

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

(Update adopted on 16 June 2017)

### Background

The purpose of this document is to establish principles to be applied in the work of MSC (between members (MSC-M) and between members and the Secretariat of MSC (MSC-S)). This part of the 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 public consultation on the SVHC Annex XV reports 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 public 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 public consultation, the Annex XV dossier for this substance is referred to MSC for agreement seeking.

ECHA will collect and use the comments of the public 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 potential 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, 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. Communication of comments to MSC

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, the following actions will be taken:

- MSC-S informs MSC that comments on the dossier have been received. This information note would alert MSC that the dossier may be addressed in the MSC.
- '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 'Public consultation' section on the ECHA website.

Same RCOM table (confidential or public) will be sent by the ECHA Secretariat 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 of substances of very high concern for authorisation ('candidate list') without MSC involvement.

After closure of the consultation period MSC-S will provide MSC with a list of substances for which comments have been received (as provided in RCOM) but which in themselves have not triggered the MSC involvement in the identification of the substance as SVHC. MSC-S will base its conclusions on the type of comments and on the criteria which are laid down in this document under heading 3.2. "Types of comments not triggering 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 (MSC-Ms) 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 MSC-S will make the decision on application of the written procedure for finding the agreement normally in the following circumstances:

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

MSC-S would normally make a decision to address the proposal in a meeting in the following circumstances:

- Valid new scientific information is provided challenging the proposal or suggesting to add new supporting scientific information in the Annex XV dossier
- Substances for which Article 57 (d) or (e) is proposed to be used as the legal basis
- Substances for which Article 57 (f) is proposed to be used as the legal basis.

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 also on proposals for SVHC identification under Article 57 (d), (e) and (f).

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

Within 15 days from the end of the 60 days consultation period MSC-S will refer the Annex XV dossier to MSC for finding an agreement. A referral letter will be uploaded on MSC S-CIRCABC 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 (in particular Annex XV report)
- Draft Agreement
- Draft Support Document (SD)
- Response to comments (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 ECHA secretariat from the original Annex XV dossier (part II). That information will be presented 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 report 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 report) 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.

MSC-S will alert MSC-Ms 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-Ms 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, response to comments, draft agreement and draft SD).

### 3.5. Preparation of the draft agreement

The draft agreement is prepared by the ECHA Secretariat. The ECHA Secretariat will work in collaboration with the dossier submitter when preparing the draft agreement 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 become the opinion document and MSC-S will change the references in that document from 'draft agreement' to the 'opinion' and will update the procedural part accordingly. 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.

MSC-S 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 uploaded on MSC S-CIRCABC indicating the deadline for the written procedure and the documents for which the agreement is sought for.

MSC-S will request the members to provide a clear agreement on draft agreement (DA) and SD (YES) or disagreement (NO) on the DA and SD. If a member disagrees on DA or SD, 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, MSC-S will prepare an opinion in line with section 3.6 as outlined above.

A member may wish to indicate to MSC-S to stop the written procedure (STOP) if he/she considers that further discussion on the proposal were 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.

After closure of any written procedure MSC-S will prepare a written procedure report that will be uploaded on MSC S-CIRCABC.

### 3.8. Suspension/Termination of written procedure

The written procedure can be suspended or terminated when *major and justified objections* (RoPs) are submitted to MSC-S 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.), MSC-S 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 or problems with the legal basis of the draft agreement.

If such major and justified objections are expressed MSC-S shall inform MSC of the termination of the written procedure and its grounds. In addition, MSC-S will notify the MSC 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 responses to the public consultation comments (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. ECHA Secretariat 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 ASO 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.

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<sup>1</sup> Code of conduct for stakeholder observers in the 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))

## 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.

If MSC cannot find unanimous agreement, MSC-S 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 MSC-S. MSC-S will upload both the MSC opinion and the minority view(s) on MSC's dedicated 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 on the designated S-CIRCABC site for MSC or by other means, organised in specific folders. Besides any S-CIRCABC notifications, the members will also be informed about the start of any written procedure/consultation by email. Any responses to any invitation for MSC members to respond or comment are to be sent to the functional mailbox [msc@echa.europa.eu](mailto:msc@echa.europa.eu).

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, MSC-S will analyse the public 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.

If such a need is identified, MSC-S will organise MSC discussions on specific SVHC proposals in a web- or teleconference or a face-to-face expert meetings.

If MSC happens to have a meeting after closure of the consultation process but before the referral of the SVHC dossier(s) to MSC, MSC may also discuss and conclude on issues that would facilitate finding an agreement.

#### *5.3.2 Communication tools*

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

#### *5.3.3 Web-conferences/Teleconferences*

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

Normally all MSC members are invited to take part in web-/ teleconferences. MSC-S decides after consulting the members whether observers would also be invited. 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 web-/teleconference as well as other practical arrangements will be communicated to the participants via MSC S-CIRCABC.

#### *5.3.4 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 MSC members, supported by the ECHA secretariat. 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.

#### *5.3.5 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.

#### *5.3.6 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 the MSC-S, MSC can decide to take up an issue into its MoD. MoD should focus on recording the principles applied in implementation of the tasks of MSC. Any procedures and format for MoD will be further developed by the secretariat jointly with MSC at a later stage.