Handling applications for authorisation and review reports under REACH

1. Purpose

This procedure describes how to handle applications for authorisation (AfA) as established by the REACH Regulation Title VII, Chapter 2 ('Granting of authorisations') and Chapter 3 ('Authorisations in the supply chain'). The outcome of the process is to provide the European Commission with the opinions of the relevant committees about the application for authorisation. These committees are the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC).This procedure is designed to ensure that:

- The opinions of RAC and SEAC meet the requirements set out in Article 64(4) so that the Commission can meet its legal obligations as specified in Article 60;
- Legislative deadlines are respected;
- Internal requirements for the efficient processing of applications for authorisation are met;
- Communications between the applicant, third parties, RAC and SEAC, the ECHA Secretariat and the European Commission are defined.

This procedure also applies to subsequent applications for authorisation and review reports.

2. Scope

The process starts when a notification to submit an application for authorisation or pre-submission information session (PSIS) is received. After the receipt of the application, RAC and SEAC evaluate the application and prepare an opinion. The final opinion of RAC and SEAC is sent to the European Commission, the Member States and the applicant. Reference to the summary of the decision of the European Commission on the Application for Authorisation is published on ECHA's website. The process ends when downstream user notifications for authorised uses are received.

3. Description

The aim of the authorisation process under REACH is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern (SVHCs) are properly controlled and that these substances are progressively replaced by suitable alternatives where these are economically and technically feasible.

Applications for authorisation can be prepared by manufacturers, importers, only representatives or downstream users of a substance on the Authorisation List.

The process following the submission of an AfA or a review encompasses a comprehensive consultation with interested parties. In the course of the process:

- RAC formulates its opinion based on an evaluation of the assessment of risk to human health and/or the environment arising from the use(s) of a 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.
- SEAC formulates its opinion based on an evaluation of the 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 during the consultation on alternatives.

The European Commission decides to grant or refuse the authorisations based on the consolidated RAC/SEAC opinions.

The procedures for opinion development are followed against fixed deadlines. A strict time regime applies to individual process steps to ensure that the overall processing of an application occurs within the legal deadlines.

Stage 1: Pre-submission

Step 1a: Notifications of intentions to submit an AfA or a request for a pre-submission information session (PSIS)

Future applicants may notify ECHA of their intention to submit an application for authorisation by submitting information using a webform on ECHA's website. A PSIS request should be submitted at least eight months before the actual AfA submission and at least two months before the preferred meeting date specified in the request. A list of notifications and PSISs is maintained in the ECM (WIN-0131).

Step 1b: Pre-submission information session

At the request of a potential applicant, the PSIS coordinator and key senior scientific officers organise a pre-submission information session (PSIS) to discuss case-specific issues regarding the regulatory and procedural aspects related to the application (WIN-0113).

Stage 2: Submission and preparatory steps

Step 2: Receive authorisation application

The Dossier Submission and Dissemination Unit receives the application for authorisation via REACH-IT (EUM-011).

Step 3: Business rules check

The Dossier Submission and Dissemination Unit and the AfA submission pipeline team perform a business rules check to verify whether the application can be processed (EUM-011 and WP3-OM-001).

Step 4: Nomination of the team

The Head of the Risk Management Implementation Unit, following agreement with relevant Heads of Unit, nominates the Authorisation Team (AT) taking into account the expertise, past experience and availability of the staff (See WIN-0112 and WIN-0105). The AfA submission pipeline team gives their initial observations on the application to the AT.

Step 5a: Development of broad information on use(s)

In parallel with steps 5b and 5c, and before the fee is paid (step 6), the AT develops a draft version of the broad information on use(s) and consults the applicant on this. On the basis of received comments from the applicant, the AT finalises the broad information on use(s) and communicates it to the applicant. If needed, the AT contacts the Substance Identification team in the Substance Identity and Data Sharing Unit to verify the substance identification in the application (WP3-OM-001).

Step 5b: Fee determination and invoicing

In parallel with steps 5a and 5c, the AT determines the fee, based on the Fee Regulation and the following fee determining parameters: number and size of applicant(s); number of substances; and number of uses applied for. The Dossier Submission and Dissemination Unit issues the invoice via REACH-IT. The Finance Unit performs an SME verification (WP3-OM-001).

Step 5c: Preparation of committees' work

In parallel with steps 5a and 5b, the AT prepares and makes the application available for subsequent evaluation by the committees. (Co-)rapporteurs are appointed for preparing the draft and final opinions of the committees (WP3-OM-001).

Step 5d: Kick-off discussion

If deemed necessary, staff members who participated in the PSIS, as well as selected senior experts as per the request of the process coordinator, hold a kick-off discussion with the AT. The purpose of this is to identify major problems and strengths of the application, if any, so as to make the opinion-making phase as efficient as possible. These staff members will support the AT during the opinion making on an ad hoc basis based on the request of the process coordinator.

Step 6: Verification of payment, and sending the acknowledgment of receipt

The Finance Unit verifies the payment against the invoice. Upon payment of the fee, the Dossier Submission and Dissemination Unit ensures that an acknowledgment of receipt of the application is sent for the applicant.

Step 7: Confirmation of rapporteurs

The appointment of rapporteurs is confirmed by sending out the rapporteurs' contracts. The Finance Unit ensures the transfer of the fee for the remuneration of the appointed (co-)rapporteurs (WIN-0116).

Stage 3: Draft opinion of RAC and SEAC

Step 8a: Launch of consultation on alternatives and informing the committees

After the acknowledgment of fee payment is sent to the applicant, the AT prepares the public consultation (PC) on alternatives, which the Digital Communications team launches on ECHA's website. The consultation is open for eight weeks, during which interested parties are invited to provide information on alternative substances and technologies. The AT informs the committees about the start of the consultation on alternatives (WIN-0137).

Step 8b: Handling of information obtained from the consultation on alternatives

The AT makes the information obtained from the public consultation on alternatives available to the committees. On the basis of the comments received, the committees may request additional information from both applicants and third parties who have sent in comments. If so, the AT requests this information on behalf of the committees (WIN-0138).

Step 8c: Trialogues with applicant and rapporteurs

When the public consultation is finished, a trialogue is organised if the rapporteurs and RAC/SEAC chairmen decide it is necessary to have one. This trialogue is an opportunity for the rapporteurs of RAC and SEAC to discuss in an interactive manner any information on alternatives in particular those generated through the PC and if necessary any other technical and scientific issues with the applications for authorisation. Third parties could also be invited and so could committee members and stakeholder observers (STOs) to provide scrutiny and transparency. The trialogue is also an opportunity for ECHA's confidentiality advisor or his/her delegate to assess with applicants and rapporteurs the likelihood that RAC/SEAC deliberations would need to refer to confidential business information. Based on the recommendation of the confidentiality advisor or his/her delegate, the RAC/SEAC chairmen will then decide whether the next plenary sessions of the committees will be observed or non-observed (WIN-0141).

Step 9: Preparation of draft opinions of RAC and SEAC and evaluation of the conformity

The AT, together with the chairmen of the committees, ensures that the draft opinions of the committees are prepared and adopted within 10 months[1] of receipt of the fee. The AT provides scientific, technical and administrative support in particular to the (co-) rapporteurs so that the draft opinions are prepared in an efficient and timely manner according to the relevant working procedures of the committees (WIN-0135).

If necessary, the committees may jointly ask the AT to request the applicant to submit additional information to bring the application into conformity. The AT will provide scientific, technical and administrative support and ensure the correct handling of such requests and their follow-up.

The AT ensures the correct handling of the requests of the committees to the applicant and to third parties to provide further information on the alternatives and on the content of the application. The AT ensures the correct follow up of such requests and makes the requested information from the applicant and from third parties available to the committees (WIN-0139 and WIN-0140).

RAC and SEAC conclude whether the application conforms with the requirements of Article 62(4) of the REACH regulation at the same time that 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.

Step 10: Submission of draft opinions to applicant

After agreement of the draft opinions by the committees, the AT prepares a consolidated version of the two draft opinions (for reasons of transparency, efficient handling and readability) and forwards the consolidated draft opinions to the applicant with an invitation to provide comments (WIN-0135).

Stage 4: Final opinions of RAC and SEAC

Step 11: Receipt of notification from applicant

[1] 5 months for the applications for authorisation submitted in accordance with Article 63(2) of REACH

The AT receives the notification from the applicant indicating if the applicant wishes to comment, ensuring that this notification has been received within one month of the applicant receiving the draft opinions of RAC and SEAC (WIN-0136).

If the applicant does not wish to comment, the AT ensures that ECHA forwards the committees' final opinions to the Commission, the MSCAs and the applicant within the deadlines set out in Article 64(5) of REACH.

Step 12: Receipt of applicant's comments

If the applicant wishes to comment, the AT receives comments from the applicant, and ensures that these have been submitted by the applicant within two months of the receipt of the draft opinions on the application for authorisation. The AT forwards the comments immediately to the committees (WIN-0136).

Step 13: Development of final opinions of RAC and SEAC

The AT provides support to (co-)rapporteurs and the chairmen of the committees with the development of the final opinions. The AT supports the rapporteurs and the chairmen of the committees so that the final opinions are prepared in an efficient and timely manner according to the committees' working procedures. The committees need to adopt the final opinion within two months of the receipt of the applicant's comments on the draft opinion (WIN-0136).

Step 14: Submission of the final opinions to the European Commission, Member States and applicant

After adoption by the committees, the RAC and SEAC chairmen send the final opinions of the committees to the European Commission for decision making; and to the applicant(s) and Member State competent authorities for their information. The AT requests the Digital Communications team to publish the appropriate parts of the opinions on ECHA's website (WIN-0136).

Stage 5: Post-processing

Step 15: Publication of the Commission decision

After the European Commission adopts the decision and publishes the summary of the decision in the Official Journal (OJ) of the European Union, the AT requests the Digital Communications team to publish a link to this decision summary on ECHA's web page. The responsibilities of the AT are finished.

Step 16: Receiving and handling downstream user notifications for authorised uses

The Risk Management Implementation Unit receives notifications from downstream users upon the first supply of the substance. These notifications are stored in a register by staff of the Risk Management Implementation Unit. This register is made accessible to national authorities for enforcement purposes (WIN-0220).

Subsequent applications for authorisation

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

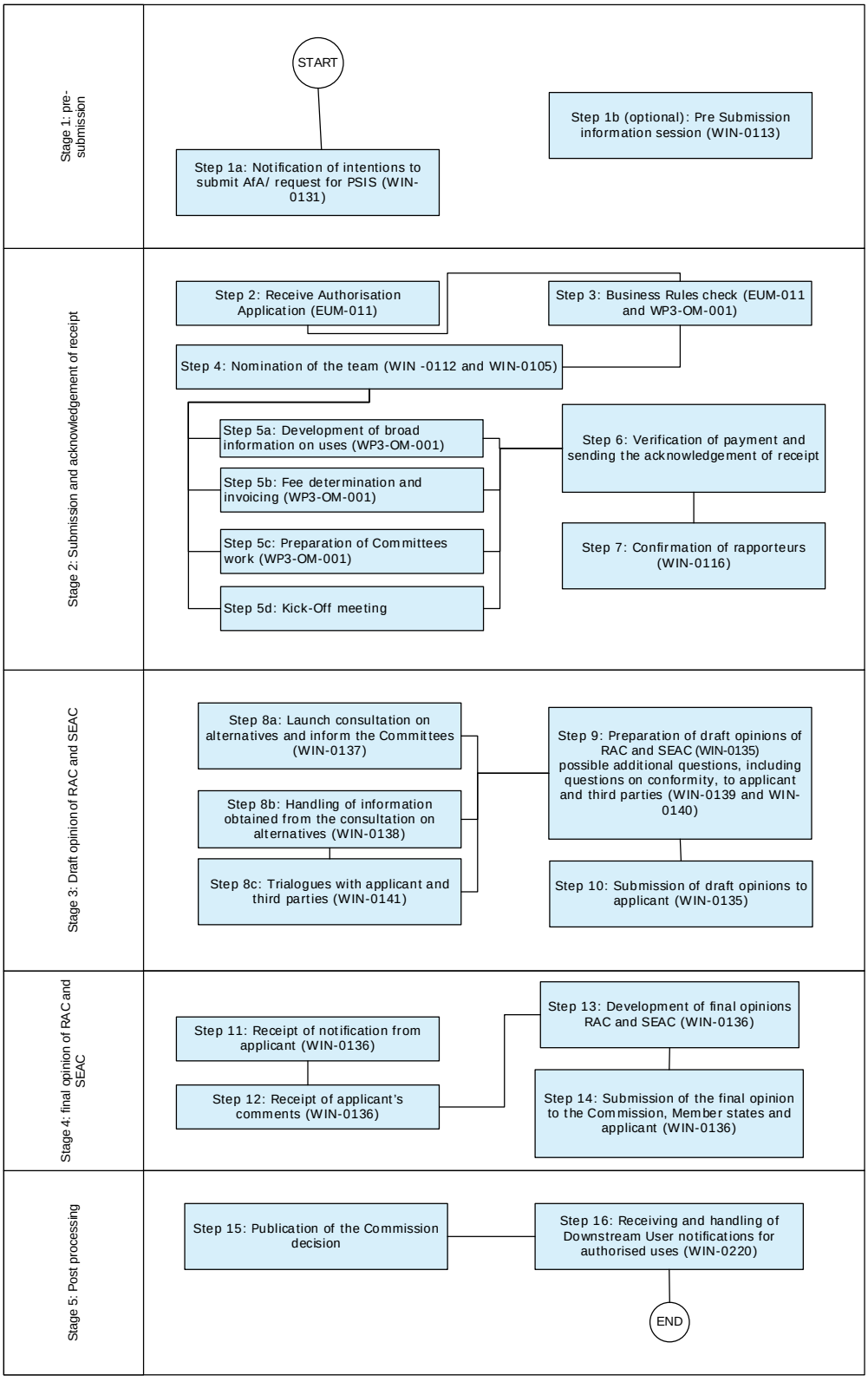
previous applicant to refer to these parts of the application. In such cases the first and the subsequent application shall be treated together provided that the deadline for the first application can be met (Article 64(7)). The same process (as described in sections 2 and 3) applies.

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 is five months. The same process (as described in sections 2 and 3) applies with the exception of a shorter timeline for issuing the RAC and SEAC draft opinions.

Reviews of authorisations (review reports)

All authorisation decisions have a time-limited review period. In order to continue using the substance in question after the end of the review period the authorisation holders shall submit a review report. The same process (as described in sections 2 and 3) applies when dealing with the submitted review reports.

4. Flowchart


Stage 1: pre-submission
START
Step 1a: Notification of intentions to submit AfA/ request for PSIS (WIN-0131)
Step 1b (optional): Pre Submission information session (WIN-0113)
Stage 2: Submission and acknowledgement of receipt
Step 2: Receive Authorisation Application (EUM-011)
Step 3: Business Rules check (EUM-011 and WP3-OM-001)
Step 4: Nomination of the team (WIN -0112 and WIN-0105)
Step 5a: Development of broad information on uses (WP3-OM-001)
Step 5b: Fee determination and invoicing (WP3-OM-001)
Step 5c: Preparation of Committees work (WP3-OM-001)
Step 5d: Kick-Off meeting
Step 6: Verification of payment and sending the acknowledgement of receipt
Step 7: Confirmation of rapporteurs (WIN-0116)
Stage 3: Draft opinion of RAC and SEAC
Step 8a: Launch consultation on alternatives and inform the Committees (WIN-0137)
Step 8b: Handling of information obtained from the consultation on alternatives (WIN-0138)
Step 8c: Trialogues with applicant and third parties (WIN-0141)
Step 9: Preparation of draft opinions of RAC and SEAC (WIN-0135) possible additional questions, including questions on conformity, to applicant and third parties (WIN-0139 and WIN-0140)
Step 10: Submission of draft opinions to applicant (WIN-0135)
Stage 4: final opinion of RAC and SEAC
Step 11: Receipt of notification from applicant (WIN-0136)
Step 12: Receipt of applicant's comments (WIN-0136)
Step 13: Development of final opinions RAC and SEAC (WIN-0136)
Step 14: Submission of the final opinion to the Commission, Member states and applicant (WIN-0136)
Stage 5: Post processing
Step 15: Publication of the Commission decision
Step 16: Receiving and handling of Downstream User notifications for authorised uses (WIN-0220)
END

5. Definitions

Term or abbreviation	Definition
AfA	Applications for authorisation
Consolidated opinion	Opinion of RAC and opinion of SEAC in one document
RAC	Committee for Risk Assessment
SVHC	Substance of very high concern
SEAC	Committee for Socio-economic Analysis
PSIS	Pre-submission information session
MSCA	Member State competent authority
AT	Authorisation team
CBI	Confidential business information

6. Records

The records mentioned in this PRO are listed in the relevant process related Work instructions.

7. References

Associated document code	Document name
Regulation (EC) No 1907/2006	REACH Regulation (in particular Chapter 2 of Title VII as well as Annex XIV)
Regulation (EC) No 340/2008	Regulation on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
Regulation (EEC, Euratom) No 1182/71	Regulation determining the rules applicable to periods, dates and time limits

Associated document code	Document name
RAC/31/2014/07 rev 2 SEAC/25/2014/05 rev 2	Working procedure for RAC and SEAC for developing opinions on the applications for authorisation (agreed by RAC at RAC-31 and by SEAC at SEAC-25)
RAC/15/2011/08 SEAC/11/2011/05	Format for an Opinion of RAC and for an Opinion of SEAC on an Application for Authorisation (agreed by RAC by written procedure and by SEAC at SEAC-11)
WP3-OM-001	Authorisation Team manual Part 1 Submission pipeline
EUM-011	Application for Authorisation (Dossier Receipt and Mandatory Business Rules)

8. Annexes

N/A