Substance Evaluation

1. Purpose

The purpose of this procedure is to describe the Substance Evaluation process including decision making, as stated in the REACH Regulation (Title VI, Chapters 2 and 4).

This procedure is designed to ensure that

- Substance evaluation has a reliable and consistent basis.
- Requests for further information that may result from substance evaluation are consistent, scientifically robust and legally accurate.
- Legislative deadlines and registrant's rights are respected.
- Internal requirements for efficient substance evaluations are met and the responsibilities of the Member State Competent Authorities (MSCAs) and ECHA in the process are clearly defined.

2. Scope

This procedure starts after the (updated) Community Rolling Action Plan (CoRAP) has been adopted and published and finish with the notification and publication of the conclusions of substances evaluation by the evaluating MSCAs.

3. Description

Substance Evaluation (SEv) is a concern driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. According to Article 45(1)[1] of the REACH Regulation, 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 outcome of substance evaluation may be:

- Decision requesting further information from the Registrant(s), in order to clarify the concern. This request can address intrinsic properties or exposure and can go beyond the standard information requirements listed in Annexes VII – X of the REACH Regulation.
- Notification of the evaluating Member State Competent Authority (MSCA) to ECHA that no further information needs to be requested for an evaluated substance. This notification should include a report on the analysis performed and the conclusions taken.

[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.

Finally, once the substance evaluation has been completed, according to Article 48 the evaluating MSCA decides and notifies ECHA on how it intends to utilise the information obtained in substance evaluation and which risk management route it anticipates will be chosen, where relevant. The possible risk management routes include: authorisation, restriction, harmonised classification, other Community wide actions (e.g. regarding Water Framework Directive 2000/60/EC, worker protection legislation) or even appropriate national actions. ECHA will share this information with the Commission, the Registrant(s) and the Competent Authorities of the other Member States.

The substance evaluation process following the establishment and updates of the CoRAP[2] can be divided in three stages:

1. Coordination of Substance Evaluation

The evaluating MSCA shall submit to ECHA a SEv IUCLID dossier that contains a draft decision (if necessary), a (interim) substance evaluation report and a time recording sheet.

To ensure that the substance evaluation is based on sound and consistent judgement, and that requests for further information are consistent, scientifically robust and legally accurate ECHA is supporting the evaluating MSCA during the 12-month evaluation period through an early interaction with an ECHA Substance Manager. If agreed between the ECHA Substance Manager and the evaluating MSCA, a preliminary SEv draft decision can be submitted for a consistency screening to ECHA, no later than two months before the end of the 12-month evaluation period.

2. Processing of substance evaluation draft decisions

ECHA is responsible for notifying any draft decision issued by the evaluating MSCA to the relevant Registrant(s). The final decision shall be taken following involvement of the Registrant(s), consultation of the other MSCAs and ECHA, and possibly the Member State Committee (MSC) and the Commission following the procedure described by Articles 50 and 52.

3. Evaluation of obtained information

At this stage an updated dossier, referring to the substance evaluation decision with a set deadline, is expected from the Registrant(s). The updated dossier will be evaluated by the responsible MSCA that shall inform ECHA of its conclusions concerning the suitability and application of the information obtained. Subsequently, ECHA shall inform the Commission, the Registrant(s) and other MSCAs of the conclusions in a timely manner.

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

3.1. Coordination of substance evaluation

Step 1 – Preparation and submission to evaluating MSCAs of aggregated IUCLID files for each substance to be evaluated

Following the establishment and respective updates of the CoRAP, ECHA will generate and submit via REACH-IT to the evaluating MSCAs an aggregated IUCLID file for each substance to be evaluated containing all information available in the latest version of registration dossiers for that substance. This will take place once at the beginning of the process.

Upon request, ECHA may provide information on other substances relevant for the evaluation process to the evaluating MSCA. Upon request of the evaluating MSCA, ECHA may also provide new aggregated IUCLID file after the start of the evaluation.

Step 2 – Receipt of substance evaluation IUCLID dossiers submitted by the evaluating MSCAs

[According to Article 45 the evaluating MSCAs have 12 months from the publication of the (updated) CoRAP to either

a) prepare a draft decision requesting further information or

b) conclude that no further information to clarify the suspected initial concern is needed and notify ECHA accordingly].

ECHA receives the results of the evaluation via web-form, in the form of a SEv IUCLID dossier that contains

- the technical dossier
- (interim) substance evaluation report
- if appropriate, a draft decision
- if appropriate, a conclusion document (combined with evaluation report) and
- time recording sheet (certified by a signature of an authorized person in the Member State).

[The submission date, will be the reference date used for the 12-month deadline starting from the CoRAP publication].

Step 3 - Early interaction between ECHA Substance Manager and evaluating MSCA

The aim of this early interaction between the ECHA Substance Manager and the evaluating MSCA is to:

- provide early support to evaluating MSCAs in considering the best approaches to clarify the concern and any risk management measures;

- follow the progress of the evaluating MSCAs evaluation, identifying and resolving potential problems at an early stage;

-provide advice and support related to consistency and to ensure scientifically and legally sound decisions.

If agreed between ECHA Substance Manager and the evaluating MSCA, a preliminary SEv draft decision can also be submitted for a consistency screening to ECHA, no later than two months before the end of the 12 month evaluation period.

In this occasion, the Substance Manager, after coordination with Legal Advisors and the SEv team, may suggest changes to the draft decision being prepared by the evaluating MSCA.

The SEv team invites the evaluating MSCA to consider the suggestions made by ECHA, to modify the draft decision if appropriate and submit, via a SEv IUCLID dossier, the revised draft decision for further processing still within the 12-month evaluation period.

*When the conclusion of a substance evaluation is that no further information to clarify the concern is necessary, i.e. the evaluating MSCA is not preparing a draft decision on substance evaluation, the procedure continues with **step 4**.*

*When the outcome of a substance evaluation is that an information request to clarify the suspected concern is deemed necessary, i.e. the evaluating MSCA is preparing a draft decision on substance evaluation, the procedure continues with **step 5**.*

Step 4 – Information to the Registrant(s), MSCAs and Commission that the evaluation is completed

[A conclusion document to inform the Registrant(s), MSCAs and Commission that the evaluation is completed and no further information to clarify the concern is needed shall be prepared by the evaluating MSCA and submitted to ECHA].

The combined or separate SEv report and the conclusion document prepared by the evaluating MSCA will be published on the ECHA website. ECHA, without undue delay, will inform the Commission, the Registrant(s) and the Competent Authorities of the other Member States that these documents have been published on the ECHA website.

In this case the procedure is finished.

Step 5 – Sign the notification letter to be sent with the draft decision to the Registrant(s)

When the outcome of a substance evaluation is a conclusion that further information from the Registrant(s) is needed in order to clarify the concern, a draft decision shall be prepared by the evaluating MSCA within the 12-month evaluation period. At this point of time ECHA is not normally modifying the content of the draft decision. A notification letter is accompanied to the draft decision by ECHA. Procedure continues to **step 6**.

3.2. Processing of substance evaluation draft decision

Step 6 – Notification of the draft decision to the Registrant(s)

ECHA notifies via REACH-IT, without undue delay[3], the draft decision to the Registrant(s) of the substance. The Registrant(s) is/are informed in the notification letter of their right to comment on the draft decision within 30 calendar days of receipt of the draft decision.

Step 7 – Information to the evaluating MSCA of the Registrant(s) comments

ECHA informs, via REACH-IT, the evaluating MSCA of any comments submitted by the Registrant(s) without undue delay.

[The evaluating MSCA shall take the comments of the Registrant(s) into account and record a response to each comment. The evaluating MSCA shall decide whether the draft decision needs to be amended on the basis of the comments/additional information provided by the

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

Registrant(s) (Article 50(1)). Substantial comments should be reflected in an appropriate manner in the draft decision and its supporting documentation.

If no comments are received from the Registrant(s) within the 30-day commenting period, the draft decision is not amended by the evaluating MSCA].

Step 8 – Receipt of the (amended) draft decision.

ECHA and other MSCAs receive notification of the (amended) draft decision from the evaluating MSCA via S-CIRCABC (Article 52(1)). The draft decision and additional documents including the original comments from the Registrant(s) and the responses provided by the evaluating MSCA to these comments shall also be available via S-CIRCABC.

Subsequently, ECHA (and the other MSCAs) may submit proposals for amendment to the draft decision within 30 calendar days starting from the date they were notified of the (amended) draft decision (Article 51(2)). ECHA proposals for amendment are submitted to the evaluating MSCA via S-CIRCABC.

*If the evaluating MSCA receives proposals for amendment, the procedure continues in **step 9**. In such cases, a response to each proposal for amendment shall be provided by the evaluating MSCA. The evaluating MSCA may modify the draft decision and provide the (amended) draft decision to ECHA (Article 51(4)) within 13 days counting from the deadline by when ECHA/other MSCAs could submit the proposals for amendment.*

*If the evaluating MSCA does not receive proposals for amendment, the procedure continues in **step 12b**.*

Step 9 - Referral to the Member State Committee

MSC Secretariat (MSC-S) notifies the MSC that the draft decision received proposals for amendment.

MSC-S refers the (amended) draft decision, together with any comments and proposed amendments, to MSC within 15 calendar days of the end of the 30-day commenting period in step 8. Within 60 days of referral, MSC shall seek agreement on the draft decision (Article 51(6)).

Step 10 – Communication of proposals for amendments (if any) to the Registrant(s)

ECHA communicates to the Registrant(s) after the end of the 30-day commenting period in step 8 the draft decision as notified to the other MSCAs and ECHA, the received proposals for amendment and a cover letter.

The cover letter notifies the Registrant(s) of their right to comment on the proposals for amendment within a 30-day of receipt (Article 51(5)).

Step 11 – Forwarding of the Registrant(s) comments on the proposals for amendment to the evaluating MSCA

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

According to Article 51(5), the Member State Committee shall take any comments received into account and record each relevant comment in the supporting documentation.

*In case of no unanimous agreement by the MSC, the procedure continues with **step 12a**. While in case of unanimous agreement reached by the MSC, the procedure continues with **step 12b**.*

Step 12a - Referral to the Commission

When MSC fails to reach unanimous agreement, MSC-S refers the case to the Commission. ECHA also informs the Registrant(s) that the case has been referred to the Commission.

Step 12b – Adoption of the decision

If no proposals for amendment to the draft decision are submitted by ECHA/other MSCAs or if MSC reached unanimous agreement, the (amended) draft decision is adopted by ECHA and it becomes the decision with legal deadline(s) (Articles 51(3) and 51(6) respectively).

Step 13 – Notification of the decision to the Registrant(s)

The decision adopted by ECHA is notified to the Registrant(s). ECHA informs also the other MSCAs of the decision. The decision will request further information to be provided by the Registrant(s) in the form of an updated dossier by a specified deadline(s).

ECHA publishes later on the ECHA website the decisions without confidential business information.

Step 13a – Decision on who shall perform studies

[When Registrant(s) are required to perform a test as a result of a decision, according to Article 53 those Registrant(s) shall make every effort to reach an agreement as to who is to carry it out on behalf of the other registrants and to inform the Agency accordingly within 90 days].

If ECHA is not informed of an agreement of the registrants within 90 days of taking the decision, it shall designate one of the registrants to perform the test(s) on behalf of all of them and issue a decision on this matter.

3.3. Evaluation of obtained information

The Registrant(s) shall, within the timeline(s) specified in the decision, submit the requested information to ECHA by updating the registration dossier(s) with that new data.

*If no Registrant(s) update addressing the requested information is received within the timeline(s) specified in the decision, the procedure continues at **step 17**.*

*If a Registrant(s) update addressing the requested information is received within the timeline(s) specified in the decision, the procedure continues at **step 14**.*

Step 14 – Communication of Registrant(s) update addressing the requested information to the evaluating MSCA

ECHA informs monthly via S-CIRCABC the evaluating MSCAs of the updated dossier(s) in relation to substances for which information has been requested..

[The evaluating MSCA shall examine the new information within 12 months of all the requested information being submitted (Article 46(3))].

Step 15 – Receipt of updated SEv IUCLID dossier submitted by the evaluating MSCA

After the evaluating MSCA has carried out the evaluation of new obtained information, ECHA receives from the evaluating MSCA via web-form an updated SEv 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 no further information is needed to clarify the concern, the process can be finalised by continuing to **step 16**.*

*If the evaluating MSCA considers that in case no 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 17**.*

*If the evaluating MSCA considers that further information is still needed to clarify the concern, due to a change of circumstances or due to new acquired knowledge, the SEv IUCLID dossier shall include a new draft decision and the process is repeated from **step 1** under the same service contract as signed before between ECHA and the evaluating MSCA.*

Step 16 – Notification of conclusions to the Registrant(s)/other MSCAs/Commission

[If the evaluating MSCA concludes that the information is sufficient to clarify the concern, it shall notify ECHA accordingly, and provide an (updated) SEv IUCLID dossier with a final substance evaluation report and a conclusion document. Once the substance evaluation has been completed, the evaluating MSCA shall in accordance with Article 48 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 merged or separate SEv report and conclusion document on the ECHA website and will share this information with the Commission, the Registrant(s) and the other MSCAs.

Step 17 – Informing that no update or insufficient update addressing the requested information was received after the deadline

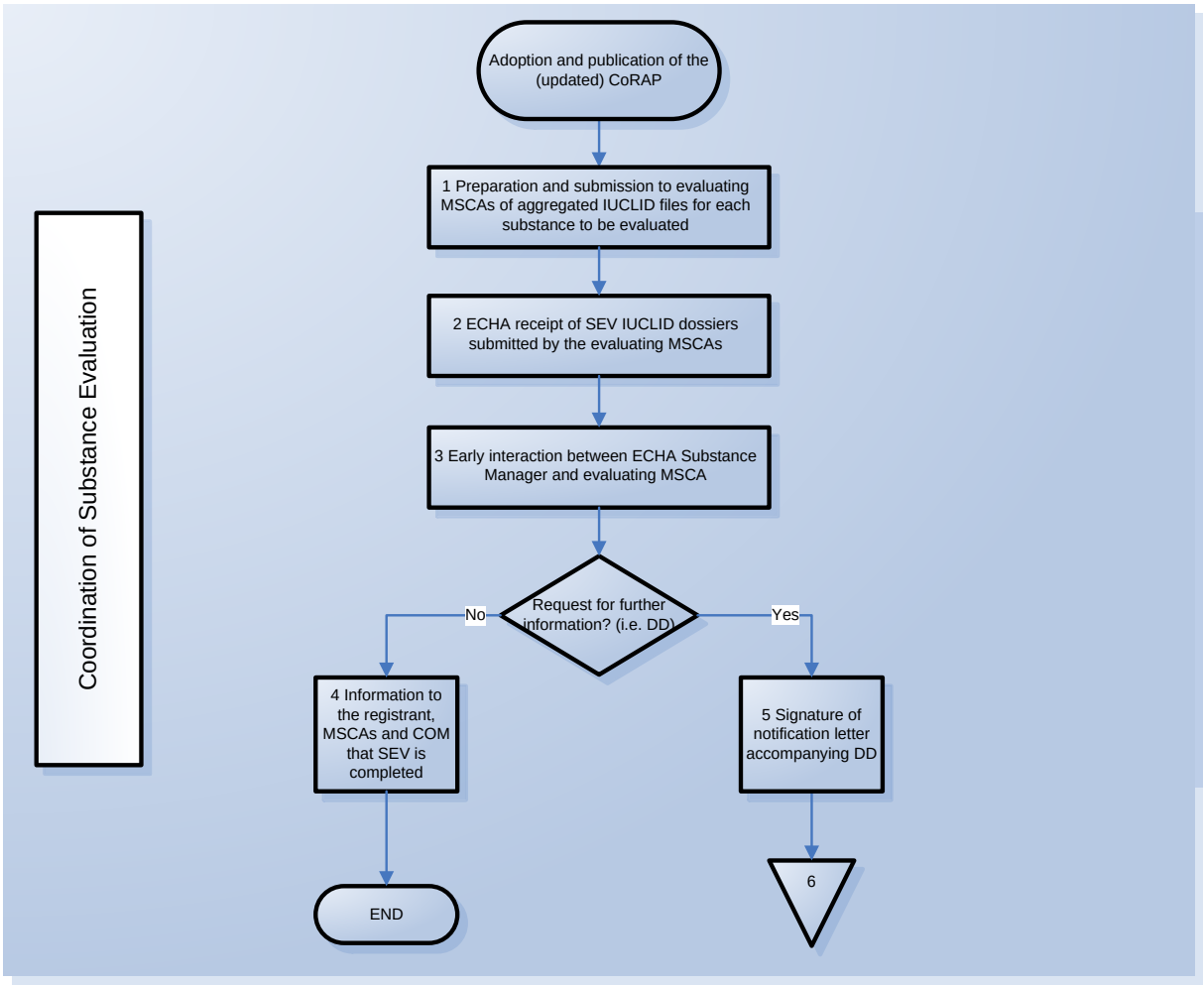
When evaluating Member State finds that no update or insufficient update from the Registrant(s) is received within the timeline(s) specified in the decision, it informs ECHA. ECHA in turn may inform the focal points of enforcement in the Member State(s) (MS(s)) where the Registrant(s) is/are located (the Lead Registrant and the evaluating MSCA in copy) that the Registrant(s) is/are in breach of their obligations following from the SEv decision (a letter of failure to comply with SEv Decision). The relevant National Enforcement Authorities shall consider appropriate follow-up enforcement actions towards the Registrant(s).

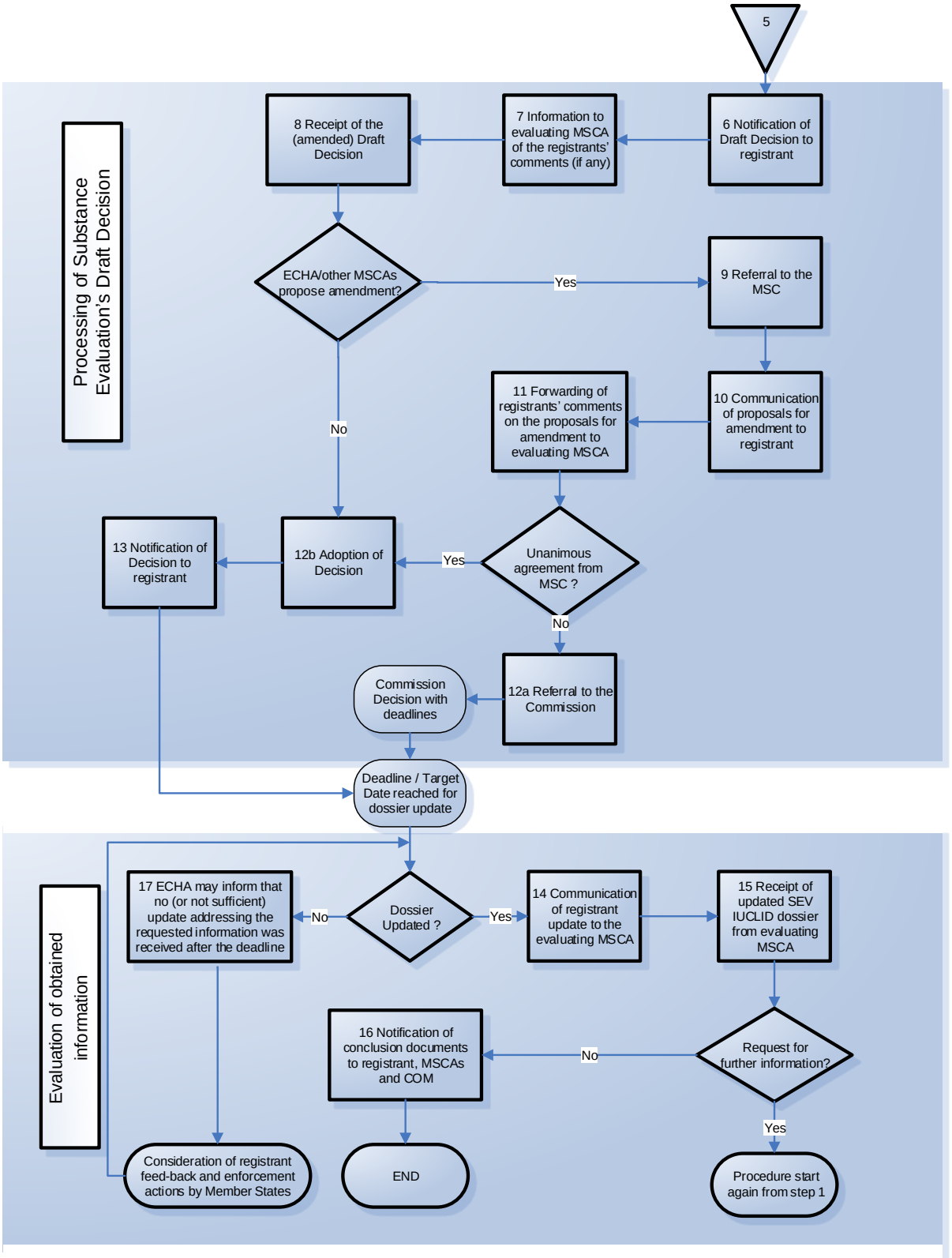
3.4. Supportive documentation

Above mentioned steps are further described in working instructions and supportive documentation. This allows ECHA and the evaluating MSCA to process steps reliably and

effectively. This documentation includes e.g. practical instructions and standard texts for documents. This documentation is controlled in analogy to the provisions given in PRO-0001. The respective document owner is responsible for keeping the documents up-to-date.

4. Flowchart




5
Processing of Substance Evaluation's Draft Decision
6 Notification of Draft Decision to registrant
7 Information to evaluating MSCA of the registrants' comments (if any)
8 Receipt of the (amended) Draft Decision
ECHA/other MSCAs propose amendment?
Yes
9 Referral to the MSC
10 Communication of proposals for amendment to registrant
11 Forwarding of registrants' comments on the proposals for amendment to evaluating MSCA
No
Unanimous agreement from MSC ?
Yes
12b Adoption of Decision
13 Notification of Decision to registrant
No
12a Referral to the Commission
Commission Decision with deadlines
Deadline / Target Date reached for dossier update
Evaluation of obtained information
Dossier Updated ?
No
17 ECHA may inform that no (or not sufficient) update addressing the requested information was received after the deadline
Yes
14 Communication of registrant update to the evaluating MSCA
15 Receipt of updated SEV IUCLID dossier from evaluating MSCA
Request for further information?
No
16 Notification of conclusion documents to registrant, MSCAs and COM
Yes
Procedure start again from step 1
Consideration of registrant feed-back and enforcement actions by Member States
END

5. Definitions

Term or abbreviation	Definition
CoRAP	Community Rolling Action Plan, which lists substances to be evaluated over a three-year period
DD	Draft Decision
eMSCA	Evaluating Member State Competent Authority
FORUM	Forum for Exchange of Information on Enforcement
IUCLID	International Uniform ChemicaL Information Database. IUCLID is a software to record, store, maintain and exchange data on intrinsic and hazard properties of chemical substances.
MS	Member State
MSC	Member State Committee
MSCA	Member State Competent Authority
MSC-S	Member State Committee Secretariat
REACH-IT	REACH-IT is the central IT system that supports Industry, Member State competent authorities and the European Chemicals Agency to securely submit, process and manage data and dossiers.
S-CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens. S-CIRCABC is a collaborative platform for distribution and management of documents.
SEv	Substance Evaluation
SEv team	Substance Evaluation Team: Team from Directorate E composed of: • Head of Unit (HoU) • Team Leader(s) (TLs) • Process Coordinator(s) (PCs) • Substance Managers (SMs) • Evaluation Assistants (EAs).

6. Records

Record name	Security level	Comments
Community Rolling Action Plan (CoRAP)	Public	
Justification Documents for the selection of candidate CoRAP substances	Internal (Conf.)	

Record name	Security level	Comments
	& Public	
Substance evaluation IUCLID dossiers submitted by the MSCAs [including substance evaluation report, draft decision (if relevant), and time recording sheet]	Internal (Conf.)	
Draft Decision sent to the Registrant(s)	Internal (Conf.)	eMSCA prepares the DD and ECHA sends it to the Registrant(s) via REACH-IT and shares with other MSCAs via S-CIRCABC
Final Decision sent to the Registrant(s) and published version of it	Internal (Conf.) & Public	
ECHA/MSCAs proposals for amendment	Internal (Conf.)	
Published Substance Evaluation Report (prepared by the MSCAs)	Internal (Conf.) & Public	
SEV Conclusion document prepared by the MSCAs (could be combined with SEv Report)	Public	
Letter of failure to comply with SEv FD	Internal (Conf.)	

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
	Service contracts with Terms of references for substance evaluation (transfer of funds)

Associated document code	Document name
	ECHA guidance on information requirements and chemical safety assessment
	OECD and EU test guidelines

8. Annexes

N/A