



Tips for registrants and downstream users

ECHA-12-L-10-EN

Substance evaluation under REACH

TIPS FOR REGISTRANTS AND DOWNSTREAM USERS

Is your company manufacturing, importing or using chemicals that have to be registered under REACH? Are any of these chemicals included in the Community Rolling Action Plan (CoRAP)?

If yes, then you may be required to contribute to the substance evaluation of the chemical to help evaluate the initial concerns identified. This is part of your responsibility to protect human health and the environment.

The inclusion of a substance in the CoRAP does not necessarily mean that the substance causes risks to human health or the environment. It does, however, mean that there is a concern which needs to be clarified.

The evaluating Member State will assess whether or not the concern can be substantiated. Further information, including further testing, may be requested from the registrant in order to reach a conclusion. There are no immediate consequences for the current uses of the substance.

This publication provides practical advice for registrants who hold a registration for a substance included in the CoRAP and for downstream users of such substances on how to participate in the substance evaluation process. Substances listed in the CoRAP will be subject to substance evaluation by an evaluating Member State.



STEP 1: CHECK IF YOUR SUBSTANCE IS IN THE UPDATED CORAP

The CoRAP is a rolling action plan covering three years, which lists the substances for substance evaluation.

The CoRAP is updated every year. Not all of the CoRAP substances are evaluated at once. Substances listed in the first year of the three-year plan are evaluated first. The evaluation starts for these first-year substances on the date of publication of the final CoRAP update every spring. In preparation for the CoRAP update, a draft of it will be published on the ECHA website during the previous autumn.

The draft CoRAP is published for information only and not for public consultation. Justification documents will be published for each of the substances listed on the final CoRAP. Contact details for the evaluating Member State are also published in the CoRAP.

STEP 2: PREPARE FOR YOUR PARTICIPATION IN SUBSTANCE EVALUATION

- **Make contact early with the evaluating Member State**

If you have any questions, especially regarding the first year substances, contact the evaluating Member State competent authority (eMSCA) early in the process. This can be useful to clarify the initial concern identified.

- **Coordinate with other registrants**

There may be many registrants of a substance on the CoRAP, so it is important to start coordinating and communicating with each other as soon as possible. Discuss with other registrants and downstream users how to coordinate your involvement in the substance evaluation.

- **Update your dossier early, if needed**

A registration dossier should always reflect all available and relevant information. There are legal obligations to update your registration dossier in certain cases, such as breaching the next tonnage band. Inclusion of a substance in the CoRAP is not a reason in itself to update your registration dossier.

ECHA recommends that you discuss any planned dossier updates which are relevant for substance evaluation with the eMSCA, especially for the first year substances. For the second and third year's substances there is more time to make the necessary dossier updates. The aim is to gain a common understanding of whether the eMSCA is able to consider new information in their assessment. The eMSCA may not be able to consider new information supplied after the evaluation has started.

Please note that updating your registration dossier is always your responsibility and the eMSCA will never update it.

Instructions for dossier updates

ECHA recommends that if you make a dossier update during substance evaluation, you use the 'dossier header' to indicate to the eMSCA its relevance to the ongoing substance evaluation. For a spontaneous update, select the justification 'other'. Then include an explanation in the adjacent field like 'information

for substance evaluation'. In the 'remarks' field add the message 'relevant for on-going substance evaluation' to inform the eMSCA. General instructions on updating your registration dossier are available in 'Data Submission Manual Part 05 - How to complete a technical dossier for registrations and PPORD notifications' available on the ECHA website.

- **Discuss any planned testing with the evaluating Member State**

Inform the eMSCA, especially if you think there is a need for further testing for first year substances. The eMSCA will identify any further information needs and prepare a respective decision. Therefore, at this stage, testing proposals submitted by the registrants in relation to the concern for the CoRAP substance will not be examined by ECHA.

- **Downstream users should share any relevant information**

Downstream users, you may hold useful information relevant to the concern, such as exposure information. If that is the case, you should provide the information to the relevant registrant for them to include in their registration dossier or update your own downstream user report. Share useful information as early as possible, even when the draft CoRAP is published.

Communicating with the evaluating Member State

The eMSCA has 12 months after publication of the CoRAP to evaluate the first year substances and propose a data request (draft decision), if necessary. Member States have agreed a common approach on interaction with registrants during substance evaluation. If the dialogue has not already started, the eMSCA will usually contact the lead registrant and offer the opportunity to meet to discuss technical issues related to substance evaluation. You should consider nominating a representative for interacting with the evaluating Member State. For example, the lead registrant may take on this role. You should agree on how to deal with confidentiality and competition issues between registrants.

STEP 3: COORDINATE YOUR COMMENTS DURING THE FORMAL DECISION-MAKING PROCESS

If the evaluating Member State concludes that further information is required, they will prepare a draft decision within 12 months from the publication of the CoRAP. The decision is normally addressed to all registrants of the substance but the addressees of the decision will depend on the information requested. In some specific cases, the decision may be addressed to only certain registrants or to certain downstream users of the substance.

Addressees have 30 days to comment on a substance evaluation draft decision and then 30 days to comment on any subsequent proposals for amendment from the authorities and/or ECHA. If proposals for amendment are received, the draft decision is referred to the Member State Committee for agreement. Otherwise, the draft decision becomes a final decision and is issued by ECHA.

- **Speak with one voice**

ECHA suggests that addressees of a draft decision nominate one representative to send comments on behalf of the whole group.

- **Comment on the draft decision**

Instructions on how to submit comments on the draft decision will be provided within the notification letter accompanying the draft decision. If you still have data that may change or make the request in the draft decision obsolete, communicate this in your comments and submit a dossier update with the new information within the first 30 days consultation period. The eMSCA will consider all your comments and may consequently modify the draft decision. Please note that the eMSCA cannot take any updates of the dossier received into consideration after the date on which the other Member State competent authorities and ECHA are notified of the draft decision in accordance with Article 52(1) of the REACH Regulation.

- **Stick to the deadlines**

Comments submitted after the deadlines will not be considered.

- **Your representation at the Member State Committee (MSC)**

The MSC will only discuss those aspects of the draft decision for which proposals for amendment have been submitted by the authorities. If your case is referred to the MSC for agreement, there may be an opportunity to send a representative to the Committee meeting. For organisational reasons, the number of participants in the meeting is limited. Normally, ECHA would invite the coordinator who has submitted comments.

Can a substance in the CoRAP also be subject to a compliance check?

A compliance check undertaken by ECHA according to Article 41 of REACH is a separate process to substance evaluation. A compliance check determines whether or not the information submitted in a particular registration dossier is in compliance with the law. The process of substance evaluation aims to clarify possible risks of the (collective) use of a substance. There is no legal requirement for a compliance check to be conducted on a registration dossier before the substance undergoes substance evaluation. However, for many CoRAP substances ECHA is initiating compliance checks to ensure that the registration dossiers contain a basic data set to assist the evaluating Member State in investigating the possible risks under substance evaluation. ECHA coordinates work on compliance checks with the evaluating Member States to avoid duplication of effort.

STEP 4: PROVIDE THE INFORMATION REQUESTED

Following a final decision taken by ECHA as an outcome of the substance evaluation, the addressees of the decision must decide who is best placed to obtain the information requested.

- **Agree within 90 days of receipt of the decision on who will perform requested studies**
If ECHA is not informed of such an agreement, it will designate one of the addressees to perform the study on behalf of all of them.
- **Agree on cost- and data- sharing**
The registrant (or downstream user) who performs the test should provide the others concerned with a copy of the full study report.
- **Update your registration dossiers**
Your registration dossiers should be updated with the requested information by the deadline indicated in the final decision.

STEP 5: FOLLOW THE CONCLUSION OF THE SUBSTANCE EVALUATION

When information requested in a final decision is submitted to ECHA, the eMSCA will examine it within 12 months. If needed, the eMSCA may initiate a further request for information by a second decision. The advice provided under Step 3 above would again apply.

Having reviewed the new information, the eMSCA will complete the substance evaluation and will consider how to use the information obtained for Community level risk management measures. In some cases, the eMSCA may conclude that risks are sufficiently under control with the measures already in place.

The decisions on requests for further information and the evaluation reports of the Member States will be published on the ECHA website. ECHA will inform the Commission, the registrants and the other Member States about the conclusions.

RIGHT TO APPEAL

All addressees of a final decision issued under substance evaluation have the right to appeal.

USEFUL LINKS

ECHA substance evaluation web page:
<http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation>

ECHA web page for CoRAP:
<http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan>

ECHA Member State Committee web page:
<http://echa.europa.eu/web/guest/about-us/who-we-are/member-state-committee>

ECHA Board of Appeal web page:
<http://echa.europa.eu/about-us/who-we-are/board-of-appeal>

OVERVIEW OF SUBSTANCE EVALUATION PROCESS

