WP 2 document, line 64) **BE PRES did not modify the proposal according to the DK comment and awaits further discussions regarding this point during WP2.**	
Article 1(4), regarding insertion of Article 6b, point (2)			
65	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).		
Article 1(4), regarding insertion of Article 6b, point (3)			

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66	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.		
Article 1(4), regarding insertion of Article 6b, point (4)			
67	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.		
Article 1(4), regarding insertion of Article 6b, point (5)			
68	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.		
Article 1(4), regarding insertion of Article 6b, point (6)			
69	6. For the purpose of adopting opinions pursuant to this article, Article 87 of Regulation (EC) No 1907/2006	**IE** proposed some additional suggestions to provide for legislative provisions for the remuneration of tasks by Rapporteurs within the OSOA Package.	

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	shall apply mutatis mutandis.	(see ROHS Directive_comments_FOR WP 2 document, line 69) **BE PRES did not modify the proposal**, as this is covered by mutatis mutandis application of Art. 87 of Regulation (EC) No 1907/2006 .	
Article 1(4), regarding insertion of Article 6c			
70	*Article 6c* **Submission of an opinion to the Commission**		
Article 1(4), regarding insertion of Article 6c, point (1)			
71	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.		
Article 1(4), regarding insertion of Article 6c, point (2)			
72	2. The Agency shall publish the opinions of both Committees on its website without delay.		

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Article 1(4), regarding insertion of Article 6c, point (3)			
73	3. The Agency shall, on request, provide the Commission or Member State with all documents and evidence submitted to or considered by it.’;		
Article 2			
74	The provisions under this Directive shall be applicable from [OJ: 12 months after the publication of this Directive].		
Article 3			
75	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			
76	This Directive is addressed to the Member States. Done at Brussels, *For the European Parliament For the Council* *The President The President*		
Additional recommendations (changes proposed regarding articles that were not included in the current COM’s proposal)			
Concerning amendments of Article 5(5):			
	An application for renewal of an exemption shall be made no later than 18	**DK** proposed extension of the deadline to 24 months as they are concerned that by aligning the exemptions assessment process with REACH, the Commission will be phased with the issue of	

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77	months before the exemption expires.	expediting delegated directives before the expiration of the concerned exemption. Therefore DK suggested to increase the deadline in order to leave more room for the assessment procedure. (see ROHS Directive_comments_FOR WP 2 document, line 77) **BE PRES did not modify the proposal based on the DK comment and awaits further discussions during WP2.**	
Concerning amendments of Article 20:			
78	**Exercise of the delegation** 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~~ **tacitly** extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 21.	DK suggested to update the language in paragraph 1 and to add paragraph 1a in which the consultation of an expert group with member state representation should be specified. (see ROHS Directive_comments_FOR WP 2 document, line 78) **BE PRES did not modify the proposal and awaits further discussions.**	

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Annex 2

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directive 2011/65/EU pf 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)

Version 1

XX-XX-XXX at XX:XX

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Summary:

During first consultation round comments from **ES**, **DE, DK, FR, HU, IE, NL, PT, SE, SI** were received. Some delegations highlighted the scrutiny reservation indicating that further comments can still be submitted at the later stage.

In general, all delegations welcomed the proposal of the Commission to amend the ROHS Directive. It is believed that the proposed changes will improve and refine the process of restricting new substances, granting new exemptions, and therefore increase transparency and legal certainty.

Number of delegations (**HU, DE, IE, NL**) however expressed their concern regarding the increase of the workload of the ECHA's scientific committees (SEAC and RAC). In their comments delegations therefore recommended the Commission to ensure sufficient resources to ECHA. **HU** underlined *the importance to have a draft of ECHA basic regulation available as soon as possible, to have a sound basis for decisions on certain issues related to this legislative package*, while **IE** proposed not to put too much emphasis on the ECHA Committees, but rather to re-attribute this task to ECHA (and its already existing Expert Groups). **IE** believes that the change proposed by them would not preclude the Executive Director from requesting the assistance of the ECHA Scientific Committees on a case-by-case basis. Moreover, **NL** underlined that attributing ECHA new tasks under ROHS Directive will require additional in-house expertise in the evaluation of the life cycle of the substance in the refurbishment, waste and recycling stage, which is according to the Commission staff document currently not available.

Some delegations appreciated the alignment of the ROHS directive with REACH Regulation (**SI, DE**), while others expressed some concerns related to that alignment (**SE, DK**).

PT is concerned about the confidentiality of the request of the companies regarding the substance requirements.

Additionally, in the view of **ES**, a clarity is needed on whether the proposal of the COM to amend the ROHS Directive requires transposition.

List of general questions to the COM:

SE: Would it be possible to amend the proposal so that exemptions will be adopted by delegated regulations instead of delegated directives? That would mean a harmonization within the EU when an exemption enters into force and would facilitate matters for actors concerned.

NL: Could the Commission elaborate how ECHA will be equipped to enable sufficient knowledge on assessing the impact of a restriction on refurbishment, and the waste and recycling phase?

HU: We would like to ask for the opinion of the Council Legal Service as to whether it is justified to include in the proposal specific provisions on transposition by Member States into their national law, taking into account that, for example, our relevant national legislation refers to procedures such as applications for exemption.

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Additional suggestions:

IE: We also recommend the OSOA legislation package amends **Article 85 & 87 of REACH** to provide for additional experts to cover the additional work and its associated remuneration. Some possible changes are suggested below:

Each Member State may nominate candidates to membership of the Committee for Risk Assessment and or expert working groups established by ECHA. The Executive Director shall establish a list of the nominees, which shall be published on the Agency's website, without prejudice to Article 88(1). The Management Board shall appoint the members of the Committee from this list, including at least one member but not more than three or four ~~two~~ from the nominees of each Member State that has nominated candidates. Members shall be appointed to the Committee or to an expert working group for their role and experience in performing the tasks specified in Article 77(3) (insert relevant Articles from other legislation that assigns ECHA tasks here).

Each Member State may nominate candidates to membership of the Committee for Socio-economic Analysis and or relevant expert working groups established by ECHA. The Executive Director shall establish a list of the nominees, which shall be published on the Agency's website, without prejudice to Article 88(1). The Management Board shall appoint the members of the Committee from this list, including at least one member but not more than three or four ~~two~~ from the nominees of each Member State that has nominated candidates. Members shall be appointed to the Committee or to an expert working groups for their role and experience in performing the tasks specified in Article 77(3) (insert relevant Articles from other legislation that assigns ECHA tasks here).

The Committees shall aim to have a broad range of relevant expertise among their members. To this end each Committee may co-opt a maximum of eight ~~five~~ additional members chosen on the basis of their specific competence.

Article 87

Rapporteurs of Committees and use of experts

1. Where, in accordance with Article 77 (the other relevant articles under this regulation and the Regulation of CLP that assign a role to the Committee would need to be included), a Committee is required to provide an opinion or consider whether a Member State dossier conforms with the requirements of Annex XV (CLH etc) it shall appoint one of its members or their advisor as a rapporteur. The Committee concerned may appoint a ~~second~~ additional member(s) or their advisors to act as co-rapporteur. For each case, rapporteurs and co-rapporteurs shall undertake to act in the interests of the Community and shall make a declaration of commitment to fulfil their duties and a declaration of interests in writing. A member of a Committee or their advisor(s) shall not be appointed rapporteur for a particular case if he indicates any interest that might be prejudicial to the independent consideration of that case. The Committee concerned may replace the rapporteur or co-rapporteur by another one of its members at any time, if, for example, they are unable to fulfil their duties within the prescribed time limits, or if a potentially prejudicial interest comes to light.

2. Member States shall transmit to the Agency the names of experts with proven experience in the tasks required by Article 77 (insert other relevant articles), who would be available to serve on ECHA expert groups or working groups of the Committees, together with an indication of their qualifications and specific areas of expertise.

The Agency shall keep an up-to-date list of experts. The list shall include the experts referred to in the first subparagraph and other experts identified directly by the Secretariat.

3. The provision of services by Committee members or any advisor or expert serving on an expert group or working group of the Committees or Forum, or performing any other task for the Agency shall be governed by a written contract between the Agency and the person concerned, or where appropriate between the Agency and the employer of the person concerned.

The person concerned, or his employer, shall be remunerated by the Agency in accordance with a scale of fees to be included in the financial arrangements established by the Management Board. Where the person concerned fails to fulfil his duties, the Executive Director has the right to terminate or suspend the contract or withhold remuneration.

4. The provision of services for which there are several potential providers may require a call for an expression of interest:

(a) if the scientific and technical context allows; and
(b) if it is compatible with the duties of the Agency, in particular the need to provide a high level of protection of human health and the environment.

The Management Board shall adopt the appropriate procedures on a proposal from the Executive Director.

5. The Agency may use the services of experts for the discharge of other specific tasks for which it is responsible. Experts or their employer, shall be remunerated by the Agency in accordance with a scale of fees to be included in the financial arrangements established by the ECHA Management Board. Where the person concerned fails to fulfil his duties, the Executive Director has the right to terminate or suspend the contract or withhold remuneration

Specific questions and/or textual proposals received during the first consultation round are copied in the rows corresponding to the sections of the proposal commented by the delegations.

	Commission Proposal	Questions/Comments by delegations
Proposal title		
1	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMAENT 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)	
Formula		
2	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	
Citation 1		
3	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,	
Citation 2		
4	Having regard to the proposal from the European Commission,	
Citation 3		
5	After transmission of the draft legislative act to the national parliaments,	
Citation 4		
6	Having regard to the opinion of the European Economic and Social Committee[1]	
Footnote 1		
7	[1] OJ C [...], [...], p. [...].	
Citation 5		
8	After consulting the Committee of the Regions,	

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Citation 6		
9	Acting in accordance with the ordinary legislative procedure,	
Formula		
10	Whereas:	
Recital 1		
11	(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.	
Footnote 2		
12	[2] Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee	

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	of the Regions, The European Green Deal (COM (2019) 640 final of 11 December 2019).	
Footnote 3		
13	[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).	
Recital 2		
14	(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.	
Recital 3		
15	(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	

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	setting detailed procedural steps for the process to review substances for a potential inclusion in the list of restricted substances.	
Footnote 4		
16	[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.	
Recital 4		
17	(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.	
Footnote 5		
18	[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	

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	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.	
Recital 5		
19	(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.	
Recital 6		
20	(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.	

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Recital 7		
21	(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.	
Recital 8		
22	(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 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.	
Recital 9		
23	(9) Directive 2011/65/EU should therefore be amended accordingly,	
Formula		
24	HAVE ADOPTED THIS DIRECTIVE:	
Article 1		
25	*Article 1* **Amendments to Directive 2011/65/EU** Directive 2011/65/EU is amended as follows:	

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Article 1(1)		
26	(1)Article 5 is amended as follows:	
Article 1(1), point (a)		
27	(a) paragraphs 3 and 4 are replaced by the following	
Article 1(1), point (a), paragraph 3		
28	'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.	
Article 1(1), point (a), paragraph 4a		
29	4. The Agency shall: (a) acknowledge receipt of an application within 15 days of its receipt, stating the date of receipt of the application;	
Article 1(1), point (a), paragraph 4b		
30	(b) verify that the application contains all the elements laid out in Annex V;	
Article 1(1), point (a), paragraph 4c		
31	(c) if necessary, request the applicant to complete the application, and provide an appropriate deadline;	**<u>Textual proposals:</u>** **DE** suggests replacing the word "appropriate" with a specific deadline in order to improve legal certainty for the actors concerned. This would also ensure that current applications are published on the Agency's website in a timely manner. **DK** considered that the applicant should be given a deadline within which the application should be completed, since the exemption continue to apply during the process of evaluation of the application. The 45 days and 60 days were proposed based on the deadlines given in REACH Article 69 (4) for restrictions proposals, as there are no similar deadlines under the authorisation scheme in REACH. Consequently, the following change was proposed:

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		(c) if necessary, request the applicant to complete the application **within 45 days of receipt of the application**, and provide an appropriate deadline **of maximum 60 days**;
Article 1(1), point (a), paragraph 4d		
32	(d) make the application and any supplementary information supplied by the applicant available to Member States;	
Article 1(1), point (a), paragraph 4e		
33	(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;	**Questions to the COM:** **SE** asking the COM according to what criteria should confidentiality be assessed? **DE** would like the Commission to assess if applications should be published on the Agency's website on reservation once at least the documents listed in Annex V a-e are available. Early publication of applications will lead to reduced bureaucracy and ensure transparency for manufacturers. Other manufacturers may then decide not to submit an application.
Article 1(1), point (a), paragraph 4f		
34	(f) invite interested parties to submit information within 3 months of its publication on the Agency's website.	
Article 1(1), point (a), paragraph 4		
35	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. Upon receipt of an application, the Agency shall notify the	

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	Commission of the application and keep it informed of any of the procedural steps under points (b) to (f).'; 	
Article 1(1), point (b)		
36	b) the following paragraph 4a is inserted after paragraph 4:	
Article 1(1), point (b), regarding inclusion of article 4a		
37	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 ©, 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:	**Textual proposals:** **SE:** 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 an application for a renewal of an** exemption **submitted to the Agency for the first time**, or where **there are amendments in an exemption that RAC has not evaluated** before ~~otherwise considered appropriate~~. " Justification: SE suggests that it needs to be clearer when RAC shall evaluate an application for exemption. Therefore, it may be good to clarify that RAC shall evaluate applications for renewal of exemptions that have previously been evaluated by external consultants or where there are amendments in the exemption that have not been evaluated before. This would have the effect of increasing consistency between the evaluations. **IE:** '4a. The Agency shall, after verifying the completeness of the application, prepare ~~request~~ a scientific and technical ~~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 ©, of Regulation (EC) No 1907/2006, in the case of an application for a new exemption, or where otherwise considered appropriate.~~ The Agency ~~Committee for Socio-economic Analysis and, where relevant, the Committee for Risk Assessment~~: **Questions:**

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		SE: Could the Commission explain why the opinion of the Committee for Risk Assessment is only requested for new applications or situations otherwise considered appropriate?
Article 1(1), point (b), regarding inclusion of article 4a (a)		
38	(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);	**Textual proposals:** **IE:** **(a) shall draw up draft scientific and technical opinions within 9 months of the date the application has been considered complete by the Agency under paragraph 4, point (b);** **DK:** (a) shall draw up draft opinions within **10** ~~**9**~~ months of the date the application has been considered complete by the Agency under paragraph 4, point (b); **DK:** It is our understanding that RAC are only to be involved where appropriate regarding renewal requests to save resources and that it is foreseen that RAC to only be involved in 10% of all exemption request assessments constituting on average 3 of 30 requests per year as set out in the Staff Working Document (p. 117-120). In light of the fact that renewal requests must meet the exact same criterions as requests for new exemptions, the technical development concerning products encompassed by the RoHS Directive is oftentimes very swift. The number and complexity of exemptions requests are foreseen to continue to increase in the coming years, we therefore find it necessary either for RAC to be involved in the assessment of all exemption request alongside SEAC or for the legal text to clarify when it is not necessary to involve RAC. In the latter, the foreseen 10% of cases should not not end up acting as a hindrance to involving RAC. If RAC is not to be involved in all application, it is relevant that the legal text should request the development of guidance for when to involve RAC and that this guidance is adopted by the expert group (see proposal for article 20). In order to align the deadline for RAC and SEAC for the assessment of exemptions with the authorisation scheme and assessment of authorisation under the REACH-Regulation, the deadline for the draft opinion should be set to 10 months. This corresponds to the deadlines in REACH, Article 64 (1).

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Article 1(1), point (b), regarding inclusion of article 4a (b)		
39	(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;	
Article 1(1), point (b), regarding inclusion of article 4a (c)		
40	(c) may request the applicant or third parties to submit, within a specified period, additional information;	
Article 1(1), point (b), regarding inclusion of article 4a (d)		
41	(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;	**Textual proposals:** **IE:** (d) ~~**upon adopting the draft opinions**~~, shall communicate those draft scientific and technical opinions to the applicant and shall allow the applicant the opportunity to comment within 4 weeks of the communication of the draft scientific and technical opinions to the applicant;
Article 1(1), point (b), regarding inclusion of article 4a (e)		
42	(e) shall adopt their final opinions, taking into account the comments from the applicant.	
Article 1(1), point (b), regarding inclusion of article 4a		
	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	**Textual proposals:** **IE:** ~~Each Committee~~ The Agency shall take into account any information submitted by third parties in accordance with the second subparagraph, point (c). The Agency shall send the final scientific and technical 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 scientific and technical opinions and of any attachments thereto should be made publicly available on its website and shall make those parts publicly available on its website.

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43	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. For the purpose of adopting opinions pursuant to this paragraph, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.'	~~For the purpose of adopting opinions pursuant to this paragraph, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.'~~; IE suggests the addition of a provisions to cover Executive Director Requests is also provided for. "The Agency at the Executive Directors request, may consult with or request its Committees or relevant Committee experts to provide technical and scientific support on technical and scientific issues relating to the preparation of its scientific and technical opinions (or advices could be used instead of opinion if the Commission want to distinguish between an Agency opinion by the Committee versus an opinion by its technical staff) for Member States and the institutions of the Community." "The Agency at the Executive Directors request, may establish expert working groups following a call for nominations from Member States to assist it in drafting technical and scientific support on technical and scientific issues relating to the preparation of technical advice(s)/opinions for Member States and the institutions of the Community." **DK:** The Agency shall send the final opinion(s) of the Committees to the Commission within 1~~2~~ months from the date an application has been considered complete by the Agency. **DK** considered that In order to align the deadline for RAC and SEAC for the assessment of exemptions with the authorisation scheme and assessment of authorisation under the REACH-Regulation, the deadline for sending the final opinion to the Commission should be set to 14 months. This will assure that ECHA will have at least the same time period as is given under Article 64 (5) in REACH, where the Committees shall adopt their final opinion within two months after receiving the comments from the applicant and send it to the Commission within 15 days after this.
Article 1(1), point (c)		
44	(c) paragraph 8 is replaced by the following:	
Article 1(1), point (c), paragraph 8		
	8. The Agency shall, in agreement with the Commission, provide a harmonised format for the	**Textual proposals:** **DK:**

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45	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.';	The Agency shall, in agreement with the Commission **and the committee set up according to article 20** provide a harmonised format for the applications referred to in paragraph 3 of this Article as well as comprehensive guidelines for such applications **including the criteria described under paragraph 1,** taking into account the situation of SMEs. Any submission to the Agency shall be made using the format and submission tool made available by the Agency. **DK** considered that a clarification is needed in relation to criterion no. 3 in art. 5 pieces. 1, letter a; *the total negative environmental, health and consumer protection impact as a result of the substitution is likely to be greater than the total environmental, health and consumer protection benefits thereof.* Many exemptions are granted or renewed with reference to this criterion, not infrequently, where the other criterions do not apply i.e. where substitution is possible or reliable alternatives are available, in spite of the weight of substation in RoHS as reflected in recital 8 *the most effective way of ensuring a significant reduction of risks to health and the environment relating to those substances, in order to achieve the chosen level of protection in the Union, is the substitution of those substances in EEE by safe or safer materials.* The criterion is often applied based on energy considerations. It is unclear if this was the intention of this criteria and, which weight to assign energy considerations compared to chemicals considerations within the frame of RoHS. In light of the experienced difficulty concerning collection of information from applicants as identified during the RoHS review process, priority should be given to clarifying the applicability of this criterion. Therefore, there is a need to clarify the applicability of this criteria and it is important that ECHA does so through following this re-attribution of tasks. ECHA should revise this guidance and that the guidance should be adopted by the expert committee (see proposal for reference to this committee in under article 20). **<u>Questions to the COM:</u>** DE supports a harmonised format for the applications and clear guidelines for applicants. Further, DE welcomes the introduction of online submissions tools for applications and finds this to be a good improvement. DE would ask for further clarification, how this process will exactly function in practice. Further, DE would like to ask if the harmonised application under RoHS will be streamlined with other exemption processes. This would be encouraged.

Article 1(2)		
46	(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.'.	
Article 1(3)		
47	(3) Article 6 is amended as follows:	
Article 1(3), point (a)		
48	(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 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.';	**<u>Textual proposals:</u>** **DK:** 1. 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 **every five year** ~~**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. **1a. The assessment referred to in paragraph 1 shall include relevant substances on Annex II of Regulation 2019/1021 of the European Parliament and the Council of 20 June 2019, which are exempted from EEE.** **DK** considered that the list of substances restricted under the ROHS directive should be evaluated on a more regular basis. Here a 5-year period is suggested. It is not paramount that it should be a 5-year period, however, a timeline is needed. Furthermore, substances restricted in the POP-regulation, and where the use in EEE is exempted, should be considered for Annex II in the RoHS-Directive. Staff working document p. 119 assesses the impact for ECHA. Here it says: *As the assessments are to be done ca. every 5 years*. Therefore, a time limit of 5 years is considered appropriate. eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52023SC0850 **<u>Questions to the COM:</u>**

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		SE: Could the Commission clarify when a review of the list of restrictions should be conducted? We note that new adoptions of restrictions have still not been made as a follow up the last review which started 2018.
Article 1(3), point (b)		
49	(b) in paragraph 1, the fourth subparagraph is deleted.	**<u>Questions to the COM:</u>** **DK** considers that it is unclear, why this subparagraph is suggested to be deleted, when Article 5(7) in the RoHS-directive not deleted. Could the Commission please clarify.
Article 1(3), point (c)		
50	(c) paragraph 2 is replaced by the following: '2. 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 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 restriction dossier shall comply with the requirements set out in Part II, point 3, of Annex XV to Regulation (EC) No 1907/2006 and shall, in addition, contain the following information: (a) information on the use of the substance or the group of similar substances in EEE; (b) information on detrimental effects and exposure in particular during waste EEE management operations.'	**<u>Textual proposals:</u>** **<u>DK:</u>** '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'. **DK** considered that the reference to the assessment of groups of substances should not be deleted. '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.' **DK** considered that any relevant assessment should be included, including assessments of waste handling, therefore "risk" should be deleted from the text. 'The restriction dossier shall~~ comply with the requirements set out in Part II, point 3, of Annex XV to Regulation (EC) No 1907/2006 and shall, in addition,~~ contain the following information: (a) information on the use of the substance or the group of similar substances in EEE; (b) information on detrimental effects and exposure in particular during waste EEE management operations.' The restriction dossier shall comply with the requirements set out in Part II, point 3, of Annex XV to Regulation (EC) No 1907/2006 **with respect to the proposal, information on hazard, information on alternatives, justification for**

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		restriction at community level, socioeconomic assessment and information on stakeholder consultation.' **DK:** Annex XV require an assessment of risk, which is the central part of the assessment. This will point the focus away from the essential part of the assessment required under the RoHS namely information on the use of the substance or the group of similar substances in EEE and information on detrimental effects and exposure in particular during waste EEE management operations. We therefore suggest to exclude the requirement in relation to assessing the risk. **<u>Questions to the COM:</u>** **SE:** We wonder how ECHA and Member States will know when they have collected all relevant and available information? **SE:** We wonder whether the reference to Annex XV in REACH could be interpreted as a substantial amendment and not just a procedural amendment considering that restrictions and exemptions in RoHS are separate processes while they are combined in REACH? Have you considered including, in a restriction proposal, when a substance restriction shall begin to apply for the different categories in RoHS?
Article 1(4)		
51	(4) the following Articles 6a, 6b and 6c are inserted:	
Article 1(4), regarding insertion of Article 6a		
52	'Article 6a **Initiation of procedure for review and amendment of the list of restricted substances**	
Article 1(4), regarding insertion of Article 6a, point (1)		
53	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.	
Article 1(4), regarding insertion of Article 6a, point (2)		

54	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.	
Article 1(4), regarding insertion of Article 6a, point (3)		
55	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.	**Textual proposals:** **DE:** The provisions are not clear where the intention to review and amend the list of restricted substances will be published. Whereas in Art. 5 it is clearly stated that the applications will be published on the Agency's website, the provisions only refer to 'publish'. DE would like to suggest to clarify the wording in this Article.
Article 1(4), regarding insertion of Article 6a, point (4)		
56	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.	**Questions to the COM:** **SE:** Does this article refer to a workplan of a review of restricted substances? Where is it supposed to be published? When are new substance restrictions supposed to be added to the list, for example in relation to the publication according to Article 6a(3)?
Article 1(4), regarding insertion of Article 6a, point (5), paragraph 1		
57	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	

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	Article 6(2), third subparagraph.	
Article 1(4), regarding insertion of Article 6a, point (5), paragraph 2		
58	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.	
Article 1(4), regarding insertion of Article 6a, point (6)		
59	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:	
Article 1(4), regarding insertion of Article 6a, point (6a)		
60	(a) comments on dossiers and the suggested restrictions;	

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Article 1(4), regarding insertion of Article 6a, point (6b)		
61	(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.	**Textual proposals**: **SE:** ~~"a~~ socio-economic **information** ~~analysis~~ including ~~an analysis of~~ **information on** alternatives, or information which can contribute to ~~one of~~ the suggested **restriction** ~~restrictions~~, examining the advantages and drawbacks of the proposed **restriction** ~~restrictions~~.
Article 1(4), regarding insertion of Article 6a		
62	The analysis referred to in the first subparagraph, point (b), shall conform to the requirements in Annex XVI to Regulation (EC) No 1907/2006.	**Textual proposals:** **SE:** ~~The analysis referred to in the first subparagraph, point (b), shall conform to the requirements in Annex XVI to Regulation (EC) No 1907/2006."~~ **SE** considers that the restriction process in ROHS may be too extensive compared to the restriction process in REACH, and with the delay of the REACH revision it is unclear how the restriction process in REACH will look like in the future.
Article 1(4), regarding insertion of Article 6b		
63	*Article 6b* **Opinion of the Agency's Committees**	
Article 1(4), regarding insertion of Article 6b, point (1)		
64	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 is appropriate in reducing the risk to human health or the environment, specifically by reference to the risks set out in Article 6(1), third subparagraph, based on its consideration of the relevant parts of the dossier. 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).	**Textual proposals:** **DK**: 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 is appropriate in ~~reducing~~ the **protection** ~~risk to~~ of human health or the environment, specifically by reference to the **concerns** ~~risks~~ set out in Article 6(1), third subparagraph, based on its consideration of the relevant parts of the dossier. 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). **DK** justified that the aim of the RoHS directive as described in article 1 of that directive is not to reduce the risk from hazardous substances in EEE, but to "*contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE*". Requesting the Agency's Committees to evaluate the reduction of risk would therefore be misleading. Furthermore, article 6.1 does not specifically refer to "risk". Rather, it

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		centralizes the above mentioned objectives of article 1 at the forefront of the review process.
Article 1(4), regarding insertion of Article 6b, point (2)		
65	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).	
Article 1(4), regarding insertion of Article 6b, point (3)		
66	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.	**Questions to the COM:** **SE:** What is the second consultation supposed to deal with in this part of the process when there is a separate exemption process in it? Could this information be handled in the first consultation according to Article 6a(6) of the proposal?
Article 1(4), regarding insertion of Article 6b, point (4)		
67	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.	
Article 1(4), regarding insertion of Article 6b, point (5)		
68	5. Where the opinion of the Committee for Risk Assessment diverges significantly from the restrictions proposed, the	

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	Agency shall postpone the deadline for the opinion of the Committee responsible for Socio-economic Analysis by a maximum of 90 days.	
Article 1(4), regarding insertion of Article 6b, point (6)		
69	6. For the purpose of adopting opinions pursuant to this article, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.	**Textual proposals:** **IE:** Additional suggestions to provide for legislative provisions for the remuneration of tasks by Rapporteurs within the OSOA Package. *Where, in accordance with Article 6b, a Committee is required to provide an opinion or consider whether a Member State dossier conforms with the requirements insert relevant article/Annex, it shall appoint one of its members as a rapporteur.* *The Committee concerned may appoint additional member(s) or their advisor(s) to act as co-rapporteur(s). For each case, rapporteurs and co-rapporteurs shall undertake to act in the interests of the Community and shall make a declaration of commitment to fulfil their duties and a declaration of interests in writing.* *A member of a Committee shall not be appointed rapporteur for a particular case if he indicates any interest that might be prejudicial to the independent consideration of that case. The Committee concerned may replace the rapporteur or co-rapporteur by another one of its members at any time, if, for example, they are unable to fulfil their duties within the prescribed time limits, or if a potentially prejudicial interest comes to light.* *Member States shall transmit to the Agency the names of experts with proven experience in the tasks required by Article 6b who would be available to serve on working groups of the Committees, together with an indication of their qualifications and specific areas of expertise.* *The Agency shall keep an up-to-date list of experts. The list shall include the experts referred to in the first subparagraph and other experts identified directly by the Secretariat.* *The provision of services by Committee members as rapporteurs/co rapporteurs or any expert serving on a working group established by ECHA, its Committees or Forum, or performing any other task for the Agency shall be governed by a written contract between the Agency and the person concerned, or where appropriate between the Agency and the employer of the person concerned.* *The person concerned, or his employer, shall be remunerated by the Agency in accordance with a scale of fees to be included in the financial arrangements established by the Management Board. Where the person concerned fails to fulfil his duties, the*

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		Executive Director has the right to terminate or suspend the contract or withhold remuneration.
Article 1(4), regarding insertion of Article 6c		
70	*Article 6c* **Submission of an opinion to the Commission**	
Article 1(4), regarding insertion of Article 6c, point (1)		
71	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.	
Article 1(4), regarding insertion of Article 6c, point (2)		
72	2. The Agency shall publish the opinions of both Committees on its website without delay.	
Article 1(4), regarding insertion of Article 6c, point (3)		
73	3. The Agency shall, on request, provide the Commission or Member State with all documents and evidence submitted to or considered by it.’;	
Article 2		
74	The provisions under this Directive shall be applicable	**<u>Questions to the COM:</u>**

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	from [OJ: 12 months after the publication of this Directive].	**DE** would like to understand better how long it will take to build up the necessary resources and expert knowledge at ECHA, as the planned transitional period of 12 months seems very ambitious. In view of the increasing complexity and volume of applications for exemptions under Art. 5 of Directive 2011/65/EU, DE has further concerns if the Committee for Socio-economic Analysis and, where relevant, the Committee for Risk Assessment, can manage the increase in work load. Well-functioning and staffed Committees will be central to ensure a real increase in efficiency with regard to the processing of requests for exemptions and substance restrictions. Otherwise, it is doubtful whether all the objectives of the OSOA initiative can be achieved. **ES**: Regarding the implementation of procedures for the European Chemicals Agency (ECHA) to analyse extension requests and possible modifications to Annex II of the RoHS Directive, which details prohibited substances and allowable limits, the proposed structure for these procedures is considered appropriate and more transparent than the previous one. However, a procedural question arises. Article 5 of the RoHS Directive addresses how operators can request exemptions. All these aspects are already transposed in our National Regulation, in Royal Decree 219/2013, of March 22, on restrictions on the use of certain hazardous substances in electrical and electronic equipment. However, the proposed amendment to the Directive, in its Article 2, does not use the same formulation as other Directives to indicate to Member States (MS) that they must transpose it. It is necessary to set whether this proposal requires transposition since the directive is addressed to MS and imposes obligations on them. If so, should Article 1 of the proposal be modified to include that the MS will adopt and publish legal, regulatory, and administrative measures, as well as the transposition deadline?
Article 3		
75	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		
76	This Directive is addressed to the Member States. Done at Brussels, *For the European Parliament* *For the Council* *The President The President*	

Additional recommendations (changes proposed regarding articles that were not included in the current COM's proposal)		
Concerning amendments of Article 5(5)		
77		**<u>Textual proposals:</u>** **DK** considered also that the articles 5(5) and 20 should be amended: *Article 5(5)* An application for renewal of an exemption shall be made no later than ~~18~~ **24** months before the exemption expires **DK** justified that when aligning the exemptions assessment process with REACH, the Commission will be phased with the issue of expediting delegated directives before the expiration of the concerned exemption. In order to alleviate this issue we suggest to leave more room for the assessment procedure.
Concerning amendments of Article 20		
		Article 20 **Exercise of the delegation** **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

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78		powers at the latest 6 months before the end of the 5-year period. The delegation of power shall be ~~automatically~~ **tacitly** extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 21. **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.** 2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council. 3. The powers to adopt delegated acts are conferred on the Commission subject to the conditions laid down in Articles 21 and 22 **DK:** Proposed changes related to an update of the language. Concerning exercising the power of delegated act, the consultation of an expert group with member state representation should be specified

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