Substance Evaluation Stage 1 - 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) - Stage 1 of the substance evaluation process, as stated in the REACH Regulation (Title VI).

2. Scope

This procedure starts with the selection of potential candidate substances for substance evaluation and ends with the publication of the Community rolling action plan (CoRAP) update.

3. Description

In cooperation with Member States, ECHA has developed criteria for prioritising substances as a prerequisite[1]. ECHA and the Member States use these criteria for selecting substances for evaluation. The resulting Community rolling action plan is the list of substances, which the Member States will evaluate in the three years covered, specifying for each substance:

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

In each update, ECHA can add new substances and revise the year of evaluation for already listed substances, when necessary. ECHA publishes the proposal on its website and asks the opinion of the Member State Committee. ECHA adopts the updated CoRAP once the Member State Committee has provided a favourable opinion and publishes the result on its website.

The evaluating Member State competent authorities have 12 months from the date of the CoRAP publication to evaluate the substances indicated for the respective first year and prepare a draft decision to request further information, if necessary. If registrants do not need to generate additional information to address a concern indicated, the competent authorities provide a conclusion document.

3.1. Establishing updates of CoRAP

Prerequisite: Established prioritisation criteria

An Executive Director decision defines the criteria for prioritising substances for substance evaluation. ECHA's Executive Director updates this decision in cooperation with Member States when necessary.

[1] https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan

Step 1-1. Selection of candidate substances

Every year and based on agreed criteria (see 'prerequisite' above), ECHA establishes a list containing additional substances for evaluation (a). Simultaneously, Member States can propose additional substances (b).

Step 1-1.a. Preparation of a SEV pre-candidate list

The ECHA secretariat identifies potential new candidates for substance evaluation. The ECHA secretariat identifies such additional substances:

- in the dossier evaluation process; or
- during screening of the REACH registration database.

Step 1-1.b. Member State proposing substances

Whenever a Member State has information for any substance which indicates that it is a priority for evaluation, it notifies this additional substance to ECHA. The ECHA secretariat inserts such notified additional substances in the preliminary draft CoRAP and allocates the substance to the proposing Member State.

Step 1-2. Pre-draft CoRAP update

The ECHA secretariat prepares a pre-draft CoRAP containing the list of substances identified in Steps 1.a. and b. ECHA then verifies that the substances included in the preliminary draft CoRAP fulfil the prioritisation criteria posing a possible risk to human health or the environment. The ECHA secretariat also considers the potential capacity of the Member States for evaluating substances when preparing the list.

The ECHA secretariat collects for each potential CoRAP candidate substance information concerning already ongoing regulatory processes or available assessment reports of such processes. This search covers any national or international activity.

The ECHA secretariat submits the preliminary draft CoRAP to the Member States for comments and expressions of interest for evaluating one or several of the substances.

Step 1-3. Substance selection

In this Step, the Member States volunteer to evaluate a given substance from the list. The Member State takes ownership of the respective case including the documentation prepared so far. The ECHA secretariat considers cases where no Member State volunteers as priority candidates for the next CoRAP update (see Step 1-2.).

In cases where two or more Member States are interested in evaluating the same substance and they cannot agree how to proceed, the ECHA secretariat refers the matter to the Member State Committee (Step 1-4.a.).

Step 1-4.a. Agreement seeking

The ECHA secretariat refers cases where two or more Member States are interested in evaluating the same substance and cannot agree on how to proceed to the Member State Committee (MSC) for resolution. The MSC has 60 days to reach agreement on which Member State will evaluate the respective substance.

Step 1-4.b. Referral to the Commission (Article 45(3))

The ECHA secretariat submits the conflicting opinions to the European Commission in cases where the MSC fails to reach a unanimous agreement. The Commission decides then in a Comitology procedure, which authority will evaluate the substance(s).

Step 1-5. Prepare the draft CoRAP and obtain an opinion from the MSC

The resulting list assigns the evaluating Member State for each substance. It indicates such cases that the ECHA secretariat referred to the Member State Committee for agreement seeking (Step 1-4.a.). The ECHA secretariat submits this resulting draft CoRAP to the Member State Committee to obtain its opinion.

The ECHA secretariat simultaneously informs the Member States of the draft CoRAP and publishes a non-confidential version on its website to inform stakeholders and the broad public of its intention to include certain substances in the new CoRAP.

Step 1-6. Forming an opinion

The MSC forms an opinion on the draft CoRAP update.

The process of obtaining an MSC opinion on the draft CoRAP update preferably happens in parallel to the agreement seeking (step 1-4.a.).

Step 1-7. Adoption and closing service contracts

Based on a favourable opinion of the MSC, the ECHA secretariat closes a service contract with the respective evaluating Member State competent authority or the appointed institution. This applies to all cases listed for evaluation within the first year of the agreed CoRAP.

ECHA will move cases where neither the Member States nor MSC could find an agreement on the evaluating Member State to a later CoRAP update. (The timing of the decision making in the Commission may not align with the timetable for adopting the CoRAP update in question.)

Step 1-8. Publication of the adopted CoRAP update

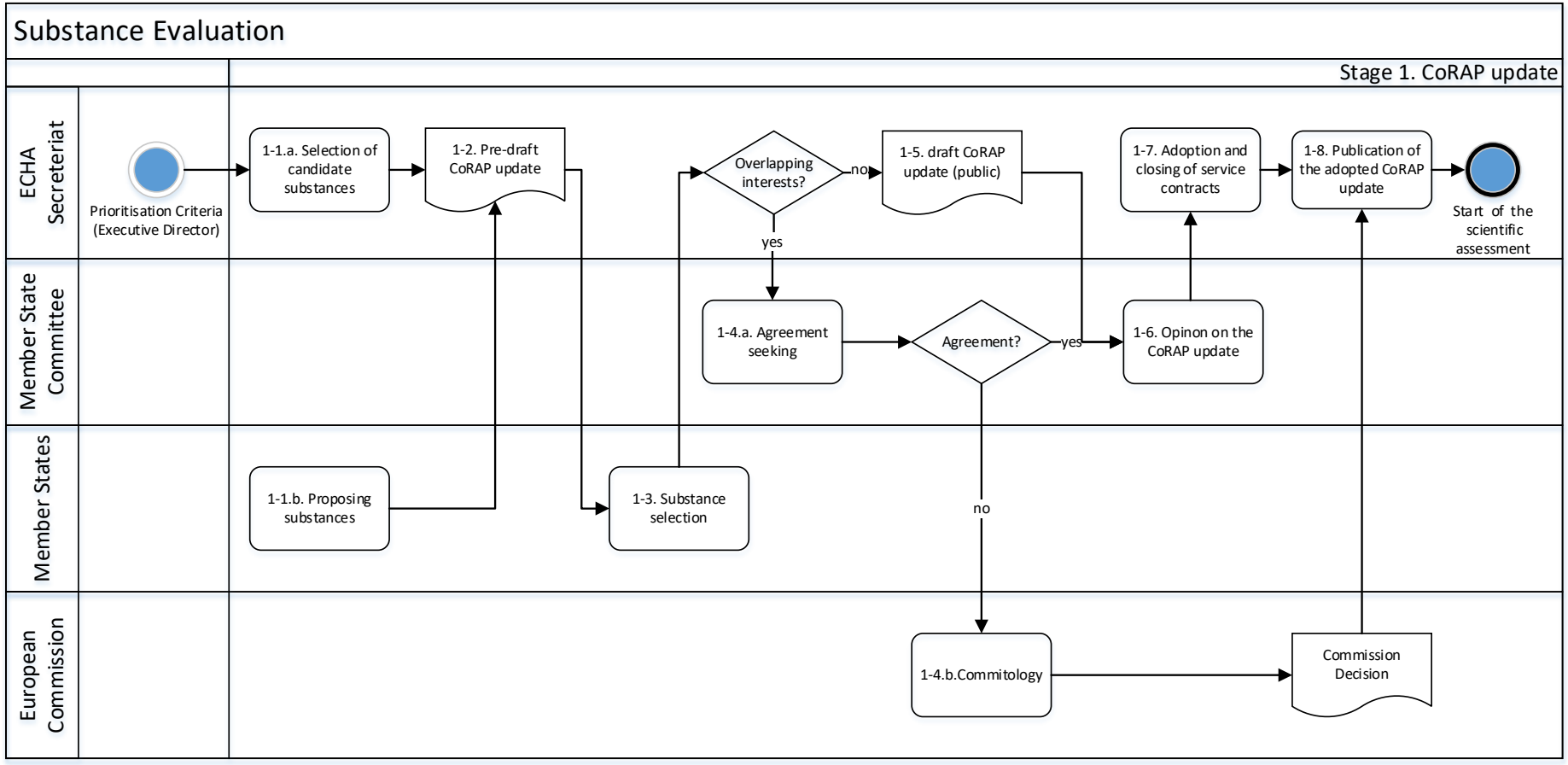
ECHA publishes the adopted CoRAP update on its website.

The designated evaluators then have 12 months to decide on potential information needs for the substances listed for this year.

3.2. Supporting documentation

Related working instructions describe the process outlined in this procedure in more detail. In addition, supporting documentation describes practical elements required when executing tasks such as instructions, templates and standard texts for documents. The ECHA secretariat controls such supporting documentation in analogy to the provisions for documentation. The respective document owner is responsible for keeping the document up to date.

4. Flowchart


Substance Evaluation
Stage 1. CoRAP update
ECHA Secreteriat
Member State Committee
Member States
European Commission
Prioritisation Criteria (Executive Director)
1-1.a. Selection of candidate substances
1-2. Pre-draft CoRAP update
Overlapping interests?
no
yes
1-5. draft CoRAP update (public)
1-7. Adoption and closing of service contracts
1-8. Publication of the adopted CoRAP update
Start of the scientific assessment
1-4.a. Agreement seeking
Agreement?
yes
1-6. Opinon on the CoRAP update
1-1.b. Proposing substances
1-3. Substance selection
no
1-4.b.Commitology
Commission Decision

5. Definitions

Term or abbreviation	Definition
CoRAP	Community rolling action plan
MSC	Member State Committee
MSCA	Member State competent authority

6. Records

Record name	Security level	Comments
Selection criteria for prioritising substances for evaluation	Public	
Existing CoRAP	Public	
Notification forms (web) for candidate substances	Internal	
Draft Justification document for the inclusion of a substance in the Community Rolling Action Plan (CoRAP)	Internal	
Confidential preliminary draft CoRAP update for next three years	Internal	
Public and confidential version of the draft CoRAP update	Committee version Internal, Extracted version, Public	
MSC opinion on draft CoRAP update	Public	
adopted CoRAP update including justification documents	Public	
Service contracts with terms of references for substance evaluation (transfer of funds)	Internal	

7. References

Associated document code	Document name
Regulation (EC) No 1907/2006	REACH Regulation
Selection criteria	Selection Criteria for prioritising substances for evaluation by including them in the Community rolling action plan

8. Annexes

N/A