ECHA
EUROPEAN CHEMICALS AGENCY

Registrant's guide – How to act in substance evaluation

November 2022

LEGAL NOTICE
This document contains guidance on REACH explaining the REACH obligations and how to fulfil them. However, users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

Version	Changes	Month & Year of updated version
1.0	Section 2 Introduction (info box) Section 3.3 selection for CoRAP Section 3.5 What else can I expect to happen Section 4.5 comments on the draft decision Section 4.5 update of the dossier Section 4.5 cease of manufacture Section 6.4 enforcement	April 2020
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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 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 is, and how substances are selected and subsequently evaluated. This guide also aims to highlight the opportunities as well as the obligations that you, as a 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) 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 the quality and adequacy of the information submitted in the registration dossiers is compliant with the legal requirements of REACH Annexes I and VI to X, including possible adaptations according to Annex XI.
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. ECHA has the duty to examine all testing proposals in the registration dossiers. Registrants have the obligation to submit such proposals before conducting any studies listed in Annexes IX and X.
3) Substance evaluation aims to assess whether further information is necessary, so that the evaluating Member State competent authorities (eMSCAs) 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 perform a compliance check first to scrutinise the substance's identification and hazard data, and 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 authorities the power to request information that can go beyond standard information requirements (see Figure 1).

It is a concern-driven process that aims to clarify concerns related to the safe use of a substance, and 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 (TIIs).

By contrast, on-site isolated intermediates (OSIIs), manufactured under strictly controlled conditions, cannot be subject to substance evaluation. Substance evaluation decisions will therefore be addressed by default to all active registrants for substances including TIIs but excluding OSIIs.

However, registrants of TIIs 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.

Under REACH, the objective of substance evaluation is to allow more information to be generated on the substance so that potential risks to human health or the environment can be clarified.

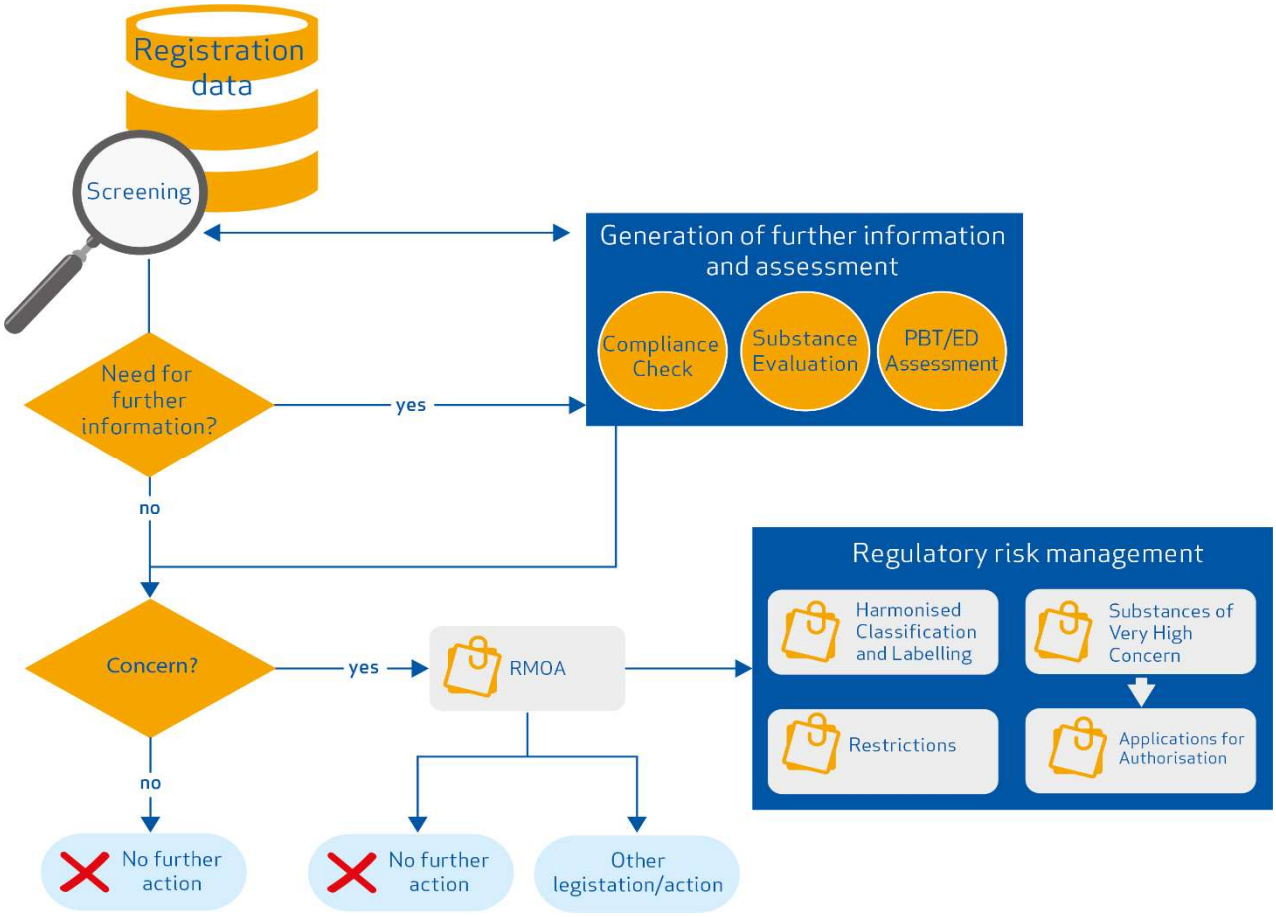


Figure 1: Substance evaluation in the regulatory context

For early information about substances that are being scrutinised by authorities, you can check the Public Activities Coordination Tool (PACT). PACT lists the substances for which a regulatory management option analysis (RMOA) or an informal hazard assessment for persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBT/vPvB) properties or endocrine disrupting (ED) properties is either under development or has been completed since the SVHC Roadmap began to be implemented in February 2013.

3. Community rolling action plan (CoRAP)

3.1 What is the CoRAP?

CoRAP is the acronym 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 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 (see Figure 2).

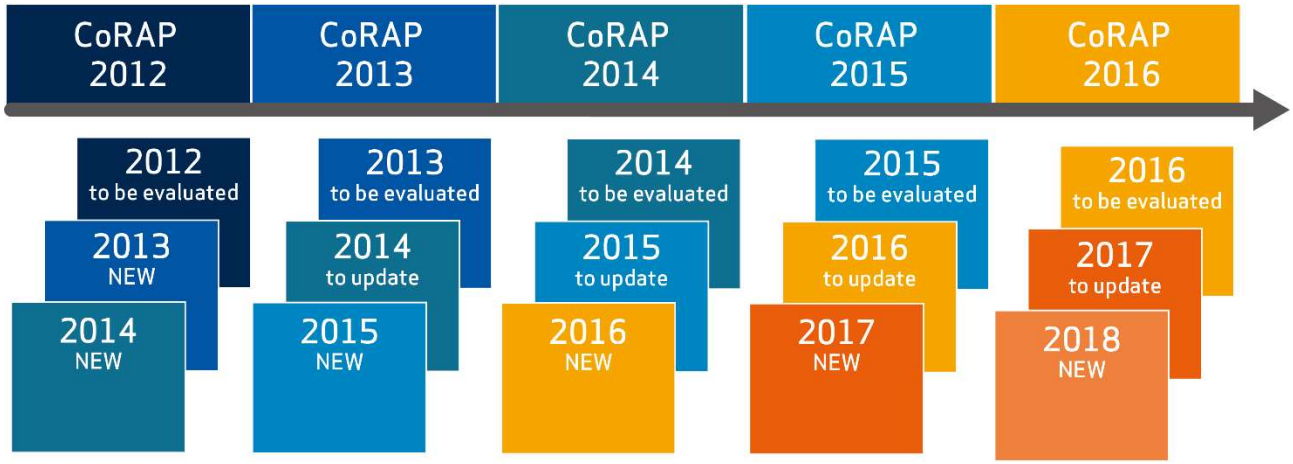


Figure 2: CoRAP's triennium and its "rolling" nature

3.2 What are the criteria for substances selected for evaluation?

Article 44(1) of REACH 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."*

So, the selection criteria need to cover both hazard (intrinsic properties) and exposure aspects (use of the substance) 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] https://echa.europa.eu/documents/10162/13628/background_doc_criteria_ed_32_2011_en.pdf

The MSCAs and ECHA also have to 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 over the substance; and
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 hazard and exposure information.

3.3 What is the process that leads to the selection of a substance?

Authorities have started addressing and screening groups of structurally similar substances rather than single substances. This grouping approach ensures that available information is used more effectively, and enhances the coherence and consistency of authorities' actions when progressing work with similar substances.

ECHA performs most of its screening work on groups of substances. Subsequently, ECHA and MSCAs decide which substances they consider relevant as CoRAP candidates. The selection process considers 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 scientifically justified, the grouping of substances that 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 depending on the strategy.

Based on the outcome of 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 validates and publishes the draft CoRAP.

The annual CoRAP cycle

The CoRAP annual update follows a cycle:

1. In autumn, ECHA submits a draft CoRAP update to ECHA's Member State Committee (MSC) for its opinion and informs the Member State competent authorities (MSCAs) about it.

The draft update is published on ECHA's website to inform stakeholders of the draft evaluation plan. The publication aims to support involved registrants to prepare and, where needed, to start interacting with the relevant evaluating Member State competent authority (eMSCA).

The draft CoRAP lists the following information:

- the non-confidential substance names;
- CAS and EC numbers;
- any concerns which triggered the inclusion of the substance in the CoRAP;
- the proposed year of evaluation; and
- 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 may be changed.

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

When a substance is included in the (draft) CoRAP list, it does not mean in itself that there is any immediate legal impact on you, nor that the substance poses a risk to human health or the environment.

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

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

The CoRAP update is published on ECHA's website[2]. Its content is also included in the dynamic table listing all substances subject to substance evaluation[4], 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; and
- the status of the evaluation ('not started', 'ongoing', 'information requested', 'conclusion under preparation', 'concluded', 'suspended').

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

- the contact information of the eMSCA; and
- a link to a 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 for the initial concerns, which require further clarification under substance evaluation. It also informs on possible follow-up actions considered by the eMSCA. The justification document can, therefore, help registrants and downstream users to orientate themselves and understand the importance of the substance's evaluation.

In addition to the regular CoRAP update, an MSCA may notify ECHA, at any time, that a substance should be evaluated (under Article 45(5) of REACH), when it has information suggesting that the substance is a priority for evaluation.

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

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

3.4 My substance is included in the CoRAP – What should I do?

Consider dossier updates and liaise with the evaluating Member State competent authority (eMSCA)

If your substance is listed in the first year, the most important thing for you to do is to thoroughly check your registration dossier and, if necessary, submit a dossier update. The timely update of dossiers before the start of evaluation is crucial and facilitates the future evaluation process. Any relevant and available information is supposed to be reported in the registration dataset.

Note that the identified grounds for concern should not be taken as a statement on known risks, but rather as an indication of what the substance evaluation will cover – although the initial concern mentioned in the CoRAP will not, as such, limit the scope of the substance evaluation, 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, focus its assessment and not necessarily cover all of the substance's properties.

Substances listed for the second or third year may be assessed later and may still be subject to reallocation in further CoRAP updates, and also possibly to withdrawal.

You should avoid submitting dossier updates when the 12-month substance evaluation process has started, unless you have otherwise agreed with your eMSCA: if the evaluation has already started but new information needs to be included in the dossier, it is essential to agree with the eMSCA whether and how a new dossier update can be considered. 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 that the identification of your substance, and of any relevant forms thereof, is clear and appropriately documented at an early stage. Indeed, information on the substance's composition and its impurities is essential for a proper assessment. As a member of a joint submission, you also need to ensure that your composition information (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 also consider updating the exposure scenarios, which often prove to be incomplete or inaccurate. 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 can 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 further information being formally requested.

Coordinate with co-registrants and speak with one voice

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

Note: Usually, the eMSCA will also 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 your (joint) registration dossier up to date, you are responsible for ensuring good communication up and down the supply chain so that necessary information on the intended uses of your registered substance is gathered. Your downstream users 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 downstream user in your dossier, or if, for reasons related to business confidentiality, a downstream user does not want to share their information with you, the downstream user may need to report such a use separately to ECHA (in a downstream user CSR).

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

After a substance is included in the CoRAP, it is important that the dossier is kept up to date – especially information on the substance's identity, uses and exposure, and intrinsic properties.

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 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 under REACH, 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[5] 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 downstream user CSR; and
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.).

[5] 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

3.5 My substance is included in the CoRAP - What else can I expect to happen?

ECHA aims to check the compliance of each substance with REACH requirements, in particular, the substance identity and intrinsic properties, before substance evaluation starts. 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 critically review the information on the identity of your substance (including its various forms), and the data you submitted on the substance's intrinsic properties (including justifications for any adaptations you used such as read-across or weight of evidence) – these areas are prone to inconsistencies and often lead to requests for further information. ECHA has updated its advice on how to avoid unnecessary testing on animals[6].

If there is a need to start the substance evaluation before ECHA has performed the compliance check, there is a possibility to perform the compliance check and substance evaluation in parallel, in 'a COMBO approach' for substances placed in the first year of the CoRAP update.

In the COMBO approach, ECHA and the eMSCA collaborate to identify information needs that fall under standard information requirements and beyond standard information requirements for clarifying a potential risk. Under the COMBO approach, you may receive both the compliance check and substance evaluation draft decisions for commenting at the same time.

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] 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 evaluating Member State competent authority (eMSCA) may identify additional concerns that also need to be clarified.

The process considers information derived from all individual and joint registration dossiers from all registrants of the same substance, to address all relevant uses and to take into account combined exposures. 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 (see Figure 3).

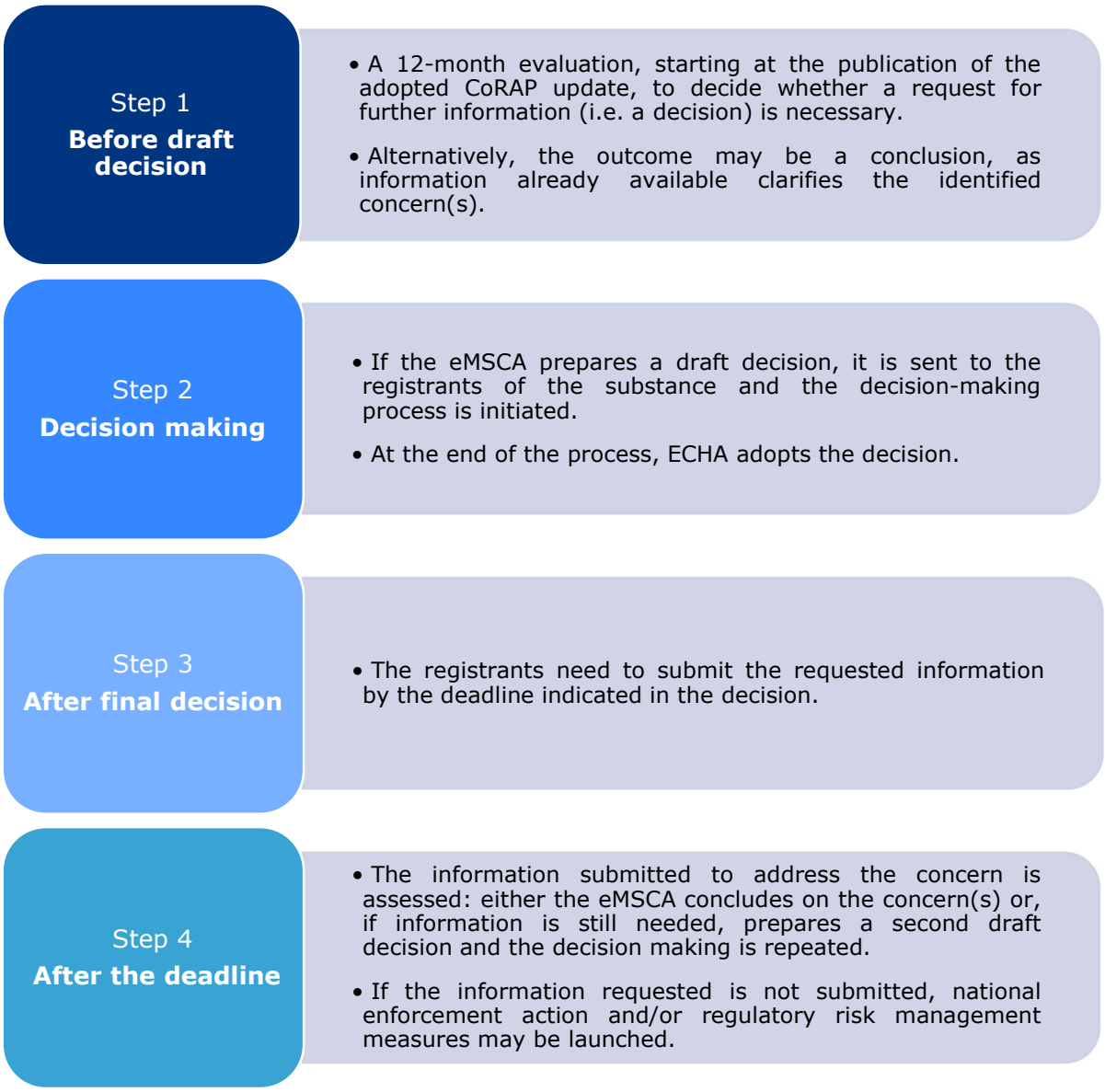


Figure 3: Main steps of the substance evaluation process.

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 registrants: this decision can address intrinsic properties or exposure and can go beyond the standard tests listed in Annexes VI-X of REACH. For example, the registrants may need to provide studies on the 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 potential risk.

At 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 (eMSCA)?

The contact information of the evaluating Member State competent authority (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 to interacting with registrants during substance evaluation[7].

Registrants that have the same substance under evaluation should consider nominating a representative, e.g. the lead registrant, to interact with the eMSCA. As the lead registrant, you are expected to interact with the eMSCA from the very beginning of the process to optimise the evaluation of your substance (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 registrants in writing to request further clarifications before they prepare the draft decision. For example, it is expected that the modelled exposure assessments (such as the 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 co-registrants should collectively reflect on how to deal with confidentiality and competition issues.

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

[7] 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 evaluating Member State competent authority (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 an administrative nature using ECHA's 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. 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 through REACH-IT'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.

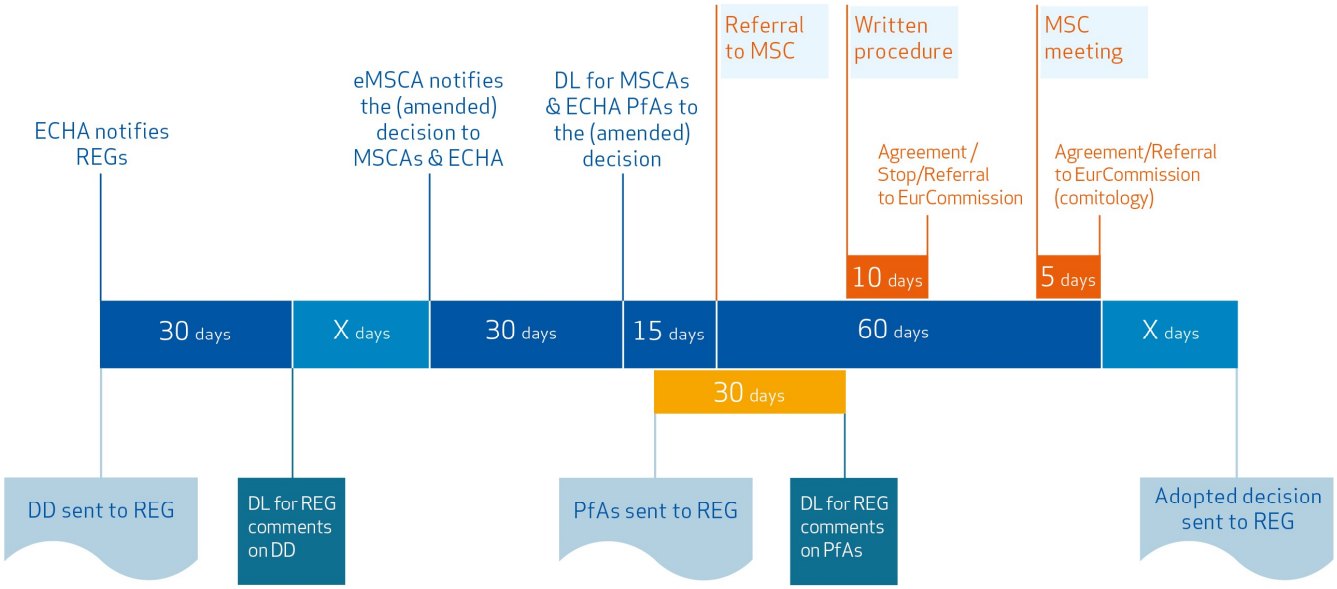
4.4 Substance evaluation decision-making process

By the end of the 12-month evaluation period, if the evaluating Member State competent authority (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; and
- possibly a testing strategy with sequential testing and multiple deadlines.

The decision-making process follows the provisions and timelines set in the legal text (Articles 51(2)-(8) and 52, and general Chapter 2 of Title VI of REACH). The decision-making steps fall on a prescribed and tight timeline, as described below (see 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 in which to review the registrants' comments.
(e) Subsequently, the eMSCA notifies ECHA and the other MSCAs of the (amended) decision, which generally occurs within 6-12 months from the 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 the MSCAs or ECHA submit proposals for amendment (PfAs), the draft decision is referred to the Member State Committee (MSC) 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 through 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 a unanimous agreement, no discussion needs to take place thereafter and the decision is adopted by ECHA.
- If one or more MSC member requests 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 a 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. If 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 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 the testing strategy). The deadline for comments and the link to the webform are specified in the notification letter.

To ensure clarity and to facilitate the eMSCAs consideration of your submitted comments, you are recommended to structure your comments according to the following approach:

- Clearly identify the specific request and the page/section of the draft decision that each comment applies to.
- For each comment, begin by providing a brief summary of your view and any proposed changes to the draft decision. A more detailed justification or explanation can be provided after this summary.

If new meaningful information becomes available after you receive the draft decision, and you think this information is relevant to the requests proposed in the draft decision (e.g. you possess a new experimental study that could potentially clarify the identified potential risk), you must include this information in your comments to the draft decision. Comments will be taken into consideration and, if needed, the draft decision will be amended accordingly.

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. To facilitate this coordination, 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 REACH-IT.

Deadline indicated in the draft decision

When setting the deadline in the draft decision, ECHA applies standard timelines that take into account the time needed to commission and perform the tests, analyse the results and update the dossier.

In exceptional circumstances, ECHA may specify a longer deadline in the final decision than the one indicated in the draft decision. This can be the case, if you provide an appropriate justification (including supporting documentation) from a contracted laboratory that the specified study cannot be performed in time, in your comments to the draft decision.

Organisation of testing

Already at this stage, you should start discussing with testing laboratories to explore their capacity for new testing, so you can 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 proposals for amendment (PfAs) may lead to changes to the requests.

Update of the registration dossier

If after receipt of a draft evaluation decision you have made an update to your registration dossier, you should fully reproduce the information that you consider relevant for the decision in your comments to the draft decision and explain how the newly submitted information affects the requests or reasoning in the draft decision.

If you change your registration type from a full registration to an intermediate registration, you will need to comply with the conditions set out in Articles 17 and 18 of REACH.

Substantial new information after the commenting period

If after the expiry of the 30-day period for submitting your comments on the draft decision, but before the adopted decision is communicated to you, you have updated your registration dossier with substantial new information that may affect the information requested in the draft evaluation decision, you should contact ECHA through the contact form. In that communication you should refer to the REACH-IT message which delivered the draft decision (in format SEV-D-XXXXXXXXXX-XX-XX/D).

You need to reproduce the information contained in your update, explain why it was not submitted in your comments to the draft decision and explain how it affects the information requests in the draft decision.

Substantial new information means:

- Recent experimental studies that became available to you after receipt of the draft decision and which address the potential risks identified in the draft decision.
- Registration type changes, e.g. from a full registration to an intermediate registration: You will need to comply with the conditions set out in Articles 17 and 18 of REACH.

Include all relevant information in your comments to the draft decision. If you have updated your dossier with substantial new information after the commenting period, you should contact ECHA through the contact form and reproduce the information that you consider relevant for the decision-making process in your communication.

Contact form:
https://comments.echa.europa.eu/comments_cms/Contact_REACH.aspx

Cease of manufacture or import after receiving a draft decision

Be aware that ceasing manufacture and/or import after receipt of the draft decision will have immediate consequences for you. When you decide to cease the manufacture and/or import of your substance in line with Article 50(3) after receiving the draft decision, you must record your cessation using REACH-IT. ECHA will then invalidate your registration number and list your registration number as 'invalid' on ECHA's website.

Consequently, you will not receive any further request or decision, and the ongoing decision-making process concerning you will be terminated. However, any already adopted ECHA decisions where you are a recipient are still valid and must be complied with.

If you then intend to manufacture and/or import the substance in registration-relevant volumes again, you will have to re-register the substance and you may have to contribute to the costs accrued for the maintenance and update of the registration dossier due to the substance evaluation process or for other reasons according to consortium-specific agreements.

Comments on the proposals for amendment (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.

To ensure clarity and to facilitate the eMSCA's consideration of your comments, you are recommended to structure comments according to the following approach:

- Clearly identify the PfA that each comment applies to.
- For each comment, begin by providing a brief summary of your view and any proposed changes to the draft decision. A more detailed justification or explanation can be provided after this summary.

The deadline for comments and the link to the webform are specified in a notification letter. Note that the MSC will only consider your comments on the PfAs (see Figure 4), whereas comments on other issues in the (amended) draft decision will no longer be considered at this stage of the process.

Your representative is expected to coordinate the (consolidated) comments to the draft decision and to the proposals for amendment (PfAs), and to submit them by the 30-day deadline, using the specified webform.

When a draft decision is specific to one registrant only, this registrant can naturally comment separately.

Explore the testing house options but do not start the testing before the decision-making 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 Member State Committee (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 proposals for amendment (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[8], invited experts and advisers to the members may attend the MSC meeting. These stakeholder representatives regularly follow 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 substance evaluation[9] and must conform with ECHA's code of conduct for case owners[10].

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[11].

If your draft decision is processed for agreement seeking through written procedure and if the process is stopped (see 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.

[8] https://echa.europa.eu/documents/10162/13578/list_aso_msc_observers_en.pdf

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

[10] https://echa.europa.eu/documents/10162/17089/code_of_conduct_msc_case_owners_en.pdf/8614a683-5d87-4bd7-b0d2-506dc275abf2?t=1381326738392

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

4.7 What happens after ECHA issues a decision?

After the agreement on the draft decision by MSCAs or the MSC, ECHA adopts the decision and sends it to registrants using REACH-IT. The decision includes the deadlines (as calendar dates) by which requested information has to be submitted in an update of the registration dossiers.

The notification starts both the three-month period to appeal the decision and the 90-day period to inform ECHA of the legal entity, which will perform each of the requested tests 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.

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 information 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

If you notify ECHA of a cease of manufacture or import of your substance after receipt of the adopted decision, you must still fulfil all information requirements applicable to you as outlined in the adopted decision. 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 receiving the decision, your representative must inform ECHA of the legal entity that will perform the requested tests on behalf of the other registrants.

The deadline set in the adopted 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 have the right to appeal against the decision to ECHA's Board of Appeal[12]. Non-addressees that are directly and individually concerned by the decision are also entitled to lodge an appeal against the decision. The appeal, together with the statements of the

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

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 registrants must inform ECHA of the legal entity that will 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.

5. Testing and sharing the requested information

5.1 Who performs the tests and submits the information requested in a decision?

Within 90 days of receipt of the decision, your representative must inform ECHA (under Article 53(1) of REACH) of the legal entity that will perform the requested test(s) on behalf of other recipients of the decision.

Your representative must 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 the information is not submitted within 90 days, or if several registrants' names are submitted for the same test, ECHA will designate the registrant to perform the requested test(s) on behalf of all of them. If you cannot reach an agreement, you must also contact ECHA, who will then designate one of the recipients of the decision to perform the test(s) on behalf of all registrants concerned. All registrants will be informed of the designation decision.

Within 90 days of receipt of the decision, recipients of the adopted decision must inform ECHA about the legal entity 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 need to 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.

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 evaluating Member State competent authority (eMSCA).

In addition and as confirmed in Commission Implementing Regulation (EU) 2016/9 on the joint submission of data and data sharing[13], registrants are principally required to share only the costs of information 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.

Under 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.*"

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

The data-sharing agreement within a substance information exchange forum (SIEF) has to 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 contribute to the concern identified in the decision on substance evaluation.

The data-sharing agreement should also determine the extent to which 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.

Registrants who ceased manufacture after the decision was issued may also 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).

Under 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[14].

- If no agreement can be found, each registrant needs to pay an equal share of the costs required for their contribution[15].
- A potential reimbursement mechanism applies equally to existing and future registrants.
- Provisions for possible future costs need to be foreseen, namely related to those following ECHA decisions for the registered substance[16].

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 consider how, in practice, to facilitate responding to such requests for information.

Reminders

The actual expenses and costs related to the registration under REACH should be shared in a fair, transparent and non-discriminatory manner. Cost sharing is not designed to generate profits for any party[17].

For further guidance on data sharing, see ECHA's Guidance on data sharing[18].

Note

If you register a substance after the initial draft decision is issued (i.e. after the start of the decision-making process; see 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.

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

The actual expenses and costs related to the registration under REACH should be shared 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.

6. Submission of requested information and follow-up

6.1 Who needs to be notified 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 evaluating Member State competent authority (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 deadlines, 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 making proposals for regulatory risk management measures.

It is your responsibility to submit a dossier update with all the data requested at the latest by the deadlines 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.

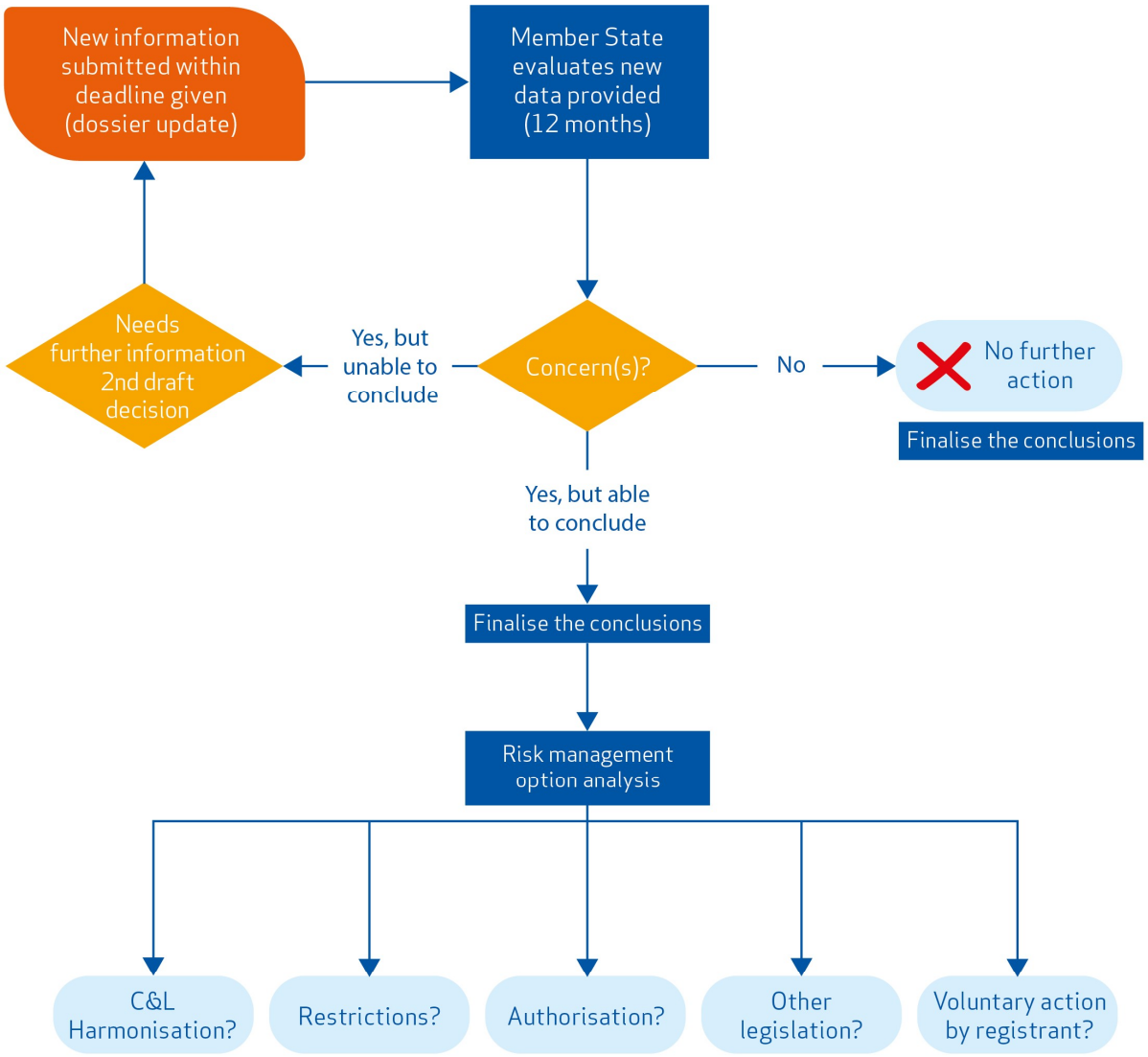
Inform the eMSCA contact person about your dossier update and send a notification to ECHA using the dedicated webform.

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 deadlines set in the decision, the eMSCA may report to the national enforcement authorities (NEAs). 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 to evaluate 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.



The MSCA informs ECHA of its conclusions as to whether or how to use the information obtained (Art. 48 - Follow up). ECHA informs the Commission, the registrant and the other MSCAs.

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 (see 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; and
- 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 REACH or CLP.

Finally, ECHA informs the Commission, the registrants and 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 can 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 on 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. 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[19].

The conclusion document and the evaluation report are published on ECHA's website, and the registrants are notified. This ends the 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 after the deadline set in the decision has passed, 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 the registrants do not submit any reply to the information requested in the decision or submit information (e.g. an adaptation) that is *'manifestly unreasonable'*, ECHA notifies the enforcement authorities of this fact with a "Failure to Respond" (FTR) notification. The information package consists of:
    - the FTR notification letter (note: where applicable, it may also mention the registrant's explanation that a study is delayed);
    - an attachment with a brief explanation why the eMSCA deems that the registrants failed to respond to the requests;
    - the original notification and decision; and
    - any relevant communication with the registrants after the original decision was taken.

    The communication is addressed to the NEAs, and it invites them to consider enforcement measures to trigger the submission of the requested information. The registrants who were addressees of the original decision receive a copy of this communication.

    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. If the registrants provide information replying to the requests in the decision, the eMSCA assesses this information. The eMSCA may consider that the information submitted does not correspond to the information requested in the decision. This may be because the study submitted is not sufficient or an adaptation submitted is not scientifically valid. In such cases, the eMSCA prepares a new draft decision according to Article 46(3), referring to the original decision and giving the reasons why the current available information is not fulfilling the request.

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.

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

This decision is subject to a new decision-making process according to Articles 51(2)-(8) and 52. Once the decision is adopted, ECHA informs all MSCAs and the NEAs and invites them to consider enforcement action. The new decision **does not contain a new deadline**. This is because it does not request further new information on the substance, but it only states that the information requested in the original decision is still missing.

In practice, documents such as those described above (an FTR 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.

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 NEAs 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 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	Substance evaluation draft decision – a proposal by an eMSCA for requesting further information on a substance.
Decision	Substance evaluation adopted 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	Substance of very high concern

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