# Substance Evaluation - Establishing updates of the Community Rolling Action Plan (CoRAP)

## 1. Purpose

The purpose of this procedure is to describe the process of establishing updates of the Community Rolling Action Plan (CoRAP) as the first part of the substance evaluation process, as stated in the REACH Regulation (Title VI, Chapter 2).

This procedure is designed to ensure that

- Substance evaluation has a reliable and consistent basis and a risk based approach is followed
- Substances chosen for substance evaluation are selected according to adopted prioritisation criteria and have a Member State Competent Authority (MSCA) responsible for the evaluation
- Legislative deadlines are respected
- Updates of the CoRAP are established efficiently and the responsibilities of ECHA in the process are clearly outlined

## 2. Scope

This procedure starts with establishing the substances prioritisation criteria for Substance Evaluation and selection of possible candidate substances and ends with adoption and publication of the final (updated) CoRAP and the management of service contracts with the evaluating MSCAs.

## 3. Description

The Community Rolling Action Plan is a list of substances to be evaluated in the three consecutive years, specifying for each substance:

- the assessment year,
- the Member State responsible for the evaluation and
- the initial grounds for concern.

According to Article 44[1] of the REACH Regulation, ECHA shall in cooperation with the Member States develop criteria for prioritising substances, which shall be used for compiling the draft CoRAP.

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

In each update new substances to be evaluated in the third year covered by the CoRAP are inserted and, if applicable, additional substances for the new first and second years can also be inserted and/or some substances be removed.

The draft CoRAP shall be submitted to the MSC and MSCAs and shall also be published on ECHA website.

ECHA shall adopt the final CoRAP on the basis of an opinion from the Member State Committee (MSC) and publish it on its website.

According to Article 45(1) and (2) 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 MSCAs have 12 months from the date of CoRAP publication to evaluate the substance and prepare any draft decision to request further information, if necessary.

## 3.1. Establishing updates of CoRAP

**Step 0 – Established prioritisation criteria**

The criteria to prioritise substances for Substance Evaluation are defined in an Executive Director Decision according to REACH Article 44(1).

The criteria will be updated, in cooperation with MSCAs, as necessary.

**Step 1: Selection of possible candidate substances**

This step can be done through a combination of 1a and 1b.

**Step 1a – Receipt of MSCAs' notifications of candidate CoRAP substances**

Based on REACH Articles 44(2) and 45(5), at any time, the evaluating MSCAs can propose to ECHA, new substances as CoRAP candidates, through notification via a web form attaching a detailed justification for the selection by completing the template "Justification for the selection of a candidate CoRAP substance".

If the notification from the MSCA is based on Article 45(5) and is indicated by the MSCA as an urgent case, the procedure continues with step 4.

If the notification from the MSCA is based on Article 45(5), but is not indicated as an urgent case, it is processed together with the normal annual update system described in step 2 and onwards.

ECHA inserts all notified substances in the preliminary draft CoRAP and allocates the substances provisionally to the notifying Member States.

**Step 1b – Preparation of a SEV pre-candidate list**

Substance Evaluation Team (SEVT) in cooperation with the MSCAs and Registration and Risk management directorates in ECHA, is responsible for identifying substances as potential candidates for substance evaluation. Substances can either be identified

- during the dossier evaluation processes or

- by selection through IT-screening of the REACH registration dossiers based on the application of the CoRAP selection/prioritisation criteria followed by manual screening by MSCAs.

MSCAs and ECHA in close collaboration conduct screening of the available information for substances in the REACH registration dossiers. The aim is to identify substances that pose a risk for human health and/or the environment and take them forward to the most appropriate REACH and CLP processes, including CoRAP under SEV, to ensure their safe use. Following an IT-mass screening of registered substances to short-list candidates for CoRAP, these candidates are manually screened by the MSCAs. If a substance is considered to be a potential candidate for the CoRAP update, MSCA performing the manual screening prepares a draft justification document. Later the ownership of the justification document is taken by the Member State that is designated as the eMSCA (see step 3).

For each potential CoRAP candidate substance information is also collected to find out if it is subject to other ongoing or finished (ECHA/MS/other international) regulatory processes.

**Step 2 – Preparation of the preliminary draft (updated) CoRAP, and submission to MSCAs for comments**

SEVT prepares a preliminary draft CoRAP containing substances identified in step 1. SEVT checks from the justification documents that all substances included in the preliminary draft CoRAP fulfil the prioritised selection criteria, or other equivalent risk based criteria (Article 45(5)), and that there are grounds for considering that the substances may constitute a risk to the human health or the environment.

If more candidate substances are available than can potentially be evaluated by the Member States, SEVT will consider which substances to propose for the current CoRAP update and which ones for the next year's update. This decision is based on the initial grounds of concern and interests from MSCAs to evaluate the substances.

SEVT may tentatively propose allocation of the substances to eMSCAs on the basis of the Member States direct notifications and interests indicated during or after the manual screening step, taking also into account plans of the Member State to assess certain number of substances per year.

SEVT submits the preliminary draft CoRAP to the MSCAs for comments and expression of interest for evaluating the substances.

**Step 3 – Receipt of comments and expressions of interest by the MSCAs to evaluate substances**

MSCAs shall confirm in writing which substances they intend to evaluate. In cases where two or more Member States have expressed an interest in evaluating the same substance and they cannot agree on who should evaluate the substance, ECHA secretariat refers the matter to MSC, see step 5.

In all cases where the MSCAs express commitment for a substance, they take ownership of the justification document prepared so far. If relevant, MSCAs may review and update the justification document. If no MSCA is volunteering to evaluate a substance on the preliminary list, the substance could be considered to be a potential candidate for the CoRAP update again the following year (see Step 2)

**Step 4 – Preparation and submission of the draft (updated) CoRAP to the MSCAs and referral to the MSC for preparation of opinion. Publication on the ECHA web site**

A draft for an annual update shall be prepared at the latest by the end of February each year (Article 44(2)), but, if possible, ECHA will try to prepare the draft CoRAP well in advance to allow for adoption of updated CoRAP by the end of March each year.

SEVT prepares and submits the draft CoRAP to the MSCAs. At the same time, the draft CoRAP is also referred to the Member State Committee for preparation of its opinion.

In the draft CoRAP, each substance is allocated to one Member State. If a substance(s) has been referred to MSC to seek agreement on eMSCA, this is also indicated in the draft CoRAP (cf. step 5). The preparation of MSC opinion on whether the substances in the draft CoRAP should be included in the CoRAP, can go in parallel with step 5, when this step is needed, regarding who shall evaluate the agreed substances.

If an urgent Article 45(5) notification on a candidate substance to CORAP is submitted, ECHA informs the other MSCAs about the proposal, and refers the case to the MSC as soon as possible.

When the draft CoRAP is sent to the MSCA and MSC, the public version of this draft is published on ECHA's web site to inform the stakeholders of the intention to include the listed substances in the CoRAP.

**Step 5 – Referral to MSC to seek agreement on evaluating MSCA(s)**

In cases where two or more Member States express an interest in evaluating the same substance and they cannot agree on who should be the competent authority, ECHA secretariat (MSC-Chair) refers the substances with disagreement to the Member State Committee, and the issue is to be solved according to Article 45(3).

If MSC reaches unanimous agreement in 60 days, the Member State authorities concerned become the responsible competent authorities for evaluation of substances, according to the agreement of MSC.

**Step 5a – Referral to the Commission (Article 45(3))**

If the MSC fails to reach a unanimous agreement, ECHA secretariat (Director of Regulatory Affairs) shall submit the conflicting opinions to the Commission, which shall decide in a Committee procedure which authority shall be the competent authority for the evaluation of this/these substance(s).

**Step 6 – Adoption and publication of the final (updated) CoRAP**

ECHA adopts the CoRAP update on the basis of the results of steps 4, 5 and 5a.

The aimed timeline for adoption is annually before 31 March. As soon as the CoRAP is adopted, it is published on ECHA website.

In case a Commission decision is needed, according to step 5a, the substance will be moved to a later CoRAP update as timing of the decision making in the Commission may not be in alignment with the timetable for adoption of the CoRAP update in question.

A justification document for the selection of the substance is also published on ECHA website (starting from the CoRAP update in 2013). From the publication date of the CoRAP, the designated MSCAs have 12 months to carry out the evaluation of the substances listed in the first year of the CoRAP.

**Step 7 Management of Service contracts with the evaluating MSCAs**

Provided that there is no disagreement on the allocation of the substance by the evaluating Member State, the Evaluation Directorate and the Finance Unit in ECHA prepare service contracts, between ECHA and the evaluating MSCA and/or Mandated Institution.

The purpose of the contract is to transfer a proportion of the fees collected by ECHA, as partial compensation for the provision of substance evaluation services, for the substances listed for evaluation within the first year covered by the CoRAP.

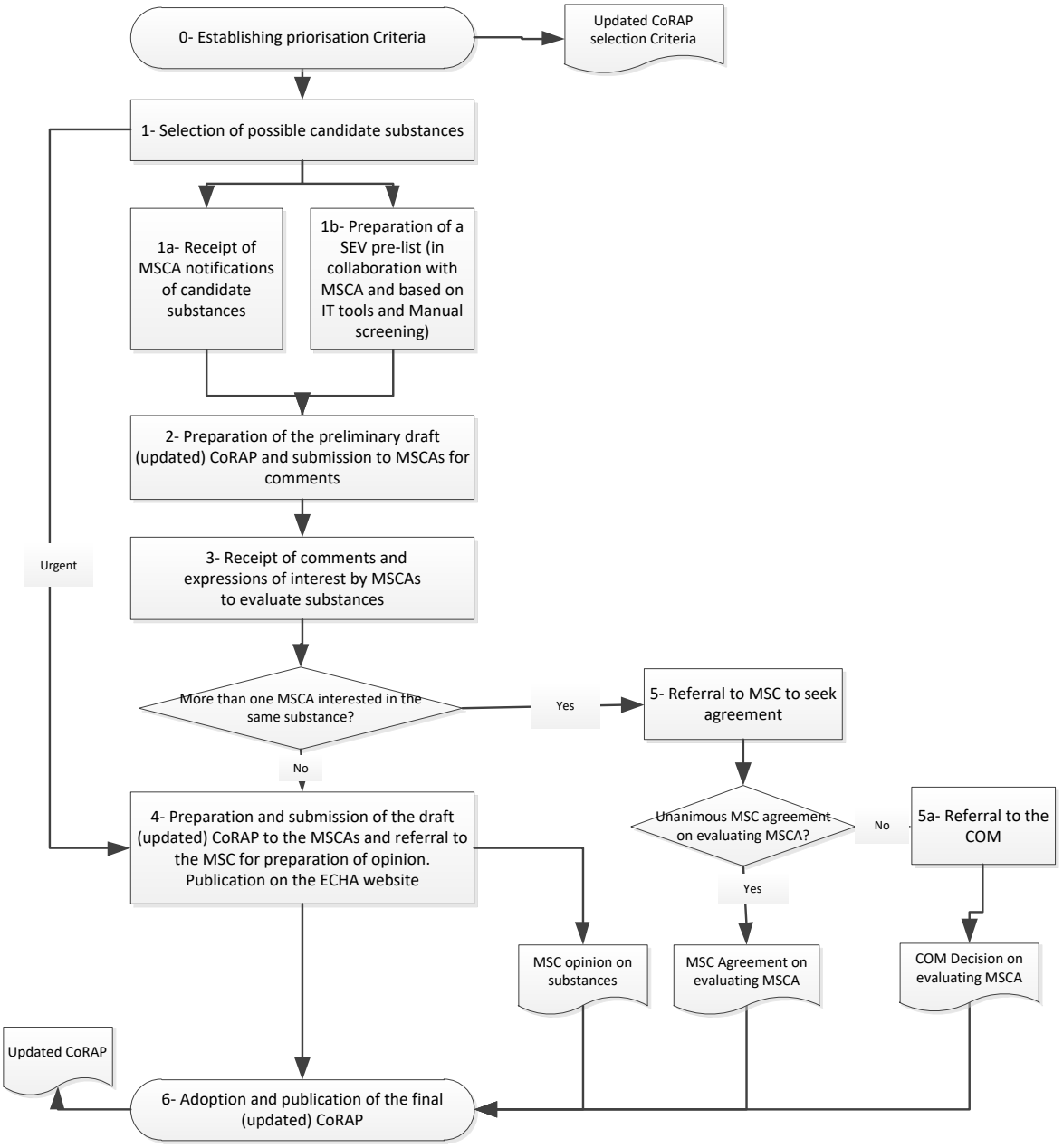
Director of Evaluation signs the service contacts on behalf of ECHA. Then the contracts are sent to Member State Competent Authorities and, where applicable, Mandated Institution(s) for signature.

The documents are filed and the appropriate transfers of funds are processed upon receipt and acceptance of relevant documentation and receipt of an invoice or comparable note from the evaluating Member State.

## 3.2. Supporting Documentation

The process described in this procedure is described in more detail in related working instructions. In addition, supporting documentation describes practical elements required when executing tasks such as instructions, templates and standard texts for documents. Supporting documentation is controlled in analogy to the provisions given in PRO-0001. The respective document owner is responsible for keeping the document up-to-date.

# 4. Flowchart


0- Establishing priorisation Criteria
Updated CoRAP selection Criteria
1- Selection of possible candidate substances
1a- Receipt of MSCA notifications of candidate substances
1b- Preparation of a SEV pre-list (in collaboration with MSCA and based on IT tools and Manual screening)
2- Preparation of the preliminary draft (updated) CoRAP and submission to MSCAs for comments
3- Receipt of comments and expressions of interest by MSCAs to evaluate substances
Urgent
More than one MSCA interested in the same substance?
Yes
5- Referral to MSC to seek agreement
No
4- Preparation and submission of the draft (updated) CoRAP to the MSCAs and referral to the MSC for preparation of opinion. Publication on the ECHA website
Unanimous MSC agreement on evaluating MSCA?
No
5a- Referral to the COM
Yes
MSC opinion on substances
MSC Agreement on evaluating MSCA
COM Decision on evaluating MSCA
Updated CoRAP
6- Adoption and publication of the final (updated) CoRAP

## 5. Definitions

| Term or abbreviation | Definition |
|---|---|
| CoRAP | Community Rolling Action Plan |
| eMSCA | Evaluating Member State Competent Authority |
| MSC | Member State Committee |
| MSCA | Member State Competent Authority |
| SEVT | Substance Evaluation Team: Team from Directorate E composed of:<br>• Team Leader(s) (TLs – Evaluation Units).<br>• The Substance Managers (SMs – Evaluation Units).<br>The Evaluation Assistants (EAs – Evaluation Units). |

## 6. Records

| Record name | Security level | Comments |
|---|---|---|
| (Current/ Revised) Selection criteria for prioritising substances for CoRAP | Public | |
| Existing CoRAP | Public | |
| Notification forms (web) for candidate substances | Internal | |
| (Draft) Justification Documents for the candidate substances for inclusion in Community Rolling Action Plan (CoRAP) | Adopted version Public | |
| MSC Opinion on draft CoRAP | Public | |
| Confidential Preliminary draft CoRAP update for next years | Internal | |
| Public and Confidential version of Draft updated CoRAP | Committee version Internal,<br>Extracted version Public | |
| Public and Confidential version of Final updated CoRAP | Committee version Internal,<br>Extracted version Public | |

| Record name | Security level | Comments |
|---|---|---|
| Service contracts with Terms of references for substance evaluation (transfer of funds) | Internal | |
| Progress Report on draft CoRAP | Internal | |

## 7. References

| Associated document code | Document name |
|---|---|
| Regulation (EC) No 1907/2006 | REACH Regulation |
| Regulation (EC) No 1272/2008 | CLP Regulation |
| ED/110/2010 | Delegation of the power to sign certain science-based regulatory decisions and communications |
| ED/51/2014 | Use of CIRCABC for Handling Restricted and Highly Restricted Information |
| | ECHA Guidance on information requirements and chemical safety assessment |

## 8. Annexes

N/A