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**Working procedure of the Member State Committee (MSC)
in providing an opinion
on ECHA's draft Recommendation of priority substances
to be included in Annex XIV**

(Update adopted on 17 June 2021)

Background

The purpose of this document is to describe principles that are applied in the work of MSC (among MSC members) themselves, and between members and the ECHA Secretariat in providing the opinion on the draft Recommendation of priority substances to be included in Annex XIV of the REACH Regulation, using the draft recommendation prepared by the ECHA Secretariat as the basis.

WORKING PROCEDURE OF THE MEMBER STATE COMMITTEE (MSC) IN PROVIDING AN OPINION ON ECHA'S DRAFT RECOMMENDATION FOR INCLUSION OF PRIORITY SUBSTANCES IN ANNEX XIV

1. Process description

The main provisions regarding the inclusion of substances in Annex XIV of the REACH Regulation are laid down in Article 58 of REACH.

ECHA's secretariat (**SECR**) regularly assesses the substances of very high concern (**SVHC**) from the Candidate List to determine which ones should be included in the Authorisation List (Annex XIV of the REACH Regulation) as a priority.

The prioritisation is based on information on the intrinsic properties, the uses (in particular their wide-dispersiveness) and the volumes of the substances on the EU market that fall within the scope of the authorisation requirement. ECHA's priority setting approach¹ currently applied to carry out the prioritisation is publicly available on ECHA's website.

Based on the priority, SECR prepares a draft recommendation and invites all interested parties to submit comments on it during a 3-month consultation. This draft includes a proposal² for Annex XIV entries, including ranges of latest application dates (LADs)³ and sunset dates.

The Member State Committee (**MSC**) prepares its opinion on the draft recommendation taking into account the comments received during the consultation. The opinion of the Committee and the comments received are considered when ECHA finalises its recommendation, which is then submitted to the European Commission, for its decision on the substances to be included in the Authorisation List.

2. MSC task

MSC forms and adopts an opinion on the draft recommendation taking into account

- the prioritisation results for the substances from the Candidate List for inclusion in the Authorisation List (Annex XIV),
- ECHA's draft recommendation and the comments received during the consultation.

MSC reviews whether the prioritised substances meet the criteria of REACH Article 58(3) and that the agreed approaches^{1,2} have been applied by ECHA. The MSC opinion usually covers:

- the content of proposed Annex XIV entries (Identity and intrinsic properties of the substance);
- Transitional arrangements (sunset date, application date);
- Review periods for certain uses, if appropriate;
- Exempted uses or categories of uses;
- Exemption for product and process oriented research and development) and
- any other issues, as relevant.

The MSC opinion should be specific enough with the necessary justifications to allow SECR to modify or amend the proposed draft recommendation where appropriate, and

¹ https://echa.europa.eu/documents/10162/13640/recom_gen_approach_svhc_prior_2020_en.pdf/fbbd748b-22dc-38c2-9b4c-58c6bc80c930

² Prepared in accordance with ECHA's General approach for defining the REACH Annex XIV entries: https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_2020_en.pdf/5d331f77-6613-2f38-e787-1b54dfcde8e5

³ The specific LAD allocation is done when finalising the recommendation taking full account of the information received in the consultation.

indicate the (lack of) support of MSC for the substances to be included in the recommendation.

For that purpose, MSC appoints a rapporteur, a co-rapporteur and a working group (as needed) to prepare a draft MSC opinion. The draft opinion is then finalised and adopted by MSC, and provided to the SECR for utilisation when finalising ECHA's recommendation for submission to the Commission.

3. Workflow

3.1. MSC consultation on prioritisation results

Based on the available information⁴ and following the "General approach¹ for prioritisation of SVHCs for inclusion in the authorisation list⁵", SECR prioritises substances from the Candidate List for inclusion in Annex XIV. SECR provide MSC with the prioritisation results of all assessed substances.

MSC may exchange views, or provide written feedback, on:

- information used for the priority assessment,
- application of the general approach,
- aspects to be further considered by SECR when prioritising substances to be recommended and/or when preparing the draft recommendation.

SECR takes into account these MSC comments when preparing its draft recommendation for the 3-month consultation.

In the event that SECR considers changing its general approach for prioritisation, the view of MSC will also be sought.

3.2 Appointment of a (co-)rapporteur(s) and potential Working Group establishment

In accordance with Article 87(1) of REACH to facilitate its work, MSC identifies and appoints one of its (alternate) members as a rapporteur and, if appropriate, another (alternate) member as co-rapporteur, assigning responsibility for drafting the opinion of MSC on ECHA's draft recommendation on substances to be included in Annex XIV.

For that purpose, the MSC Chair⁶ or SECR on his/her behalf, invites MSC (alternate) members to express their interest in acting as a rapporteur or co-rapporteur for the opinion development on the draft recommendation.

When considering the appointment of a (co-)rapporteur(s), the number of rapporteurships already taken up by the volunteering member(s) is to be taken into account in order to ensure an equitable sharing of the burden of work. Furthermore, potential interest(s) regarding any of the substances included in the draft Recommendation, as declared by the (alternate) member prior to their appointment, has to be taken into account. Upon request of the rapporteur and (co-)rapporteur, MSC may establish a working group consisting of volunteering (alternate) members⁷.

SECR prepares a 'Terms of reference' document, specifying the tasks of the (co-)rapporteur(s) and, if applicable, a draft mandate of the working group as the basis for agreement by MSC.

MSC needs to:

- appoint the MSC (co-)rapporteur(s),
- decide on the establishment of a Working group to support the MSC recommendation opinion development,

⁴ Available information from registration dossiers, SVHC Annex XV dossiers, consultations during the SVHC identification process, other REACH data, and other sources where relevant.

⁵ List of substances subject to authorisation (Annex XIV of REACH)

⁶ The MSC Chair may actively invite members for a rapporteurship in line with the MSC-agreed approach (see MSC-68 and MSC-69 meeting minutes).

⁷ A MSC member may also nominate his/her adviser with proper expertise for MSC WG membership

- appoint the volunteering members and their experts as working group members

and to decide on any other issues arising, either at a meeting or in written procedure launched in accordance with Article 20 of the MSC Rules of procedure (RoPs).

Following the MSC decisions, SECR finalises the appointment process by sending the letters of appointment to the (co-)rapporteur(s), including a request to sign and return the letter of commitment and declaration of (the absence of) potential interests. SECR provides continuous support to the (co-)rapporteur(s) and the working group members during the working group set-up and the whole opinion forming process.

3.3 MSC consultation on ECHA's draft recommendation prior to the consultation process

SECR consults MSC on its draft recommendation and takes into account the comments received from the Committee before publishing it on ECHA's website for a 3-month consultation.

In the event that SECR considers changing its approach for the preparation of draft Annex XIV entries, the view of MSC will also be sought.

3.4 Preparation of MSC opinion

Timelines for developing the opinion of MSC are to be agreed in advance for each recommendation (see 5.1).

Compiled comments are made available without undue delay after the end of the consultation by SECR.. SECR's draft responses and reactions to them, typically in form of response documents, revised prioritisation table (with reasoning) and suggested LAD assignment are provided to MSC as early as possible, in line with the agreed timeline. A compilation of frequently submitted comments and references to the responses (**ComRefs**) may also be made available to MSC. Draft documents may be shared with the (co-)rapporteur and working group before they are shared with MSC to allow more efficient and effective consideration of the comments in preparation of the MSC draft opinion. Further documents are provided by SECR to support the opinion forming as necessary.

Once the draft recommendation is under consultation, MSC may start the preparation of its eventual opinion, while taking full account of the comments received during the consultation. However, it is sufficient for the (co-)rapporteur⁸ to start their work only once ECHA's first draft response documents or any specific summary documents are available. Furthermore, the MSC members and observers are encouraged to provide their contributions and views during the MSC opinion forming process to the MSC rapporteur and SECR.

The (co-)rapporteur(s) and the working group consider contributions and comments received from the MSC members at all opinion-forming stages, as well as the comments received from interested parties during the consultation.

The (co-)rapporteur(s) and the working group prepare the first draft opinion⁹ of MSC on the draft recommendation (i.e. on the version published for consultation), considering the comments received from the interested parties through consultation and from MSC, if appropriate. The first draft opinion is then submitted to SECR for a confidentiality check and is made available to the MSC members and observers for their consultation.

Following the exchange of views in MSC, either at a plenary meeting or in written form, the draft opinion may need to be further modified. The (co-)rapporteur(s) in close collaboration with the working group, if established, ensures that the draft opinion is modified accordingly and provides the revised draft opinion¹⁰ to SECR for MSC adoption.

⁸ And the working group, if established.

⁹ Initially, this may consist solely of the text for the support document.

¹⁰ The draft opinion and its annexed support document

3.5 Adoption of MSC opinion

MSC shall use its best endeavours to reach a consensus on the MSC opinion. In case MSC fails to adopt its opinion by consensus, MSC rapporteur and the working group members prepare an opinion following the majority view(s) of the members. At the time of the adoption, members with a different view shall provide their minority position(s) that are to be annexed to the MSC opinion.

If a member wishes to express a different view on any of the documents (draft opinion and its annexed support document) or parts thereof, justification for the minority view (focusing on scientific and technical information, the match with the criteria or the legal basis) is required which constitutes a minority position.

Usually, MSC is requested to adopt its opinion in a plenary meeting. However, the adoption of a draft opinion may be sought also in written procedure. After closure of any written procedure, SECR will inform MSC about the written procedure outcome.

The adopted MSC opinion, with an Annex containing also the draft recommendation used as the basis for this MSC opinion, are submitted by the MSC Chair to the SECR for consideration when finalising ECHA's recommendation of priority substances to be included in Annex XIV prior to its submission to the Commission for further decision-making.

At the same time, the MSC opinion and its supporting documentation is uploaded to the MSC IT platform and published on the ECHA/MSO website.

4. Interested parties and stakeholder organisations' participation to the MSC meetings during MSC discussions

4.1. 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 may participate in the MSC Recommendation opinion forming process while respecting the provisions of the ECHA Code of conduct for observers¹¹.

Unless the plenary session is closed for stakeholder observers¹², MSC ASO observers may contribute to the Committee's discussions, where necessary.

4.2. Participation of interested parties to MSC meetings

In principle, the interested parties are invited to submit their comments during the consultation on ECHA's draft recommendation. When an MSC member or the MSC Chair identifies a need for further clarification on some comments received, following a member's request and/or with the MSC Chair's decision, in accordance with Article 6 (10) of the MSC RoPs, a representative of this interested party may be invited to a specific part of the MSC plenary discussion.

5. Deadlines, communication, ways to facilitate finding consensus

5.1. Deadlines

Based on SECR's proposal, MSC agrees on the timelines for developing its opinion in advance of the consultation on a draft recommendation.

The deadlines for any expected responses from the members are clearly indicated in all communications with the Committee. The MSC RoPs specify some deadlines linked to the operation of the Committee and the working procedures respect those as well.

5.2. Communication

¹¹ Code of conduct for observers at ECHA meetings

(http://echa.europa.eu/documents/10162/13559/conduct_code_stakeholder_observers_en.pdf)

¹² 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)

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

The rapporteurs and the WG members may be provided with a designated place in MSC IT platform where they can work on relevant opinion forming documentation during this MSC process.

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 the development of an opinion in the MSC

5.3.1 Informal exchange of views on MSC draft opinion

MSC members and observers are encouraged to provide their contributions during the MSC opinion forming process in writing or during the plenary discussions to the MSC rapporteur and SECR.

The rapporteur may request for a meeting of the working group at any point in time during the opinion-forming process, as necessary.

If such a need is identified, SECR will organise these working group discussions in a specific web-/teleconference or a face-to-face meeting.

5.3.2 Working outside the MSC plenary meeting

To facilitate the building-up of the MSC opinion during a MSC meeting with the aim of adoption by consensus, a sub-group may be established consisting of the (co-) rapporteur(s) and selected working group members, as relevant, and any interested MSC members, supported by MSC-S. Such a subgroup would work on texts or specific wordings, in parallel with the plenary meeting, which then could be brought back at the same MSC meeting for adoption, or for finding other solutions.

5.3.3 Working groups

If a working group is established to support MSC and the appointed (co-)rapporteur(s), this will be in accordance with Article 17 of the MSC RoPs. Such working group is composed of MSC (alternate) members and nominated experts/advisers.

5.3.4 Manual of Decisions and Opinions (MoD)

The MoD, in accordance with Article 77 (2) (m) of the 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. The MoD should focus on recording the principles applied in implementation of the tasks of MSC.

Abbreviations

Authorisation List	Annex XIV of the REACH Regulation
ComRefs	Compilation of comments and references to the responses that are provided in a separate Response document
LAD	Latest Application Date
MSC	Member State Committee
MSC MoD	Manual of Decisions and Opinions of MSC
MSC RoPs	Rules of procedure of MSC
Response document	SECR's responses per substance or substance group to comments received
SECR	ECHA secretariat according to Article 76 (g) of REACH Regulation
SVHCs	Substances of very high concern