

## **Working procedures of the Member State Committee (MSC) in the identification of substances of very high concern (SVHC)**

**(Update adopted on 17 June 2021)**

### **Background**

This document describes principles to be applied in the work of MSC (between members (**MSC-M**) and between MSC-M and ECHA Secretariat (**SECR**)). These working procedures will be applicable to the process of identification of SVHC when comments on SVHC Annex XV dossier(s) have been received.

Involvement of the MSCAs in the processes related to the identification of SVHCs is not covered in this document.

## **WORKING PROCEDURES OF THE MEMBER STATE COMMITTEE (MSC) IN IDENTIFICATION OF SUBSTANCES OF VERY HIGH CONCERN (SVHC)**

### **1. Process description**

The main provisions regarding the identification of substances as substances of very high concern (**SVHC**) are laid down in Articles 57 and 59 of REACH, respectively.

The SVHC identification process starts when a Member State or ECHA, on request of the European Commission, (so called 'dossier submitter') submits an Annex XV dossier proposing the identification of a substance as an SVHC following the criteria laid down in Article 57 of the REACH Regulation.

ECHA shall launch on its website a 45-day consultation on the SVHC Annex XV dossier(s) when all interested parties and the Member State Competent Authorities (**MSCAs**) could comment. An extra 15 days period is allowed for late comments of MSCAs.

When no comments or only comments concerning issues such as uses, exposures, emissions, alternatives which are outside the identification basis of SVHCs have been received in the consultation on an SVHC proposal, ECHA will include the substance subject to an SVHC identification in the candidate list of substances of very high concern for authorisation ('candidate list') directly, without referral of the case to MSC for decision making.

If new information or comments challenging the identification basis of Article 57 of the substance proposed as an SVHC are received in the consultation, the Annex XV dossier for this substance is referred to MSC for agreement seeking.

ECHA will collect and use the comments of the consultation on uses, exposures, emissions, alternatives etc. later in the authorisation process; in particular, when considering prioritisation of the substances from the candidate list to the authorisation list (Annex XIV of REACH).

### **2. MSC task**

MSC plays a vital role in seeking agreement on the identification of substances to be included on the candidate list for eventual inclusion in Annex XIV (list of substances subject to authorisation) (Articles 59(7)-(8)).

If the MSC members do not reach a unanimous agreement on the SVHC identification of a substance, in accordance with Article 59(9) and Article 85(8) of the REACH Regulation, the MSC opinion to be sent to the Commission shall be the majority view of members on this SVHC proposal. Members having minority position(s) shall provide them to the Committee in writing, stating clearly their grounds. Then the MSC opinion, the minority position(s), the original Annex XV dossier and all supporting documentation will be referred to the European Commission for final decision making on the identification of the substance as an SVHC in accordance with the procedure referred to in Article 133(3) of REACH.

### **3. Workflow**

#### **3.1. Comments on the proposals**

When during the consultation period of an Annex XV dossier comments have been received providing new information in support of or against the Annex XV dossier, at the end of the 60-day consultation period,

- 'Comments and response to comments' table (**RCOM**) containing the compiled non-confidential comments only received within the consultation period will be uploaded to the substance-specific information under 'Consultations' section on the ECHA website.

Same RCOM table (confidential or public) will be provided by SECR to the dossier submitter for preparation of responses to the comments.

If during the consultation period of an Annex XV dossier ECHA does not receive any comments or only receives comments not adding any new information to the identification basis of the substance as an SVHC, all of these comments will be made available to the MSC via ECHA website at the end of the consultation period in the RCOM document. However, the Annex XV dossier will then not be referred to MSC for identification of the substance as SVHC and ECHA will include the substance in the candidate list without MSC involvement.

### 3.2. Types of comments not triggering MSC involvement

The following types of comments should not trigger MSC involvement and agreement seeking:

- Comments not providing any kind of new information on the SVHC Annex XV dossier. Typical examples of this kind are expressions of support for the proposal without any new scientific information. Another example is a comment challenging identification of the substance as an SVHC but not giving references or scientific justification why the substance should not be an SVHC.
- Comments on alternatives, use, exposures and risks which do not affect identification of an SVHC. Such comments would be considered in the context of the next step in the authorisation procedure when ECHA prepares its recommendation on substances that would be prioritised for inclusion in Annex XIV (List of substances subject to authorisation).
- Comments not questioning the properties for identification of SVHC but suggesting use of other regulatory processes than authorisation. Such comments should be considered in the context of the next step when ECHA prepares its recommendation on substances that would be prioritised for inclusion in Annex XIV (List of substances subject to authorisation).

### 3.3. When to apply the written procedure and when to address the dossier in MSC meeting

By the time a substance is referred to MSC, it has to be decided whether the dossier will be addressed via a written procedure or at a MSC meeting.

Rules regarding written procedures in general are laid down in Article 19 of MSC Rules of Procedure (RoPs), but they do not explicitly define who can decide whether or not the written procedure has to be applied and what the basis of the decision is. Application of the written procedure should be considered in the light of the main task of MSC, *i.e.*, to resolve divergences of opinions. Thus the decision should be based on likelihood for finding an agreement through the written procedure. On the basis of the comments received, it will be decided whether the written procedure should be applied.

The kinds of comments received and the reasons provided for identification of the substance as an SVHC may justify use of the written procedure. The MSC members are welcome to indicate after the commenting period is over (60 days after the start of the procedure) and before the referral (75 days after the start of the procedure) if any of the issues raised in the consultation would need to be discussed in a meeting. Otherwise, the MSC Chair, in close consultation with the Dossier Submitter and the MSC member from the dossier submitter's member state proposes the route for agreement seeking. A decision on application of the written procedure for finding the agreement applies normally in the following circumstances:

- Annex XV dossiers concerning CMR substances included in Annex VI of Regulation (EC) No. 1272/2008

The MSC Chair would normally make a decision to address the proposal in a meeting in cases where valid new technical/scientific information is provided challenging the proposal in the Annex XV dossier.

When comments received are of editorial nature and/or are considered as properly responded by the dossier submitter, MSC Chair may propose to seek agreement in written procedure.

Taking into account the MSC members' indications/preferences (if any) on the way for addressing a substance for agreement seeking, the MSC Chair will make the final decision on the chosen procedure (written procedure versus meeting) after closure of the consultation period (60 days after start of the procedure) and before the referral (75 days after the start of the procedure).

#### 3.4. Referral of the Annex XV dossier to MSC and basis for seeking agreement in MSC

When MSC involvement is triggered, within 15 days from the end of the 60 days consultation period the MSC Chair will refer the Annex XV dossier to MSC for finding an agreement. A referral letter will be shared via MSC IT platform indicating the referral period (starting and closing date for agreement seeking) and documents that are/will be referred to MSC as well as the procedure (written procedure or meeting) that will be used for finding the agreement.

The documents that will be provided for finding the MSC agreement are:

- Annex XV dossier
- Draft Agreement
- Draft Support Document (**SD**)
- RCOM document, as provided by the dossier submitter.

For SD all information that is not related to identification of the substance as an SVHC (like information on uses and exposures) will be removed by SECR from the original Annex XV dossier (part II). That information is used for the next step of the authorisation process when ECHA prepares its recommendation on substances that would be prioritised for inclusion in Annex XIV (List of substances subject to authorisation). Otherwise SD consists of part I of the original Annex XV dossier updated by the dossier submitter due to any relevant new information and/or additional data received in the consultation period. New information in SD (added/deleted from Annex XV dossier) will be indicated to MSC in a tracked changes version.

Background information is provided in RCOM (including comments and response to comments prepared by the dossier submitter).

Because of the short preparation time after the closure of the consultation the draft agreement, SD and RCOM may be submitted to MSC some days after the formal referral of the Annex XV dossier to MSC. In such case, this will be indicated in the referral letter. It is noted that the ultimate deadline set by the RoPs for submission of documents for a meeting is 10 days before the meeting.

SECR will alert MSC members also by email about the referral and start of the MSC agreement seeking period.

Once an SVHC Annex XV dossier is referred to MSC, MSC members are not expected to make new comments in the course of the discussion but seek agreement on the basis of the documents they have been provided with (Annex XV dossier, comments, RCOM, draft agreement and draft SD).

#### 3.5. Preparation of the draft agreement

The draft agreement is prepared by SECR who will work in collaboration with the dossier submitter to be able to ensure that the draft agreement, SD and RCOM are in line with each other. A standard format for an agreement is used containing information on the preceding process of identification of the particular substance as an SVHC, the agreement text and its legal basis as well as a summary of the justification from SD. The draft agreement will refer to SD which provides the detailed justification for the agreement.

### 3.6. Preparation of the opinion

If MSC has not been able to find unanimous agreement on the identification of an SVHC an opinion of the MSC reflecting the majority view of members shall be prepared in accordance with Article 59(9) and Article 85(8) of the Regulation. In case the majority agrees with the MSC draft agreement used for the MSC vote, the draft agreement document will be the basis for the opinion document. In case the majority view disagrees with the draft agreement a separate document will be prepared in which the reasons for that disagreement are provided. That document shall then constitute the opinion of the MSC. A member having a minority view is expected to prepare a document in writing for the minority view stating clearly the grounds for the minority view. MSC-Ms may decide to jointly submit a minority view.

The MSC majority opinion and the MSC minority view(s) (provided in (a) separate document(s)) on the identification of the substance as SVHC will be provided to the Commission together with other documentation that is needed to support their further decision making.

### 3.7. Written procedure

Written procedure can be applied for

- seeking the MSC agreement on identification of an SVHC
- any other issues arising.

SECR will alert MSC-Ms by email about the start of a written procedure.

When a written procedure is launched for finding an agreement on identification of an SVHC, a launching note is shared via the MSC IT platform indicating the deadline for the written procedure and the documents for which the agreement is sought for.

SECR will request the members to provide a clear agreement on draft agreement and SD. Members may agree (YES), disagree (NO), request the Chair to stop the written procedure (STOP) or abstain.

If a member disagrees (a NO vote), justification for the vote is required which constitutes a minority view. Justification should focus on scientific and technical information and their match with the criteria or on the legal basis of the draft agreement. In case there is not a unanimous agreement, SECR will prepare an opinion in line with section 3.6 as outlined above.

A member may wish to indicate to SECR to stop the written procedure (STOP) if he/she considers that further discussion on the proposal is necessary. The Chair may then decide to terminate (see 3.8) the written procedure on that specific proposal and move the agreement seeking to take place in the following plenary meeting.

Abstention in written procedure is when the votes submitted contains an entry without a vote, and such a submission is counted for the quorum.

A written procedure report will be prepared and presented at the next MSC meeting after the written procedure closes.

### 3.8. Suspension/Termination of written procedure

The written procedure can be suspended or terminated when *major and justified objections* (RoPs) are submitted to SECR by MSC members.

When the reasons for the suspension of the written procedure are, e.g. requests for clarification on documents subject to written procedure, editorial errors spotted, procedural mistake identified, missing/wrong documents provided, etc.), SECR may suspend the written procedure for a certain period of time to make the necessary corrections and then re-open it for agreement seeking on the SVHC proposal under consideration with an extended deadline for members' voting.

When a MSC member submits *major and justified objections* during the written procedure, the agreement seeking for identification of an SVHC shall then be postponed to the next MSC meeting, which must take place within the 30 days referral period for finding the agreement on identification of a SVHC.

Objections shall be *considered major and justified* when they express lack of clarity of scientific and technical information, problems with match of data with the criteria as provided in Art. 57 or problems with the legal basis of the draft agreement.

If such major and justified objections are expressed SECR shall inform MSC of the termination of the written procedure and its grounds. In addition, the MSC will be notified about the meeting (within 30 days from referral) where a draft agreement and draft SD would be on the agenda.

Objections shall **not** be *considered major and justified* when there is an agreement on the identification of SVHC, but one or more members suggest modification of certain details of SD.

#### **4. Dossier submitters' and stakeholder organisations' participation to the MSC meetings during SVHC discussions**

##### 4.1. Participation of dossier submitter to MSC meetings

As a general rule the dossier submitter (MSCAs or ECHA) are invited to make an introduction to their SVHC proposal at the meeting and to respond to questions concerning their RCOM and draft SD. The dossier submitters are expected to be present for their specific agenda item as well as to prepare the necessary modifications to the draft SD and draft agreement of MSC due to the conclusions drawn as result of discussion at the MSC meeting. SECR will assist the MSCA dossier submitter in revision of the documents.

##### 4.2. Participation of observers from accredited stakeholder organisations (ASO) in MSC meetings

As referred to in Article 6 (6)-(10) of MSC RoPs, the ASO observers agreed by MSC to be invited to take part in its work may participate in the SVHC identification process while respecting the provisions of the ECHA Code of conduct for observers<sup>1</sup>.

Unless the plenary session is closed for stakeholder observers<sup>2</sup>, MSC ASO observers may contribute to the Committee's SVHC discussions, where necessary.

#### **5. Deadlines, communication, ways to facilitate finding an agreement**

##### 5.1. Deadlines

Following the referral of an SVHC Annex XV dossier, MSC will have 30 calendar days to find an agreement on this SVHC proposal.

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<sup>1</sup> Code of conduct for observers at ECHA meetings  
([http://echa.europa.eu/documents/10162/13559/conduct\\_code\\_stakeholder\\_observers\\_en.pdf](http://echa.europa.eu/documents/10162/13559/conduct_code_stakeholder_observers_en.pdf))

<sup>2</sup> Open and closed and open sessions of the MSC plenary meetings  
([http://echa.europa.eu/documents/10162/13578/Closed\\_and\\_open\\_sessions\\_of\\_msc\\_plenary\\_meetings.pdf](http://echa.europa.eu/documents/10162/13578/Closed_and_open_sessions_of_msc_plenary_meetings.pdf))

If MSC cannot find unanimous agreement, SECR will prepare the opinion, according to section 3.6 outlined above. Any member holding a minority view shall submit a document with the minority position and grounds to SECR. SECR will upload both the MSC opinion and the minority view(s) on MSC's IT platform without undue delay after the meeting or closure of a written procedure.

### 5.2. Communication

All documentation to the members and other meeting participants will be made available via the MSC IT platform or by other means,. The members will also be informed about the start of any written procedure/consultation by email, which will also specify how and by when they should respond.

All documentation, except those including confidential information or prepared for a closed session, will be made available to the observers similarly as for the members and other meeting participants.

### 5.3. Ways to facilitate finding an agreement in MSC

#### *5.3.1 Informal exchange of views on SVHC proposals before referral to MSC*

Following the end of the consultation period and prior to the referral of the relevant SVHC cases for which comments have been received that trigger the MSC involvement, SECR will analyse the consultation comments (based on the criteria specified in section 2) and the dossier submitter's responses and will inform MSC of the chosen decision making procedure (written procedure or meeting) envisaged for each of the submitted SVHC proposals.

#### *5.3.2 Communication tools*

For all formal communications between MSC and SECR, the MSC functional mailbox ([msc@echa.europa.eu](mailto:msc@echa.europa.eu)) or MSC IT platform for confidential information is to be used.

#### *5.3.3 Discussions on online platforms*

Members may be offered an option to discuss online among members before expressing formally a position on a document. It is important to ensure that all comments and positions will be available to all MSC members and the administration of these comments (e.g. chats or online comments) can be carried out in a more efficient and smooth way.

#### *5.3.4 Preparatory web-conferences/teleconferences*

To facilitate the reaching of an agreement either in a written procedure or in a foreseen meeting preparatory web- or teleconferences may be organised by SECR as appropriate. MSC members proposals for such meetings, including justification for the need for such, shall be submitted by e-mail to SECR ([msc@echa.europa.eu](mailto:msc@echa.europa.eu)).

Normally all MSC members are invited to take part in the preparatory web-/teleconferences. SECR decides after consulting the members whether observers would also be invited. Web/teleconferences could also be organised for a specific group of members (e.g. standing working group or *ad-hoc* working group).

The agenda, the relevant documents if needed and the exact date and time of preparatory web-/teleconference as well as other practical arrangements will be communicated to the participants via MSC IT platform.

#### *5.3.5 Working outside the MSC plenary meeting*

To facilitate reaching an agreement during a MSC meeting, a subgroup may be set up consisting of the dossier submitter(s) and any interested Committee members/experts, supported by SECR. Such a subgroup would work under control of plenary to draft

compromise texts or wordings, in parallel with the plenary meeting, which then could be brought back to the same MSC meeting for agreement seeking, or for finding other solutions.

#### *5.3.6 Working groups*

Working groups can be established, in accordance with Article 17 of the MSC RoPs, to help the MSC finding an agreement on specific SVHC proposals or other relevant issues, if necessary.

#### *5.3.7 Manual of Decisions (MoD)*

MoD in accordance with Article 77(2) (m) of REACH Regulation is intended for keeping consistency on conclusions of MSC. Following a proposal made by any MSC Member or SECR, MSC can decide to take up an issue into its MoD. MSC Stakeholder Observers may make proposals for additions to the Chair of MSC. MoD should focus on recording the principles applied in implementation of the tasks of MSC.