

Update adopted 17 June 2021

## **Working procedures for the MSC in**

### **a) providing the opinion on the draft Community Rolling Action Plan (CoRAP) updates – workflow, tasks, procedures and communication**

### **b) seeking agreement on which authority to evaluate a substance when two or more Member States have expressed interest to evaluate the same substance**

#### **Background**

These working procedures are applicable to the process of the Member State Committee (**MSC**) in providing the opinion:

- i. on the annual updates of the draft Community Rolling Action Plan (**CoRAP**) in accordance with Article 44(2) of REACH, using the draft CoRAP update prepared by ECHA Secretariat (**SECR**) as the basis.
- ii. on the proposals from the Member State Competent Authorities (**MSCAs**) for addition of substances to the CoRAP under Article 45(5) of REACH.

This document describes principles to be applied in the work of the MSC (between members and between members and SECR).

#### **PROCESS FOR PREPARING MSC OPINION**

#### **TASK OF THE MSC**

1. The task of the MSC is to adopt an opinion on the draft CoRAP to be provided to SECR. The process workflow is described below under 'Workflow'.
2. The final annual CoRAP update will be established by ECHA on the basis of the

opinion of the MSC. If a MSCA makes a proposal for additional substance to be included in the CoRAP in accordance with Article 45(5) of REACH, ECHA will update the CoRAP after a MSC opinion.

3. The items of the opinion, that need to contain the necessary justifications, may cover:
  - a. The content of draft CoRAP and supporting documentation:
    - i. Lists of substances to be evaluated for each year in the next three years' period
    - ii. For each of the substances in the draft CoRAP
      1. Substance name
      2. EC number
      3. CAS number
      4. Evaluating MS
      5. Reasons for initial concern and supporting documentation
  - b. Any other issues

The opinion should be specific enough to allow SECR to modify or amend the proposed draft CoRAP where appropriate, or the opinion could indicate MSC's support for the draft CoRAP update.

4. The CoRAP is updated on an annual basis, and at other times on the basis of a proposal from a MSCA based on Article 45(5) if the update is considered urgent.
5. The items of the opinion on annual updates or additions based on Article 45(5), that need to contain the necessary justifications, may cover the same items as listed in point 3.

## **WORKFLOW**

6. The steps in brief of the CoRAP development process are as follows:
  - ECHA compiles a draft CoRAP update annually, in cooperation with the Member States.
  - For each new entry to the draft CoRAP, a Justification Document is prepared.
  - ECHA submits the draft CoRAP to the MSs and this draft is referred to the MSC
  - MSs may, if appropriate, suggest additional priority substances for inclusion in the CoRAP
  - Opinion of the MSC is requested on ECHA's draft CoRAP update including any additional substances notified by MSs outside the normal CoRAP development procedure (ref. Article 45(5))
  - SECR will prepare the final CoRAP, which will be adopted, taking into account the MSC opinion.

## **APPOINTMENT OF A RAPPORTEUR AND POSSIBLE CO-RAPPORTEUR AND WORKING GROUP**

7. The MSC will specify the tasks for the Rapporteur (Terms of Reference). The Rapporteur is appointed to facilitate the process in which the Committee is to provide an opinion, in line with Article 87(1) of REACH. In general, the Rapporteur is responsible for drafting the opinion based on contributions of the MSC and the discussions at the MSC meeting(s).

For that purpose, the MSC Chair<sup>1</sup>, or SECR on his/her behalf, invites MSC (alternate) members to express their interest in acting as a rapporteur or co-rapporteur for the opinion development on the draft CoRAP update.

8. At the latest, when the draft CoRAP is submitted to the MSC, the MSC would need to identify and appoint one of its (alternate) members as Rapporteur, and possibly another (alternate) member as Co-Rapporteur, responsible for drafting the opinion of the MSC on ECHA's draft CoRAP update. The Rapporteur (and the Co-Rapporteur) would be appointed for one year at the time taking the responsibility also for drafting the opinion in cases referred to in paragraph 9. The Rapporteur and Co-Rapporteur would receive any necessary administrative and technical support from SECR.

9. In case a separate opinion (from the opinion on the annual update) is needed following a proposal from a MS in accordance with Article 45(5) of REACH, the Rapporteur (and Co-rapporteur) appointed for one year at a time will be responsible for drafting the separate opinion following the same principles as for preparation of the annual CoRAP opinion.

10. When considering the appointment of a Rapporteur and a Co-Rapporteur, the number of rapporteurships already allocated to the member should be taken into account to promote sharing the burden of work. Furthermore, potential interest(s) regarding any of the substances included in the draft CoRAP update, as declared by the (alternate) member prior to their appointment, has to be taken into account. Upon request of the Rapporteur and Co-Rapporteur, MSC may establish a working group consisting of volunteering (alternate) members<sup>2</sup>. Any administrative and technical support needed can be received from SECR.

SECR prepares a 'Terms of reference' document, specifying the tasks of the (co-) rapporteur(s) as the basis for agreement by MSC.

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<sup>1</sup> The MSC Chair may actively invite members for a rapporteurship in line with the MSC-agreed approach (see MSC-68 and MSC-69 meeting minutes).

<sup>2</sup> A MSC member may also nominate his/her adviser with proper expertise for MSC WG membership

MSC needs to:

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

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

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

## **MSC OPINION ON THE DRAFT CoRAP UPDATE**

11. The first draft opinion of the MSC on the draft CoRAP, as issued by ECHA, will be prepared by the Rapporteur, assisted by the Co-Rapporteur, if appointed and the working group as necessary, considering the comments received from the members, as appropriate. The draft opinion may focus on any new substance additions to the draft update and their respective justification documents. MSC may also consider the changes in year of evaluation and the withdrawals of substances from the CoRAP in its opinion. MSC will review any updates to the justification documents that are received during the opinion-development. The first draft opinion will be made available to SECR. SECR will make the document available to the MSC members/alternates and after a check on the confidentiality issues, will make available the non-confidential version of the document to the MSC regular observers.
12. The draft opinion will be the starting point for collection of feedback to the Rapporteur. Following such exchange, either at the meeting or under written procedure, the opinion on the draft CoRAP update should be adopted.
13. The MSC shall use its best endeavours to reach a consensus on the MSC opinion on the draft CoRAP update. If it fails to reach a consensus, the opinion shall consist of the position of the majority of members including its grounds, as well as the minority position(s), including their grounds.

14. The MSC opinion with non-confidential information will be published on the ECHA/MSO website.

### **MSO OPINION ON A MS PROPOSAL IN ACCORDANCE WITH ARTICLE 45(5)**

15. The proposals of MSs in accordance with Article 45(5) should be addressed in MSO as soon as practically possible. In general, for these proposals, the procedure of paragraphs 11 – 14 will apply *mutatis mutandis*.
16. The MSO opinion with non-confidential information will be published on the ECHA/MSO website.

### **SEEKING AGREEMENT ON WHICH AUTHORITY TO EVALUATE A SUBSTANCE WHEN TWO OR MORE MEMBER STATES HAVE EXPRESSED INTEREST TO EVALUATE THE SAME SUBSTANCE**

#### **Background**

This working procedure will be applicable to the process of the MSO in seeking unanimous agreement in accordance with Article 45(3) of REACH in the case where two or more MSs have expressed an interest in evaluating the same substance and they cannot agree who should be the competent authority for the purposes of Article 46, 47 and 48 of REACH.

#### **Seeking unanimous agreement on the competent authority to be responsible for the substance evaluation**

1. If two or more MSs would like to (or insist to) choose the same substance for evaluation from the draft CoRAP (Article 45(3)), the issue shall be referred by ECHA to MSO in order to agree which authority shall be the competent authority, taking into account the factors listed in Article 45(3)(2) of REACH.
2. MSO should try to reach unanimous agreement within 60 days of the referral on which authority shall be the competent authority. This agreement seeking shall take place before the MSO opinion on the draft CoRAP is to be issued.
3. The MSs wanting to evaluate the same substance shall make available to ECHA the detailed justification for their wish to act as an evaluating MS for the same substance taking into account the arguments of Article 45(3), 2<sup>nd</sup> paragraph. ECHA will make this documentation available to MSO for the basis of preparation of the MSO agreement.

4. If MSC fails to reach the unanimous agreement, the conflicting opinions shall be prepared by SECR in consultation with MSC. ECHA shall submit, in accordance with Article 45(3)(4) of REACH, the conflicting opinions to the Commission which shall decide which authority shall be the competent authority for the evaluation of the specific substance.

## **DEADLINES AND TOOLS FOR THE WORKING PROCEDURES IN DEVELOPING AN OPINION ON THE DRAFT CoRAP**

### **I. 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 planned working procedures respect those as well.

The deadlines for the (Co)-Rapporteur / working group, for the preparation of:

- the draft opinion/opinion on the draft CoRAP
- the draft opinion/opinion on the substance proposed by the MS

will be clearly described when appointing the (Co-)Rapporteur and the working group, if necessary, and agreed to in the terms of reference for the (Co-)Rapporteur.

### **II. Communication**

All documentation to the members and other meeting participants will be made available on the designated MSC IT platform. MSC Members will also be informed about the start of any written 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.

### **III. Ways to facilitate the development of an opinion in the MSC**

#### *Working outside the MSC plenary meeting*

To facilitate the building up of the MSC opinion during a MSC meeting, a subgroup may be established consisting of the Rapporteur, the Co-Rapporteur and the working group and any interested MSC members, supported by SECR. Such a subgroup would work on compromise texts or wordings, in parallel with the plenary meeting, which then could be presented at the same MSC meeting for adoption, or for finding other solutions.

#### Working groups

Working group may be established to help MSC develop its opinion on the CoRAP. It is proposed to use a working group, as necessary, from among the MSC (alternate) members to support the Rapporteur and the Co-Rapporteur, if appointed, to draw up the opinion of the Committee.

#### **IV. Manual of Decisions (MoD)**

The MoD, in accordance with Article 77 (2) (m) of REACH Regulation, is intended for keeping consistency on conclusions of MSC. Following a proposal made by any MSC Member or SECR, MSC can decide to take up an issue into its MoD. MSC Stakeholder Observers may make proposals for additions to the Chair of MSC. MoD should focus on recording the principles applied in implementation of the tasks of MSC.