Follow-up to dossier evaluation decisions

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http://echa.europa.eu/contact

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Introduction

In dossier evaluation, ECHA checks whether the information provided by registrants in their registration dossiers complies with the requirements set out in the REACH Regulation. If the information does not comply, ECHA sends a dossier evaluation decision to all registrants in the joint submission asking them to provide further information by a given deadline.

Follow-up to dossier evaluation starts when the deadline in the dossier evaluation decisions has passed.

How does follow-up to dossier evaluation work?

If you receive a dossier evaluation decision from ECHA that the information in your registration is not compliant, you must follow the methods and conditions specified in the decision to fulfil the information requirements in an update of your registration by the deadline set.

Once this deadline has passed, ECHA verifies that the information you have provided in your update (including any adaptations you submit) complies with the corresponding information requirements in the decision. During this follow-up, ECHA also identifies and addresses issues with any new information you have submitted.

For example, if you provide a study, ECHA checks that it is on the requested substance, that the specified test method is used, and that a proper (robust) study summary has been included. The Agency also verifies whether the conclusions are reasonable, that they are based on new information and that you have (self-)classified correctly, where applicable.

Possible outcomes

Once ECHA has examined the new information, one of the following actions will be taken:

a) Requested information provided

If the update contains the requested information, ECHA informs[1] the Member State competent authorities (MSCAs) and the European Commission that the dossier evaluation process is completed. A copy of this communication is also sent to all concerned registrants. ECHA can still open a new compliance check, if needed, at a later stage.

> If a dossier evaluation decision contains several information requests, the evaluation process is only completed once you have successfully addressed **all** the requests.

b) Valid adaptations

[1] ECHA sends a notification under Article 42(2) of REACH.

If you have used alternative methods (e.g. read-across) or other adaptations to successfully fulfil the information requirements, ECHA informs the MSCAs and the Commission that the evaluation process is completed. A copy of this communication is also sent to all concerned registrants. If needed, ECHA can still open a new compliance check at a later stage.

c) Failure to respond

If you do not send an update at all, or the adaptations you use in response to the requests in the decision are *manifestly unreasonable*, ECHA sends a *Failure to Respond* (FTR) notification[2] to the national enforcement authority of the country where you are located. A copy is also sent to all concerned registrants.

FTR notifications outline the requests for which no information was submitted. Where applicable, they may also mention that you have indicated that a study is delayed.

> The submission of information such as preliminary results, interim/draft reports or dose range finding (DRF) studies, **cannot** be considered as a viable response to the information requested in the decision. Submitting such information would, therefore, not postpone the notification to the NEAs. **It is the NEA's role to assess the reason for the delay and to consider enforcement measures, where required.**

d) Information provided does not comply with information request

If the updated data does not comply with the information request, ECHA issues a follow-up draft decision[3] stating the reasons for non-compliance and sends it to you.

This could happen, for instance, due to a non-compliant study or an invalid adaptation. If the adaptation submitted is '*manifestly unreasonable'*, ECHA directly notifies the national enforcement authority as described in the 'Failure to respond' scenario in section c).

The adopted follow-up decision contains ECHA's definitive position on the compliance of the information requirement in question. It can be appealed to the Board of Appeal within three months of the date of adoption.

> The adopted follow-up decision **does not give a new deadline**[4] as the information requested has not changed. You must still comply with the information requirements set out in the original decision.

[2] FTR notifications include ECHA's original dossier evaluation decision and any relevant communication with registrants received by the Agency after the decision has been notified to them.

[3] This draft decision is notified according to Article 42(1) of REACH. It refers to the original (adopted) dossier evaluation decision, addresses the information which the registrants have subsequently provided and explains why the information requirement has still not been fulfilled. The adoption of the follow-up decision follows the procedure described in Articles 50 and 51, as with any other evaluation decision.

[4] This point was recently confirmed by ECHA's Board of Appeal in its decision in case A-001-2019.

> Example: the registrants submit a valid pre-natal developmental toxicity study, but the doses used in the test are too low and do not comply with the OECD test guideline requirements.

After the three-month appeal period has passed, ECHA notifies the national enforcement authority in the country where you are located. The authority is responsible for making sure the decision is enforced and complied with, carrying out checks and imposing effective, proportionate and dissuasive penalties[5].

e) Information provided triggers a new information request

If the update complies with the information requirements in the original decision, but the updated data triggers a request for new information, ECHA may issue a new dossier evaluation decision.

> This new decision **contains a new deadline**. While the update complies with the information requirements in the original decision, the information submitted triggers new information requirements on the substance.
>
> Example: the original decision requested a pre-natal developmental toxicity study on a first species. Registrants provide the requested study and the results identify the need to request a pre-natal developmental toxicity study on a second species[6].

Contact national authorities

You can contact ECHA's Helpdesk if you have concrete questions about your obligations related to the dossier evaluation decision. The Helpdesk can clarify the obligations but cannot advise you on how to meet the information requirements or comment on any alternative strategies.

ECHA cannot change the content or the deadline of the decision, as these have been agreed together with the Member States. The Agency can also not give any preliminary information related to cases before the deadline of the decision has passed.

The Member States are solely responsible for enforcement. Once the case has been handed over to national authorities, all communication should take place with the relevant national authority. You may want to discuss with the national authority whether the way you intend to fulfil the information requirements is acceptable, for example, by using general or specific adaptations.

Cease of manufacture

Even if you **stop manufacturing or importing** your registered substance, **once an evaluation decision has been adopted**, you will still have to provide the requested information by the

[5] See judgment of the Court in Case C-471/18 P Germany v. Esso Raffinage, paragraph 143.
[6] If the registrant submits a testing proposal for the pre-natal developmental toxicity study on the second species, ECHA will assess this under Article 40 and not in a new decision under Article 42(1).

deadline. As the decision was adopted while you were still manufacturing or importing the substance, it is still relevant to obtain information to clarify the possible hazards and risks caused by the use of the substance.

ECHA will send a *'Failure to Respond'* notification to the relevant national authorities if you have not provided the information requested in the original decision because you have ceased manufacture.

If you cease manufacture and notify ECHA **after receiving a draft decision issued according to Article 42(1)** that establishes non-compliance with a previous evaluation decision (i.e. the new decision **without a deadline** outlined under point d), you continue to be bound by that decision.

Articles 50(2) and (3) of REACH **do not apply to the draft decision on the follow-up** because the new decision does not request '*further information*'. It only states that ECHA examined the information provided in response to the original decision, that the registration still does not comply with the information requirements and that enforcement authorities will be informed of the decision. So, the requirements of the initial decision will still apply.

Tonnage downgrade

Once an evaluation decision is adopted, you have to provide the information requested in the decision regardless of whether you downgrade your tonnage band after receiving the final decision.[7] Failing to provide the requested information based on tonnage downgrade will also result in a *'Failure to Respond'* notification.

Registering a substance at a certain tonnage band gives you the right to market the substance in those quantities. In exchange, you have to provide ECHA with the relevant standard information on your substance for the registered tonnage band. You cannot lower your tonnage band to avoid providing the information requested in the original evaluation decision.

As you were manufacturing or importing the substance in a certain tonnage band when the evaluation decision was adopted, you must be able to clarify the possible hazards and risks caused by that use.

Transfer of lead registrant role

The lead registrant role can be transferred to a new lead registrant after an evaluation decision has been adopted. In such cases, the new lead registrant can submit the dossier update including the information requested in a decision. However, the legal responsibility to comply with the decision stays with the original addressees of the decision.

[7] Note that if the registrant – following a technical downgrade of the tonnage - receives a letter of acceptance from ECHA, this does not mean that it is exempted from complying with the requests in the adopted evaluation decision.

General advice for registrants

Update your dossier **by the deadline** set in the 'original decision'.

If you are requested to generate **new hazard information**, you must comply with Article 10 of REACH - submission of (robust) study summaries[8].

Your update must also include any changes to your registration dossier that follow from the new information required – for example, regarding classification and labelling, the chemical safety report, or the submission of testing proposals.

Any adaptation you submit needs a valid scientific reasoning and comprehensive documentation, including scientific evidence. If these conditions are not met, ECHA will not accept the adaptation.

> If you have difficulties in submitting the requested information **in due time**, you should update your dossier by the deadline in any case, adding **any relevant explanation and proof concerning the reasons for the delay**.
>
> ECHA is **not** competent to draw any conclusion from this information and cannot delay informing the relevant national enforcement authority if you fail to provide the requested information on time. However, the national enforcement authority may use the information you submit when considering their enforcement actions.

Links

Evaluation and its process
https://echa.europa.eu/regulations/reach/evaluation/evaluation-procedure

Questions and answers
https://echa.europa.eu/support/qas-support/qas

National helpdesks
https://echa.europa.eu/support/helpdesks

Contact ECHA
https://echa.europa.eu/contact

[8] See Practical Guide on 'How to report robust study summaries' for detailed information – this will ensure that ECHA can conduct an independent assessment and conclude the follow-up process without needing to request for additional information in a new dossier update.

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