

Dossier Evaluation

1. Purpose

The purpose of this procedure is to describe the dossier evaluation process, which includes compliance check and testing proposal examination, as stated in the REACH Regulation (EC) No 1907/2006 (Title VI).

2. Scope

The dossier evaluation procedure applies to any registration dossier once selected for evaluation: namely, when a dossier contains one or more testing proposals or when a substance has been selected for compliance check, according to pre-defined criteria.

3. Description

Dossier evaluation distinguishes compliance check and testing proposal examination. Both processes are based on the same principles, and follow the same decision-making procedure.

Information provided in the dossiers of registered substances are assessed by the ECHA Secretariat with regard to the adequacy of the proposed tests and compliance of the information provided.

When ECHA sends a decision as a result of its assessment, the registrants may comment on the draft document. Then the decision-making process is initiated, during which Member State competent authorities take part and may propose amendments. Registrants are informed of the proposed amendments if any and may comment on those. If amendments are proposed, the Member State Committee and (if necessary) the European Commission may be involved in reaching an agreement on the content of the decision.

Dossier evaluation may lead to a decision by ECHA or the European Commission. This decision contains requests for new information to be provided by the registrants in an updated dossier. The new information is evaluated by ECHA against the respective information requirement after the deadline given in the decision.

When this information is not submitted or is deemed inadequate, enforcement actions or additional information requirements follow.

Dossier evaluation is divided into four stages:

1. Initiation

In this stage, dossiers are selected for processing and the necessary preparatory work is conducted to ensure the cases are fit for processing. All valid testing proposals are selected for examination. Any dossier could be selected for evaluation. Selection is normally done in line with ECHA's strategic objectives and the regulatory strategy.

Dossier Evaluation

Further information on the regulatory strategy can be found at <https://echa.europa.eu/understanding-assessment-regulatory-needs>.

2. Scientific and legal assessment

This stage involves the scientific and legal analysis of the information provided by the registrants in their dossiers. Under testing proposal examination, third parties are also consulted on the proposals involving vertebrate testing and asked to submit existing relevant scientific information concerning the proposed test.

The scientific and legal assessment produces:

- a conclusion with no action or
- a draft decision requesting new or updated information or
- a draft decision rejecting a testing proposal.

The draft decision is made available to the registrants concerned for commenting.

3. Decision-making

Adoption of an ECHA decision is achieved either by:

- acceptance of the draft decision by the Member State competent authorities or
- unanimous agreement in the Member State Committee on proposed amendments to the draft decision.

When unanimous agreement is not reached, the European Commission is requested to take the decision.

4. Follow-up

The decision specifies by when the registrants must deliver the required information in an updated registration dossier. Once the deadline has passed, ECHA checks whether the information requested has been provided. The following scenarios may happen:

- The information received meets the requirement. The Member State competent authorities and the Commission (the registrants receive a copy) are notified that the dossier evaluation process is completed.
- The information received complies with the request in the decision but the information requirement is nevertheless not fulfilled. ECHA then drafts a new decision (see Stage 2 below).
- The requested information has not been submitted or is irrelevant: ECHA sends a simple information to the relevant Member State and the registrant on the failure to respond following a dossier evaluation decision.

ECHA also draws conclusions recommending further regulatory action where it appears necessary.

Stage 1: Initiation

1-1. Identify and prepare dossiers for evaluation

Dossiers are selected for compliance check based on the selection criteria.

In addition, all registration dossiers containing testing proposals are assigned for examination of the said testing proposal upon arrival.

Irrespective of the dossier type, this step entails preparatory steps, such as case creation, the checking of the substance identity and the allocation of the case to the relevant team.

Stage 2: Scientific and legal assessment

2-1. Start evaluation

The case is assigned for evaluation by the ECHA Secretariat.

2-2. Third party consultation

When a submitted dossier contains a testing proposal involving vertebrate animals, information relating to this proposed test is published on ECHA's website. Third parties are invited to submit scientifically-valid information and studies (relating to the substance and endpoint) within 45 days of the date of publication.

2-3. Scientific and legal assessment

Under compliance check, the experts consider whether the information provided in the dossiers meets the information requirements of the REACH Regulation. The conclusions on the identified shortcomings are converted into regulatory requests for information to the registrants concerned.

Under testing proposal examination, the experts consider the need and adequacy of the testing proposed, taking into account the information in the respective dossier and all relevant scientifically valid information received from third parties during consultation.

2-4. Conclude case with no action

This step is only performed during a compliance check where no formal action towards the registrants is deemed necessary.

Evaluation is completed and the Member State competent authorities are notified.

2-5. Prepare the draft decision

Steps 2-5. to 2-8. are performed for all testing proposals and under compliance check when request for information from the registrants is deemed necessary and for any proposed test.

The outcome of the testing proposal examination is explained in the draft decision.

Any shortcomings identified during compliance check are addressed in the draft decision containing a request to provide additional information.

2-6. Notify the draft decision to the registrants concerned

The draft decision is sent to all the registrants in the joint submission having obligations to comply with the decision (Henceforth "Registrants concerned"). It is accompanied by any third party information received. The recipients are informed in the notification letter of their right to comment on the draft decision and of the means to do so.

2-7. The comments from the registrants concerned are received

The registrants concerned have 30 days starting from the date of receipt of the draft decision to comment on the decision. ECHA recommends that they submit a consolidated set of their comments.

2-8. Consider the comments from the registrants concerned

Comments provided by the registrants concerned are taken into account and, where appropriate, the request in the draft decision is amended. The reasoning for the request can also be modified on the basis of the comments provided.

If no comment is received from the registrants within the 30-day commenting period, the draft decision remains unchanged.

Stage 3: Processing of the draft decision

3-1. Notify the Member States of the draft decision

The draft decision is submitted to the Member State competent authorities for consultation. All information are made available to the competent authorities: whether they are obtained from the consultation of third parties on proposed testing involving vertebrate animals, or comments from the registrants on the draft decision, together with ECHA's responses to these comments.

3-2. Member States may propose amendment

The Member States may submit proposals for amendments to the draft decision within 30 days starting from the date of notification.

If no proposal for amendment is submitted by any of the Member States, ECHA takes the decision (Step 3-7.), *i.e.* the draft decision becomes an ECHA decision.

3-3. Notify the registrants concerned of the proposals for amendments

Any proposal for amendment received from the Member States and the draft decision as notified to the Member States are sent to the registrants concerned immediately after the commenting period. A cover letter notifies the registrants of their right to comment on the proposals for amendments within a 30-day period.

3-4. Amend the draft decision

ECHA may amend the draft decision on the basis of a proposal made by a Member State, and taking into account any comments from the registrants.

3-5. Refer the case to the Member State Committee (MSC)

When at least one proposal for amendment is received, the draft decision is referred to the Member State Committee for seeking agreement within 60 days. ECHA refers the comment from the registrants concerned, the current version of the draft decision and the amendment proposed, to the Member State Committee no later than 15 days after the end of the 30-day consultation period. ECHA forwards any comment from the registrants on the proposal for amendment to the MSC for consideration.

3-6. Consider the Member State's proposal for amendment together with comment from the registrants

The Member State Committee considers the comments of the registrants concerned on the proposal for amendment together with the Member State's proposal for amendment. It aims to reach a unanimous agreement on the request in the ECHA decision.

3-7. Adoption of the ECHA decision

The decision is adopted either when none of the Member States propose an amendment to the draft decision during Step 3-2 or when a unanimous agreement on the proposed amendment is reached by the Member State Committee in Step 3-6.

This ECHA decision is notified to the registrants concerned, and also notified to the Member State competent authorities. The ECHA decision contains an exact date by which the registrants must provide the requested information in an updated dossier.

The registrants are expected to notify ECHA within 90 days of whom will perform the necessary test(s) to obtain the necessary information. If the registrants fail to do so, ECHA designates one of the registrants to perform the test(s) on the behalf of all of them.

After consultation of the recipients of the ECHA decision, ECHA publishes a non-confidential version on ECHA's website.

3-8. Refer the case to the Commission

Where the Member State Committee cannot reach a unanimous agreement, ECHA refers the case to the European Commission. ECHA informs the registrants concerned thereof.

The decision-making process of the Commission is not covered by this document. Further details concerning the European Commission taking such a decision are provided under Article 133(3) of the REACH Regulation.

Stage 4: Follow-up of dossier evaluation decisions

4-1. ECHA decision becomes effective

Any of the recipient of the ECHA decision may file an appeal to the ECHA Board of Appeal within three months of receiving the decision.

The appeal is handled by the Board of Appeal of ECHA according to the rules of procedure laid down in Regulation (EC) 771/2008.

In any case, the follow-up evaluation process starts when the date set in the ECHA decision for updating the dossier with the requested information has passed.

Dossier Evaluation**4-2. Check for compliance with the information requirement**

ECHA evaluates whether the information of the joint submission are provided in the form of an updated registration dossier and whether they now meet the information requirements addressed in the respective ECHA decision.

4-3. Inform the relevant Member State about the failure to respond following a dossier evaluation decision

When no relevant information has been submitted and, therefore, the requested information is still missing, ECHA informs the relevant Member States about the **failure to respond to the dossier evaluation decision**. The registrants concerned receive a copy of the document.

Member States have the duty to ensure that the requests in the original decision are enforced and complied with and, to that end, inter alia, to carry out checks and impose effective, proportionate and dissuasive penalties. ECHA expects to receive the requested information in an updated registration dossier following the action of the respective Member States.

4-4. Prepare a new draft decision

When the registrants provide information relevant to the requests of the ECHA decision, but there are remaining or new concerns that need to be clarified with additional information from the registrants concerned, ECHA may prepare a new draft decision. The relevant recipients are notified accordingly. The new draft decision is processed further as described above (Steps 2-6. to 3-8.).

4-5. Inform the Member States and the Commission about completion of a dossier evaluation

If the information received meet the information requirements addressed in the ECHA decision, ECHA informs the Member State competent authorities, the registrants concerned and the Commission that the process of dossier evaluation is complete.

ECHA also informs the Member State competent authorities and the Commission on any conclusion made concerning the substance covered by the respective registration dossier.

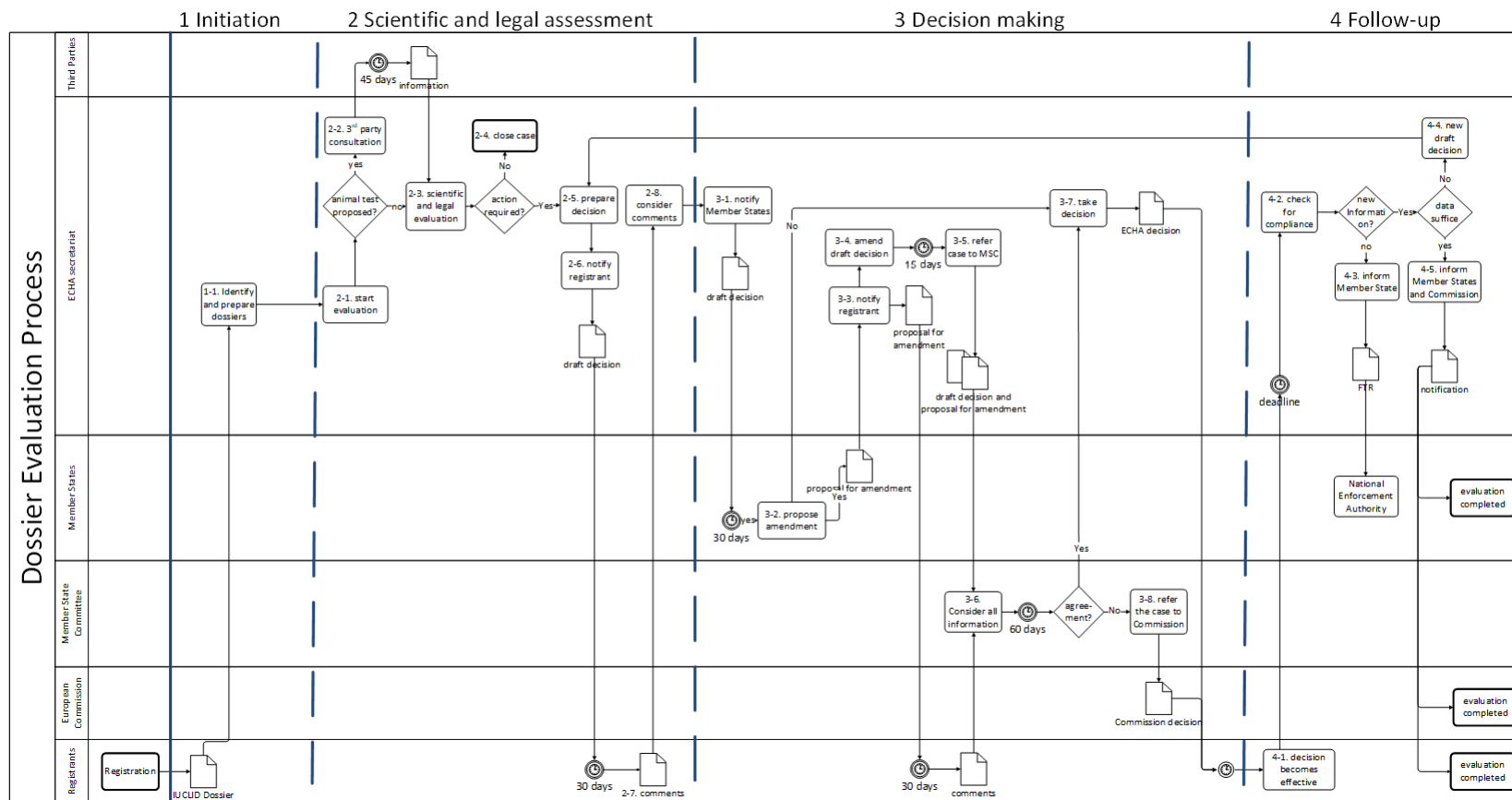
Based on the information in the notification, competent authorities may trigger the application of other REACH processes for the substance in question, e.g. identification as a candidate for substance evaluation, authorisation, restriction, or harmonised classification and labelling.

3.1. Supporting Documentation

The process is described in more detail in related work instructions. In addition, supporting documentation describes practical elements required when executing tasks. These supporting documents include instructions and standard texts for documents. This documentation is controlled in analogy to the provisions of ECHA's Integrated Management System. The respective document owner is responsible for keeping the document up-to-date.

4. Flowchart

The flowchart below gives an overview on the process stages and steps. Please note that the flowchart is not suited for detailed printing and that it should be viewed electronically rather than in print.



5. Definitions

Term or abbreviation	Definition
IUCLID	International Uniform Chemical Information Database
MSC	Member State Committee
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and restriction of Chemicals (REACH Regulation)

6. Records

Record name	Security level	Comments
Information submitted by the 3rd parties	Internal	
Draft Decision	Internal	
ECHA Decision	Internal	

7. References

Associated document code	Document name
(EC) No 1907/2006	REACH Regulation
(EC) No 1272/2008	Regulation on Classification, Labelling and Packaging of substances and mixtures (CLP Regulation)
(EC) No 440/2008	Test Methods Regulation
	ECHA Practical guide 12: how to communicate with ECHA in dossier evaluation
MB/45/2011	Policy for Managing potential Conflicts of Interests (CoI)
(EC) No 771/2008	Regulation on Rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency
PRO-BOA-001	Appeal proceedings before the Board of Appeal

8. Annexes

N/A