

**TERMS OF REFERENCE  
FOR (CO-) RAPPORTEURS OF RAC AND SEAC FOR AUTHORISATION  
APPLICATIONS**

**1. INTRODUCTION**

In accordance with Article 64(1) of the REACH Regulation, RAC and SEAC shall give their draft opinions on authorisation applications within ten months of the date of receipt of an application.

Article 64(3) specifies that in preparing its opinion, each Committee shall first check that the application includes all the information specified in Article 62 that is relevant to its remit. If necessary, the Committees shall, in consultation with each other, make a joint request to the applicant<sup>1</sup> for additional information to bring the application into conformity with the requirements of Article 62. In addition, Article 64(3) foresees that SEAC may, if it deems it necessary, require the applicant or request third parties to submit, within a specified time period, additional information on possible alternative substances or technologies.

Article 64(4) specifies that the draft opinions of the Committees shall include the following elements:

- a) RAC: an assessment of the risk to human health and/or environment arising from the use(s) of the substance, including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives;
- b) SEAC: an assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as described in the application, when an application is made in accordance with Article 62 and of any third party contributions submitted under Article 64(2).

Article 64(5) foresees that the ECHA Secretariat shall send the draft opinions of the Committees to the applicant by the end of the ten months deadline. Within one month of receipt of the draft opinion, the applicant may provide written notice that he wishes to comment<sup>2</sup>.

If the applicant does not wish to comment, the Secretariat shall send the RAC and SEAC opinions to the Commission, the Member States (MSs) and the applicant, within 15 days of the end of the period within which the applicant may comment or within 15 days of receipt of notice from the applicant that he does not intend to comment.

If the applicant wishes to comment, their written comments are to be sent to the ECHA Secretariat within two months of the receipt of the draft opinion. RAC and SEAC shall

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<sup>1</sup> In these terms of reference "applicant" means one or several applicants, who have submitted a joint application.

<sup>2</sup> The draft opinion shall be deemed to have been received seven days after the ECHA Secretariat has sent it.

consider the comments and adopt their final opinions within two months of receipt of the written argumentation, taking this argumentation into account where appropriate. Within a further 15 days the Secretariat shall send the opinions, with the written argumentation attached, to the Commission, the MSs and the applicant.

Following the requirements of Article 87(1) of REACH, both Committees shall appoint one of its members as a rapporteur for each authorisation application and may also appoint a second member to act as a co-rapporteur for the same application. In these terms of reference rapporteur and co-rapporteur are referred to as "(co-) rapporteur".

The (co-)rapporteur shall prepare the draft opinion and, if relevant, the final opinion in dialogue with the (co-)rapporteur of the other Committee for the same application in order to have a consistent technical and scientific basis for the respective conformity checks and opinions.

For conducting all these tasks, the (co-) rapporteur will receive support from the ECHA Secretariat, so that the opinions are timely, fit-for-purpose and consistent with other opinions of similar uses.

## **2. TASKS**

### **2.1 Formulation of opinion**

#### **2.1.1 Formulation of RAC and SEAC draft opinion**

For formulating the RAC and SEAC draft opinion, the (co-) rapporteur will be provided by the ECHA Secretariat with the following:

- The application for authorisation;
- Additional information provided by the applicant to bring the application in conformity with Article 62 (if requested by RAC and SEAC);
- Additional information provided by the applicant and/or third parties on possible alternative substances or technologies (if required from the applicant and/or requested from third parties by SEAC);
- Information submitted by third parties during the public consultation;
- Additional information from the applicant to bring the application into conformity with the requirements of Article 62 (if requested);
- Additional clarification from the applicant on content-related questions (if asked).

The (co-)rapporteur is required to:

- Formulate and propose a draft opinion on the submitted authorisation application for adoption by RAC/SEAC.

The (co-)rapporteur shall carry out this task in consultation with the (co-)rapporteur from the other Committee, both by informal exchange and by structured dialogues. To

undertake this task the (co-)rapporteur shall:

- a) Review the authorisation application.
- b) Identify potential issues in the application, which could compromise conformity of the application in accordance with Article 62 of the REACH Regulation. A joint request to the applicant for additional information to bring the application into conformity with the requirements of Article 62 shall be prepared together with the (co-)rapporteur of the other Committee and with the assistance of the ECHA Secretariat<sup>3</sup>.
- c) Review comments received during the public consultation. The applicant may provide comments on this information. The ECHA Secretariat will ask the applicant for these comments.
- d) For the SEAC (co-)rapporteur: decide whether it is necessary to require the applicant and/or request third parties to submit additional information on alternatives, and compile these requirements and/or requests. If required/requested, review the received information (if needed, this is done in co-operation with the RAC (co-) rapporteur). The ECHA Secretariat will assist in this task.
- e) Consider and respond to comments received from other RAC/SEAC members on the different versions of the draft opinion.
- f) Formulate a draft opinion<sup>4</sup> and, if necessary, modify the draft opinion in dialogue with the (co-)rapporteur of the other Committee. If relevant, modify the draft opinion during the plenary meetings in order to find an agreed wording to represent the consensus or majority view of the Committee with the assistance of the ECHA Secretariat.
- g) As necessary prepare and modify any draft supporting document that supports the technical and scientific justifications in the RAC/SEAC draft opinion. This shall be carried out jointly with the (co-)rapporteur of the other Committee and with the support from the ECHA Secretariat.
- h) If key data submitted by the interested parties form a core element to justify the draft opinions, verify the data with the assistance of the (co-)rapporteur of the other Committee, other RAC and SEAC members and with the support from the ECHA Secretariat.
- i) Present the draft opinion and the technical and scientific rationale behind their position, at a plenary (and/or working group) meetings.

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<sup>3</sup> The ECHA Secretariat will assist the (co-)rapporteur by providing a partly filled template, but the (co-) rapporteur will perform the conformity check and is free to modify the preliminary version prepared by ECHA.

<sup>4</sup> The opinion will consist of a standardised text together with justifications as outlined in the document "The opinions of RAC and SEAC on Applications for Authorisations".

### **2.1.2. Formulation of the RAC/SEAC final opinion<sup>5</sup>**

For formulating the RAC/SEAC final opinion, the (co-)rapporteur will be provided by the ECHA Secretariat with the argumentation sent by the applicant on the RAC/SEAC draft opinion.

The (co-)rapporteur is required to:

- Consider the applicant's comments, and draft and propose a final opinion on the authorisation application for adoption by RAC/SEAC.

The (co-)rapporteur shall carry out this task in consultation with the (co-)rapporteur from the other Committee. To undertake this task the (co-)rapporteur shall:

- j) Review and respond to comments received from the applicant on the RAC/SEAC draft opinion. The ECHA Secretariat will assist in this task.
- k) Formulate a final opinion and, if necessary, modify the final opinion in order to find an agreed wording to represent the consensus or majority view of the Committee with the assistance of the ECHA Secretariat and in dialogue with the (co-)rapporteur of the other Committee.
- l) If necessary, modify any other supporting document to be in line with the RAC/SEAC final opinion. This shall be carried out jointly with the (co-) rapporteur from the other Committee and with the support from the ECHA Secretariat.

### **3. EXPECTED OUTCOMES / DELIVERABLES**

Following the requirements of REACH and the RAC/SEAC working procedures for the authorisation process, the (co-)rapporteur is expected to prepare and provide to RAC/SEAC the following key documents (including drafts as appropriate):

- 1) the draft opinion,
- 2) the final opinion, if the applicant provides comments on the draft opinion.

### **4. TIMELINES AND MILESTONES**

The (co-)rapporteur should provide the deliverables pointed out in the previous section according to the timelines specified in the letter of appointment or the service contract and which are defined in the working procedure for RAC and SEAC on conformity check of authorisation applications and the working and the working procedure for RAC and SEAC on developing RAC and SEAC opinions on authorisation applications. If the applicant does not comment on the RAC and SEAC draft opinions, the draft opinions are

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<sup>5</sup> RAC/SEAC shall formulate its final opinion if the applicant provides comments on the RAC/SEAC draft opinion. If the applicant does not provide comments within the commenting period, the adopted RAC and SEAC draft opinions are considered as the final opinions.

considered as final and the ECHA Secretariat sends the opinions to the Commission, MSs and the applicant. If the applicant provides comments on the RAC/SEAC draft opinion, the Committee continues the work with the application for two more months following the receipt of the applicant's comments until the final opinion is adopted by RAC/SEAC.

## **5. REVIEW OF THE QUALITY**

The (co-) rapporteur shall fulfil all the assigned tasks to a high quality. All members of the Committee and the Chairs of RAC and SEAC have the shared responsibility to ensure a fit-for-purpose quality of the opinion and its justifications, which should demonstrate that the opinion is based on robust and valid scientific and technical information.

## **6. REMUNERATION OF RAPPORTEURS**

Article 87(3) of REACH stipulates that those RAC and SEAC rapporteurs that are appointed shall receive remuneration for their rapporteurship. The amount that shall be remunerated is laid down in the Management Board decision of 21 December 2020 ([MB/41/2020](#)) establishing the financial arrangements for transfer of proportion of fees to the member states.

Where Co-opted members are appointed as rapporteurs, then their remuneration is based on the Management Board decision of 16 December 2022 ([MB/46/2022](#)). The MB decision states that the remuneration for (co-) rapporteurship of co-opted members shall be paid per actual day of work (450 Euro/day of work) to a maximum ceiling of 9000 Euro.

The distribution of work between rapporteurs and co-rapporteurs for certain dossiers has been pre-fixed to a 50/50 split to ensure a timely issuing of the service contracts. The (co-) rapporteurs may indicate a change in the split of work between them before the end of the service. In this case, the remuneration amounts will be changed accordingly, and amendments to the service contracts will be issued with the relevant change.

The final payments shall be done upon the receipt of the report of the number of worked days (timesheet) and the invoice which the (co-)rapporteur will send after adoption of opinion.