PRO-0023.01 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 (updated) CoRAP has been adopted and published and finish with the notification and publication of the conclusions of substances evaluation by the evaluating MSCA.

The relevant processes and sub processes covered by this procedure are:

1. Work Programme Activity:	2	Evaluation
2. Process Area:	2.2	Substances Evaluation
3. Sub-process:	2.2.2	Coordination of Substance Evaluation by MSCAs
	2.2.3	Processing of draft decisions
	2.2.5	Follow-up to substance evaluation

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:

[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.

- 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 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.

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 and labelling, 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 Community Rolling Action Plan (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.
If received at least two months before the end of the 12-month evaluation period from the evaluating Member State, ECHA aims at performing a scientific and legal consistency screening on the draft decision 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.

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 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 initial substance evaluation decision with a set deadline, is expected from the Registrant(s). The updated dossier will be re-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.

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 REACH-IT or according to a temporary submission procedure, in the form of a SEV IUCLID dossier that contains

- the technical dossier,
- a (interim) substance evaluation report and,
- if appropriate, a draft decision.

[The submission date, as indicated in REACH-IT (or during the temporary submission procedure), will be the reference date used for the 12-month deadline starting from the CoRAP publication].

Step 3 - Scientific and legal consistency screening (if requested) of outgoing documents

If received at least two months before the end of the 12-months evaluation period from the evaluating Member State, ECHA aims at performing a scientific and legal consistency screening of the draft decision on the basis of the interim substance evaluation report to ensure that the substance evaluation is based upon sound and consistent judgement and that requests for further information are consistent, scientifically robust and legally accurate.
In this occasion, the Substance Manager, after coordination with Legal Advisors and SEV team, may suggest changes to the draft decision prepared by the evaluating MSCA. The SEV Team invites the MSCA to consider the suggestions made by ECHA, to modify the draft decision if appropriate and submit, via an updated 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].

ECHA, without undue delay, will share this information with the Commission, the Registrant(s) and the Competent Authorities of the other Member States.

At the same time, or shortly after, the non-confidential version of the SEV report prepared by the evaluating MSCA will be published on the ECHA website. In this case the procedure is terminated.

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 modifying the content of the draft decision.

The Director of Evaluation signs the notification letter accompanying the draft decision issued by the evaluating MSCA. In this case the 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 CIRCABC, 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 Registrant(s) (Article 50(1)). Comments should be reflected in an appropriate manner in the draft decision or 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].

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

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

ECHA and other MSCAs receive notification of the (amended) draft decision from the evaluating MSCA (Article 52(1)). The draft decision and additional documents including the original comments from the Registrant(s) and the responses provided by the evaluating MSCAs to these comments shall also be available via 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 prepared by the Substance Manager, signed by the Director of Evaluation and submitted to the evaluating MSCA via CIRCABC.

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

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)), or communicate to ECHA that it does not consider that there are sufficient grounds to amend the draft decision, within 13 days from the deadline for ECHA/other MSCAs to make proposals for amendment].

Step 9 - Referral to the Member State Committee

MSC secretariat on behalf of MSC receives a notification from the evaluating Member State that because of proposals for amendment the draft decision is referred to the MSC.

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 signed by the Substance Manager.

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].

Step 12a - Referral to the Commission

When MSC fails to reach unanimous agreement, MSC-S refers the case to the Commission. Such a letter with accompanying documents is signed by the Director of Regulatory Affairs. ECHA also informs the Registrant that the case has been referred to the Commission.

Step 12b – Adoption of the final 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 final decision (Articles 51(3) and 51(6) respectively).

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

The final decision signed by the Director of the Regulatory Affairs is notified to the Registrant(s) by ECHA. ECHA informs also the other MSCAs of the final decision. The final decision will request further information to be provided by the Registrant(s) in the form of an updated dossier by a specified deadline.
ECHA publishes on the ECHA website final 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 final 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 final 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. Also in cases where registrants indicate who will perform the test(s), ECHA will confirm this agreement by issuing a decision on who shall perform the test(s).This decision shall be signed by the Director of Regulatory Affairs.

3.3 Evaluation of obtained information

The Registrant(s) shall, within the timelines 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 specified in the decision, the procedure continues at step 17.
If a Registrant(s) update addressing the requested information is received within the timeline 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

After receiving Registrant(s) update addressing the requested information, ECHA informs via CIRCABC the evaluating MSCA of the updated dossier(s) without undue delay.

[From the date of receipt the evaluating MSCA has 12 months to evaluate the new information (Article 46(3))].

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

ECHA receives via REACH-IT, after the evaluating MSCA has carried out the evaluation of new obtained information, 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.

In case no or only part of the requested information is provided in the Registrant(s) update, ECHA considers sending a letter to the evaluating MSCA (with the Registrant and the other MSCAs in copy). In such case, continue to step 17.

If the evaluating MSCA considers that further information is still needed to clarify the concern, due to a change of circumstances or acquired knowledge, the SEV IUCLID dossier shall include a new draft decision and the process is repeated from step 3 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 inform ECHA of its conclusions].

ECHA will share this information with the Commission, the Registrant(s) and the Competent Authorities of the other Member States. At the same time, the SEV report prepared by the evaluating MSCA will be published on the ECHA website.

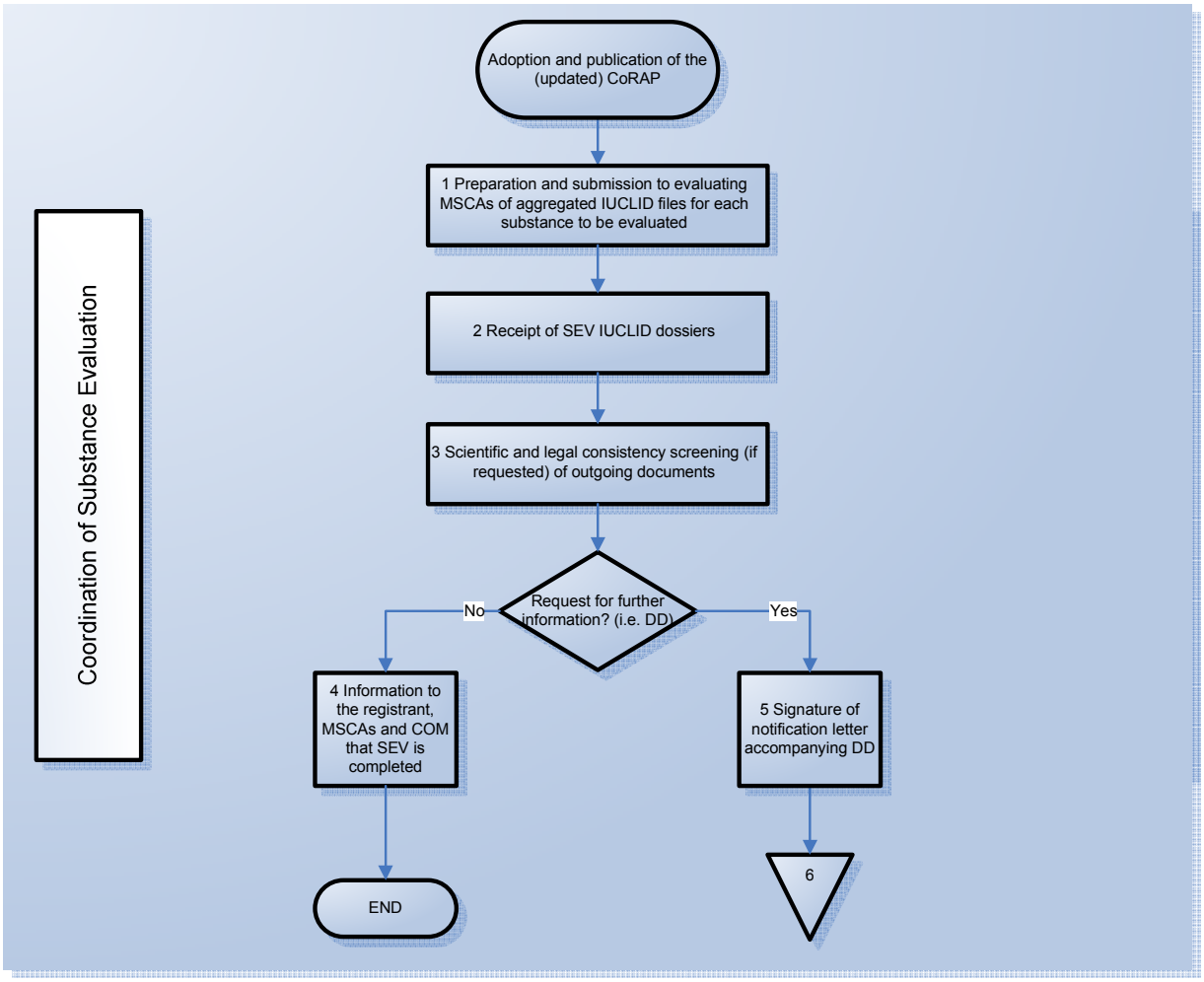
Step 17 – Informing that no update addressing the requested information was received after the deadline

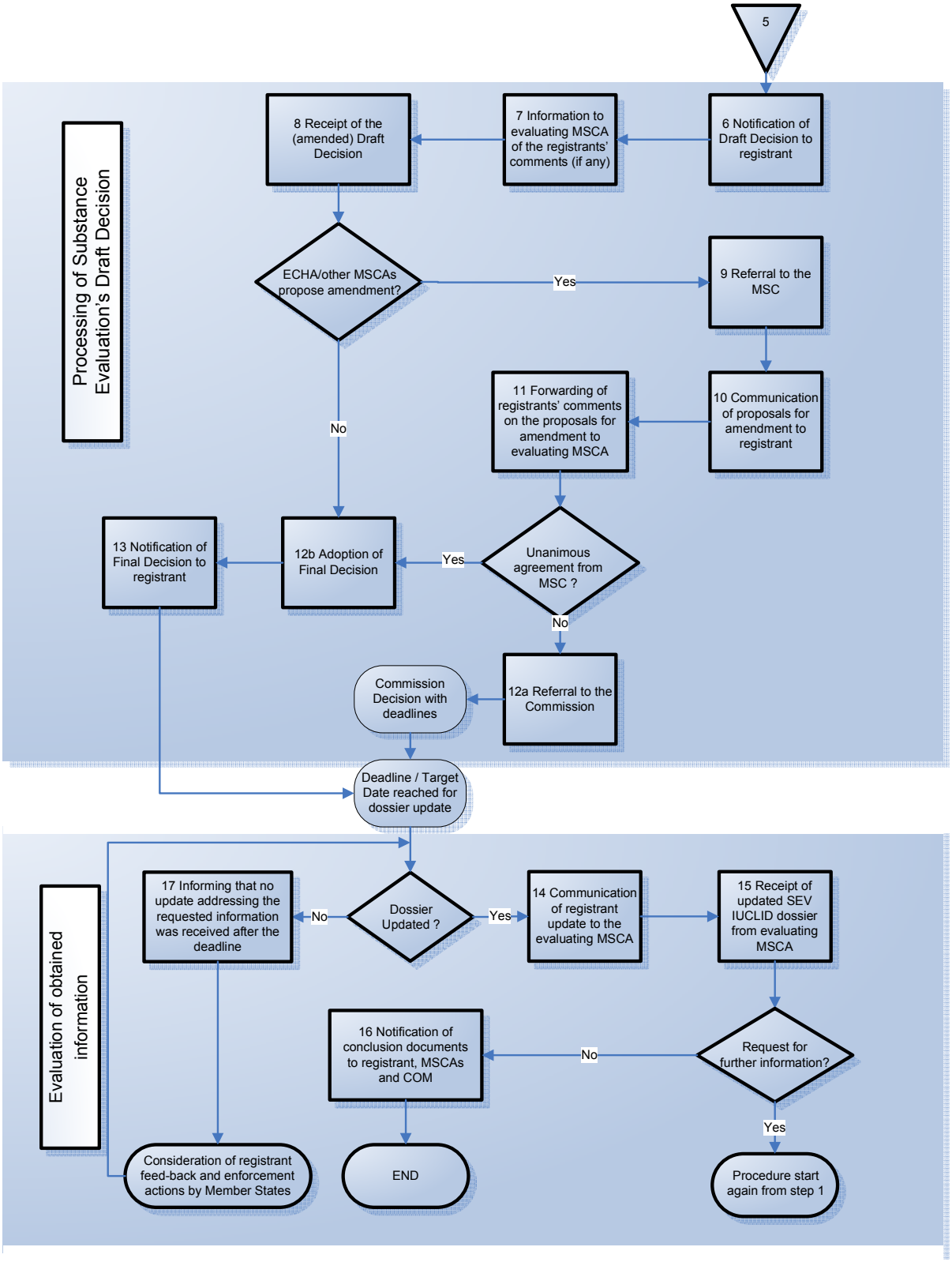
When no update from the Registrant(s) is received within the timeline specified in the decision, ECHA sends a letter of failure to comply with the SEV decision to the evaluating MSCA (with the Registrant and the other MSCAs in copy) informing that Registrant(s) are in breach of their obligations following from the SEV decision and informs the evaluating MSCA and Forum, which shall consider making recommendations for enforcement actions towards the Registrant(s).

The notification of a similar letter can be sent to the evaluating MSCA (with the Registrant and the other MSCAs in copy) also in the case where only part of the requested information is provided in the Registrant(s) update.

These letters are signed by Director of Evaluation.

4. Flowchart


Coordination of Substance Evaluation
Adoption and publication of the (updated) CoRAP
1 Preparation and submission to evaluating MSCAs of aggregated IUCLID files for each substance to be evaluated
2 Receipt of SEV IUCLID dossiers
3 Scientific and legal consistency screening (if requested) of outgoing documents
Request for further information? (i.e. DD)
No
Yes
4 Information to the registrant, MSCAs and COM that SEV is completed
5 Signature of notification letter accompanying DD
END
6


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 Final Decision
13 Notification of Final 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 Informing that no 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
END
Consideration of registrant feed-back and enforcement actions by Member States

5. Definitions and acronyms

Term/Abbreviation/Acronym	Definition
CoRAP	Community Rolling Action Plan
SEVT	Substance Evaluation Team: Team from Directorate E composed of: • Team Leader(s) (TLs - Evaluation Units). • The Substance Managers (SMs - Evaluation Units). • The Evaluation Assistants (EAs - Evaluation Units).
MSCA	Member State Competent Authority
SEV	Substance Evaluation
MSC	Member State Committee
MSC-S	Member State Committee Secretariat
eMSCA	Evaluating Member State Competent Authority
DD	Draft Decision

6. References

IQMS document code	Document name
PRO-0022	Substance Evaluation-Establishing updates of the Community Rolling Action Plan (CoRAP)

Associated document code	Document name
Regulation (EC) No 1907/2006	REACH Regulation
Directive 67/548/EEC	Dangerous Substances Directive
Regulation (EC) No 1272/2008	CLP Regulation
Regulation (EC) No 440/2008	EU Test Methods Regulation
	Guidance on information requirements and chemical safety assessment
	Guidance on dossier and substance evaluation
	OECD test guidelines