

26 April 2017

**Working procedures for the Member State Committee
(MSC) to process
draft decisions under substance evaluation -
process description and tasks, including case-owner and
stakeholder participation**

(Update adopted by MSC on 26 April 2017)

This document describes principles that are applied in the work of MSC (between members and the Secretariat of MSC (MSC-S) and amongst the members themselves) in the processing of draft decisions prepared by Member State Competent Authorities (MSCAs) under substance evaluation. It also outlines how case-owners' and stakeholder organisations' participation in the MSC meetings is organised and taken into account when draft decisions from substance evaluation are being discussed.

These working procedures describe handling of draft decisions for a single substance. However, messages (e-mails, notifications) submitted by MSC-S to the members of MSC normally cover several substances that will be in the same phase of the decision making process (cases in one 'round').

List of acronyms/abbreviations is available in an Annex at the end of this document.

1. Process description

1.1 The process of substance evaluation draft decisions

According to Article 45(1)¹ of the REACH Regulation, ECHA is responsible for coordinating the substance evaluation process and ensuring that substances on the Community Rolling Action Plan (CoRAP) are evaluated. In doing so, ECHA shall rely on the Competent Authorities of the Member States.

The outcome of substance evaluation may be:

- Decision requesting further information from Registrant(s) or Downstream Users (DU(s)) where applicable, in order to clarify the concern. This request can address intrinsic properties or exposure and can go beyond the standard information requirements listed in Annexes VII – X.
- Notification of the evaluating Member State to ECHA that no further information needs to be requested for an evaluated substance. This notification should include a report on the analysis performed and the conclusions taken.

Finally, once the substance evaluation has been completed, according to Article 48, the evaluating MSCA decides and notifies ECHA on how it intends to utilise the information obtained in substance evaluation and which risk management route it anticipates will be chosen, where relevant. The possible risk management routes include: authorisation, restriction, harmonised classification and labelling, other Community wide actions (e.g. regarding Water Framework Directive 2000/60/EC, worker protection legislation) or even appropriate national actions. ECHA will share this information with the Commission, the Registrant(s)/DU(s) of the substance and the Competent Authorities of the other Member States.

1.2 Processing of the Draft Substance Evaluation Decisions before referral to the MSC

1.2.1 Examination of a substance evaluation decision requesting for further information

According to Article 46(1), if the evaluating MSCA (eMSCA) considers that further information is required, including, if appropriate, information not required in Annexes VII to X, it shall prepare a draft decision (DD), stating reasons, requiring the Registrant(s)/DU(s) to submit the further information and setting a deadline for its submission.

A draft decision shall be prepared by the eMSCA within 12 months of the publication of the CoRAP on ECHA's website for substances to be evaluated that year. The eMSCA has to first formally submit the draft decision (DD-REG) to ECHA together with the Substance Evaluation report in IUCLID format then ECHA Secretariat (ECHA-S) will distribute it to Registrant(s)/DU(s) for their comments.

The decision making process shall then follow the steps set out in Articles 50(1) and 51(2) to (8).

¹In the following, all references Recitals, Articles or Annexes refer to those of Regulation (EC) No 1907/2006 (REACH Regulation) if not stated differently.

1.2.2 Consultation of the registrant/downstream user on the draft decision

After formally receiving the draft decision from the eMSCA, ECHA-S sends the DD-REG to Registrant(s)/DU(s) (Article 50(1)) without undue delay. According to Article 46(1), any DDs on substance evaluation (*DD-REG prepared by eMSCA*) will be notified to the Registrant(s)/DU(s).

The Registrant(s)/DU(s) has the right to comment on the DD-REG within 30 days. ECHA-S shall inform the eMSCA of the Registrant(s)/DUs' comments (Article 50(1)) without undue delay.

The evaluating MSCA shall take any comments into account and may amend the draft decision accordingly (*DD-MSCA/ECHA*). The REACH Regulation does not specify any deadline for the evaluation by MSCA for taking into account the comments and continue the process. It is expected that the draft decision is however processed within a reasonable time that avoids unnecessary delays in the decision making.

1.2.3 Consultation of the Member State Competent Authorities on the substance evaluation draft decision

Pursuant to Article 52(1) after receipt of comments of the Registrant(s)/DU(s) and consequently possible amendment of the draft decision by the evaluating MSCA, MSCA shall notify the draft decision (*DD-MSCA/ECHA*) to the other MSCAs and ECHA including the comments of the Registrant(s)/DU(s)². MSCAs and ECHA-S may propose amendments to the draft decision within 30 days of circulation (Article 51(2)).

If no proposals for amendment (PfA) are submitted from the MSCAs and ECHA (Article 51(3)), ECHA shall take the decision as final in the version notified to MSCAs (*DD-MSCA/ECHA becomes ECHA-D*), without any involvement of MSC.

1.2.4 Referral of the draft decision to MSC and role of MSC in decision making of substance evaluation

If there are proposals for amendment from other MSCAs and/or ECHA, ECHA-S shall refer the draft decision (*DD-MSCA/ECHA*) with any proposal(s) for amendment within 15 days after the end of the 30-day commenting period for MSCAs and ECHA to MSC (Article 51(4)). Table with responses to the PfAs prepared by the eMSCA (RCOM document) is made available to MSC at this stage. The evaluating MSCA may modify the DD on the basis of proposed amendment(s). MSC has 60 days to reach unanimous agreement on the draft decision after the referral³ (Article 51(6)).

In parallel, ECHA-S shall forthwith communicate the proposals for amendment of the MSCAs/ECHA to the Registrant(s)/DU(s) and allow 30 days to comment (Article 51(5)) on these proposed amendments. Registrant(s)/DU(s) comments on the PfA(s), if any, will be submitted to MSC for MSC to take them into account (Article 51(4)) in the decision making process.

It should be noted, that the 30-day period for the Registrant(s)/DU(s) to comment on the proposal(s) for amendment of MSCAs/ECHA will expire at the earliest only 15 days after the referral of the case to MSC. The referral date triggers the commencement of the 60 day-period for the MSC to find unanimous agreement.

² Evaluating MSCA needs to know at this stage to which MSC meeting the DD will potentially be addressed and start the MSCA and ECHA consultation at the dates previously fixed to reach such meeting.

³ In cases where MSC fails to reach unanimous agreement see point 3.11 of the Workflow.

2. Task of the MSC

The task of MSC is to resolve potential divergence(s) of opinion on the substance evaluation DD proposed by the eMSCA (Article 76(1)(e)) by finding unanimous agreement on the draft decision referred by ECHA-S to MSC, within 60 days of the referral (Article 51(6)).

In performing this task, MSC is invited to seek agreement on the DD based on the PfAs received.

The members of MSC are expected to take into account the documents they have been provided with (draft decision, proposals for amendment of MSCAs/ECHA to the draft decision, responses of the eMSCA to proposals for amendments, and the Registrant(s)/DU(s) comments on the proposed amendments).

The agreement seeking will take place on the basis of the proposed amendments of the MSCAs/ECHA to the (modified) draft decision (*DD-MSCA/ECHA*) and the Registrant(s)/DU(s) comments on these proposed amendments.

3. Workflow

3.1 Notification of the draft decision to MSCAs

The starting point for the current working procedure is the eMSCA notifying the draft decision, possibly modified on the basis of the comments of the Registrant(s)/DU(s) (*DD-MSCA/ECHA*) to MSCAs/ECHA.

Following this notification, MSC-S will inform MSC of the start of the 30-day period for MSCAs/ECHA to propose amendments to the draft decision. The purpose of giving this information is to indicate to MSC as early as possible that in 45 days at the latest (30+15 d), a draft decision may be referred to MSC.

The substance evaluation case related to the draft decision will be given an MSC identification number (SEV-eMSCA-xx/evaluation year) which will also be communicated to MSC at this stage.

3.2 No proposals for amendment from MSCAs

If no proposal(s) for amendment from MSCAs/ECHA were received by the end of the 30-day commenting period, the draft decision will not be referred to MSC. ECHA will then take the decision in accordance with Article 51(3).

3.3 Proposals for amendment from MSCAs/ECHA

If proposal(s) for amendment from MSCAs/ECHA are received, MSC-S will inform MSC after the end of the 30-day commenting period that the draft decision will be referred to MSC. The probable referral date and an estimate for timing of the possible written procedure/MS meeting to find a unanimous agreement on the draft decision will also be provided. MSC-S can indicate which substances will go for written procedure/MS meeting only at the referral stage of the process.

3.4 Selection of procedure for MSC decision making

MSC may seek agreement in written procedure or discuss and seek agreement at its meeting. The eMSCA indicates its preference for the route for agreement seeking i.e. whether agreement should be sought via written procedure or in the MSC meeting. MSC-S is open to discuss these options with the eMSCA if needed. This preference of the eMSCA comes first to MSC-S 13 days after the

ending of the 30-day commenting period of the MSCAs/ECHA on *DD-MSCA/ECHA*, after considering the proposal(s) for amendment. The MSC Chair, in close consultation with eMSCA and the MSC member from the evaluating Member State, determines without undue delay the route for agreement seeking after the end of the Registrant commenting period.

3.5 Referral of the draft decision to MSC

Within 15 days after the end of the MSCA/ECHA's 30-day commenting period the substance evaluation case is referred to MSC. The referral includes the following documents being made available on MSC's designated IT-platform:

- Draft decision as notified by ECHA-S to the MSCAs (DD-MSCA/ECHA) (with notification letter to the MSCAs where appropriate);
- the Response to Comments table (RCOM), which includes
 - all the comments the registrant(s)/DU(s) made on the DD-REG they received from ECHA-S and eMSCA's responses to them and proposal(s) for amendment of MSCAs/ECHA made to the DD-MSCA/ECHA with eMSCA's responses to them. Should the responses of the eMSCA to PfAs not be available on the day of the referral, these responses are to be provided to MSC within three working days;

The RCOM on MSC's designated IT-platform will be updated by MSC-S shortly after the 30-day period for the registrant(s)/DU(s) to comment on MSCA/ECHA's proposal(s) for amendments, with an indication whether comments were received (yes/no), and in case comments were received these will be included.

3.6 Agreement seeking of MSC

The eMSCA may modify the draft decision on the basis of the proposed amendments of MSCAs/ECHA. This DD-MSC (in track changes indicating the modifications) would then serve as the basis of the agreement seeking of MSC and would be provided to MSC as a meeting document or as a document on which the agreement would be sought in written procedure.

MSC will be invited to seek agreement on the draft decision (either DD-MSCA/ECHA or DD-MSC) taking into account all the documents provided. The agreement seeking will take place on the basis of the draft decision, proposed amendments of MSCAs/ECHA to the MSCAs' draft decision (*DD-MSCA/ECHA*) and the Registrant/DU's comments on them. MSC may decide to seek agreement on DD further amended/modified during the meeting.

3.7 Organising a written procedure for agreement seeking

MSC-S will launch the agreement seeking on the draft decision via written procedure if the Chair decides in accordance with point 3.4 that the written procedure is the route of preference. MSC will be requested by a deadline to express clearly if they agree (YES) or if they do not agree (NO) with the draft decision or whether they abstain or whether they would like the MSC Chair to terminate the written procedure for specific DDs (STOP) and justifying why. The draft decision should then be raised for agreement seeking in the next MSC meeting. The written procedure is to be carried out according to the Rules of Procedure of MSC. Abstention in written procedure is when the votes submitted contains an entry without a vote, and such a submission is counted for the quorum.

In case a MSC member does not agree with the draft decision in the written procedure, a justification for disagreement needs to be provided.

If there is an indication that a unanimous agreement would not be reached in the written procedure, the MSC Chair may terminate the written procedure and propose the draft decision for discussion in the MSC meeting in order to find a unanimous agreement.

The MSC Chair may suspend the written procedure (for a specific case or for all the cases) and continue after the reason for suspension has been removed. If there is a risk that the continued written procedure cannot be finished within 60 days after referral, the MSC Chair will terminate the written procedure and propose the impacted draft decision(s) for discussion in the MSC meeting in order to find a unanimous agreement.

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

3.8 Documents for the MSC meeting and agreement seeking at the meeting

All draft decisions referred to MSC will be included on the provisional draft agenda of the next MSC meeting that will be held within the 60-day period starting from the referral of the dossier to MSC. A draft decision for which unanimous agreement in written procedure has been reached will be deleted from the draft agenda as appropriate.

If the DD is to be discussed and to be agreed on in a MSC meeting, all the relevant documents will be provided on MSC's designated IT-platform 10 days before the meeting at the latest.

3.9 Finalisation after unanimous agreement by MSC

If a unanimous agreement in MSC was found, the decision on substance evaluation will be taken by ECHA accordingly after performing a final legal check by ECHA. Following this legal check, ECHA-S may amend the Statement of Reasons in the decision and non-fundamental parts of the decision so as to accurately reflect the agreement of the MSC and remove any inconsistencies in the decision. The decision, amended and agreed at the meeting, will be made available to MSC on its designated IT-platform as soon as possible after the meeting.

3.10 Failing to find unanimous agreement of MSC

If MSC fails to find a unanimous agreement, MSC-S will prepare the documentation to be sent to the Commission where the decision shall be taken with the procedure referred to in Article 133(3). This documentation will include the DD as presented to MSC for agreement seeking, the updated RCOM including also the comments of the Registrant(s)/DU on the proposal(s) for amendment of the MSCAs/ECHA, and the relevant part of the minutes of the MSC meeting or the written procedure report reflecting minority views of the members on the DD.

4. Case-owners⁴ and stakeholder organisations' participation to the MSC meetings during discussions on draft decisions

⁴ MSC Rules of Procedure Article 6, paragraph 7: A case-owner is a registrant concerned or a representative of a group of registrants concerned in the case of joint submissions.

4.1 Codes of conduct

Codes of conduct⁵ apply to nominated representatives of stakeholder organisations, case-owners and other observers invited to take part in MSC meetings as referred to in Article 6 paragraphs 6 to 10 of MSC's Rules of Procedure.

4.2 Protection of confidential business information

Protection of confidential business information, including intellectual property rights, is to be safeguarded. Therefore the following will apply:

The nominated representatives of stakeholder organisations normally participate in the sessions of the MSC meeting where substance evaluation cases are presented to the Committee and initially discussed (Session 1) by the Committee. In the following cases the nominated representatives of stakeholder organisations will not be permitted to participate in such sessions as observers:

- a) the full chemical (IUPAC) name of the substance is claimed confidential under Article 119(2) of REACH;
- b) data on the precise use of the substance (Article 118 of REACH) is relevant for the decision discussion in the MSC meeting, unless the data is known to already be disseminated;
- c) there is another reason to consider the information to be confidential and sensitive to the business of the registrant/DU (e.g. the cases related to the name of unclassified substance referred to in Article 119(1) of REACH, cases referred to in Article 119(2) or in Article 118 of REACH); or
- d) when the Committee decides to hold a discussion in closed session for other reasons.

The MSC Chair, supported by the ECHA-S, decides in advance of the meeting whether the substance evaluation draft decision can be discussed in the presence of nominated representatives of stakeholder organisations. This decision is made after careful examination of the case for potentially confidential information the disclosure of which could undermine the protection of the commercial interests of the Registrant.

The MSC Chair may also always close an open session before or during the proceedings at the written or oral request of a member or when the MSC-Chair considers this as otherwise appropriate. Members should indicate well in advance of the meeting if they request a closed session.

In cases where discussion is held in closed session, the nominated representatives of stakeholder organisations will be briefed in general terms on the conclusions afterwards.

4.3 Admission of a case-owner to an MSC meeting

The case-owner(s) concerned may, as appropriate, be admitted to the Committee meetings when DDs on substance evaluation referred to MSC are presented to the Committee and initially discussed by the Committee (Session 1). This initial discussion at MSC (Session 1) will always take place after the deadline for the Registrant(s)/DU(s) to submit comments on the amendments proposed by MSCAs has passed.

A case-owner is informed by MSC-S of the meeting where the DD is to be discussed. He/She is invited to indicate (by a specified deadline) in advance of

⁵ Code of conduct for stakeholder observers in the ECHA meetings and Code of Conduct for case owners as observers at meetings of Member State Committee

the meeting if he/she wishes to participate in the Session 1 and whether he/she objects to the presence of the nominated representatives of the stakeholder organisations (see also point 4.7).

4.4 Participation of a case-owner in a MSC meeting

Participation of a case-owner in the meeting is not in any way intended to expand or circumvent the provisions of Articles 50 and 51 of REACH, including the right of the case-owners (Registrant(s)/DU(s)) to comment on ECHA's draft decision, the right of the competent authorities of the Member States to propose amendments to the draft decision or the case-owners' (Registrants'/DUs') right to comment on the proposals for amendment of the MSCAs/ECHA.

During the initial discussion (Session 1) the evaluating MSCA presents to the Committee the draft decision, its rationale and background, together with the proposed amendments from the MSCAs/ECHA, as well as the Registrant(s)/DU(s) comments if any, and eMSCA's responses. The Committee may ask any clarifications and exchange initial views during the initial discussion. Representatives of stakeholder organisations (unless the session is closed for stakeholder observers for reasons set out in point 4.2 or 4.3 above) and case-owners may follow this part of the discussion, and contribute to clarifying any discussion items where necessary.

4.5 Case-owners in a MSC meeting

The potential number of case owners interested to participate in the initial discussion may be high. Taking into account the time constraints of the MSC meeting, the space and logistics available and the maintenance of a proper balance of attendance in the Committee as well as the informal nature of the exchange of views at the MSC meetings, the MSC Chair in consultation with the eMSCA will decide which case-owners will be invited to an MSC meeting, choosing from those case-owners that commented on the PfAs received. Normally, for the same SEv substance, MSC-S will invite one case owner representative on behalf of all registrants of the substance in question. Potentially, additional case owners may be invited if necessary, depending on the case. When several substances related to a same substance group are discussed, the Chair may define the relevant representation.

4.6 Session for decision making

Decision making phase (Session 2), *i.e.* when MSC is seeking agreement on the draft decision, shall always be held in closed session, without participation of case-owners.

4.7 Meeting documents for case-owners or stakeholder observers

Case-owners and the nominated representatives of the stakeholder organisations are not provided with access to the meeting documents except for non-confidential presentations at Session 1 in order to respect the confidentiality requirements and sensitivities related to content of the draft decisions, other documents created during the process and registration dossiers. Case-owners should already have in their possession copies of the main documents of the process (*i.e.* the registration dossier, the draft decision and proposals for amendment from MSCAs/ECHA). However, observers are referred to the information on registration dossiers that is published on ECHA's dissemination website.

Confidentiality declarations from case-owners and observers from stakeholder organisations will be required before attendance to a meeting.

4.8 Participation of an accompanying expert of a case-owner or a stakeholder observer

When indicated and justified by the case-owner or a stakeholder observer, participation of an accompanying expert may be permitted following a decision of the Chair of the Committee if the Chair considers that such accompanying expert can bring added value to the MSC discussion. The case-owner or a stakeholder observer shall request permission from the Chair to bring along an accompanying expert at least five days before the meeting. Confidentiality declarations from these accompanying experts will be required before attendance to a meeting.

5. Other practicalities

5.1 Deadlines

The deadlines for any expected responses from the members will be clearly indicated in all the communications with the members. The MSC Rules of Procedure 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 will be made available on MSC's designated IT-platform, organised in specific folders, or by other means. Besides the possibility for automatic IT-platform notifications, the members will also be informed about the start of any written procedure or consultation by email. Responses to any invitation for MSC members to respond or comment are to be sent to the generic email address (functional mail box) MSC@echa.europa.eu or uploaded to the IT-platform's folder for members, unless otherwise specified.

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 Discussions on electronic platforms

Members may be offered an option to discuss among members before expressing formally a position on a document. Advisers and experts might upon request of the member be granted full access to such discussions. It is important to ensure that all comments and positions will be available to all MSC members and the administration of these comments can be carried out in a more efficient and smooth way. If needed, the access to such discussions can be restricted to certain individuals or groups.

5.3.2 Web conference/Teleconferences (TC)

To facilitate the reaching of an agreement either in a written procedure or in a foreseen meeting, web conference or TCs may be organised by MSC-S as appropriate. Committee Member's proposals for a web conference/TC, including justification for the need for such, shall be submitted by e-mail to MSC-S.

Normally all MSC members are invited to take part in web conference/TC. TC's 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 such conference as well as other practical arrangements and MSC conclusions will be communicated to the participants.

5.3.3 Working outside the MSC plenary meeting

To facilitate finding an agreement during a MSC meeting, an informal exchange of views may be arranged between any interested Committee members/experts, supported by the MSC-S and ECHA-S. Such discussions would take place to be able to understand the scientific or technical rationale for different views and to find a solution or a compromise. Reports to the plenary from such informal discussions, as appropriate, would take place at the same MSC meeting for getting response from the plenary to the ideas developed.

5.3.4 Working groups

Working groups can be established to help MSC to find an agreement on draft decisions, if necessary.

5.3.5 Manual of Decisions (MoD)

A MoD in accordance with Article 77 (2) (m) of the REACH Regulation is kept by MSC-S. It is intended for keeping consistency on conclusions of MSC. Following a proposal made by any Committee Member or the MSC-S, 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.

Annex I

LIST OF ACRONYMS

DD-REG: draft decision with statement of reasons on substance evaluation, to be provided for comments to Registrants/DUs.

DD-MSCA/ECHA: draft decision with statement of reasons on substance evaluation, possibly modified on the basis of Registrant(s)/DU(s) comments to be provided for proposal for amendment to MSCAs/ECHA

DD-MSc: draft decisions with statement of reasons on substance evaluation, possibly modified on the basis of Registrant(s)/DU(s) comments and of proposal(s) for amendment of MSCAs/ECHA

ECHA-D: Final decision of ECHA after the MSCA-DD did not receive proposal for amendments from MSCAs or else after unanimous agreement has been reached on MSCA-DD in MSC.

RCOM: response to comments table with evaluating MSCA's responses to the Registrant(s)/DU(s) comments on the DD-REG

Updated/Final RCOM: response to comments table with evaluating MSCA's responses to the

- Registrants'/DUs' comments on the DD-REG and
- proposal(s) for amendment of MSCAs/ECHA on the DD-MSCA/ECHA

DU: Downstream user

DD: Draft decision

ECHA-S: ECHA Secretariat

eMSCA: evaluating Member State Competent Authority

MSC: Member State Committee

MSCA: Member State Competent Authority

MSC-S: Secretariat of the MSC

PfA: Proposal for amendment

Annex II - Timeline for substance evaluation for MSC

