

Helsinki, 9 February 2018

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

(Update adopted on 9 February 2018)

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 processing draft decisions prepared by ECHA under dossier 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 dossier evaluation are being discussed.

This document describes working procedures for handling a single draft decision. However, messages (e-mails, notifications) submitted by MSC-S to the members of MSC normally cover several substances that are in the same phase of the process (cases in one 'round').

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

1. Process description

1.1 The process of testing proposal examinations and compliance checks

The main provisions regarding testing proposal examinations and compliance checks are laid down in Art. 40 and Art. 41 of REACH, respectively. The decision making process is the same for both (see below *1.2 Processing draft decisions*). According to Art. 130 of REACH, all decisions prepared by ECHA shall include a Statement of Reasons.

1.1.1 Examination of testing proposals

All testing proposals submitted in a registration dossier or a downstream user report shall be examined by ECHA Secretariat (ECHA-S) for provision of information specified in Annexes IX and X of REACH for a substance. Subsequently, ECHA-S shall make a draft decision for each testing proposal based on one of the five decisions stipulated in Art. 40 (3) (a-e) of REACH, specifying adequate time limits for submission of the required information (Art. 40 (4)).

ECHA-S shall prepare the draft decision on testing proposals in accordance with the time periods for examination set out in Article 43 of the REACH Regulation.

On testing proposals involving tests on vertebrate animals ECHA-S will launch a public consultation on its website for a period of 45 days (Art. 40(2)). All relevant valid scientific information gathered via such public consultation shall be taken into account by ECHA-S in preparing the draft decision¹.

1.1.2 Compliance checks

Registration dossiers for compliance check will be selected by ECHA-S based on Art. 41 (5) and examined for compliance according to Art. 41(1)(a-d). Within 12 months of starting the compliance check, ECHA-S may draft a decision requiring the registrant to submit any information needed to bring the registration into compliance with the relevant information requirements and specifying adequate time limits for submission of further information (Art. 41(3) and (4)).

1.2 Processing of Draft Decisions

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

According to Art. 50(1), any draft decisions (DDs) on testing proposal examinations and compliance checks prepared by ECHA-S, the DD (draft decision, abbreviated for this step as DD-ECHA) will be notified to the registrant and/or downstream user (DU). The registrant/DU has the right to comment within 30 days. ECHA-S shall take any comments into account and may amend the draft decision accordingly. The REACH Regulation does not specify any deadline for ECHA-S for taking into account the comments and continuing the process.

1.2.2 Consultation of the Member State Competent Authorities on the draft decision

Pursuant to Art. 51(1) after receipt of comments of the registrant/DU and consequently possible amendment of the draft decision by ECHA-S, ECHA-S shall notify the draft decision (DD-MSCA) to the Member State Competent Authorities (MSCAs) including the comments of the registrant/DU. MSCAs may propose amendments to the draft decision within 30 days of circulation (Art. 51(2)).

¹ The 45-day period of public consultation takes place before the Agency prepares and submits its draft decision to the registrant(s)/downstream user(s) so that this period does not affect the later processes of the MSC described in the present working procedures.

If ECHA-S does not receive any proposal for amendment (PfA) from the MSCAs (Art. 51(3)), ECHA shall take the decision in the version notified to MSCAs (DD-MSCA), without any involvement of MSC.

1.2.3 Referral of the draft decision to MSC and role of MSC in decision making of dossier evaluation

If ECHA-S receives proposal(s) for amendment from MSCAs, it shall forthwith communicate the proposals for amendment to the registrant/DU and allow 30 days to comment (Art. 51(5)) on these proposed amendments.

MSC-S shall refer the draft decision as notified to MSCA's (DD-MSCA) with the proposal(s) for amendment received to MSC within 15 days after the end of the 30-day commenting period for MSCAs (Art. 51(4)).

Based on the proposed amendments of the MSCAs ECHA-S may modify the draft decision (Art. 51(4)).

MSC has 60 days to find unanimous agreement on the draft decision after the referral² (Art. 51 (6)).

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

2. Task of the MSC

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

In performing this task, MSC is invited to seek agreement on the information requirements specified in the draft decision on a compliance check in order to bring the dossier into compliance with the REACH requirements referred to in Art. 41(1).

As for draft decisions on a testing proposal examination, MSC is invited to seek agreement on the testing proposal taking into account the options listed in Art. 40 (3)(a-e).

Once a draft decision is referred to MSC, the members of MSC are provided with all the documents used during the dossier evaluation process. The comments of the registrant on the proposed amendments submitted within 15 days after the referral will be made available to MSC shortly after the deadline for the registrant for commenting has passed.

The agreement seeking will take place on the basis of the (modified) draft decision, the proposals for amendment by the MSCAs and the registrant's comments on these proposed amendments.

3. Workflow

3.1 Notification of the draft decision to MSCAs

² In cases where MSC fails to reach unanimous agreement, see 3.11 of the Workflow)

The starting point for the current working procedure is the notification of a draft decision, possibly modified on the basis of the comments of the registrant(s)/DU(s), to MSCAs by ECHA-S.

Following this notification, MSC-S will inform MSC of the start of the 30-day period for MSCAs 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 draft decisions related to a relevant registration dossier will be identified with the name, EC number and CAS number of the substance, the registration number and the latest submission number of the dossier. The dossier evaluation case related to the draft decision will be given an MSC identification number (TPE-xxx/year, CCH-xxx/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 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

If proposal(s) for amendment from MSCAs 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.

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 decision on which agreement seeking procedure to initiate should be made by MSC-S based on the proposed amendments and on the likelihood of finding an agreement through a written procedure. If a dossier evaluation case is considered to be complex and require exchange of views by the members for coming to an agreement MSC-S would address the case at the following MSC meeting. MSC-S may organise web/teleconference with MSC to seek advice which procedure to select for a dossier evaluation case.

3.5 Referral of the draft decision to MSC

Within 15 days after the end of the MSCAs' 30-day commenting period the dossier 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);
- the Response to Comments table (RCOM), which includes
 - all the comments the registrant(s)/DU(s) made on the DD-ECHA they received from ECHA-S and ECHA-S' responses to them, proposal(s) for amendment of MSCAs made to the DD-MSCA with ECHA's responses to them;

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'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

ECHA-S may modify its draft decision on the basis of the proposed amendments of MSCAs. This DD-MSC (in track changes) would then serve as the basis of

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 the DD-MSCA or the DD-MSC) taking into account the documents provided. The agreement seeking will take place on the basis of the draft decision, proposed amendments of MSCAs and the registrant's comments on the proposed amendments. MSC may decide to seek agreement on a draft decision which is 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 MSC-S 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), if they do not agree (NO) with the draft decision or whether they abstain or whether they would like MSC-S to stop the written procedure for specific draft decisions (STOP). The written procedure is to be carried out according to the Rules of Procedure of MSC.

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.

MSC Chair may suspend the written procedure (for a specific case or 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 closed.

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 within the 60-day period starting from the referral of the draft decision. A draft decision for which unanimous agreement in written procedure has been reached will be deleted from the draft agenda as appropriate.

If the draft decision 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 the compliance check or the testing proposal examination will be taken by ECHA accordingly after performing a final (legal) check by ECHA. Following this check, ECHA may introduce editorial changes in the decision that are of a non-fundamental nature 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. ECHA-S will make a non-confidential version of this decision available on its website once issued to the Registrant.

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 draft decision as presented to MSC for agreement seeking, the updated RCOM including also the comments of the registrant/DU on the proposal(s) for amendment of the MSCAs, and the relevant part of the minutes of the MSC meeting or the written procedure report reflecting the minority views of the members on the draft decision.

4. Case-owners³ and stakeholder organisations' participation to the MSC meetings during discussions on draft decisions

4.1 Codes of conduct

Codes of conduct⁴ 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 dossier 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 indispensably linked to the question whether an animal test is necessary or in a compliance check case where data is proposed to be waived based on limited exposure or where precise use of the substance would otherwise be relevant for the decision, 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 (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); or
 - d) when the Committee decides to hold a discussion in closed session for other reasons.

³ 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 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 MSC Chair, supported by the ECHA-S, decides in advance of the meeting whether the dossier 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 concerned may, as appropriate, be admitted to the Committee meetings when draft decisions on dossier evaluation referred to MSC are presented to the Committee and initially discussed by the Committee (Session1). This initial discussion at MSC (Session 1) will always take place after the deadline for the registrant to submit comments on the amendments proposed by MSCAs has passed.

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

During the initial discussion (Session 1) the Committee is presented the draft decision, its rationale and background, together with the proposed amendments from the MSCA's, as well as the registrant's/ DU's comments if any, and ECHA'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 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 or nominated stakeholder observers.

4.6 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). 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.

4.7 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 current 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 mailbox) 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 Secretariat. 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 group 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.

LIST OF ACRONYMS

DD-ECHA: draft decision with statement of reasons on testing proposal examinations or compliance checks, to be provided for comments to registrants/DUs

DD-MSCA: draft decision with statement of reasons on testing proposal examinations or compliance checks, (possibly) modified on the basis of registrants'/DUs' comments to be provided for proposal for amendment to MSCAs

DD-MS: draft decision with statement of reasons on testing proposal examinations or compliance checks, possibly modified on the basis of registrants'/DUs' comments and of proposal(s) for amendment of MSCAs provided for MSC

RCOM: response to comments table with

- registrants'/DUs' comments on the DD-ECHA
- proposal(s) for amendment of MSCAs on the DD-MSCA
- ECHA Secretariat's responses to the above comments/proposal(s) for amendment

Updated RCOM: response to comments table

- updated with the registrants'/DUs' comments on the proposal(s) for amendment of MSCAs

DD: Draft decision

DU: Downstream user

ECHA-S: ECHA Secretariat

MSC: Member State Committee

MSCA: Member State Competent Authority

MSC-S: Secretariat of the Member State Committee

MoD: Manual of Decisions

PfA: Proposal for amendment

ANNEX 2 - Timeline of dossier evaluation for MSC

