

WORKING PROCEDURE FOR RAC AND SEAC FOR DEVELOPING OPINIONS ON THE APPLICATIONS FOR AUTHORISATION

1. Introduction and legal basis

The purpose of this document is to outline the procedure for developing RAC and SEAC opinions on authorisation applications submitted under the framework of Title VII of the REACH Regulation. It describes the main roles and tasks of the rapporteurs, the members of RAC and SEAC, and the ECHA Secretariat, as well as giving the timelines for different tasks.

According to Article 60(7) of the REACH Regulation, an authorisation application shall be granted by the Commission only if the application is made in conformity with the requirements of Article 62. 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 for additional information to bring the application into conformity with the requirements of Article 62.

The RAC and SEAC rapporteurs check whether the application conforms with the requirements of Article 62(4). However, RAC and SEAC will only conclude on conformity at the same time when they agree on the draft opinions, or earlier, if it is considered that the information provided is sufficient and no conformity issues have been raised by the rapporteurs. Rather, any issues relating to conformity will be raised and documented as part of the questions that will be sent to the applicant. No other communication with the applicant relating to conformity is expected.

According to Article 64(1) of the REACH Regulation, RAC and SEAC shall give their draft opinions within ten months of the date of receipt of the application. Article 64(4) specifies that the draft opinions shall include the following elements:

a) RAC: an assessment of the risk to human health and/or the 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.

The following information will serve as the main input for the formulation of the RAC and SEAC draft opinions:

- Application for authorisation;
- Conformity and the key issues identified by the Rapporteurs with an input from the ECHA Secretariat in the application for authorisation;
- Any information on alternative substances and technologies submitted by third parties, including the stakeholder observers, within the public consultation carried out based on Article 64(2);
- Additional information provided by the applicant and/or by third parties on possible alternative substances or technologies as required and/or requested by SEAC (based on Article 64(3));
- Any other information submitted by the applicant or third parties in response to requests by RAC and SEAC.

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. If the draft opinion is developed earlier than the aforementioned deadline, the consultation with the applicant may start earlier. The applicant then has a possibility to comment on the RAC and SEAC draft opinions.

If the applicant does not wish to comment, the Secretariat shall send these opinions to the Commission, the Member States (MSs) and the applicant.

If the applicant wishes to comment, written argumentation shall be sent to the ECHA Secretariat within two months of the receipt of the draft opinions. RAC and SEAC shall consider the comments and adopt their final opinions within two months of receipt of the written argumentation, taking this argumentation into account where appropriate. The final opinions of the Committees are sent to the Commission, the MSs and the applicant.

2. Additional information

As a general rule, requests for and submission of additional information will take place during the first three months of the opinion development process, starting from the payment of the fee by the applicant, to allow enough time for the rapporteurs and the Committees to consider such responses.

Additional information on alternatives

The SEAC rapporteur and co-rapporteur will compile additional information to be required from the applicant on possible alternative substances or technologies (based on Article 64(3)). Furthermore, they will also compile additional information to be requested from third parties on possible alternative substances or technologies (based on Article 64(3)).

When carrying out this task (formulating questions to the applicant and/or third parties) the SEAC rapporteurs will work in close co-operation with the RAC rapporteurs.

The SEAC rapporteur and co-rapporteur will also decide on the time period for the submission of the requested/required information¹. Information submitted after the set deadline should normally not be considered by the Committees.

Other information

In addition, although the legal text does not specifically foresee this option, the RAC and SEAC rapporteurs may request additional information from the applicant or third parties so as to help them in formulating the draft opinions in accordance with Article 64(4). The focus of this request will be to obtain clarifications on essential points in the application or in the third party submissions. This should be done as early as possible, e.g. to be included in the first draft opinion; caution should be exercised regarding additional information requests later on in the process.

In such requests for information, a reasonable time period for providing this information (e.g. one month) would also need to be established. Information submitted after the set deadline should normally not be considered by the Committees.

Information submitted by a third party outside of the scope or timeframe of the public consultation will normally not be taken into account. However, the rapporteurs, supported by the ECHA Secretariat, can decide on a case-by-case basis if the information is relevant and if it can be handled within the available timeline².

3. Procedure for the opinion development³

3.1. Development of the RAC/SEAC draft opinion

The table below outlines the main steps in the development of the RAC and SEAC draft opinions starting from receipt of an authorisation application by RAC and SEAC until the adoption of the draft opinions by the Committees.

¹ Normally a deadline of one month will be given to the applicant for submitting additional information on alternatives. Deadlines for requests to third parties will be established on a case-by-case basis. To ensure that all additional information is available for consideration in the preparation of the first versions of the draft opinions in month 5 and the subsequent commenting rounds by the Committees, deadlines should normally not be set for later than half way through month 4.

² If such information is submitted late in the process, it will only be taken into account in exceptional cases (only if the late submission is justified and if there is enough time to consider the information for the rapporteurs and the Committees).

³ The number of plenary discussions and their timing should be considered indicative and will be adapted according to the number and timing of plenary meetings and the deadline for each application.

	Step	Deliverables and milestones	Timeline starting from the date of receipt of the application – Day 1⁴
a	RAC and SEAC members are informed that the Secretariat has published on the ECHA website broad information on uses for which the application has been received and has invited interested third parties to submit information on alternative substances or technologies (within an eight week period).	Information	Date of the start of the public consultation (week 1)
b	Newsgroups are initiated in collaboration platform allowing RAC and SEAC members to submit initial comments on the application (within an eight week period). Kick-off meeting discussion on the application (content, preliminary observations of quality etc.) and in particular on the conformity issues is organised by the Secretariat. The key issues in the application for authorisation are identified by the Rapporteurs with the help of the ECHA Secretariat, which are made available to RAC and SEAC.	Initial comments Key issues	Date of the start of the public consultation (week 1) By week 2 By week 3
c	If necessary, the SEAC rapporteurs compile questions to the applicant on alternative substances or technologies (in co-operation with the RAC rapporteurs). If necessary, the RAC and SEAC rapporteurs jointly compile questions to the applicant related to the content of the application. When the RAC and SEAC rapporteurs ask questions to the applicants, they will signal when these relate to conformity in order to support compliance of the applications with the requirements of	Questions to the applicant on alternatives and content related questions	Week 4

⁴ Article 8(4) of the Regulation (No) 340/2008 (REACH Fee Regulation) states: "The date on which the fee levied for the application for an authorisation is received by the Agency shall be considered to be the date of receipt of the application."

WORKING PROCEDURE FOR RAC AND SEAC FOR DEVELOPING OPINIONS ON THE APPLICATIONS FOR AUTHORISATION

	Article 62(4). They should also decide on the deadline for submission of this information. ⁵		
d	PLENARY 1: Key issues discussion RAC/SEAC plenary discussion on key issues identified in the application for authorisation and anything relevant to conformity.	First exchange of views on content of the application for authorisation	Week 4-5
e	Information submitted by the third parties within the public consultation and additional information on alternatives submitted by the applicant (if required by SEAC) as well as the applicant's responses to the content related questions (if asked by RAC and SEAC) are made available to RAC and SEAC.	Information	Week 9
f	First dialogue ⁶ between the RAC and SEAC rapporteurs is convened for the first exchange of views on the submitted application and any additional information available, such as information obtained during the public consultation, answers provided by the applicant, as well as on any comments received by RAC and SEAC members within the initial commenting round. ⁷	Exchange of views	Weeks 11-12
g	A trialogue ⁸ discussion between the applicant, the RAC and SEAC rapporteurs and interested third parties invited by the Secretariat is convened to discuss with the applicants and invited third parties any information on alternatives generated through the public consultation or any other technical or scientific issues with the application.	Exchange of views	Week 13
h	The RAC/SEAC rapporteurs prepare the 1 st version of the RAC/SEAC draft opinion. The rapporteurs ask the applicant to comment on	Rapporteurs' 1 st version of the RAC/SEAC draft	Week 14

⁵ Normally a deadline of one month will be given to the applicant.

⁶ The dialogue could take the form of a teleconference, videoconference or face-to-face meeting on a case-by-case basis.

⁷ Following the end of the public consultation, if the outcome for an application is a clear-cut case (depending on the application, the nature of additional information received from the applicant (if required) and of information received within the public consultation), the Chairmen of RAC and SEAC may decide in consultation with the RAC and SEAC rapporteurs to aim to adopt the RAC and SEAC draft opinions earlier than in month 10 (e.g. in the first or second plenary meeting or by written procedure).

⁸ The trialogue could take the form of a teleconference, videoconference or face-to-face meeting on a case-by-case basis.

	<p>information obtained through the public consultation.</p> <p>The 1st versions of the RAC/SEAC draft opinions prepared by the rapporteurs are distributed to RAC and SEAC for a written consultation.</p> <p>The RAC/SEAC rapporteurs respond to comments received from other RAC/SEAC members within the written commenting round (in the form of an ORCOM⁹) and draft the 2nd version of draft opinion.</p>	<p>opinion; Members provide written comments</p>	
i	<p>PLENARY 2: 2nd version of the draft opinion</p> <p>The item is discussed in plenary and at this stage may be presented for agreement depending on the degree of complexity.</p>	<p>RAC/SEAC plenary discussion / agreement, if possible</p>	<p>Weeks 16-17</p>
	<p>If RAC and/or SEAC do not agree on the 2nd version THEN, steps j to n should be followed.</p>		
j	<p>RAC/SEAC rapporteurs prepare the 3rd version of the RAC/SEAC draft opinion. The documents prepared by the rapporteurs are distributed to RAC and SEAC.</p>	<p>3rd version of the RAC/SEAC draft opinion</p>	<p>Week 20</p>
k	<p>The RAC/SEAC members provide written comments on the 3rd version of the RAC and/or SEAC draft opinion normally within 14 calendar days.</p>	<p>Written commenting</p>	<p>Week 21</p>
l	<p>The second dialogue between the RAC and SEAC rapporteurs is convened. For exchange of views, including conformity of the application, and to agree on the 4th version of the RAC and SEAC draft opinion.</p>	<p>Exchange of views</p>	<p>Weeks 25-26</p>
m	<p>The RAC/SEAC rapporteurs respond to comments received from other RAC/SEAC members within the written commenting round and send the 4th version of the RAC/SEAC draft opinion within seven calendar days. The documents prepared by the rapporteurs are distributed to RAC and SEAC.</p>	<p>ORCOM; 4th version of the RAC/SEAC draft opinion</p>	<p>Week 27</p>

⁹ ORCOM – response to comments table on the RAC/SEAC members’ comments on a specific version of the opinion.

n	<p>PLENARY 3: 4th draft opinion</p> <p>It is foreseen that this plenary meeting would only be utilised for complex/difficult applications.</p> <p>The item is discussed in plenary.</p> <p>The 4th version of the draft opinion, following adequate scrutiny by the Rapporteurs and commenting members, supported by the Secretariat, may be included on an A-list of items for agreement without plenary discussion at this meeting.</p>	RAC/SEAC plenary discussion	Weeks 29-30
	If RAC and/or SEAC do not agree on the 4 th version of the draft opinion THEN steps o to q should be followed.		
o	Third dialogue between the RAC and SEAC rapporteurs is convened to agree on the 5 th version of the RAC and SEAC draft opinion.	Exchange of views	Weeks 38-39
p	The RAC/SEAC rapporteurs prepare the 5 th version of the RAC/SEAC draft opinion taking into account comments received from other RAC/SEAC members in the previous plenary meeting. The documents prepared by the rapporteurs are distributed to RAC and SEAC.	5 th version of the RAC/SEAC draft opinion	Week 41
q	<p>PLENARY 4: 5th draft opinion</p> <p>It is not foreseen that this plenary meeting would be utilised under normal circumstances. The item is discussed in plenary.</p> <p>Following the discussion RAC/SEAC agrees on its draft opinion.</p>	RAC/SEAC plenary	Weeks 43-44

The adopted RAC and SEAC draft opinions (incl. the RAC and SEAC working document on the Opinion on an Application for Authorisation) are sent by the Secretariat to the applicant without undue delay. Within one month of receipt of the draft opinion¹⁰, the applicant may provide written notice that he wishes to comment.

¹⁰ According to Article 64(5), the draft opinion shall be deemed to have been received seven days after the ECHA Secretariat has sent it.

3.2. Development of the RAC/SEAC final opinion

If the applicant does not wish to comment, the Secretariat shall send the RAC and SEAC opinions (incl. the RAC and SEAC working document on the Opinion on an Application for Authorisation) to the Commission, the 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. Further supporting documentation can be forwarded to the Commission on request. The Secretariat informs the Committees of this outcome.

If the applicant wishes to comment, written argumentation shall be sent to the Secretariat within two months of receipt of the draft opinions. RAC and SEAC shall consider the comments and adopt their final opinions within two months of receipt of the written argumentation, taking this argumentation into account where appropriate (for details see section 3.2).

The table below describes the main steps in the preparation of the RAC/SEAC final opinion starting from the receipt of the applicant's comments on the RAC/SEAC draft opinion until the adoption of the RAC/SEAC final opinion.

	Step	Deliverables and milestones	Timeline starting from the date of receipt of the application – Day 1
r	Comments received from the applicant on the RAC/SEAC draft opinion are distributed to RAC and SEAC.	Applicant's comments on the RAC/SEAC draft opinion	Day 1
s	The RAC/SEAC rapporteurs prepare a draft version of the RAC/SEAC final opinion taking into account the applicant's comments on the RAC/SEAC draft opinion and reply to the applicant's comments in form of an ORCOM. The documents prepared by the rapporteurs are distributed to RAC and SEAC.	Draft version of the RAC/SEAC final opinion	Week 4
t	The RAC/SEAC members provide written comments on the rapporteurs' draft version of the RAC/SEAC final opinion normally within 10 calendar days.	Written commenting	Weeks 4-6
u	The RAC and SEAC rapporteurs respond to comments received from other RAC/SEAC	ORCOM; revised draft	Week 6

	members within the written commenting round (in the form of an ORCOM) and revise the draft version of the final opinion. The Secretariat, together with the RAC and SEAC rapporteurs, revise the RAC and SEAC working document on the Opinion on an Application for Authorisation to be in line with the revised draft versions of the RAC and SEAC final opinions. The documents are distributed to RAC and SEAC.	version of the RAC/SEAC final opinion	
v	<p>Following the discussion at the RAC/SEAC plenary meeting, RAC/SEAC adopts its final opinion.</p> <p>The Secretariat launches a written procedure in RAC/SEAC to adopt the RAC/SEAC final opinion and the RAC/SEAC-related parts of the final RAC and SEAC working document on the Opinion on an Application for Authorisation. The Secretariat informs RAC and SEAC about the outcome of the written procedures.</p>	Adoption in the RAC/SEAC plenary or written procedure	Weeks 8-9

Within a further 15 days the Secretariat will send the RAC and SEAC final opinions (incl. the final RAC and SEAC working document on the Opinion on an Application for Authorisation), with the applicant's written argumentation attached, to the Commission, the MSs and the applicant. Further supporting documentation (ORCOMs, minutes of the RAC and SEAC plenary meetings and written procedure reports, if any) can be forwarded to the Commission on request.

3.3. Reviews of authorisations and subsequent applications

For reviews of authorisations the same procedure should be used in principle as described in sections 3.1 and 3.2.

According to Article 63(1) of the REACH Regulation, if an application has been made for a use of a substance, a subsequent applicant may refer to the appropriate parts of the previous application, provided that the subsequent applicant has permission from the previous applicant to refer to these parts of the application. In such cases the first and the subsequent application shall be treated together provided that the deadline for the first application can be met (Article 64(7)). Working procedures for subsequent applications according to Article 63(1) will be similar to the procedure described in 3.1 and 3.2 but timelines will be developed on a case-by-case basis.

According to Article 63(2), if an authorisation has been granted for a use of a substance, a subsequent applicant may refer to the appropriate parts of the previous application, provided that the subsequent applicant has permission from the holder of the authorisation to refer to these parts of the application. In such cases the deadline for RAC and SEAC to formulate their draft opinions shall be five months.