

Helsinki, 12 March 2020

Agreed at RAC-52 and SEAC-46

WORKING PROCEDURE FOR RAC AND SEAC ON DEVELOPING OPINIONS ON ANNEX XV RESTRICTION DOSSIERS

1. INTRODUCTION AND LEGAL BASIS

The purpose of this document is to outline the procedure for developing opinions on Annex XV restriction dossiers submitted under the framework of Title VIII of the REACH Regulation. It describes the main roles and tasks of the Secretariat, (co-)rapporteurs and members of RAC and SEAC and gives the timelines for different tasks.

According to Article 70 of the REACH Regulation, within 9 months from the start of consultation on an Annex XV restriction proposal, RAC shall formulate an opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment, based on its considerations of the relevant parts of the dossier and taking into account the views of interested parties received within the 6 month consultation.

According to Article 71 of the REACH Regulation, within 12 months from the start of consultation, SEAC shall formulate an opinion on the suggested restrictions, based on its considerations of the relevant parts of the dossier and the socio-economic impact and taking into account the views of interested parties received within the 6 month consultation. SEAC shall first prepare a draft opinion, which the Agency shall publish on its website for 60 days consultation. SEAC shall then adopt its opinion, taking into account where appropriate further comments received within the 60 days consultation.

This working procedure replaces the previous working procedure for RAC and SEAC on developing opinions on Annex XV restriction dossiers agreed at RAC-48 and SEAC-42.

2. PROCEDURE FOR OPINION DEVELOPMENT

The table below outlines the main steps of the opinion development from starting the consultation until the adoption of the RAC/SEAC opinion.

	STEP	Timeline¹	Deliverables and milestones
1	RAC and SEAC are informed about the start of the consultation on an Annex XV restriction proposal.	Day 1	Information
2	The first dialogue ² between the RAC and SEAC (co-)rapporteurs is convened for the first exchange of	Weeks 2-4	First dialogue

¹ Starting from the date of publication of an Annex XV restriction proposal for consultation.

² Dialogue could take the form of a tele-, videoconference or face-to-face meeting as decided by the (co-)rapporteurs on a case-by-case basis. The first and the second dialogues are normally face-to-face as this promotes better discussion between the parties.

	views on the proposed restriction ³ . The dossier submitter ⁴ , the Forum rapporteur and any other relevant participants to be invited on request of the (co-)rapporteurs.		
3	The (co-)rapporteurs provide to the Secretariat the first draft opinion , taking into account the discussion on key issues held within the conformity check and initial comments by other members. The Secretariat makes the draft opinions available to RAC and SEAC.	Week 6	First draft opinion
4	Newsgroups are initiated allowing RAC/SEAC members to submit comments on the first draft opinion (open for 7 weeks, with plenary discussion in between). In parallel, the draft opinions are provided to the Commission for comments as well as to the dossier submitter for possible observations.	Weeks 8-14	Comments
5	Comments received within the consultation are made available to RAC and SEAC.	Week 10	Compiled comments from consultation
6	The Forum advice on the Annex XV restriction proposal is made available to RAC and SEAC ⁵ .	Week 12	Forum advice
7	The first plenary discussion takes place, where the (co-)rapporteurs present the first draft opinion and the Committee members are expected to provide feedback sufficient to enable the (co-)rapporteurs to formulate a next version of the draft opinion. At the plenary, the (co-)rapporteurs are also expected to respond to members` comments submitted within the written commenting round.	Weeks 11-12 (RAC)/ 12-13 (SEAC)	First plenary discussion
8	The second dialogue is convened between the RAC and SEAC (co-)rapporteurs for discussion of issues related to further work on the opinion as well as on the background document. The dossier submitter, the Forum rapporteur or any other relevant participants to be invited on request of the (co-)rapporteurs.	Weeks 15-17	Second dialogue

³ Consider the need for establishing a rapporteurs` discussion group consisting of other Committee members.

⁴ Dossier submitter is either a submitting MS (or MSs) or/and ECHA (when ECHA is requested to prepare an Annex XV dossier by the Commission). The dossier submitter is always invited to the first and second dialogues.

⁵ Further support by the Forum is provided through possible participation of Forum rapporteur in the dialogues and responding to questions of RAC, SEAC and/or their rapporteurs.

9	The (co-)rapporteurs provide to the Secretariat the second draft opinions . The Secretariat makes the documents available to RAC and SEAC.	Week 19	Second draft opinion
10	The restriction support group, consisting of the Secretariat, the (co-)rapporteurs and the dossier submitter, prepares the background document (BD) in line with the second draft opinions. The Secretariat makes the document available to RAC and SEAC.	Week 19	BD in line with the second draft opinions
11	Newsgroups are initiated allowing RAC/SEAC members to submit comments on the second draft opinion (within 2 weeks). In parallel, the draft opinions are provided to the Commission for comments as well as to the dossier submitter for possible observations.	Weeks 21-22	Comments
12	Comments received within the consultation are made available to RAC and SEAC.	Week 23	Compiled comments from consultation
13	The second plenary discussion takes place, where the second draft opinion is discussed, with the aim of reaching agreement on all the main components of the restriction and enabling the (co-)rapporteurs to develop a final version of the opinion or identify where remaining work is needed. At the plenary, the (co-)rapporteurs are also expected to respond to members` comments submitted within the written commenting round.	Weeks 24-25(RAC)/ 25-26 (SEAC)	Second plenary discussion
	End of consultation	End of month 6	
14	Comments received within the consultation are made available to RAC and SEAC.	Week 27	Compiled comments from consultation
15	The dossier submitter provides responses to comments received within the consultation. The RCOM ⁶ prepared by the dossier submitter is made available to RAC and SEAC.	Week 30	RCOM
16	The third dialogue is convened between the RAC and SEAC (co-)rapporteurs with the aim for RAC of resolving any remaining issues related to the preparation of the third draft opinion to a standard ready for the adoption of the text by the Committees. The dossier submitter, the Forum rapporteur or any other relevant participants to be	Week 31	Third dialogue

⁶ Response to comments table.

	invited on request of the (co-)rapporteurs.		
17	The (co-)rapporteurs provide to the Secretariat the third draft opinion and reviewed RCOM. The Secretariat makes the documents available to RAC and SEAC.	Week 32	Third draft opinion, reviewed RCOM
18	The restriction support group, consisting of the Secretariat, the (co-)rapporteurs and the dossier submitter, prepares the background document (BD) in line with the third draft opinions. The Secretariat makes the document available to RAC and SEAC.	Week 32	BD in line with the third draft opinions
19	Newsgroups are initiated allowing RAC/SEAC members to submit comments on the third draft opinion (within 2 weeks). In parallel, the opinions are provided to the Commission for comments as well as to the dossier submitter for possible observations.	Weeks 33-34	Comments
20	The third plenary discussion takes place, where the third draft opinion is discussed and the text of the RAC opinion adopted/SEAC draft opinion agreed. At the plenary, the (co-)rapporteurs are also expected to respond to comments submitted within the written commenting round. Parties should avoid any reopening of already agreed issues or discussion of any extraneous procedural matters at this point. The opinion may be adopted either by consensus or by simple majority. In the latter case the minority positions are recorded and published with the opinion.	Weeks 37-38 (RAC)/38-39 (SEAC)	Third plenary discussion
21	The agreed SEAC draft opinion is published on the ECHA website for consultation. The adopted RAC opinion is published on the ECHA website.	Weeks 39-40	SEAC draft opinion RAC opinion
	End of the procedure for RAC	End of month 9	
	Start of consultation on the SEAC draft opinion	Beginning of month 10	
22	SEAC is informed about the start of the consultation on the SEAC draft opinion.	Week 40	Information
23	Comments received within the consultation are made available to SEAC.	Week 49	Compiled comments from consultation
24	The SEAC (co-)rapporteurs provide to the	Week 50	Draft of the

	Secretariat the draft of the final SEAC opinion and response to comments received within the consultation (ORCOM ⁷). The Secretariat makes the documents available to SEAC.		final SEAC opinion, ORCOM
25	The restriction support group, consisting of the Secretariat, the SEAC (co-)rapporteurs and the dossier submitter, revises the background document (BD) in line with the draft of the final SEAC opinion. The Secretariat makes the document available to SEAC.	Week 50	BD in line with the draft of the final SEAC opinion
26	The fourth plenary discussion takes place, where the draft of the final SEAC opinion is discussed and the SEAC opinion adopted. The opinion may be adopted either by consensus or by simple majority. In the latter case the minority positions are recorded and published with the opinion.	Weeks 51-52	Fourth plenary discussion
27	The RAC and SEAC opinions are compiled and published on the ECHA website. The RAC and SEAC opinions and the BD are forwarded to the Commission.		RAC and SEAC final opinions, final BD
	End of the procedure for SEAC	End of month 12	

In some cases, described in the "Framework of RAC and SEAC in checking conformity and developing opinions on restriction proposals", a deviation from the procedure described above could be applied for the sake of efficiency and in order to avoid unnecessary work. This flexible procedure will be proposed to the Committee on the advice of the Chairman and the (co-)rapporteurs and will mean that some of the steps and/or plenary discussions foreseen by this working procedure could be skipped⁸ (more details are provided in the above-mentioned framework). In addition, a fast track procedure could be used for adoption/agreement of opinions or parts of opinions, for which a separate working procedure will be developed for RAC and SEAC.

In exceptional cases, where the SEAC rapporteurs propose conditions in their opinion that have not been discussed in the context of the RAC opinion, the SEAC (co-) rapporteurs may consult the RAC rapporteurs on such changes, on the joint agreement of the Chairmen of the Committees. If appropriate, the RAC Chairman may also agree that the RAC (co-)rapporteurs present this information to the Committee for comment.

Final RAC and SEAC opinions (including any minority position(s)) and BD will be forwarded to the Commission at the end of month 12 to support the further decision-making process. Further supporting documentation (RCOMs, ORCOMs, minutes of the RAC and SEAC meetings and written procedure report(s), if any) can be forwarded to the Commission on request.

⁷ Response to comments table on comments received within the consultation on the SEAC draft opinion.

⁸ Such decisions will be recorded in the minutes of the relevant meeting.

According to Article 71(3) of the REACH Regulation, ECHA may postpone the deadline for the SEAC opinion by a maximum of 90 days in cases where the RAC opinion diverges significantly from the restriction suggested in the original Annex XV dossier. The way the prolongation will affect the deadlines of different steps in the procedure will be decided on a case-by-case basis, depending on the point of time in the process the decision on the prolongation is made as well as on the content of the RAC opinion and the work SEAC will have to do consequently. In each particular case, after ECHA has made a prolongation decision, the SEAC (co-)rapporteurs together with the SEAC Chairman will draw a new timeline taking into account the period by which the deadline for the adoption of the SEAC opinion was extended (up to 90 days). Development of the SEAC opinion will then take place according to this new timeline.

If RAC/SEAC fails to formulate an opinion within the deadline set, the reasons would be documented in the minutes of the respective plenary meeting.