Substance Evaluation

1. Purpose

The purpose of this procedure is to describe the substance evaluation process, as stated in the REACH Regulation[1] (Title VI, Chapters 2 and 4).

2. Scope

The substance evaluation process assesses all registration dossiers from all registrants specific to the same substance or group of substances. Other available sources of information are also considered.

3. Description

Substance evaluation allows for the generation of information on the substance to clarify a potential risk to human health or the environment. ECHA coordinates the substance evaluation process and ensures that substances on the Community Rolling Action Plan (CoRAP) are evaluated by the evaluating Member State Competent Authorities (MSCAs).

The outcome of substance evaluation may be:

- Decision requesting further information from the registrant(s), to clarify the potential risk. This request can address intrinsic properties or exposure of the substance, which information goes beyond a standard information requirement listed in Annexes VII to X of REACH. When ECHA sends a substance evaluation draft decision, the decision-making process is initiated; the registrant(s) may comment on the draft decision, and ECHA and/or MSCAs may propose amendments. The registrant(s) are informed of any proposed amendments and may comment on them. If amendments are proposed, the Member State Committee and (if necessary) the European Commission may be involved in reaching an agreement on the content of the decision.

  Substance evaluation may lead to a decision by ECHA or the European Commission. This decision contains requests for new information to be provided by the registrant(s) in an updated dossier. The new information is evaluated by the evaluating MSCA after the deadline given in the decision. When this information is not submitted or is deemed inadequate, enforcement actions or additional information requirements follow.

- Notification of the evaluating MSCA to ECHA that no further information is necessary to clarify the potential risk. This notification includes a report on the evaluation performed and any proposal(s) for EU-wide risk management measures such as restrictions, identification of substances of very high concern or other actions outside the scope of REACH e.g., harmonised classification. ECHA shares this information with the Commission, the registrant(s) and the other MSCAs.

[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.

Following the yearly (update) publication of the CoRAP[2], the substance evaluation process can be divided into three stages:

Stage 1: Coordination of substance evaluation

To ensure that substance evaluation is based on sound and consistent judgement, and that requests for further information are necessary, consistent, scientifically robust, and legally accurate, ECHA supports the evaluating MSCA during the 12-month evaluation period.

As an outcome of the 12-month evaluation period, the evaluating MSCA submits to ECHA either:

- a draft decision requesting further information from the registrant(s), to clarify the potential risk; or
- a draft conclusion and substance evaluation report summarising the evaluation performed and the conclusions taken.

Stage 2: Processing of substance evaluation draft decisions

ECHA is responsible for notifying to the registrant(s) any draft decision issued by the evaluating MSCA. Adoption of an ECHA decision is achieved either by:

- acceptance of the draft decision by the MSCAs, or
- unanimous agreement in the Member State Committee (MSC) on proposed amendments to the draft decision.

When unanimous agreement is not reached, the European Commission is requested to take the decision.

Stage 3: Evaluation of the requested information

The decision specifies by when the registrant(s) must provide the required information in an updated registration dossier. Once the deadline has passed, the evaluating MSCA evaluates the updated dossier and informs ECHA of one of the following outcomes:

- The information submitted is considered to meet the requests in the decision and no further information is needed to clarify the potential risk. The evaluating MSCA will submit a draft conclusion summarising the analysis performed and the conclusions taken. ECHA informs the Commission, the registrant(s) and other MSCAs of the conclusions.
- Further information is considered necessary to clarify the potential risk, due to a change of circumstances or new acquired knowledge. The evaluating MSCA will submit a new draft decision.
- None or only part of the requested information was submitted, ECHA may inform the enforcement contact points.

[2] Described in the procedure: "Establishment and update of the Community Rolling Action Plan (CoRAP)"

Stage 1: Coordination of substance evaluation

1.1 Provision of aggregated IUCLID datasets

Following establishment of the CoRAP update, ECHA provides the evaluating MSCA with an aggregated IUCLID dataset for the substance to be evaluated, which contains all information available in the latest version of all registration dossiers for that substance.

1.2 Interaction between ECHA and evaluating MSCA

The aim of this interaction is for ECHA to:

- provide support in considering the best approaches to clarify the potential risk and any risk management measures.
- provide advice and support related to necessity and consistency of the requests and to ensure scientifically and legally sound written decisions.

Where agreed between ECHA and the evaluating MSCA, ECHA performs a consistency screening of any preliminary substance evaluation draft decision submitted to ECHA, no later than two months before the end of the 12-month evaluation period. ECHA reviews the preliminary draft decision and may suggest changes for the evaluating MSCAs consideration.

The evaluating MSCA considers ECHAs suggestions to modify the draft decision, if appropriate, and submits the revised draft decision for further processing within the 12-month evaluation period.

1.3 Receipt of evaluation outcome documents

The evaluating MSCA submits their draft evaluation outcome documents to ECHA.

When the outcome of a substance evaluation is that an information request to clarify the potential risk is deemed necessary, the procedure continues with ***step 1.4****.*

When the conclusion of a substance evaluation is that no further information to clarify the potential risk is necessary, the procedure continues with ***step 3.4****.*

1.4 Sign the notification letter to be sent with the draft decision to the registrant(s)

Before the end of the 12-month evaluation period, the evaluating MSCA submits the draft decision. ECHA sends the draft decision accompanied by a notification letter to the registrant(s).

Stage 2: Processing of substance evaluation draft decision

2.1. Notification of the draft decision to the registrant(s)

ECHA notifies without undue delay[3], the draft decision to the registrant(s) of the substance. The registrant(s) are informed in the notification letter of their right to comment on the draft decision within a 30-day period, and how to do so.

[3] The registrant(s) may receive the draft decision after the end of the 12-month evaluation period.

2.2. Provide registrant(s) comments to the evaluating MSCA

The evaluating MSCA must take the comments of the registrant(s) into account and, where appropriate, modify the request in the draft decision. The reasoning for the request can also be modified based on the comments provided. If no comment is received from the registrants within the 30-day commenting period, the draft decision remains unchanged.

ECHA provides, without undue delay, the evaluating MSCA with any comments submitted by the registrant(s).

Where agreed between ECHA and the evaluating MSCA, ECHA performs a verification review of the (modified) draft decision, no later than two months before the evaluating MSCA notifies the draft decision to ECHA and other MSCAs for consultation. ECHA reviews the (modified) draft decision and may suggest changes for the evaluating MSCAs consideration.

2.3 Receipt of the (modified) draft decision for consultation.

ECHA and the other MSCAs are notified of the (modified) draft decision from the evaluating MSCA for consultation. The draft decision and additional documents including the comments from the registrant(s) are made available.

ECHA and the other MSCAs may submit proposals for amendments to the draft decision within 30 days starting from the date of notification.

*If the evaluating MSCA receives proposals for amendment, the procedure continues in **step 2.4**.* In such cases, the evaluating MSCA will provide a response to each proposal for amendment. The evaluating MSCA may amend the draft decision and provide the (amended) draft decision to ECHA within 13 days after the end of the 30-day consultation period.

*If no proposal for amendment is submitted, ECHA adopts the decision (**Step 2.8**), i.e., the draft decision becomes an ECHA decision.*

2.4 Notify the proposal(s) for amendment to the registrant(s)

ECHA sends all proposal(s) for amendment received, and the draft decision as notified for consultation, to the registrant(s) immediately after the consultation period. A cover letter notifies the registrant(s) of their right to comment on the proposals for amendments within a 30-day period, and how to do so.

2.5 Referral to the Member State Committee

When at least one proposal for amendment is received, the draft decision is referred to the MSC for seeking agreement within 60 days. ECHA refers the comments from the registrant(s), the current version of the draft decision, and the amendment(s) proposed to the MSC no later than 15 days after the end of the 30-day consultation period.

Within 60 days of referral, the MSC shall seek agreement on the draft decision.

2.6 Provide the registrant(s) comments on the proposals for amendment to the evaluating MSCA

ECHA informs the evaluating MSCA and the MSC of any registrant's comments on the proposals for amendment.

The MSC considers the registrant(s) comments on the proposal(s) for amendment together with the proposal(s) for amendment from other MSCAs and ECHA. It aims to reach a unanimous agreement on the request(s) in the decision.

*If no unanimous agreement is reached by the MSC, the procedure continues with **step 2.7**.*

*While if unanimous agreement is reached by the MSC, the procedure continues with **step 2.8**.*

2.7 Referral to the Commission

Where the MSC cannot reach a unanimous agreement, ECHA refers the case to the European Commission. ECHA informs the registrant(s) thereof.

The decision-making process of the Commission is not covered by this document. Further details concerning the European Commission taking such a decision are provided under Article 133(3) of the REACH Regulation.

2.8 Adoption of the decision

The decision is adopted either when no proposal(s) for amendment to the draft decision are submitted during Step 2.3 or when a unanimous agreement is reached by the MSC in Step 2.6.

2.9 Notification of the decision to the registrant(s)

ECHA notifies the adopted decision to the registrant(s), and the other MSCAs. The ECHA decision contains an exact date by when the registrant(s) must provide the requested information in an updated dossier.

The registrant(s) are expected to notify ECHA within 90 days of whom will perform the necessary test(s) to obtain the necessary information. If the registrants fail to do so, ECHA designates one of the registrants to perform the test(s) on the behalf of all of them.

After consultation of the recipients of the ECHA decision, ECHA publishes a non-confidential version on ECHA's website.

Stage 3: Evaluation of obtained information

3.1 ECHA decision becomes effective

Any recipient of the ECHA decision may file an appeal to the ECHA Board of Appeal within three months of receiving the decision.

The appeal is handled by the Board of Appeal of ECHA according to the rules of procedure laid down in Regulation (EC) 771/2008.

In any case, the evaluation of the obtained information process starts when the date set in the ECHA decision for updating the dossier with the requested information has passed.

The registrant(s) must, within the timeline(s) specified in the decision, submit the requested information to ECHA in an update of their registration dossier(s).

*If no registrant(s) update addressing the requested information is received within the timeline(s) specified in the decision, the procedure continues at **step 3.5**.*

3.2 Communication of registrant(s) update addressing the requested information to the evaluating MSCA

ECHA informs monthly the evaluating MSCAs of the dossier update(s) submitted in relation to substances for which information was requested.

The evaluating MSCA must examine the new information within 12 months of all the requested information being submitted.

3.3 Receipt of updated IUCLID dossier submitted by the evaluating MSCA

Following completion of their 12-month evaluation of the submitted information, the evaluating MSCA provides ECHA with an updated IUCLID dossier including a revised substance evaluation report and, if applicable, a new draft decision. Without undue delay, ECHA takes note of the conclusions from this new evaluation.

*If the evaluating MSCA considers that the information submitted meets the requests in the decision and that no further information is needed to clarify the potential risk, the process can be finalised by continuing to **step 3.4**.*

*If the evaluating MSCA considers that none or only part of the requested information is provided in the registrant(s) update, ECHA may inform the enforcement contact points. In such case, the procedure continues with **step 3.5**.*

*If the evaluating MSCA considers that further information is still needed to clarify the potential risk, due to a change of circumstances or due to new acquired knowledge, the IUCLID dossier will include a new draft decision and the process is re-started from **step 1.3** (under the same service contract as signed before between ECHA and the evaluating MSCA).*

3.4 Notification of conclusions to the registrant(s)/other MSCAs/Commission

If the evaluating MSCA concludes that the information is sufficient to clarify the potential risk, it shall notify ECHA accordingly, and provide an (updated) IUCLID dossier with a final substance evaluation report and a conclusion document. Once the substance evaluation has been completed, the evaluating MSCA shall consider how to use the information obtained (e.g., for the purpose of authorisation, restriction, harmonised classification and labelling) and informs ECHA of its conclusions.

ECHA will publish the combined conclusion and substance evaluation report document on the ECHA website and will share this information with the Commission, the registrant(s) and the other MSCAs.

The substance evaluation procedure is finished.

3.5 Informing that no update or insufficient update addressing the requested information was received after the deadline

When the evaluating MSCA finds that none or only part of the requested information is provided in the registrant(s) update within the timeline(s) specified in the decision, it informs ECHA. ECHA in turn may inform the enforcement focal points, in the Member State(s) where the registrant(s) are located, that the registrant(s) are in breach of their obligations following from the substance evaluation decision (Failure to Respond letter).

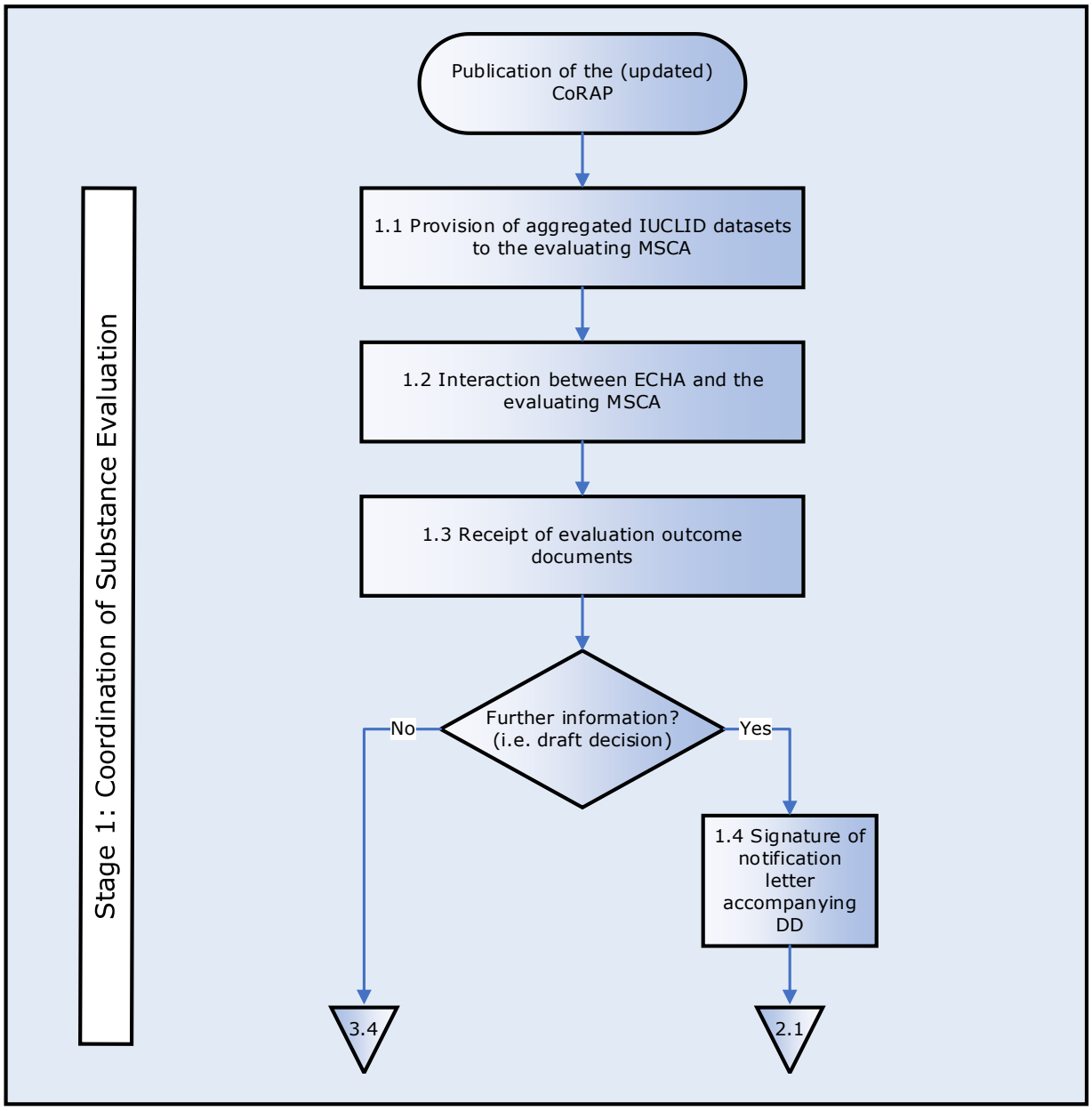
Member States have the duty to ensure that the requests in the original decision are enforced and complied with and, to that end, inter alia, to carry out checks and impose effective, proportionate, and dissuasive penalties. ECHA expects to receive the requested

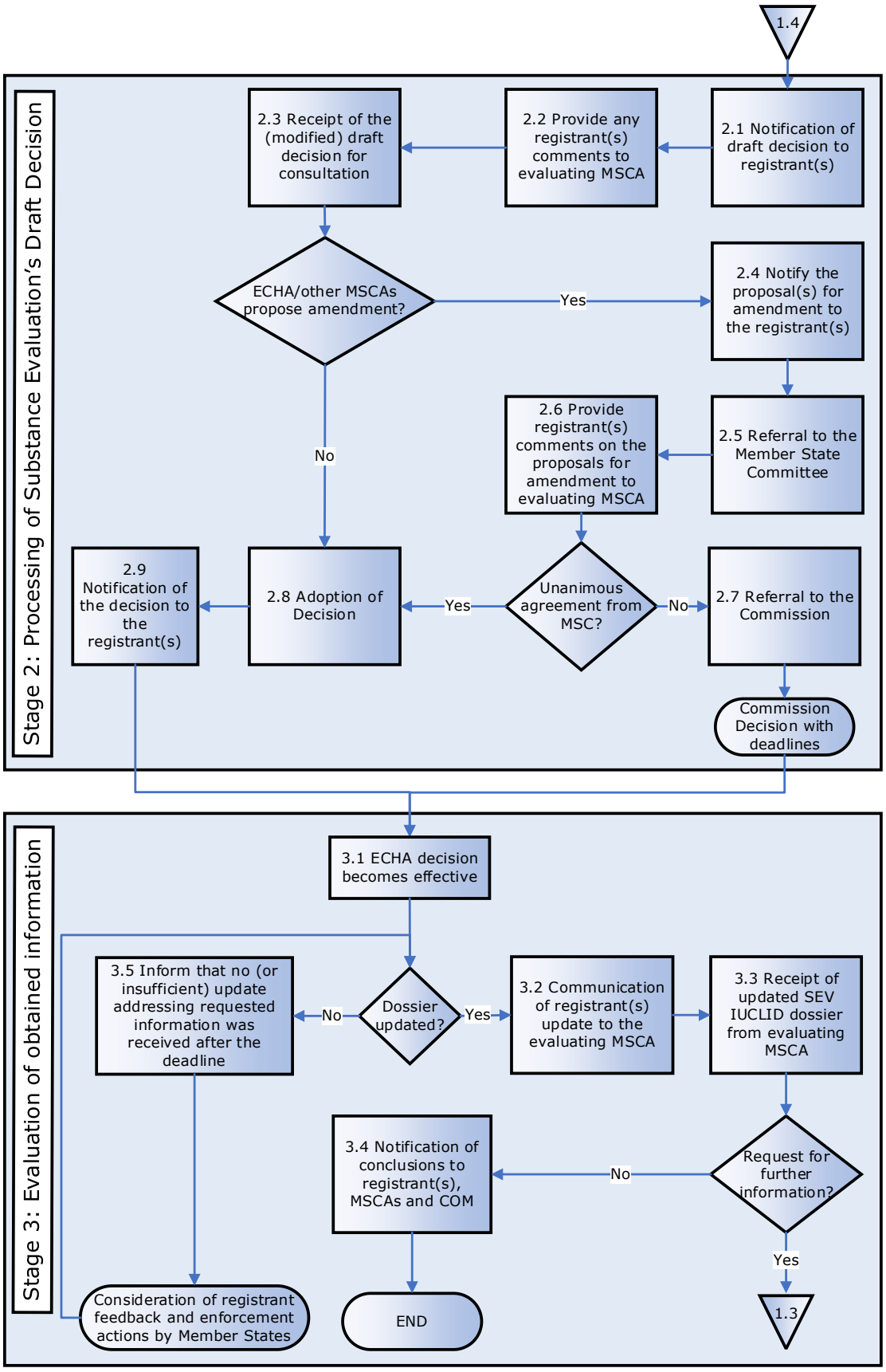
information in an updated registration dossier following the action of the respective Member State(s).

3.1. Supportive documentation

The process is described in more detail in related work instructions. In addition, supporting documentation describes practical elements required when executing tasks. These supporting documents include instructions and standard texts for documents. This documentation is controlled in analogy to the provisions of ECHA's Integrated Management System. The respective document owner is responsible for keeping the document up to date.

4. Flowchart


Publication of the (updated) CoRAP
1.1 Provision of aggregated IUCLID datasets to the evaluating MSCA
1.2 Interaction between ECHA and the evaluating MSCA
1.3 Receipt of evaluation outcome documents
Further information? (i.e. draft decision)
No
Yes
1.4 Signature of notification letter accompanying DD
3.4
2.1
Stage 1: Coordination of Substance Evaluation


1.4
Stage 2: Processing of Substance Evaluation's Draft Decision
2.1 Notification of draft decision to registrant(s)
2.2 Provide any registrant(s) comments to evaluating MSCA
2.3 Receipt of the (modified) draft decision for consultation
ECHA/other MSCAs propose amendment?
Yes
2.4 Notify the proposal(s) for amendment to the registrant(s)
2.5 Referral to the Member State Committee
2.6 Provide registrant(s) comments on the proposals for amendment to evaluating MSCA
No
Unanimous agreement from MSC?
No
2.7 Referral to the Commission
Yes
2.8 Adoption of Decision
2.9 Notification of the decision to the registrant(s)
Commission Decision with deadlines
Stage 3: Evaluation of obtained information
3.1 ECHA decision becomes effective
Dossier updated?
No
3.5 Inform that no (or insufficient) update addressing requested information was received after the deadline
Yes
3.2 Communication of registrant(s) update to the evaluating MSCA
3.3 Receipt of updated SEV IUCLID dossier from evaluating MSCA
Request for further information?
No
3.4 Notification of conclusions to registrant(s), MSCAs and COM
Yes
1.3
Consideration of registrant feedback and enforcement actions by Member States
END

5. Definitions

Term or abbreviation	Definition
CoRAP	Community Rolling Action Plan
IUCLID	International Uniform Chemical Information Database
MSC	Member State Committee
MSCA	Member State Competent Authority
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and restriction of Chemicals (REACH Regulation)

6. Records

Record name	Security level	Comments
Community Rolling Action Plan (CoRAP)	Public	
Justification Document for the selection of candidate CoRAP substances and published version of it	Internal (Confidential) & Public	
Substance evaluation IUCLID dossiers	Internal (Confidential)	
Draft Decision	Internal (Confidential)	
Decision sent to the registrant(s) and published version of it	Internal (Confidential) & Public	
ECHA/MSCAs proposals for amendment	Internal (Confidential)	
Combined Conclusion document and Substance Evaluation Report and published version of it	Internal (Confidential) & Public	
Letter of Failure to Respond with substance evaluation decision	Internal (Confidential)	

7. References

Associated document code	Document name
Regulation (EC) No 1907/2006	REACH Regulation
Regulation (EC) No 1272/2008	CLP Regulation
Regulation (EC) No 440/2008	EU Test Methods Regulation
MB/45/2011	Policy for Managing potential Conflicts of Interests (CoI)
(EC) No 771/2008	Regulation on Rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency
PRO-0022	Establishing updates of the Community Rolling Action Plan (CoRAP)
PRO-BOA-001	Appeal proceedings before the Board of Appeal
	ECHA Practical guide: how to act in substance evaluation
	Service contracts with Terms of references for substance evaluation (transfer of funds)

8. Annexes

N/A