Helsinki, 17 June 2021

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 17 June 2021)

This document describes principles that are applied in the work of MSC (between members and the ECHA Secretariat (**SECR**) and amongst the members themselves) in the processing of draft decisions prepared by Member State Competent Authorities (**MSCA**s) 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 SECR 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 Secretariat (**SECR**) is responsible for coordinating the substance evaluation process and ensuring that substances on the Community Rolling Action Plan (**CoRAP**) are evaluated. In doing so, SECR shall rely on the Competent Authorities of the Member States (**eMSCA**).

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(s). The request(s) can address intrinsic properties or exposure and can go beyond the standard information requirements listed in Annexes VII – X.

Following review of the available and new information, the eMSCA will either:

- conclude that the risks are sufficiently under control with the measures already in place, or will propose EU-wide risk management measures[2].

  Or,

- if necessary, initiate a new decision-making process for requesting further information by sending a new draft decision to ECHA.

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

1.2.1 Examination of a substance evaluation decision requesting further information

According to Article 46(1), if the eMSCA considers that further information is necessary, 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 DD 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. Then SECR will notify 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).

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

After formally receiving the DD from the eMSCA, SECR 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).

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

[2] Further information on the substance evaluation process is available on ECHA's website: https://echa.europa.eu/regulations/reach/evaluation/substance-evaluation

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

The eMSCA shall consider any Registrant(s)/DUs' comments and may amend the DD accordingly *(**DD-MSCA/ECHA**)*. The REACH Regulation does not specify any deadline for the evaluation by MSCA of the Registrant(s)/DUs' comments and the continuation of the process.

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 DDby the eeMSCA, the eMSCA shall notify the draft decision *(DD-MSCA/ECHA)* to the other MSCAs and ECHA including the comments of the Registrant(s)/DU(s)[3]. MSCAs and SECR may submit proposals for amendment (PfAs) to the DD within 30 days of circulation (Article 51(2)).

If no PfAs 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)*. In such instances, MSC involvement is not triggered.

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

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

In parallel, SECR shall communicate the PfAs of the MSCAs/ECHA to the Registrant(s)/DU(s) and allow 30 days to comment (Article 51(5)) on these PfAs. Registrant(s)/DU(s) comments on the PfA(s), if any, will be submitted to the eMSCA and MSC to consider (Article 51(4)) in the agreement seeking process.

It should be noted, that the 30-day period for the Registrant(s)/DU(s) to comment on the PfAs 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. 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 DD referred by SECR to MSC, within 60 days of the referral (Article 51(6)).

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

[3] Evaluating MSCA must 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.

[4] In cases where MSC fails to reach unanimous agreement see point 3.7 of the Workflow.

The MSC members are expected to consider the provided DD, PfAs, responses of the eMSCA to PfAs, and the Registrant(s)/DU(s) comments on the PfAs.

The agreement seeking will be based the PfAs of the MSCAs/ECHA to the (modified) draft decision and the Registrant(s)/DU(s) comments on these PfAs.

3. Workflow

3.1 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 substance evaluation case related to the DD will be assigned an MSC identification number (SEV–eMSCA-xx/evaluation year) which will also be communicated to MSC at this stage. The referral includes the following documents being made available on MSC IT platform:

- DD as notified by SECR to the MSCAs (DD-MSCA/ECHA);
- the Response to Comments table (RCOM), which includes
    - PfA(s) 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 IT platform will be updated by SECR shortly after the 30-day period for the registrant(s)/DU(s) to comment on MSCA/ECHA's PfAs, with an indication whether comments were received (yes/no), and in case comments were received these will be included.

3.2 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 Chair and SECR/ discuss these options with the eMSCA and the MSC member from the eMSCAs Member State, if needed. This preference of the eMSCA comes first to SECR 13 days after the ending of the 30-day commenting period of the MSCAs/ECHA on *DD-MSCA/ECHA,* after considering the PfAs. The MSC Chair, in close consultation with eMSCA and the MSC member from the eMSCA, determines without undue delay the route for agreement seeking after the end of the Registrant's commenting period.

3.3 Agreement seeking of MSC

The eMSCA may modify the DD on the basis of the PfAs of MSCAs/ECHA. This DD-MSC (in track changes indicating the modifications) would then serve as the basis of the agreement seeking of MSC.

The agreement seeking will take place on the basis of the DD, PfAs 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 the DD further amended/modified during the meeting. RCOM updated with registrant's comments on PfAs will be provided to support agreement seeking (updated RCOM).

3.4 Organising a written procedure for agreement seeking

SECR will launch the agreement seeking on the DD via written procedure if the MSC Chair decides in accordance with point 3.2 that the written procedure is the route of preference. MSC will be requested by a deadline to express clearly if they agree (YES) with the DD, if they do not agree (NO) with the DD or whether they abstain or whether they would like the MSC Chair to terminate the written procedure for specific DDs (STOP), indicating the issue that is to be discussed at the meeting. The DD should then be raised for agreement seeking in the next MSC meeting. The written procedure is to be performed 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.

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 DD 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 DD(s) for discussion in the MSC meeting in order to find a unanimous agreement.

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

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

All DDs 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 DD. A DD 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 IT platform 10 days before the meeting at the latest.

3.6 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. Following this legal check, SECR 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 IT platform as soon as possible after the meeting. SECR will make a non-confidential version of this decision available on its website once issued to the Registrants/DUs.

3.7 Failing to find unanimous agreement of MSC

In case a MSC member does not agree with the DD, a justification for disagreement needs to be provided.

If MSC fails to find a unanimous agreement, SECR 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 PfAs 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-owners'[5] and stakeholder organisations' participation to the MSC meetings during discussions on draft decisions

4.1 Codes of conduct

Codes of conduct[6] 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 SECR, decides in advance of the meeting whether the substance evaluation DD 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 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. Generally, Members should indicate well in advance of the meeting the reasons for requesting a closed session.

[5] 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.

[6] Code of conduct for observers at ECHA meetings and Code of Conduct for case owners as observers at meetings of Member State Committee

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 of the meeting round where the DD is to be agreed and at the same time is informed that Stakeholder representatives normally participate in Session 1 in case the decision is included on the draft agenda of the meeting for decision making. Normally, the representative submitting comments to the PfAs on behalf of all addressees of the DD is invited to indicate (by a specified deadline) in advance of the meeting if he/she wishes to participate in the Session 1.

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 DD, the right of the competent authorities of the Member States to propose amendments to the DD or the case-owners' (Registrants'/DUs') right to comment on the PfAs of the MSCAs/ECHA.

During the initial discussion (Session 1) the eMSCA presents to the Committee the DD, its rationale and background, together with the PfAs 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 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-owner(s) will be invited to an MSC meeting, choosing from those case-owners that commented on the PfAs received. Normally, for the same SEv substance, SECR 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 DD, 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 DDs, 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 DD and PfAs 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 or ten days before the meeting, respectively. 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 IT platform or by other means. The members will be informed about the start of any written procedure or consultation by email, which will also specify how and by when they should respond.

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 online platforms

Members may be offered an option to discuss oline among members before expressing formally a position on a document. It is important to ensure that all comments and positions will be available to all MSC members and the administration of these comments (e.g. chats or online comments) can be carried out in a more efficient and smooth way.

*5.3.2 Preparatory Web conferences/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 SECR 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 SECR.

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 draft 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 bySECR. 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 DDs, if necessary.

*5.3.5 Manual of Decisions (**MoD**)*

The MoD in accordance with *A*rticle 77 (2) (m) of the REACH Regulation is intended for keeping consistency on conclusions of MSC. Following a proposal made by any Committee 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. 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

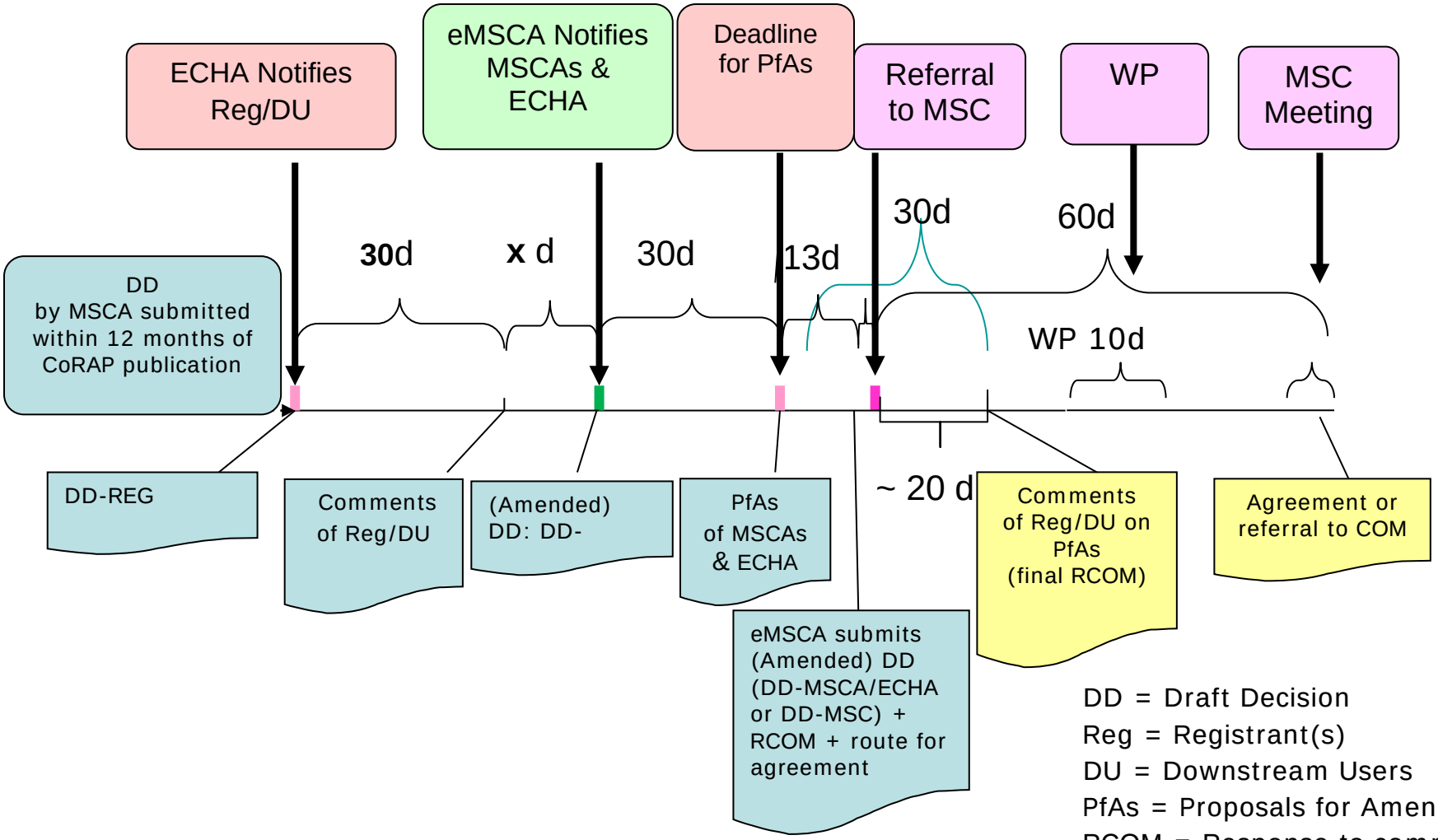
ECHA-D: Final decision of ECHA after the MSCA-DD did not receive proposal for amendments from MSCAs or else after unanimous agreement has been reached on MSCA-DD in MSC.

RCOM: response to comments table with:

- Proposal(s) for amendment of MSCAs on the DD-MSCA.
- eMSCAs responses to the above proposal(s) for amendment

Updated RCOM: response to comments table
updated with the registrants'/DUs' comments on the proposal(s) for amendment of MSCAs/ECHA
DU: Downstream user
DD: Draft decision
SECR: ECHA Secretariat
eMSCA: evaluating Member State Competent Authority
MSC: Member State Committee
MSCA: Member State Competent Authority
PfA: Proposal for amendment

Annex II - Timeline for substance evaluation for MSC



DD = Draft Decision
Reg = Registrant(s)
DU = Downstream Users
PfAs = Proposals for Amendment
RCOM = Response to comments table
COM = Commission
WP = Written procedure