ECHA
EUROPEAN CHEMICALS AGENCY

Registrant's guide - How to act in substance evaluation

February 2018

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Version	Changes

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1. THE PURPOSE AND NATURE OF PRACTICAL GUIDES

Practical Guides aim to help duty holders to fulfil their obligations in relation to the REACH Regulation (or "REACH"). They provide practical tips and advice and explain ECHA's processes and scientific approaches. Practical Guides are produced by ECHA, under its sole responsibility. They do not replace the formal Guidance (which is established under the formal guidance consultation process involving stakeholders) that provides the principles and interpretations needed for a thorough understanding of the requirements of REACH. However, they explain, in a practical way, specific issues presented in the formal Guidance. ECHA invites interested parties to submit experiences and examples to be incorporated in future updates of this document. These can be submitted using the contact form[1].

The purpose of this practical guide is to explain in simple terms what substance evaluation (SEv) is, and how substances are selected and subsequently evaluated. This guide aims also to highlight the opportunities as well as the obligations that you, as registrant, have in providing the information requested under substance evaluation. This guide describes (i) what kind of different administrative outcomes you can expect from the substance evaluation process and (ii) how and when you can react to communications received from an evaluating Member State competent authority (eMSCA) and/or from ECHA. This guide also addresses data sharing and communication between registrants of the same substance.

[1] http://echa.europa.eu/contact

2. INTRODUCTION

Substance evaluation is one of three different evaluation processes specified in REACH, which have distinct scopes:

1) Compliance check of dossiers assesses whether or not the information submitted by a registrant is compliant with the legal requirements according to Annexes VI-X. The REACH Regulation requires that ECHA must check at least 5 % of the registration dossiers per tonnage band.
2) Examination of testing proposals submitted in dossiers aims to ensure that adequate and reliable data are generated, and that testing is tailored to real information needs, in particular to prevent unnecessary testing on vertebrate animals. Proposals, which involve vertebrate animal tests lead to a public call for scientific information that may then be taken into account in the decision-making process. Registrants must always seek permission from ECHA before conducting any higher-tier studies listed in Annexes IX-X, and ECHA examines all testing proposals in the registration dossiers.
3) Substance evaluation aims to assess whether further information is necessary, so that the eMSCA can conclude if the use of a substance presents a risk to human health or to the environment. The substances to be evaluated are selected by ECHA in cooperation with the Member States in a risk-based approach. For each substance subject to substance evaluation, ECHA aims to first perform a compliance check to scrutinise in particular the substance's identification and hazard data to ensure an adequate basis for the eMSCA's evaluation.

The substance evaluation process is an important part of the regulatory measures set in REACH giving the authorities the power to request information that can go beyond the standard information requirements (Figure 1). It is a concern-driven process with the aim to clarify concerns related to safe use of the substance, and it may lead to regulatory risk management measures.

Addressees subject to substance evaluation:

Substance evaluation of substances with intermediate uses may occur only for transported isolated intermediates (TII).
By contrast, on-site isolated intermediate substances (OSII), manufactured under strictly controlled conditions cannot be subject to substance evaluation. SEv decisions will thus be addressed by default to all active registrants for substances including TII but excluding OSII.

However, the registrants of TII may seek to demonstrate that the concern identified in the draft decision is not relevant to their specific strictly controlled conditions of use. The eMSCA will take the comments and reasons into account and come to a case-by-case conclusion on whether the TII registrant remains an addressee.

The aim of the substance evaluation process is to clarify the concerns identified by eMSCAs and ECHA and to conclude on whether the prioritised substances may pose risks to human health or to the environment.

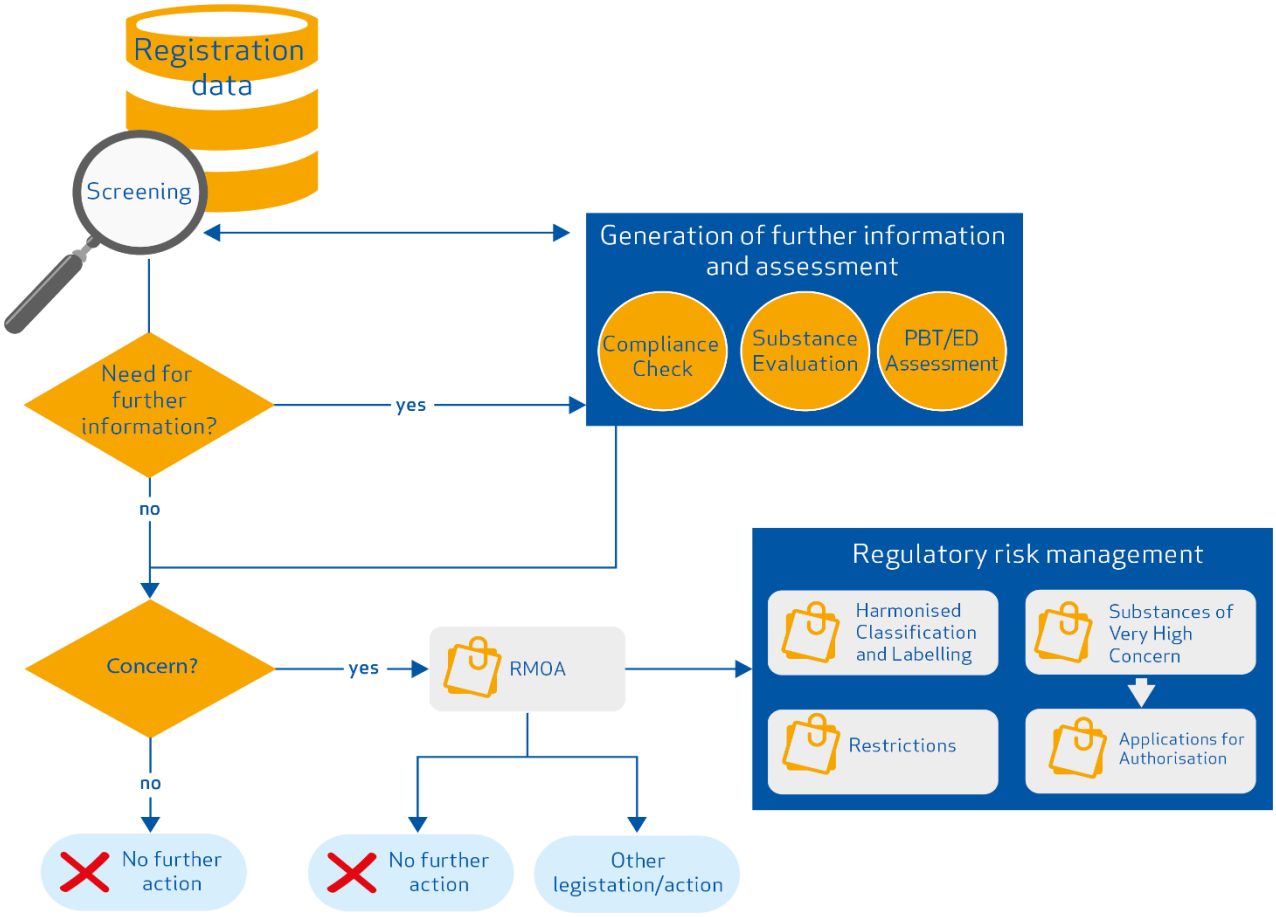


Figure 1: Substance evaluation in the regulatory context.

For early information about substances that are under scrutiny of authorities, please check the Public Activities Coordination Tool (PACT). This tool lists the substances for which a risk management option analysis (RMOA) or an informal hazard assessment for PBT/vPvB (persistent, bioaccumulative and toxic/very persistent and very bioaccumulative) properties or endocrine disrupting properties is either under development or has been completed since the implementation of the SVHC Roadmap commenced in February 2013.

3. COMMUNITY ROLLING ACTION PLAN (CoRAP)

3.1 WHAT IS THE CoRAP?

CoRAP is the abbreviation for the Community Rolling Action Plan that is published on ECHA's website[2]. It specifies the substances that are prioritised by the evaluating Member State Competent Authorities (eMSCAs) and ECHA. The plan covers three years and it is updated every year. The annual update (in year N) includes substances for an additional (new N+2) year as well as any revision to the substances that were included in the previous plan (Figure 2).

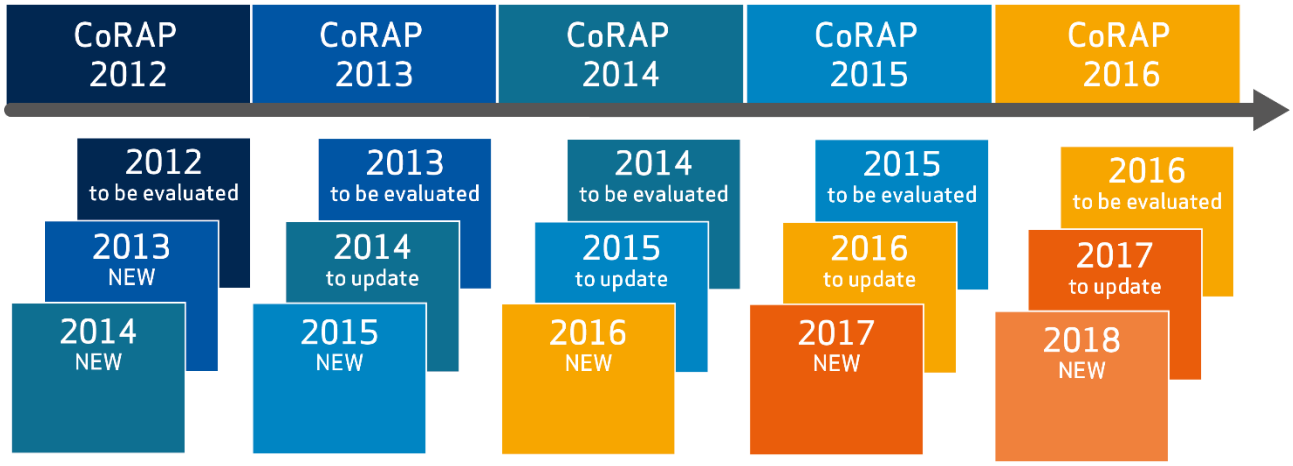


Figure 2: CoRAP's triennium and its "rolling" nature.

3.2 WHAT ARE THE CRITERIA FOR SUBSTANCES SELECTED FOR EVALUATION?

REACH Article 44(1) provides the general criteria for substances to be selected for substance evaluation:

"Prioritisation shall take place on a risk-based approach. The criteria shall consider:

(a) hazard information, for instance structural similarity of the substance with known substances of concern or with substances which are persistent and liable to bio-accumulate, suggesting that the substance or one or more of its transformation products has properties of concern or is persistent and liable to bio-accumulate;
(b) exposure information;
(c) *tonnage, including aggregated tonnage from the registrations submitted by several registrants."*

Hence, the selection criteria need to cover both hazard (intrinsic properties) and exposure aspects suggesting a general risk-based approach. ECHA has refined the criteria in cooperation with the MSCAs and has published them on its website[3].

However not all substances meeting the criteria will be included in the CoRAP list for evaluation (see section 3.3).

[2] https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-list-of-substances
[3] http://echa.europa.eu/documents/10162/13628/background_doc_criteria_ed_32_2011_en.pdf

The MSCAs and ECHA have to also consider:

i. whether a request for further information at the end of the evaluation process can reasonably lead to the clarification of the initial concern raised by the substance;
ii. whether the priorities and capacities of the Member States are compatible with the substance evaluation process.

In addition to common screening of potential candidates for substance evaluation, the MSCAs can propose other substances based on other risk-based grounds for concern founded on e.g. national priorities.

The criteria for selecting substances for evaluation take into consideration both hazard and exposure information on a substance.

3.3 WHAT IS THE PROCESS LEADING TO THE SELECTION OF MY SUBSTANCE?

Step 1: Shortlisting

A screening of registered substances, also named common screening, is repeated every year to identify substances of potential concern and select the most appropriate regulatory action, among which substance evaluation, if it appears to be the most effective way to clarify the concern. After applying the selection criteria to the database of all registered substances and using advanced screening algorithms, ECHA communicates a list of substances of potential concern ("shortlist") to the MSCAs. The choice of algorithms is agreed with the MSCAs and is generally described in a definition document updated each year and published on ECHA's screening website[4].

For screening, all information available to ECHA is utilised, including data from external sources, such as accessible databases with experimental data or structural alerts and international assessments. Furthermore, structural similarities, same uses, or other communalities can be used to identify groups of substances that would benefit from being assessed together.

Step 2: Refining of the shortlist and communication to registrants concerned

From February-March until the end of May, the MSCAs "filter" substances of potential concern from the shortlist to select substances for manual screening. During the manual screening, MSCAs decide which substances they consider relevant as CoRAP candidates. The selection process takes into consideration whether the substances are already subject to regulatory measures and whether the substance evaluation process is the most effective way to clarify the concern.

Furthermore, for efficiency reasons and where it is scientifically justified, grouping of substances whose properties are likely to be similar or follow a regular pattern as a result of structural similarity may be envisaged. Subsequently, an eMSCA would evaluate those substances together, in parallel or in sequence.

While the shortlist is not published, the registrants concerned are informed (normally around February-March) that their substance has been shortlisted and of the concerns that were identified. If you receive such information, you are strongly encouraged to update your dossier, providing the most recent and accurate information, especially on actual tonnage band, uses, and tonnage per use. You are also invited to include in your update any available information to clarify the hazardous properties of your substance.

[4] https://echa.europa.eu/screening

Step 3: Informing ECHA of the substances proposed for (draft) CoRAP and publication

Based on the outcome of their manual screening and taking into account other potential CoRAP candidates, the MSCAs inform ECHA of their preferences and the list of substances they intend to evaluate in the coming years. ECHA then crosschecks and publishes the draft CoRAP.

The annual CoRAP cycle

The CoRAP annual update follows a cycle with two publication periods:

1. In autumn, usually in October, ECHA submits a draft update of the CoRAP to the MSCAs and to ECHA's Member State Committee (MSC) for opinion.

The draft update is published on ECHA's website to inform stakeholders of the draft evaluation plan. There is no public consultation on the draft, but the publication helps the registrants involved to prepare and start interaction with the relevant eMSCA.

The draft CoRAP lists the following information:

- the non-confidential substance names;
- CAS and EC numbers;
- the initial concerns which triggered the inclusion of the substance in the CoRAP;
- the proposed year of evaluation;
- the contact details of the eMSCA that intends to conduct the substance evaluation.

Before formal adoption, substances may be added or removed from the draft CoRAP or the year of evaluation changed.

The inclusion of a substance in the (draft) CoRAP list does not in itself have any immediate legal impact on you, and does not mean that the substance poses a risk to human health or to the environment.

2. In spring, usually in March, after consultation among the eMSCAs and based on the opinion of the MSC, ECHA adopts the final CoRAP update.

The published final CoRAP update provides transparency on authorities' intentions. The indicated "grounds for concern" are only an indication of the possible areas of risk, as they are based on the selection criteria and screening, and because a selected substance has not been evaluated in detail by the MSCAs before its inclusion in the CoRAP.

The date of publication of the CoRAP update marks the start of the evaluation of the substances listed for the CoRAP update year. The publication also starts the 12-month period for an eMSCA to prepare, if necessary, a draft decision requesting further information.

The final CoRAP update is published on ECHA's website[2]. Its content is also included in the dynamic overview table of all substances[5], providing the following information for each substance:

- the non-confidential substance name;
- EC and CAS numbers;
- the year for which the evaluation is scheduled;
- the name of the eMSCA responsible for carrying out the evaluation;
- the initial grounds for concern which triggered the inclusion in the CoRAP;
- the status of the evaluation ('not started', 'ongoing', 'information requested', 'conclusion under preparation', 'concluded').

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

By clicking on the icon, you can access more details, including:

- the contact information of the eMSCA;
- the link to the substance-specific justification document which describes why the substance has been selected for the CoRAP.

The justification document is prepared by the eMSCA and describes the scientific grounds of the initial concerns which require further clarification under substance evaluation. It also informs on possible follow-up actions considered by the eMSCA. Hence the justification document can help registrants and downstream users to orientate and take on board the importance of the substance evaluation.

In addition to the regular CoRAP update, a MSCA may notify ECHA, at any time, that a substance should be evaluated (Article 45(5)), when it has information suggesting that the substance is a priority for evaluation. The CoRAP may then be amended *ad hoc* after a MSC consultation, i.e. a substance can in principle be included for evaluation at any time during the year. In practice, such *ad hoc* updates are rare.

The selection of relevant CoRAP substances is a three-step process: shortlisting of registered substances using screening algorithms, manual screening by MSCAs, and finalisation (respecting the national priorities) towards publication of the yearly outcome.

The CoRAP is updated annually in March. It lists substances planned for evaluation by the Member States in the upcoming three years (N, N+1 and N+2) and starts the evaluation process for 'year N' substances.

3.4 MY SUBSTANCE IS INCLUDED IN THE CoRAP - WHAT SHOULD I DO?

Consider dossier updates and liaise with the eMSCA

When your substance is listed in the first year, the most important thing for you to do is to perform a thorough check of the registration dossier and to submit a dossier update, if needed, to facilitate the future evaluation process: the timely update of dossier(s) before the start of the evaluation process is a crucial asset. Any relevant and available information is supposed to be reported in the registration data set anyway.

Note that the identified grounds for concern should not be taken as a statement on a known risk, but rather as an indication of what the substance evaluation will cover, although the initial concern mentioned in the CoRAP will not *per se* limit the scope of the evaluation of the substance, as other areas may be identified and investigated further. Nonetheless, for the sake of efficiency and reaching the ultimate goals of substance evaluation, the eMSCA will in most cases target its assessment and not necessarily cover all properties of the substance. Substances listed in the second or third year list may be assessed later and may still be subject to reallocation in further CoRAP updates, and possibly to withdrawal.

You should avoid submitting dossier updates when the 12-month substance evaluation process has started, unless you have agreed otherwise with your eMSCA: if the evaluation has already started but new information needs to be included into the dossier, it is essential to agree with the eMSCA whether and how a new dossier update can be taken into consideration. An update need may also arise from bilateral discussions between you and the eMSCA to clarify concerns before entering the decision-making phase.

In particular, you should ensure at an early stage that the identification of your substance, and of any relevant forms thereof, is clear and appropriately documented. Indeed, information on the composition of the substance and its impurities is essential for a proper assessment.

As member of a joint submission, you also need to ensure that your information on composition (including impurities) is consistent with the Substance Identity Profile (SIP) defined in the lead dossier.

Accurate and up-to-date exposure and use information are critical. You should consider updating also the exposure scenarios, which often prove not to be complete or accurate. Exposure information should be detailed enough to enable ECHA and the eMSCA to assess the substance under worst-case scenarios and realistic situations. In its substance evaluation, the eMSCA should be able to reproduce the exposure assessment and estimates on the basis of the details and parameters provided in the dossier and the chemical safety report (CSR).

You may also consider attaching full study reports to your IUCLID file, as this is an easy and secure way to make those available to the eMSCA.

In summary, providing accurate information in your dossier in a timely manner facilitates and accelerates the whole evaluation process. Furthermore, it will help to clarify a concern and to potentially avoid the formal request of the further information.

Coordinate with co-registrants and speak with one voice

You and your co-registrants are recommended to speak with one voice. Thus, preferably the lead registrant should proactively contact the eMSCA whenever there are questions or you wish to clarify issues to the eMSCA.

Note: Usually also the eMSCA will contact the lead registrant and offer the opportunity to discuss technical issues related to substance evaluation.

Contact and involve downstream users

When preparing and keeping up to date your (joint) registration dossier, you are responsible for ensuring good communication up and down the supply chain in order to gather the necessary information on the intended uses of your registered substance. Your downstream users (DUs) have information on different uses and on relevant exposure scenarios, and may even have measured exposure/emission data.

If you do not want to support a certain use by a DU in your dossier, or if, for reasons related to business confidentiality, a DU does not want to share their information with you, the DU may need to report such a use separately to ECHA (in a DU CSR).

Therefore, ECHA recommends that you contact your DUs as early as possible to have all the relevant information in place. You may also consider being in contact with specific DU organisations. Indeed, when the formal decision-making process of substance evaluation starts, the deadlines for commenting decisions may be too short to get new DU information.

After a substance is included in the CoRAP, ensure that its dossier is up to date, especially the information on substance's identity, uses and exposure, as well as intrinsic properties of the substance.

Co-registrants should speak with one voice and contact the eMSCA to familiarise themselves with the issues at hand.

Involve your downstream users in particular to ensure that all relevant exposure information is available.

If you are a downstream user

If you are a downstream user of a substance listed in the (draft) updated CoRAP and you own or have access to useful information (e.g. use, exposure and risk assessment data, and even measured data), besides your obligations outlined in the REACH Regulation, you are advised

to:

1. Contact the supplier of the substance and inform them about the data you own or have access to. If your supplier is not a registrant, ask them to put you in contact with the registrant. Note that once a registrant has received the draft decision on substance evaluation, they only have 30 days to provide comments, so you should ensure that you take action before the registrant receives a draft decision;
2. Contact and ensure that the Lead Registrant[6] of the substance is informed about the data you own or have access to;
3. Contact and inform the eMSCA about the data you own or have access to – this may be the best option if you are in possession of confidential business information, or are required to prepare a DU CSR;
4. Contact and inform a trustee that is designated by the registrants, either collectively or even individually for their specific supply chain, if you are in possession of confidential business information (see the Guidance on Data sharing, section 7.3.3.3.).

3.5 MY SUBSTANCE IS INCLUDED IN THE CoRAP – WHAT ELSE CAN I EXPECT TO HAPPEN?

For each substance, ECHA aims to perform a check of compliance with REACH requirements, in particular relating to substance identity and intrinsic properties, prior to the start of the substance evaluation process. This is to ensure an adequate basis for the eMSCA to accomplish their evaluation task.

Therefore, you are advised to carefully check your dossier with regard to compliance with your obligations under REACH. In particular, you should review critically the information on the identity of your substance, including its various forms, and the data you submitted on the substance's intrinsic properties, including the justifications of any adaptations you used (e.g. read-across and weight of evidence) – these areas are prone to inconsistency and often lead to requests of further information. ECHA has updated its advice on how to avoid unnecessary testing on animals [7].

Note

In some cases, a compliance check may make the whole substance evaluation process obsolete if the identified concerns can be clarified by filling the data gaps in the standard information requirements.

Be prepared for a compliance check in connection with a substance evaluation.

[6] ECHA publishes the name of the Lead Registrants if permitted by the companies. For more information, check the "Lead registrant list" and "Technical notes" at: https://echa.europa.eu/regulations/reach/registration/registration-statistics/technical-notes.

[7] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals

4. SUBSTANCE EVALUATION PROCESS

4.1 THE PROCESS IN A NUTSHELL

The substance evaluation process usually targets specific concerns and aims to clarify whether a substance poses a risk to human health or to the environment. During the evaluation, the eMSCA may identify additional concerns which also need clarification.

The process considers information derived from all individual and joint registration dossiers from all registrants of the same substance, in order to address all relevant uses and to take into account the combined exposure(s). The eMSCA may also use other available sources of information to investigate a specific concern, including information on analogue substances.

The evaluation of a substance by an eMSCA comprises several steps (Figure 3).

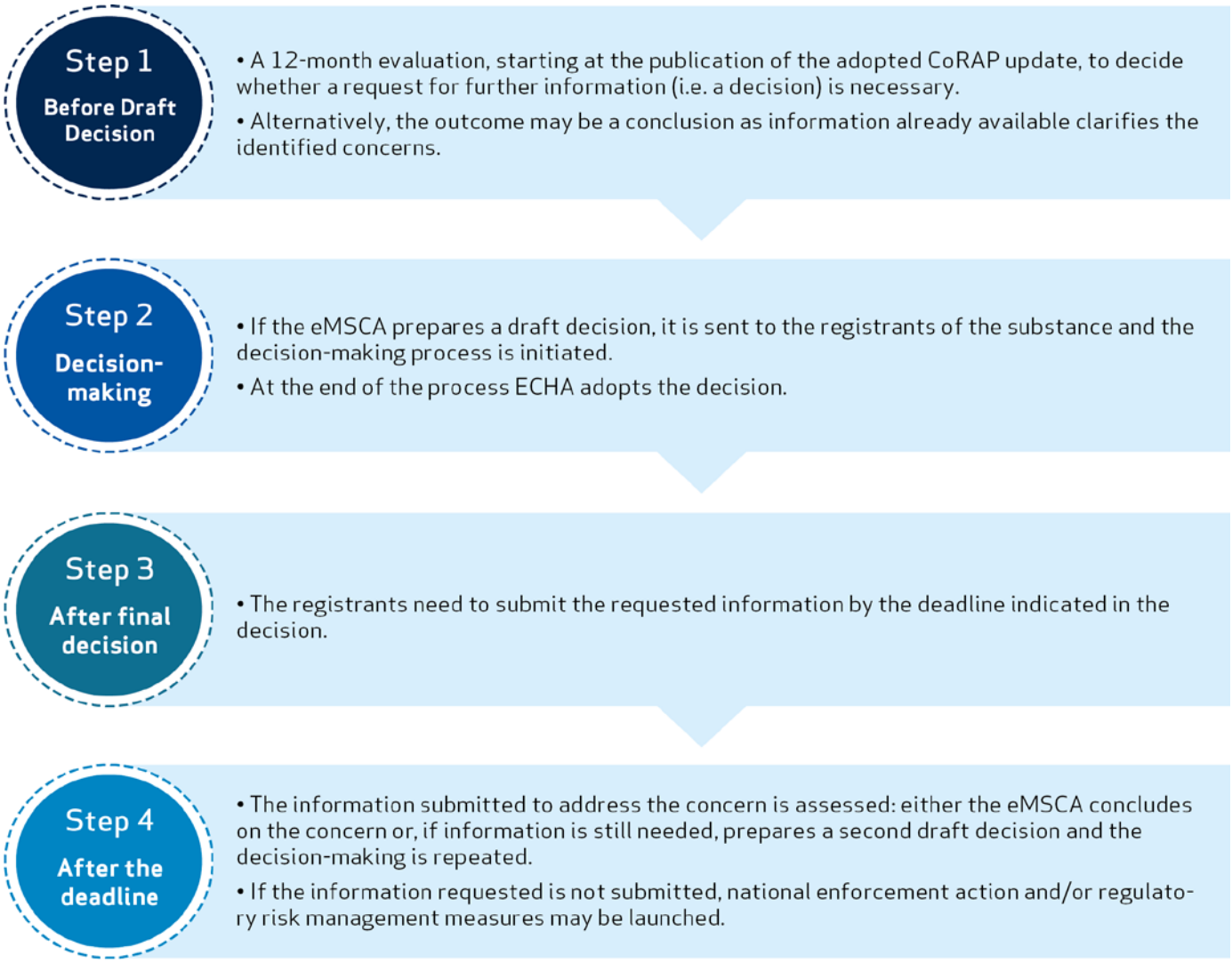


Figure 3: Main steps of the Substance Evaluation process.

By the end of the 12-month evaluation period, the substance evaluation may lead to one of the following outcomes:

- A draft decision requesting further information from the registrants: this decision can address intrinsic properties or exposure and can go beyond the standard tests listed in Annexes VI to X of REACH. For example, the registrants may need to provide studies on mode of action, on monitoring of concentration levels in organisms or the environment, etc.
- No further information needs to be requested: the eMSCA informs ECHA that it was able to clarify the concerns already during the 12-month evaluation. The evaluation may conclude that the risks are sufficiently under control with the measures already in place, or it may lead to the proposal of EU-wide risk management measures such as harmonised classification, restrictions, identification of substances of very high concern (SVHCs), or other actions outside the scope of REACH (see section 6.2).

During substance evaluation, the eMSCA has 12 months from the publication of the CoRAP to evaluate whether further information needs to be requested to clarify the concern.

By the end of this period, the outcome may be a draft decision or a conclusion.

4.2 HOW DO I INTERACT WITH THE EVALUATING MEMBER STATE COMPETENT AUTHORITY?

The contact information of the eMSCA is provided in the CoRAP published on ECHA's website[5]. ECHA has published some recommendations on best practice for informal interactions, as eMSCAs have agreed on a common approach on interaction with registrants during substance evaluation[8].

Registrants that have the same substance under evaluation should consider nominating a representative, e.g. the lead registrant, to interact with the eMSCA. To optimise the evaluation of your substance, you, as (lead) registrant(s), are expected to interact with the eMSCA from the very beginning of the process (see section 3.4). It is an opportunity for the eMSCAs to explain in more detail their concerns and for you to explain the information you have provided, e.g. the uses of the substance and the foreseeable exposure of consumers, workers, professionals and the environment from these uses.

If the dialogue has not already started, the eMSCA will usually contact the lead registrant and offer an opportunity to meet to discuss technical issues related to substance evaluation at the start of the 12-month evaluation period. The eMSCA may approach the registrant(s) in writing to request further clarifications before they prepare the draft decision. For example, it is expected that the modelled exposure assessments (such as selection of assessment factors, definition of use conditions) in the registration dossiers are clearly understandable and reproducible for the eMSCA. Clarifications on exposure assessment may be sought to consider the relevance of potential risks otherwise requiring specific experimental tests on exposure or hazard.

During this process, you, and other o-registrants should collectively reflect on how to deal with confidentiality and competition issues.

ECHA recommends that you respond in a timely manner and discuss with the eMSCA the need and timing of an update of the registration dossier. You can contact the eMSCA, through the appointed representative, if you have received the draft decision and need further clarifications on its content.

[8] https://echa.europa.eu/documents/10162/13628/interaction_ms_reg_sev_en.pdf

You should nominate a representative to interact with the eMSCA.

Early and timely interaction between you and the eMSCA is essential for the success of the substance evaluation process.

4.3 HOW DO I INTERACT WITH ECHA?

While the eMSCA performs the evaluation, ECHA coordinates the overall substance evaluation process (in accordance with Article 45 of REACH). Therefore, you can contact ECHA to request clarification on issues of more administrative nature using the ECHA contact form[1].

Furthermore, ECHA is the recipient of all the information you submit during the process, such as comments to the draft decision and to proposals for amendment (PfAs), the information on who is to perform the requested test(s), and comments on a non-confidential version of the decision to be published on ECHA's website. Thus, to submit any such information, you should always use the webform, as requested also in the notification letters sent to you by ECHA during the process.

ECHA usually communicates with registrants by using the REACH-IT tool's messaging function, in particular when sending confidential information. Keep your REACH-IT contact point information up to date, as ECHA may sometimes also need to call you or to send the lead registrant an invitation to participate in the discussion of your case at one of the MSC meetings.

As with any other dossier update, you will need to use REACH-IT to submit dossier updates relevant to substance evaluation.

Use webforms and keep your contact details in REACH-IT up to date.

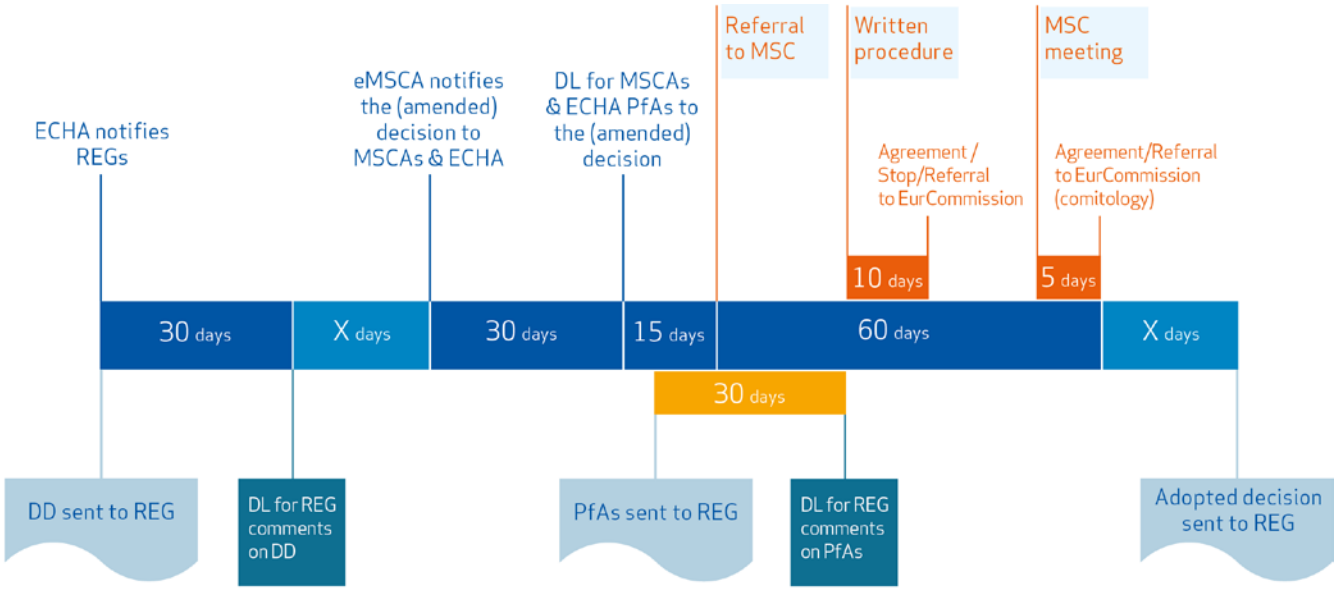
4.4 SUBSTANCE EVALUATION DECISION-MAKING PROCESS

By the end of the 12-month evaluation period, if the eMSCA considers that further information is needed to clarify a concern on the substance, it prepares a draft decision and sends it to ECHA.

The draft decision specifies the need for further information by stating:

- the type of information necessary to clarify the concern;
- the test methods to be used;
- the deadline by which the information must be submitted;
- possibly a testing strategy with sequential testing and/or multiple deadlines.

The decision-making process follows the provisions and timelines set in the legal text (Articles 51(2) to (8) and 52, and general Chapter 2 of Title VI). The decision-making steps fall on a prescribed and tight timeline, as described below (Figure 4).



NB: A decision can be adopted directly if no PfAs are received.

Figure 4: Timeline for decision making - from draft to adopted decision.

(a) The eMSCA submits the draft decision to ECHA.
(b) ECHA sends (after some technical steps) the draft decision (DD) to all relevant registrants (REGs) (see section 2).
(c) You have 30 days to provide your (consolidated) comments.
(d) ECHA forwards all comments received by the deadline to the eMSCA. The eMSCA reviews those comments and considers whether to amend the draft decision. Note that the eMSCA is not set a defined time period over which to review the registrants' comments.
(e) Subsequently, eMSCA notifies ECHA and the other MSCAs of the (amended) decision, which generally occurs within 6-12 months from receipt of your comments.
(f) ECHA and the other MSCAs can propose amendments within 30 days.
(g) If no proposal to amend the notified draft decision is received, ECHA formally adopts the decision and you are informed accordingly. If MSCAs or ECHA submit proposals for amendment (PfAs), the draft decision is referred to the MSC in order to seek unanimous agreement.
(h) You are notified of the PfAs received and you have 30 days to provide your (consolidated) comments on them. You also receive, for information, the (amended) notified decision.
(i) The MSC will seek unanimous agreement, either in a plenary meeting or in written procedure, considering the various inputs: the (amended) notified draft decision, the PfAs as well as your (consolidated) comments on the PfAs received within the commenting period:

Scenario 1: If your substance is subject to a plenary meeting discussion (without preliminary written procedure), your representative is invited to attend the respective agenda point (open session).

Scenario 2: A decision can be agreed by the MSC via written procedure, during which MSC members indicate their agreement or disagreement to the (amended) notified draft decision, or their wish to stop the written procedure.

* If there is unanimous agreement, no discussion needs to take place thereafter and the decision is adopted by ECHA.
* If one or more MSC members request the written procedure to be stopped, the (amended) notified draft decision will be discussed at the MSC meeting, and will only be addressed in closed session (see section 4.6).

(j) If the MSC reaches unanimous agreement on the draft decision, either in written procedure or after discussion at the meeting (closed session), ECHA proceeds to formally adopt the decision.

(k) If the MSC does not reach a unanimous agreement, either in written procedure or at the MSC meeting, the MSC Secretariat refers the draft decision to the European Commission. The further decision making takes place under a committee procedure ("comitology"). In both cases you are informed of the MSC outcome.

Due to the tight decision-making timelines foreseen by REACH, the deadline for delivering the comments on the draft decision cannot be extended unless there are technical reasons (e.g. malfunction of the submission tools) or if the commenting period falls during closure periods of the Agency (e.g. Christmas break).

Notes for specific addressees

In some cases, a decision may be addressed specifically to only one of the several registrants of a substance, and they will receive their own separate decision, whereas the other registrants will be addressed by a common decision.

In principle, a downstream user can also become an addressee of a decision, if a downstream user report was provided to ECHA that indicates a concern and the need to ask for further information. In case a downstream user is indicated as a specific addressee of a draft decision, they are entitled to provide comments to the draft decision during the process.

You will not become an addressee of the decision if you register the substance after the initial draft decision is issued. However, as a co-registrant you may subsequently be required to share the costs resulting from the requests related to this evaluation (see section 5.2).

Once a substance enters the decision-making process, you should be prepared for the tight deadlines.

In principle, no extension can be granted to the commenting period.

4.5 WHAT SHOULD I DO WHEN I RECEIVE A DRAFT DECISION?

Comments on the draft decision

Once you and co-registrants have received the draft decision, sent through REACH-IT, you should review its content to understand the requests (including the test methods and/or the testing strategy). The deadline for comments and the link to the webform are specified in the notification letter.

Your representative – the contact point for the eMSCA – should coordinate the response to the draft decisions among the co-registrants and submit a single set of consolidated comments within 30 days. In order to facilitate this co-ordination, all relevant registration numbers are listed in an appendix to the draft decision. Alternatively, you can refer to the Co-Registrants page, which displays the contact details and roles of the existing registrants of your substance. Further guidance on this functionality is provided in the help texts within the REACH-IT tool.

Organisation of testing

Already at this stage, you should start discussing with testing laboratories to explore their capacity for new testing, so as to prepare for a smooth start of activities once you receive the final decision. You can use that information to let the eMSCA know about realistic deadlines to be included in the decision, for example, based on the capacity of test laboratories for a specific information requirement and its related test.

Note that testing must not be conducted before the decision-making process is completed (see section 4.4), as the submission of PfAs may lead to changes to the request(s).

Update of the registration dossier

In general, updates of the registration dossiers cannot be taken into consideration if they are received after the day on which you receive the draft decision. However, if you have agreed in advance with the eMSCA to submit such an update, it must (i) support the comments you submitted during the 30-day commenting period and (ii) be received within 60 days of the receipt of the draft decision.

Cease of manufacture or import after receiving a draft decision – reminder

If you wish to cease the manufacture or import of the substance upon receipt of the draft decision, you should notify ECHA, and confirm your intention in response to an ECHA communication. Your registration number will then be revoked (Article 50(3)), and you will not have market access and will not receive any further request or decision, unless the request falls within the cases listed in Article 50(4)(a) and (b).

ECHA checks the intentions for ceasing manufacture in REACH-IT periodically, and at the latest before issuing the adopted decision. ECHA sends you a letter in REACH-IT requesting you to confirm your intention to cease manufacture. When you confirm that you will cease manufacture or if you do not respond, ECHA proceeds and revokes your registration.

If after the cease of manufacture you intend to start to manufacture or import the substance again, you will have to register the substance again and you may have to contribute to a fair share of the costs accrued for the maintenance and update of the registration dossier due to the substance evaluation process or for other reasons.

Comments on the PfAs

As with the comments on the draft decision, your representative should coordinate the response to the PfAs and submit a single set of consolidated comments within 30 days. The deadline for comments and the link to the webform are specified in a notification letter. Note that the MSC will only take into consideration your comments on the PfAs (Figure 4), whereas comments on other issues in the (amended) draft decision will no longer be taken into consideration at this stage of the process.

Your representative is expected to coordinate the (consolidated) comments to the draft decision and to the PfAs, and to submit them within the 30-day deadline, using the specified webform. When a draft decision is specific to one registrant only, this registrant can naturally comment separately. If you intend to update your dossier during the substance evaluation process, you must agree the timelines with the eMSCA.

Explore the testing house options but do not start the testing before the decision-amking process is completed.

REACH imposes very strict timelines on the decision-making process, so it is not possible to extend the deadlines for submitting comments on the draft decision or on the PfAs.

4.6 CAN I ATTEND THE MSC MEETING?

Structure of the MSC meeting

The discussion on draft decisions at the MSC meeting occurs in two sessions: an open session, where the presentation of the PfAs and registrants' comments on the PfAs takes place together with the scientific discussion; and a closed session, where the decision-making happens, including discussions on regulatory strategy and REACH interpretation.

Besides Committee members and nominated representatives of invited stakeholder organisations[9], invited experts and advisers to the members may attended the MSC meeting. These stakeholder representatives follow regularly the MSC meetings, and can only participate to the open sessions where evaluation cases are initially discussed. As observers, these representatives, like any other meeting participants, are bound by a confidentiality declaration.

Registrants' attendance

When the draft decision addressed to you is discussed during the MSC meeting, your representative, as a "case owner", is invited to attend the open session in person. Note that this is not a legal requirement, but is based on an initiative from the MSC secretariat. Your representative's attendance is meant to provide the MSC with further clarifications on scientific and technical issues. Such attendance has to be in line with the working procedure of the MSC related to SEv[10] and must conform with the ECHA Code of Conduct for Case Owners[11].

Subsequently, the case owners are offered the possibility to provide comments on the draft minutes of the discussions they were present in. The final version of the minutes is available on ECHA's website after being approved by the MSC[12].

If your draft decision is processed for agreement-seeking via written procedure and if the process is stopped (Figure 4), the decision is then discussed only in a closed session of the MSC meeting. You, as the case owner, are not invited to attend and cannot participate in the discussion.

4.7 WHAT HAPPENS AFTER ECHA ISSUES A DECISION?

After the agreement by MSCAs or the MSC on the draft decision, ECHA adopts the decision and sends it to the registrant(s) using REACH-IT. The decision includes the deadline(s) (as calendar dates) by which the requested information has to be submitted in an update of the registration dossiers. Note that ECHA is not in the position to change the deadline(s) once the decision is adopted as it was unanimously agreed by the MSCAs.

Within 90 days of receipt of the decision, your representative must inform ECHA of the legal entity which is to perform the requested test(s) on behalf of the other registrants (see section 5.1).

Comments on the non-confidential version of the decision

For transparency purposes, ECHA publishes a non-confidential version of all substance evaluation decisions. Before publication, ECHA sends a draft of the non-confidential version of the decision, together with the adopted decision, to the addressees of the decision.

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[9] http://echa.europa.eu/documents/10162/13578/list_aso_msc_observers_en.pdf

[10] https://echa.europa.eu/documents/10162/13578/msc_working_procedure_for_processing_sev_draft_decisions_en.pdf/b8e1ed7d-641d-4faf-845b-7283b48ffac2

[11] https://echa.europa.eu/documents/10162/13578/code_of_conduct_msc_case_owners_en.pdf/8614a683-5d87-4bd7-b0d2-506dc275abf2

[12] https://echa.europa.eu/about-us/who-we-are/member-state-committee/meetings-of-the-member-state-committee

In this draft, any confidential business information and company-specific information is already redacted. Your representative is invited to comment on the non-confidential version within 21 calendar days, coordinating the consolidated input and informing ECHA on whether any further information in the decision should be redacted. As detailed in the notification letter sent with the final decision, it is your duty to justify and provide evidence to support your additional requests for confidentiality.

You are invited to respond also when you agree on the non-confidential version of the decision you received. Nevertheless, in the case of no response, ECHA considers that you have no objection to the publication of the non-confidential decision.

You can consult the decisions published by ECHA on its website[5], by clicking on the icon. This will inform you if the is requested (registrants were sent a decision) or if the evaluation is concluded (process closed).

Cease of manufacture or import after receiving an adopted decision – reminder

You may cease the manufacture or import upon receipt of the final decision. However, the decision and your legal obligations to fulfil the requests will remain. Consequently, you will need to contribute to the generation of the requested information. This is different from ceasing manufacture or import after receiving the draft decision (see section 4.5).

With respect to confidential business information, you are given an opportunity to comment the non-confidential version of the substance evaluation decision published on ECHA's website.

Within 90 days of receipt of the decision, your representative must inform ECHA of the legal entity which is to perform the requested test(s) on behalf of the other registrants.

The deadline set in the final decision is legally binding.

The eMSCA will pursue the substance evaluation once all the information requested has been submitted.

Right to appeal

Any of the addressees of a decision has the right to appeal against the decision to ECHA's Board of Appeal[13]. Also the non-addressees that are directly and individually concerned by the decision are entitled to lodge an appeal against the decision. The appeal, together with the statements of the grounds thereof, must be lodged in writing to ECHA within three months of the notification of the decision. An appeal is subject to a fee, the payment of which is a condition for the notice of appeal to be formally filed.

The appeal has a suspensive effect only on the elements of the decisions which are contested by the Appellant. All other elements of the decision need to be provided by the deadline set in the decision.

If the Board of Appeal confirms the decision taken by ECHA, it issues a new deadline for submission of the information and the registrants must inform ECHA of the legal entity which is to perform the tests on behalf of the others (see section 5.1).

Note

The appeal fee can be refunded if the Board of Appeal decides the case in favour of the Appellant.

[13] http://www.echa.europa.eu/regulations/appeals

5. TESTING AND SHARING THE REQUESTED INFORMATION

5.1 WHO SHALL PERFORM THE TESTS AND SUBMIT THE INFORMATION REQUESTED IN A DECISION?

Within 90 days of receipt of the decision, your representative must inform ECHA (Article 53(1)) of the legal entity which is to perform the requested test(s) on behalf of the other registrants (addressees of the decision). Your representative should submit that information using the webform specified in the notification letter accompanying the decision. The deadline in the substance evaluation decision takes into account the additional three months that you may need to agree on the test performer.

If you cannot agree within 90 days on the legal entity, which is to generate the new information on behalf of the co-registrants, you need to contact ECHA, who will designate one of the addressees of the decision to perform the test on behalf of all registrants concerned. All addressees will be informed of the decision.

Within 90 days of receipt of the decision, registrants must inform ECHA about the addressee that is taking the responsiblity to perform the requested test(s) on behalf of all registrants impacted by the decision.

5.2 WHAT ARE THE RULES FOR SHARING DATA AND COSTS?

The basic principle of the data-sharing rules is that co-registrants shall make "every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way". The main aim of data sharing is to avoid unnecessary animal testing and to reduce costs for the co-registrants.

As laid down under REACH, the data sharing obligations continue to apply after the registration has been submitted. Co-registrants may need to share data and their related cost, for example, when new information has to be generated as a result of a decision following (i) ECHA's assessment of testing proposals, (ii) a compliance check, or (iii) a substance evaluation by an eMSCA.

In addition and as confirmed in the Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data sharing[14], registrants are in principle required to share only the costs of information that they are required to submit to satisfy their own registration requirements. However, when you are among the addressees of the substance evaluation decision, you may subsequently be required to share the costs resulting from the requests related to this evaluation. As per the Commission Implementing Regulation (EU) 2016/9, all registrants of the substance under evaluation have the obligation to organise and agree the individual arrangements for sharing data and their related (administrative) costs, as these studies are necessary to clarify the identified concern.

In particular, the regulation provides that a data-sharing agreement should include a model for sharing all relevant costs. This cost-sharing model (Article 4(2)) "*shall also include for all registrants of a particular substance provisions for sharing any costs resulting from a potential substance evaluation decision.*"

The data-sharing agreement within a substance information exchange forum (SIEF) shall determine the conditions under which you must pay a share of the costs, including the proportion of your contribution. It can for instance be set in relation to the proportion that you

[14] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016R0009

contribute to the concern identified in the decision on substance evaluation. The data sharing agreement should also determine to what extent a future registrant must contribute to the cost of a study. Factors for you to consider when agreeing on the proportion of the contribution to the costs may include each registrant's tonnage band, or whether the request for information under substance evaluation relates to a specific exposure or use.

Also registrants who ceased manufacture after the decision was issued may still be required to share the costs resulting from a substance evaluation decision (Article 50(4) of REACH and Article 4(6) of the Implementing Regulation).

As per the Implementing Regulation, the rules for sharing data apply both to new registrants joining a data-sharing agreement that has already been concluded, and to co-registrants setting up a new data-sharing agreement. Therefore, co-registrants must agree on a cost-sharing model, including a reimbursement mechanism[15].

- If no agreement can be found, each registrant needs to pay an equal share of the costs required for their contribution[16].
- A potential reimbursement mechanism shall apply equally to existing and future registrants.
- Provisions for possible future costs shall be foreseen, namely related to those following ECHA decisions for the registered substance[17].

Sharing information on analogue substances

In addition, the Implementing Regulation explicitly encourages the sharing of relevant studies that are conducted on a substance, which is structurally similar to the substance being registered. This is significant in promoting the development and use of alternative methods for the assessment of hazards of substances and to minimise animal testing. The data sharing agreement should also take into consideration how to facilitate responding to such requests for information in practice.

Reminders

Cost sharing aims at sharing the actual expenses and costs related to the registration under REACH in a fair, transparent and non-discriminatory manner. It is not designed to generate profits for any party[18].

For further guidance on data sharing, see ECHA's Guidance on data sharing[19].

Note

If you register a substance after the initial draft decision is issued (i.e. after the start of the decision-making process; Figure 4), you will not be formally considered in the decision-making process and you will not be an addressee of the decision. However, the data-sharing rules still apply as explained above.

Cost sharing aims at sharing the actual expenses and costs related to the registration under REACH in a fair, transparent and non-discriminatory manner.

All registrants, including future registrants, have to agree on a cost-sharing mechanism which addresses potential costs resulting from a substance evaluation decision.

[15] Article 2(1)(c) of the Implementing Regulation.
[16] Article 4(3) of the Implementing Regulation.
[17] Article 4(2) of the Implementing Regulation.
[18] SIEF participants, inquirers and existing registrants are subject to REACH provisions on data sharing.
[19] https://echa.europa.eu/guidance-documents/guidance-on-reach

6. SUBMISSION OF REQUESTED INFORMATION AND FOLLOW-UP

6.1 WHOM SHALL I NOTIFY ONCE THE INFORMATION REQUESTED IN THE DECISION HAS BEEN SUBMITTED?

Once the new information has been generated, the designated registrant (Article 53(1)) needs to submit an updated registration dossier with the data requested, at the latest by the deadlines indicated in the decision, and to subsequently inform ECHA as well as the eMSCA.

To notify ECHA, you must use the webform indicated in the notification letter accompanying the decision. To inform the eMSCA, you may use your Member State contact person information.

Partial information available

Even if only a part of the requested information can be submitted by the set deadline(s), you should nevertheless complete the ECHA webform and indicate the deficiencies of your update. You should also update your registration dossier by the deadline in any case and, if necessary, include any relevant explanations and proof concerning the status of any pending information requirements, including their expected submission dates. You should then update your dossier again as soon as the missing information is available.

Be aware that non-compliance with an ECHA decision may result in enforcement actions by the national authorities of the Member States (see section 6.4).

At the same time, you should also inform the eMSCA about the dossier update situation, i.e. if all or only some of the data requests are submitted. This interaction should enable the eMSCA to make a fully-informed decision on whether to undertake specific actions, e.g. enforcement, or make a proposal for regulatory risk management measures.

It is your responsibility to submit a dossier update with all the data requested at the latest by the deadline(s) indicated in the decision, and to subsequently inform ECHA as well as the eMSCA. Non-compliance with the deadlines may result in enforcement actions by national authorities.

Inform the eMSCA contact person about your dossier update and send a notification to ECHA using the dedicated webform.

6.2 WHAT HAPPENS AFTER THE DEADLINE IN A SUBSTANCE EVALUATION DECISION?

ECHA monitors the cases in follow-up and informs the MSCAs of the dossier updates received. If no or only a partial submission is received by the deadline(s) set in the decision, the eMSCA may report to the National Enforcement Authorities (NEA). NEAs will consider appropriate enforcement actions for obtaining the requested information (see section 6.4).

Once all the requested information is submitted, the eMSCA can start its evaluation of the new information – over the 12 months that follow, the eMSCA has to either come to a conclusion on the substance evaluation, or initiate a new decision-making process for requesting further information by sending a new draft decision to ECHA, if necessary.

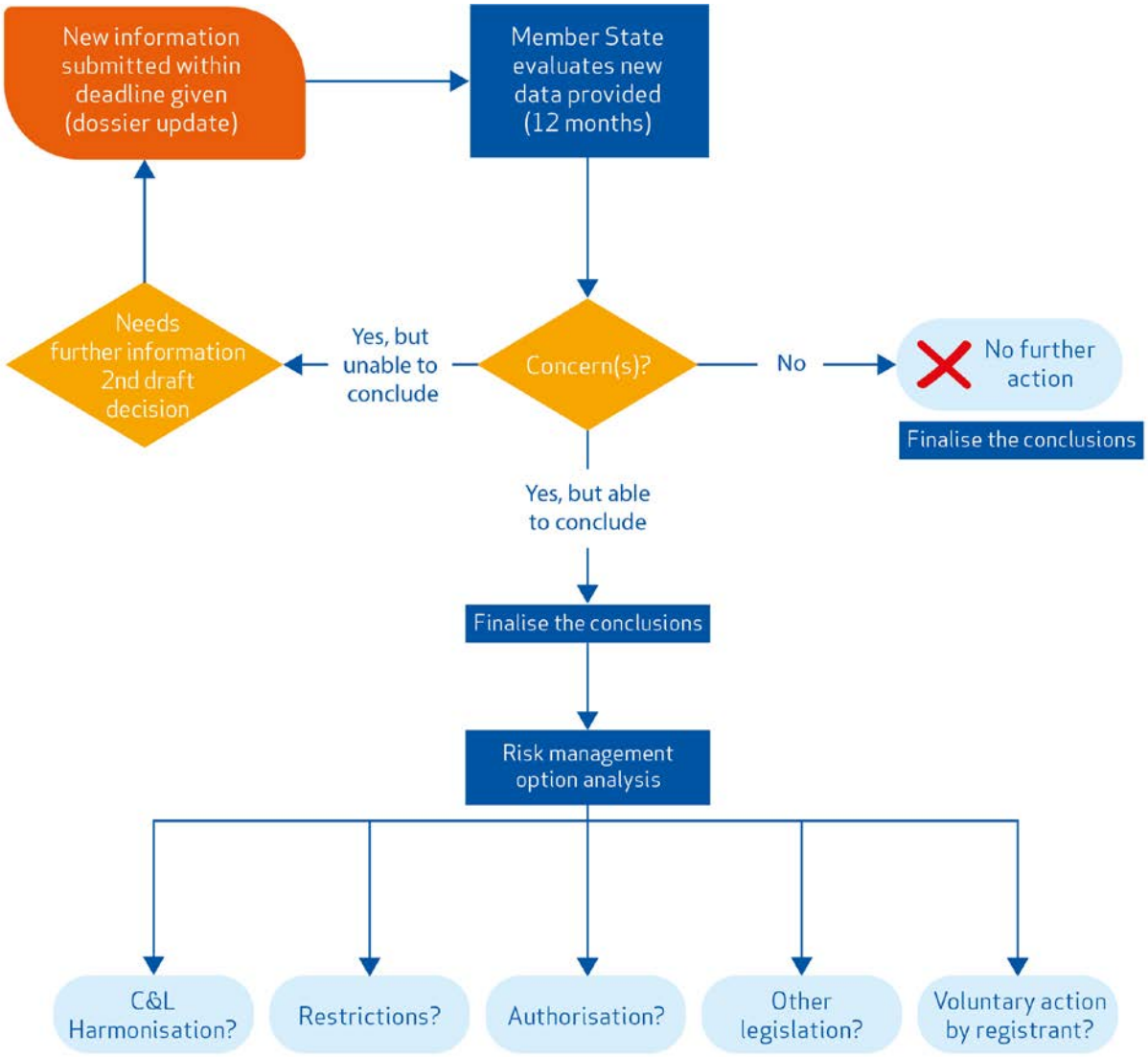

Figure 5: Overview of potential substance evaluation follow-up actions.

Within 12 months of the information having been submitted, the eMSCA evaluates whether the information provided is sufficient and subsequently completes the evaluation, considering whether and how to use the information obtained for the purposes of EU-level risk management measures (Figure 5).

Different scenarios may occur:

1- The eMSCA may conclude that, based on the available information, the concerns are not confirmed. The eMSCA does not then propose any further regulatory actions. The conclusion can also be that the risks are sufficiently under control with the measures already in place.

2- The eMSCA may conclude that the concern is still not clarified or that the new information raises further concerns. The eMSCA may then issue a new data request. The decision-making process as described earlier will then be repeated (see section 4.4).

3- The eMSCA may conclude that the concerns are confirmed. The eMSCA is then expected to propose further regulatory risk management measures in the substance evaluation conclusion document. This indication does not automatically initiate any process, and further analysis of the most appropriate regulatory risk management options may first

need to be performed. Possible measures may be restriction, authorisation, harmonised classification and labelling, occupational exposure limits, or measures for the protection of the environment under the Water Framework Directive. MSCAs can also impose national measures or request for non-regulatory initiatives and actions to be carried out the registrant (e.g. voluntary monitoring programmes).

To complete the substance evaluation, the eMSCA will:

- finalise its evaluation report, which explains how the data were assessed and the conclusions taken;
- prepare a conclusion document, which presents the considerations on how to use the information on the substance for subsequent regulatory risk management, such as identification of substances of very high concern (SVHCs), restriction, harmonised classification, or other actions outside the scope of the REACH and CLP regulations outside REACH or CLP.

Finally, ECHA informs the Commission, the registrants and the other MSCAs about the conclusions.

The eMSCA examines the new information and either concludes the evaluation or drafts a second decision within 12 months, if the concern is still not clarified or if the new information raises further concerns.

ECHA informs all parties involved about the conclusion.

6.3 HOW AM I INFORMED OF THE CONCLUSION OF THE MEMBER STATE?

In some cases, the eMSCA may approach you when finalising the documents, to ensure that no confidential business information is included in the public versions.

ECHA publishes the non-confidential versions of the eMSCA's conclusion document and evaluation report (in a combined document) on its website[5], along with the decisions requesting further information. You may access the documents by clicking on the icon next to the substance entries.

When the documents are published on ECHA's website, ECHA sends you a REACH-IT notification about the publication and the conclusion of the substance evaluation process. There is no possibility for you to comment the conclusion document and evaluation report. However, some eMSCAs may on their own initiative share with you the draft of the evaluation report to explain their approach.

The publication of the conclusion and evaluation documents marks the end of the substance evaluation process for a substance. However, this does not exclude the possibility that the substance may be re-inserted in the CoRAP in the future if so warranted.

Note

The conclusion document and evaluation report may be publised as separate documents (for CoRAP substances evaluated in 2012–2014) or as a single combined document (as of 2015). These two documents are not subject to any formal approval and are not reviewed by ECHA or other MSCAs. They represent the views of the eMSCA and are without prejudice to any further regulatory work that the Agency or Member States may initiate at a later stage.

Further information on actions on substances that were undergoing substance evaluation can be viewed in the Public Activities Coordination Tool (PACT) available on ECHA's website[20].

The conclusion document and the evaluation report are published on ECHA's website, and the registrants are notified. This ends the ongoing substance evaluation process.

As a follow-up action, the eMSCA may propose EU-wide risk management measures.

6.4 WHAT IF THE DECISION IS NOT COMPLIED WITH?

Non-compliance with an ECHA decision and REACH may be subject to enforcement actions by the national authorities of the Member States (Articles 125 and 126). The enforcement responsibility lies solely with the Member States.

When the information requested is not provided or is insufficient upon reaching the deadline set in the decision, the eMSCA informs ECHA that the addressees have not complied with the decision and the eMSCA is not able to conclude on the identified concerns. Appropriate enforcement measures are considered by the national enforcement authorities (NEAs) to enable the substance evaluation process to be carried out.

There are two possible subsequent actions.

1. If no information or no new and substantial data is provided by the registrants, ECHA prepares a statement for not meeting the request(s) following a substance evaluation decision, and an information package consisting of:

- a notification letter explaining the legal background and that the information request has not been fulfilled;
- an attachment with the scientific facts (prepared by the eMSCA);
- the original notification and decision;
- any relevant communication with the registrant(s) after the original decision was taken.

The communication is addressed to the NEAs, and invites them for action due to the request(s) in the substance evaluation decision not being fulfilled. ECHA also sends a copy of such statement, for information, to the lead and member registrants who were the addressees of the original decision.

In addition, the eMSCA may, based on the available information, propose regulatory risk management action because it cannot confirm that the risks are under control.

2. The eMSCA prepares a new draft decision (Article 46(3)), referring to the original decision and giving the reasons for why the current available information is not fulfilling the request. This option applies in the exceptional case where new and substantial information was provided but, when assessed by the eMSCA, it was deemed not to meet the information requirements.

The new decision is issued to all original addressees, stating the reasons why they have not fully met their obligations as requested in the original substance evaluation decision. This decision is subject to a new decision-making process. Once the decision is adopted, ECHA informs all MSCAs and the NEAs and invites them to consider enforcement action.

In practice, documents such as those described above (a statement or a new decision according to Article 46(3)) are sent to the national focal points of the NEAs relevant to all registrants of a given substance.

[20] https://echa.europa.eu/pact

Even though all registrants remain responsible for the submission of the requested data, for practical reasons ECHA first requests action only from the lead NEA, i.e. the NEA from the country where the lead registrant is situated, or from the NEA relevant to the registrant designated to carry out the testing to provide the missing information. This is to ensure coordinated actions among the NEAs and to avoid multiple, overlapping communications. All other relevant NEAs are invited to keep action on hold until further notice, and are asked to address the issues identified within their own areas of competence. They may, where appropriate, adopt enforcement measures.

If the actions with a given registrant do not bring about the desired outcome, the enforcement actions can be expanded to involve all other NEAs relevant to the other registrants of the substance under evaluation.

It is acknowledged that failure to deliver the requested information may be due to disagreement on the strategy or over the costs resulting from the requests. However, bear in mind that these disagreements have to be solved as part of the data-sharing agreement and related civil laws. Your representative still needs to inform the NEAs of such issues.

Once the case has been handed over to the NEAs, any further communication takes place between the registrant and the designated NEA(s) until the case is solved. When the registrants submit an update of the registration dossier in response to the decision, they need to simultaneously inform their NEA.

When information requests are not or only insufficiently fulfilled, appropriate enforcement is organised by the National Enforcement Authorities.

In addition, the eMSCA may consider proposing risk reduction measures.

7. USEFUL LINKS

LEGAL TEXTS

REACH Legislation
https://echa.europa.eu/regulations/reach/legislation

REACH Regulation
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R1907:EN:NOT

REACH Regulation, consolidated version (with all amendments and corrigenda to the date marked on the first page)
https://echa.europa.eu/regulations/reach/legislation

Commission Implementing Regulation on joint submission of data and data sharing
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016R0009

CoRAP

Community Rolling Action Plan
https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan

Substance evaluation - CoRAP
https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

CoRAP list of substances
https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-list-of-substances

Information on Chemicals
https://echa.europa.eu/information-on-chemicals

Q&As
https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/REACH/corapandsubstanceevaluation

Substance evaluation

Substance Evaluation
https://echa.europa.eu/regulations/reach/evaluation/substance-evaluation

Substance evaluation procedure
https://echa.europa.eu/documents/10162/13607/pro_0023_01_substance_evaluation_en.pdf

Tips for registrants and downstream users
https://echa.europa.eu/documents/10162/13628/sub_eval_under_reach_leaflet_en.pdf

Interaction between the evaluating Member State and the Registrants under Substance Evaluation – Recommendations
https://echa.europa.eu/documents/10162/13628/interaction_ms_reg_sev_en.pdf

Member State Committee
https://echa.europa.eu/about-us/who-we-are/member-state-committee

Factsheets
https://echa.europa.eu/publications/fact-sheets

Factsheet – Substance evaluation
https://echa.europa.eu/documents/10162/13628/fs_substance_evaluation_en.pdf

Guidance on REACH
https://echa.europa.eu/guidance-documents/guidance-on-reach

Guidance for downstream users (21/10/2014)
https://echa.europa.eu/documents/10162/23036412/du_en.pdf/9ac65ab5-e86c-405f-a44a-190ff4c36489

Public Activities Coordination Tool (PACT)
https://echa.europa.eu/pact

8. DEFINITIONS

Term / abbreviation	Definition
CSR	Chemical Safety Report
CLP	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
Commission	European Commission
CoRAP	Community Rolling Action Plan, a list of substances that are currently or are planned to be evaluated under substance evaluation by eMSCAs.
DD	SEv Draft Decision– a proposal by an eMSCA for requesting further information on a substance.
Decision	SEv final decision – a legally binding decision taken by ECHA, upon agreement with all MSCAs, to request further information on a substance.
ECHA	European Chemicals Agency
eMSCA	Evaluating Member State competent authority under the substance evaluation process.
MS	EU Member State
MSC	Member State Committee
MSCA	Member State competent authority
PfA	Proposal for Amendment – non-evaluating MSCAs and ECHA can make proposals to amend the draft decision after the commenting period of the registrant.
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals.
REACH-IT	Central IT system that supports industry, MSCAs and ECHA to securely submit, process and manage substance data and registration dossiers.
Registrant	A natural or legal person established within the EEA, manufacturing or importing a substance into the EEA at quantities of one tonne or more per year, or who has been appointed as an only representative according to Article 8 of the REACH Regulation.
RMM	Risk management measures
SEv	Substance Evaluation process
SIEF	Substance Information Exchange Forum
SVHC	Substances of Very High Concern

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