

## REVISED 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 a 60 day consultation. SEAC shall then adopt its opinion, taking into account where appropriate further comments received within the 60 day consultation.

This working procedure replaces the previous working procedure for RAC and SEAC on developing opinions on Annex XV restriction dossiers agreed at RAC-62 and SEAC-56.

### 2. PROCEDURE FOR OPINION DEVELOPMENT

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

	<b>STEP</b>	<b>Timeline<sup>1</sup></b>	<b>Deliverables and milestones</b>
1	RAC and SEAC are informed about the start of the third-party consultation on an Annex XV restriction proposal.	Day 1	Information
	<b>FIRST OPINION MAKING CYCLE</b>		
2	RAC and SEAC rapporteurs are requested to provide the <b>first draft opinion</b> .  The Secretariat provides the opinion format template to the RAC and SEAC (co-)rapporteurs.	Day 1  By week 1	Information  Opinion format template
3	The first restriction opinion making cycle	By week 4	First restriction

\* Numbering of the timelines updated in November 2023 to reflect on the new timing of the RAC REST WGs.

<sup>1</sup> Starting from the date of publication of an Annex XV restriction proposal for consultation.

	<p>meeting with the Secretariat, RAC and SEAC (co-)rapporteurs is convened<sup>2</sup>. The Dossier Submitter (DS)<sup>3</sup>, the Forum rapporteur and any other relevant participants will be invited to relevant parts of the meeting.</p> <p>A mid-cycle review may be organised after RAC draft opinion is available, where relevant.</p>		opinion making cycle meeting
4	The (co-)rapporteurs develop the first draft opinion, taking into account the discussion on key issues held at the conformity check and, the initial comments by members and make it available to the Secretariat for their review.	By week 6	Draft version of the first draft opinion
5	During this cycle, the DS may revise the submitted Annex XV report to address the RAC and SEAC recommendations (if needed).	By week 10	Draft BD1 by DS
6	<p>RAC and SEAC (co-)rapporteurs address the suggestions provided by the Secretariat and update the first draft opinions (if relevant).</p> <p>The Secretariat makes the draft opinions available to RAC and SEAC for consultation.</p>	<p>By week 10</p> <p>By week 10</p>	<p>First draft opinion</p> <p>Launch of the RAC/SEAC consultation</p>
7	<p>RAC/SEAC members are expected to comment on the first draft opinion during the consultations (usually open for two weeks).</p> <p>In parallel, the draft opinions are provided to the Commission for comments as well as to the Dossier Submitter for possible observations.</p>	By week 12	Comments
8	Comments by RAC and SEAC members received within the consultation are made available to RAC and SEAC.	By week 12	Compiled comments from RAC/SEAC consultation
9	<b>The first discussions<sup>4</sup></b> take place, where the (co-)rapporteurs present the first draft opinion and RAC and SEAC members are expected to provide feedback sufficient to enable the (co-)rapporteurs to formulate a next version of the draft opinion. At this stage, the (co-)rapporteurs are also expected to respond to	Weeks 12-13 (RAC WG/RAC)/ 12-13 (SEAC)	First discussion

<sup>2</sup> On a case-by-case basis (at the request of the RAC or SEAC chair), additional committee members may be nominated to be part of a support group to assist the Rapporteurs and may attend cycle planning meetings.

<sup>3</sup> 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, second and third cycle planning meetings.

<sup>4</sup> Discussion can either take place in RAC working group or in RAC/SEAC plenary.

	members' comments submitted within the written commenting round either in writing or addressing comments in the presentations. Detailed discussions in RAC should take place primarily in the restrictions working group, with recommendations to the plenary. Topics for agreement at the plenary are determined on a case-by-case basis informed by the recommendations of the working group and/or by the Chair.		
	<b>SECOND OPINION MAKING CYCLE</b>		
10	RAC and SEAC rapporteurs are requested to provide the <b>second draft opinion</b> .	Week 13	Information
11	The Forum advice on the Annex XV restriction proposal should preferably be made available to RAC and SEAC at this point of time <sup>5</sup> .	By week 14	Forum advice
12	The second restriction opinion making cycle meeting with the Secretariat, RAC and SEAC (co-)rapporteurs is convened. The Dossier Submitter, the Forum rapporteur or any other relevant participants will be invited to relevant parts of the meeting.  Mid-cycle review may be organised after RAC draft opinion is available.	By week 17	Second restriction opinion making cycle meeting
13	The (co-)rapporteurs develop the second draft opinion, taking into account the RAC WG/RAC/SEAC discussions, the comments from the RAC and SEAC members and the update of the Background Document by the Dossier Submitter (BD1), and make the documents available to the Secretariat for their review.	By week 19	Draft version of the second draft opinion
14	RAC and SEAC (co-)rapporteurs address the suggestions provided by the Secretariat and update the second draft opinions (if relevant).  The Secretariat makes the draft opinions available to RAC and SEAC for consultation	By week 23	Second draft opinion  Launch of the RAC/SEAC consultation
15	RAC/SEAC members are expected to comment on the second draft opinion (usually within 2 weeks).  In parallel, the draft opinions are provided to the Commission for comments as well as to	By week 25	Comments

<sup>5</sup> 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.

	the dossier submitter for possible observations.		
16	Comments received within the RAC/SEAC consultation are made available to RAC and SEAC.	By week 25	Compiled comments from RAC /SEAC consultation
17	<b>The second discussion</b> takes place, where the second draft opinion is discussed, with the aim of reaching agreement on elements included in the plenary plan and enabling the (co-)rapporteurs to develop a final version of the opinion or identify where remaining work is needed. At this stage, the (co-)rapporteurs are also expected to respond to members` comments submitted within the written commenting round either in writing or addressing comments in the presentations. Detailed discussions in RAC should take place primarily in the restrictions working group, with recommendations to the plenary. Topics for agreement at the plenary are determined on a case-by-case basis informed by the recommendations of the working group and/or by the Chair.	Weeks 25-26(RAC WG/RAC)/ 25-26 (SEAC)	Second discussion
	<b>THIRD OPINION MAKING CYCLE</b>		
18	RAC and SEAC rapporteurs are requested to provide the <b>third draft opinion</b> .	Week 26	Information
	<b>End of the consultation of interested parties on the Annex XV report</b>	<b>End of month 6</b>	
19	Comments received within the third party consultation are made available to RAC and SEAC.	By week 27	Compiled comments from consultation
20	The Dossier Submitter provides responses to comments received in the consultation on the Annex XV report. The RCOM <sup>6</sup> can be seen as main basis for (co-)rapporteurs to update the draft opinions.  In this cycle, the Dossier Submitter may revise the draft Background Document (BD) based on the comments received from the consultation, if applicable.	By week 30  By week 32	RCOM  Draft BD2 by DS
21	The third restriction opinion making cycle meeting is convened between the RAC and SEAC (co-)rapporteurs. The Dossier Submitter, the Forum rapporteur or any other relevant	By week 32	Third restriction opinion making cycle meeting

<sup>6</sup> Response to comments table.

	<p>participants will be invited to relevant parts of the meeting.</p> <p>Mid-cycle review might be organised after RAC draft opinion is available.</p>		
22	<p>The (co-)rapporteurs develop the <b>third draft opinion</b>, taking into account the RAC WG/RAC/SEAC discussions, the comments from the RAC and SEAC members and the RCOM by the Dossier Submitter and make the documents available to the Secretariat for their review.</p> <p>The (co-)rapporteurs provide to the Secretariat the reviewed RCOM including their response to the comments from the consultation.</p> <p>RAC and SEAC (co-) rapporteurs may optionally annotate the BD with boxes highlighting key parts of the evaluation.</p>	By week 34	<p>Draft version of the third draft opinion</p> <p>Draft version of the reviewed RCOM.</p> <p>Draft version of the draft final BD</p>
23	<p>RAC and SEAC (co-)rapporteurs address the suggestions provided by the Secretariat and update the third draft opinions, reviewed RCOM and draft BD (if relevant).</p> <p>The Secretariat makes the draft opinions for consultation, the reviewed RCOM and the draft BD available to RAC and SEAC.</p>	By week 34	Third draft opinion, reviewed RCOM, draft final BD
24	<p>RAC/SEAC members are expected to comment on the third draft opinion (usually within 2 weeks).</p> <p>In parallel, the opinions are provided to the Commission for comments as well as to the Dossier Submitter for possible observations.</p>	By week 36	Comments
25	<p><b>The third discussion</b> 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 either in writing or addressing comments in the presentations. Detailed discussions in RAC should take place primarily in the restrictions working group, with recommendations to the plenary. Topics for agreement at the plenary are determined on a case-by-case basis informed by the recommendations of the working group and/or by the Chair.</p>	Weeks 38-39 (RAC WG/RAC)/38-39 (SEAC)	Third discussion

	<p>In this cycle the draft RAC and the SEAC opinion may be updated following the written commenting round and RAC working group discussions and made available prior to the plenary, where relevant.</p> <p>Parties should avoid any reopening of already agreed issues or discussion of any extraneous procedural matters at this point.</p> <p>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.</p>	Weeks 36-38	
	<b>End of the procedure for RAC</b>	<b>End of month 9</b>	
	<b>Start of third-party consultation on the SEAC draft opinion</b>	<b>Beginning of month 10</b>	
26	SEAC is informed about the start of the third party consultation on the SEAC draft opinion.	Week 40	Information
	<b>FOURTH OPINION MAKING CYCLE</b>		
27	SEAC rapporteurs are requested to provide the <b>final SEAC opinion</b> .	Week 40	Information
28	Comments received within the third-party consultation are made available to SEAC.	By week 49	Compiled comments from consultation
29	<p>The SEAC (co-)rapporteurs provide to the Secretariat the draft of the final SEAC opinion and response to comments received within the consultation (ORCOM<sup>7</sup>) for their review.</p> <p>SEAC may optionally annotate the BD with boxes highlighting key parts of the evaluation.</p>	By week 50	<p>Draft of the final SEAC opinion draft version of the ORCOM,</p> <p>Draft version of the final BD</p>
30	<p>SEAC (co-)rapporteurs address the suggestions provided by the Secretariat and update the final SEAC opinion, ORCOM and final BD (if relevant).</p> <p>The Secretariat makes the documents available to SEAC.</p>	By week 50	Draft final SEAC Opinion, ORCOM, final BD
31	<b>The fourth discussion</b> takes place, where the draft of the final SEAC opinion is discussed and the SEAC opinion adopted.	Weeks 51-52	Fourth discussion

<sup>7</sup> Response to comments table on comments received within the consultation on the SEAC draft opinion.

	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.		
	<b>End of the procedure for SEAC</b>	<b>End of month 12</b>	
32	The RAC and SEAC opinions are compiled and published on the ECHA website, together with the ORCOM and final BD. The RAC and SEAC opinions and the final BD are forwarded to the Commission.		RAC and SEAC final opinions, ORCOM, final BD

In some cases, described in the "Framework of RAC and SEAC in checking conformity and developing opinions on restriction proposals", a deviation from the standard procedure described above could be applied for the sake of efficiency and in order to avoid unnecessary work. This flexible procedure would typically mean that some of the steps and/or opinion cycles foreseen by this working procedure could be skipped<sup>8</sup> (more details are provided in the above-mentioned framework).

The RAC and SEAC Chairs may also propose a deviation from the standard procedure when a more in-depth assessment by either RAC or SEAC is required based on the complexity and/or the broadness of the restriction proposal. In such cases, the Chairs of the Committees will inform the RAC and SEAC of the deviation of the standard procedure which will be reflected in the plenary minutes.

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.

The different opinion making cycles consist of draft opinions processed by either in the RAC working group on restrictions or in RAC/SEAC plenary meetings.

Each opinion making cycle is planned similarly consisting of the following:

- Cycle meeting (1-4 weeks after the previous plenary meeting)
- Opinion deadline (4 weeks minimum after the previous plenary meeting)
- Internal review by Secretariat (before making the documents available to RAC and SEAC)
- One draft opinion version per each opinion cycle – principle (except prior to adoption)
- Consultation in the committees (usually for two weeks)
- WG/plenary discussion.

The Dossier Submitter has the possibility to update the draft background document twice during the process:

- Version 1, based on RAC and SEAC recommendations made during the conformity check procedure (by week 8).
- Version 2 based on the comments received from the consultation (by week 32).

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-)

<sup>8</sup> Such decisions will be recorded in the minutes of the relevant meeting.

rapporteurs may consult the RAC rapporteurs on such changes, on the joint agreement of the Chairs of the Committees. If appropriate, the RAC Chair 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 by the Secretariat after 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.

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 Chair 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 and communicated to the Commission.