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Working procedures for the MSC in providing the opinion on the draft Community Rolling Action Plan (CoRAP) – workflow, tasks, possible procedures and communication

Working procedure for MSC agreement seeking when two or more Member States (MSs) have expressed interest to evaluate the same substance

Background

These working procedures will be applicable to the process of the MSC in providing the opinion:

i. on the draft Community Rolling Action Plan (CoRAP) and its annual updates in accordance with Article 44(2) REACH, using the draft CoRAP prepared by ECHA Secretariat 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) REACH.

The purpose of this document is to establish principles to be applied in the work of the MSC (between members and the Secretariat of the MSC (MSC-S) and amongst the members themselves). This paper shall be subject to further elaboration once more experience is gained.

The opinion of the MSC will not address the substances included in the specific section of CoRAP on the basis of Article 135(2) and Article 136(2) of REACH.

PROCESS FOR PREPARING MSC OPINION

TASK OF THE MSC

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

the MSC. If MSs make proposals for additional substances 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 ECHA to modify or amend the proposed draft CoRAP where appropriate, or the opinion could indicate the MSC's support for the draft CoRAP.

4. Once the CoRAP has been adopted for the three years' period, it will be updated on an annual basis, and at other times on the basis of proposals of MSs 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:

- Pre-selection pool of substances containing candidate substances is identified by ECHA and the Member State Competent Authorities (MSCAs).
- ECHA in cooperation with MSs ranks the substances leading to a prioritised list of candidate CoRAP substances, i.e. preliminary draft CoRAP.
- Preliminary draft CoRAP is submitted to MSCAs for comments and possible commitments for evaluation.
- Comments and confirmation/expression of interest by MSCA to evaluate a substance is submitted by MSCA to ECHA.

- ECHA develops the draft CoRAP
- ECHA submits the draft CoRAP to the MSs
- MSs provide comments to ECHA's draft CoRAP and, if appropriate, suggest additional priority substances for inclusion in the draft CoRAP
- Opinion of the MSC is requested on ECHA's draft CoRAP including any additional substances notified by MSs outside the normal CoRAP development procedure (ref. Article 45(5))
- The ECHA Secretariat 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) and provide an outline for the opinion. 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).

8. At the latest, when the draft CoRAP is submitted to the MSC, the MSC would need to identify and appoint one of its members as Rapporteur, and possibly another member as Co-Rapporteur, responsible for drafting the opinion of the MSC on ECHA's draft CoRAP. 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 the MSC-S.

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) 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. To assist the Rapporteur and the Co-Rapporteur, if appointed, a working group could be established from amongst the members, alternates and experts of the members of the MSC. Any administrative and technical support needed can be received from the MSC-S. It is expected that the Rapporteur, Co-Rapporteur, if appointed, and the working group will mainly work using electronic means. The Rapporteur may propose a meeting of the working group or a teleconference, as necessary, for drafting the MSC opinion. The invitation for any meeting requiring reimbursement of travel

costs must be sent by the MSC-S.

11. 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.

MSC OPINION ON THE DRAFT CoRAP

12. The Rapporteur, the Co-Rapporteur, if appointed, and the working group if established, should consider all contributions and comments provided by MSC members at all stages. During this period, MSC members might wish to comment further using CIRCABC newsgroups or other means.

13. 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 and the MSCAs via the members, as appropriate. The first draft opinion will be made available to MSC-S. The MSC-S will make the document available to the MSC members/alternates and after a check on the confidentiality issues the non-confidential version of the document to nominated stakeholder observers.

14. The draft opinion will be the starting point for the exchange of views and discussion at the meeting of the MSC. Following such discussion, either at the meeting or under written procedure, the opinion on the draft CoRAP should be adopted.

15. The MSC shall use its best endeavours to reach a consensus on the MSC opinion on the draft CoRAP. 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.

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

MSC OPINION ON A MS PROPOSAL IN ACCORDANCE WITH ARTICLE 45(5)

18. The proposals of MSs in accordance with Article 45(5) should be addressed in MSC as soon as practically possible. In general, for these proposals, the following procedure will be used, unless the requesting MS indicates that the proposal is intended for the annual update only:

19. The Rapporteur, the Co-Rapporteur, if appointed, and the working group should consider all contributions and statement of reasons provided by the MS in its proposal. During this period, MSC members might wish to comment further using CIRCABC newsgroups or other means.

20. The MSC will consider a substance for addition to the CoRAP based on a statement of reasons provided by the MS, showing or indicating that the substance fulfils the selection criteria used for the establishment of the CoRAP and/or providing other arguments. The information should be sufficient to indicate that there are grounds for considering that a given substance may constitute a risk to human health or the environment.

21. The procedure of paragraphs 12 – 15 will apply *mutatis mutandis.*

22. The MSC opinion with non-confidential information and with the MS proposal which was used as its basis as an Annex, will be published on the ECHA/MSC website.

MSC AGREEMENT SEEKING WHEN TWO OR MORE MS'S HAVE EXPRESSED AN INTEREST TO EVALUATE THE SAME SUBSTANCE

Background

This working procedure will be applicable to the process of the MSC 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 MSC 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. MSC 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 MSC 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), 2nd paragraph. ECHA will make this documentation available to MSC, the Rapporteur (and the Co-rapporteur) and the working group, if established, for the basis of preparation of the MSC agreement.

4. If MSC fails to reach the unanimous agreement, the conflicting opinions shall be prepared by MSC-S in consultation with MSC. ECHA shall submit in accordance with Article 45(3)(4) in 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 discussed during the MSC meeting appointing the (co)rapporteur and the working group, if necessary, and agreed to in the terms of reference for the (co)rapporteur and the working group.

II Communication

All documentation to the members and other meeting participants will be made available on the designated CIRCABC site for the MSC, organised in specific folders. Besides the automatic CIRCABC notifications, the members will also be informed about the start of any written consultation by email. Any responses to any invitation for MSC members to respond or comment are to be sent to the functional mail box MSC@echa.europa.eu (except in case of invitation for informal commenting using CIRCABC newsgroup which is explained below). The MSC-S will place documents provided by the Rapporteur on CIRCABC as necessary.

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

Newsgroup discussions on CIRCABC

The section on Newsgroup from *Working procedures of the Member State Committee (MSC) in the identification of substances of very high concern (SVHC) (4 September 2008)* is also directly applicable to this process. The newsgroup functionality on CIRCABC will provide the members with an opportunity to discuss particular issues informally before they express their formal position on a document. It will also ensure that all comments and positions will be available to all members of the MSC. Documents can also be uploaded and shared when using the Newsgroup functionality. This can be found on CIRCABC in the General Information-Confidential folder.

Teleconferences (TC)

The section on Teleconferences in the *Working procedures of the Member State Committee (MSC) in the identification of substances of very high concern (SVHC) (4 September 2008)* is also applicable to this process *mutatis mutandis*.

Working in parallel in the MSC 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 the MSC-S. 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 can be established to help MSC develop its opinion on the CoRAP. It is proposed to use a working group, as necessary, from among the 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 section on MoD in *Working procedures of the Member State Committee (MSC) in the identification of substances of very high concern (SVHC) (4 September 2008)* is also directly applicable to this process.

Annex I

Draft Template for the opinion on a draft CoRAP

1. **The process for adoption of the opinion**

2. **The draft CoRAP and focus of the opinion**

3. **The opinion on the justification/statement of reasons for inclusion of the substance in CoRAP and on any supporting documentation**