

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

(Adopted on 25 October 2017)

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 Secretariat of MSC 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 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 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 public consultation. This draft includes a proposal² for Annex XIV entries, including the latest application dates and sunset dates.

The Member State Committee (MSC) prepares its opinion on the draft recommendation taking into account the comments received during the public 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 a public 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/or the opinion could indicate the support of MSC for the recommendation.

For the 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 information³ and following the "General approach² for prioritisation of substances of very high concern (SVHCs) for inclusion in the list of

¹ http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

² Prepared in accordance with ECHA's General approach for defining the REACH Annex XIV entries²:
http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf

³ Available information from registration dossiers, SVHC Annex XV dossiers, public consultations during the SVHC identification process, other REACH/CLP data and other sources where relevant.

substances subject to authorisation”, SECR prioritises substances from the Candidate List for eventual inclusion in Annex XIV. Prior to presenting the outcome of the priority assessment to MSC SECR provides MSC with preliminary prioritisation results of newly assessed substances (i.e. those that were included recently in Candidate List and will only be considered for the first time in the next recommendation round).

MSC exchanges views 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 public consultation.

In the event that ECHA Secretariat 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, at the latest when the draft recommendation is published, MSC identifies and appoints one of its members as a rapporteur and, if appropriate, another 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.

In addition, MSC may establish a working group to support the MSC (co-)rapporteur(s) when preparing the opinion on ECHA’s draft recommendation.

For the purpose, MSC secretariat (MSC-S) invites MSC members to express their interest in acting as a rapporteur, a co-rapporteur or, if relevant, as a working group member⁴ 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, MSC may consider participation by the volunteering member as working group member in the MSC opinion forming on a former ECHA draft recommendation as a potential factor in the appointment.

MSC-S 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,
- 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, MSC-S finalises the appointment process by sending the letters of appointment to the (co-)rapporteur(s) and 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.

⁴ A MSC member may also nominate his/her adviser with proper expertise for MSC WG membership.

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

SECR consults with 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 public consultation.

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). Once the draft recommendation is under public consultation, MSC reviews any available material to facilitate the preparation of its eventual opinion, while taking full account of the comments received during the public consultation.

Compiled comments are made available to MSC and also published on ECHA website. SECR's responses to them, typically in form of response documents and a compilation of comments and references to the responses (ComRefs), are made available to MSC as early as possible in line with the agreed timeline. Draft responses 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.

Furthermore, the MSC members and observers are encouraged to provide their contributions during the MSC opinion forming process to the MSC rapporteur and MSC-S.

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

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

Following the exchange of views in MSC, either at a plenary meeting or in written consultation, 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 opinion to MSC-S for MSC adoption.

3.4 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, MSC-S 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 provided 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 designated IT-platform of MSC and published on the ECHA's 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 agreed by MSC to be invited to take part in its work may participate in the MSC Recommendation opinion forming process while respecting the provisions of the ECHA Code of conduct for ASO observers⁵.

Unless the plenary session is closed for stakeholder observers⁶, 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 public 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 the SECR's proposal, MSC agrees on the timelines for developing its opinion in advance of the public consultation on a draft recommendation.

The deadlines for any expected responses from the members are clearly indicated in the regular communication 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

All documentation to the members and other meeting participants is made available on the designated IT-platform for MSC or by other means, organised in specific folders. The members are also 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.

The rapporteurs and the WG members are 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 finding an agreement in MSC

5.3.1 Informal exchange of views on MSC draft opinion

⁵ Code of conduct for stakeholder observers in the ECHA meetings
(http://echa.europa.eu/documents/10162/13559/conduct_code_stakeholder_observers_en.pdf)

⁶ 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)

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 MSC-S.

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, MSC-S will organise these working group discussions in a specific web-/teleconference or a face-to-face meeting.

5.3.2 Communication tools

For all formal written communications between MSC and MSC-S, the MSC functional mailbox (msc@echa.europa.eu) is to be used. Confidential information may only be exchanged via the designated IT-platform for MSC.

5.3.3 Web-conferences/Teleconferences

To facilitate the MSC opinion forming web- or teleconferences may be organised by MSC-S as appropriate. Any proposals for such meetings, including justification for the need for such, are to be submitted by e-mail to MSC-S (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 are communicated to the participants via MSC-designated IT-platform.

5.3.4 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.

5.3.5 Working groups

If a working group is established to support MSC and the appointed (co-)rapporteur(s) in the development of its opinion on ECHA's draft recommendation and/or on other relevant issues, this will be in accordance with Article 17 of the MSC RoPs. Such working group is composed of MSC members and nominated experts/advisers.

The (co-)rapporteur(s) and the working group work mainly via electronic means. However, the rapporteur may propose a face-to-face meeting of the working group in the remit of a MSC plenary or a web-/teleconference, as necessary, during the opinion-forming process.

5.3.6 Manual of Decisions and Opinions (MoD)

The MoD based on MSC conclusions regarding interpretation and implementation of the REACH Regulation, in accordance with Article 77 (2) (m) of that 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. 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
MSC	Member State Committee
MSC MoD	Manual of Decisions and Opinions of MSC
MSC RoPs	Rules of procedure of MSC
MSC-S	MSC secretariat
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