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 dossier 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 draft 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 information requested in the decision after the deadline given in the decision.

When the requested information is not submitted or the submitted information is deemed inadequate, enforcement authorities are informed of a failure to respond (see 4.3 below) or a new draft decision is sent (see 4.4. below).

ECHA can open a compliance check to address data gaps at any point in time.

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, expressed in ECHA's Work Programme documents.

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 information or
- a draft decision rejecting a testing proposal.

The draft decision is made available to the registrants concerned for commenting. Comments provided by the registrants are taken into account and, where appropriate, the requests in the draft decision are amended.

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 in the Member State Committee is not reached, the European Commission is requested to take the decision.

The ECHA decision may be appealed by the addressees of the decision, or any other party whom the decision concerns directly and individually. Appeals before the Board of Appeal of ECHA have a suspensive effect. Therefore, the decision only becomes final when any possible appeals have been processed by the Board of Appeal of ECHA or by the Court of Justice of the European Union.

4. Follow-up

The decision specifies a deadline by when the registrants must submit 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 dossier has been updated with information compliant with the decision. The Member State Competent Authorities and the European Commission informed about

the completion of the dossier evaluation and any conclusions thereof. The Registrant(s) receives a copy of the information letter.
- The dossier has been updated with new relevant information, but is still not compliant. In this case a new decision is drafted and sent to the Registrant(s).
- The dossier has not been updated with new and relevant information. A notification on a Failure to Respond following a dossier evaluation is sent to the respective Member State Competent Authorities. The Registrant(s) receive(s) a copy of the notification.

Stage 1: Initiation

1-1. Identify and prepare dossiers for evaluation

Dossiers are selected for compliance check based on the set of 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 evaluation process applied, 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 to evaluators 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 the proposed test(s) is published on ECHA's website. Third parties are invited to submit scientifically-valid information and studies (relating to the substance and endpoint for which the test is proposed) 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.

Under testing proposal examination, the experts consider the need for 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 the public 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 and the European Commission are notified.

2-5. Prepare a 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.

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

Any shortcomings identified during a 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 ("Registrants concerned"). In case of a testing proposal draft decision addressing vertebrate animal studies, itis 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 set of requests 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 set of requests and the justification for those requests in 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 agreement seeking 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 requests in the draft 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, to the Member State Competent Authorities and to the European Commission. 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 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 (Step 3-6 above), 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.

3-9. Appeals and court proceedings

Any of the recipients of the ECHA decision, or other party whom the decision concerns directly and individually, may file an appeal to the ECHA Board of Appeal (BoA) within three months of the notification of the decision. The appeal is processed by the BoA according to the rules of procedure laid down in Regulation (EC) 771/2008.

ECHA processes the appealed decision as appropriate based on the ruling of the ECHA Board of Appeal for an annulment, partial annulment or upholding of the decision.

If the ECHA decision is not appealed within three months of its notification to the addressees, it becomes final.

Any upholdings, annulments and new deadlines are recorded in the case folder for the Follow-up evaluation to take into account.

Stage 4: Follow-up of dossier evaluation decisions

4-1. Identify and prepare dossiers for follow-up evaluation

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

4-2. Check for compliance with the information requirement

ECHA evaluates whether the requested information, or an acceptable adaptation, is provided in an updated registration dossier and whether it now meets the information requirements addressed in the respective ECHA decision.

4-3. No information submitted by the deadline - Inform the relevant Member State about the failure to respond following a dossier evaluation decision

If 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. Information received is incompliant - Prepare a new draft decision

If the registrants provide information relevant to the requests of the ECHA decision, but the information is not adequate to fulfil the information requirement(s), ECHA may prepare a new draft decision. This draft decision addresses one or more of the information requests in the original decision, and no new data can be requested. The relevant recipients are notified accordingly. The new draft decision is processed further as described above (Steps 2-6. to 3-9.). The adopted decision is also notified to the National Enforcement Authorities for enforcement actions.

4-5. Information received is compliant - 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 dossier evaluation process is complete.

ECHA also informs the Member State competent authorities and the Commission on any conclusion made based on the received information.

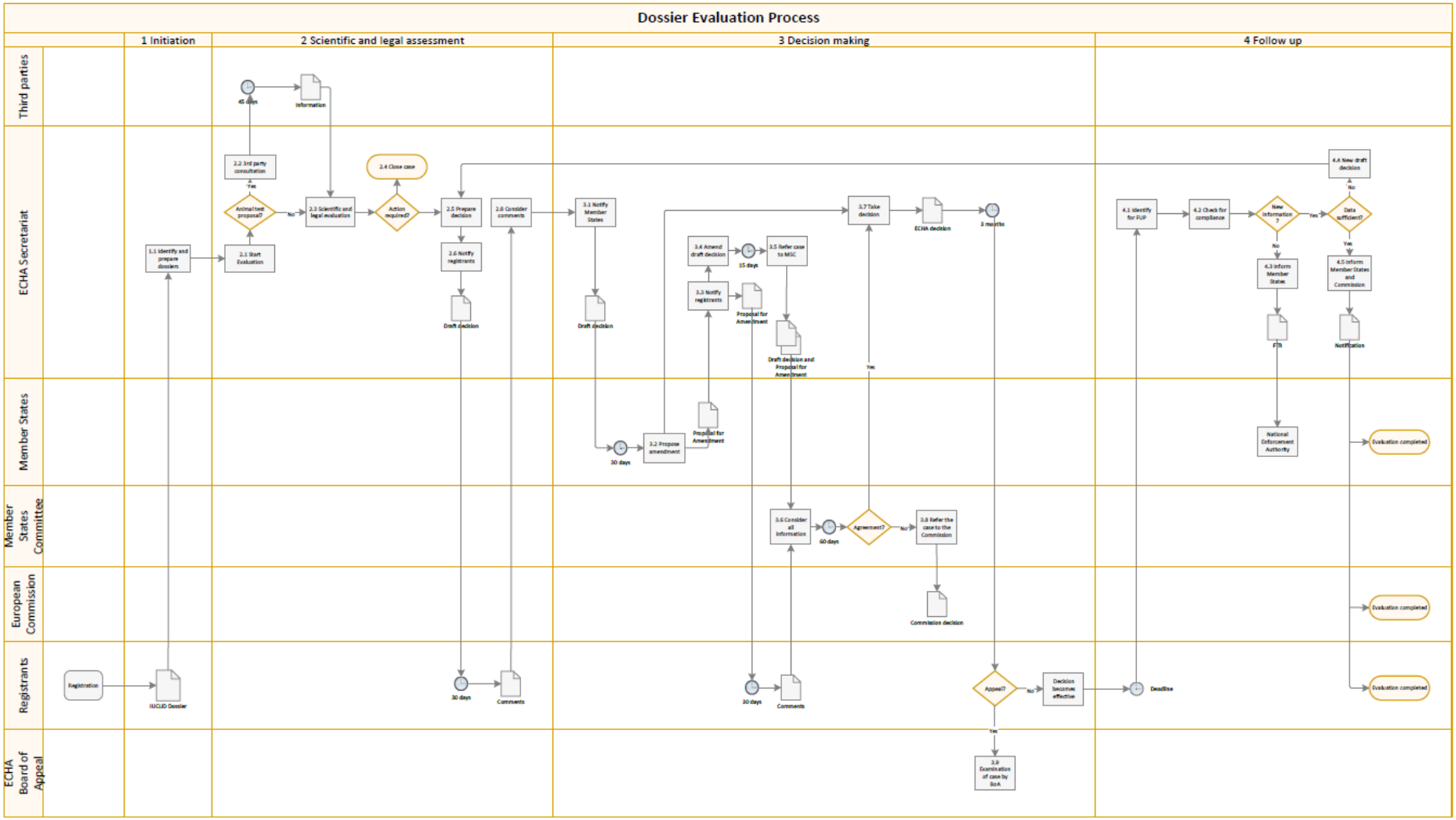
Based on the information in the notification, competent authorities may trigger the application of other REACH processes for the substance in question, *e.g.* identification as a candidate for substance evaluation, authorisation, restriction, or harmonised classification and labelling.

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.


Dossier Evaluation Process
1 Initiation
2 Scientific and legal assessment
3 Decision making
4 Follow up
Third parties
ECHA Secretariat
Member States
Member States Committee
European Commission
Registrants
ECHA Board of Appeal
45 days
Information
2.2 3rd party consultation
Yes
Animal test proposal?
No
2.3 Scientific and legal evaluation
Action required?
2.4 Close case
2.5 Prepare decision
2.6 Notify registrants
2.8 Consider comments
Draft decision
1.1 Identify and prepare dossiers
2.1 Start Evaluation
3.1 Notify Member States
Draft decision
30 days
3.2 Propose amendment
Proposal for Amendment
3.3 Notify registrants
3.4 Amend draft decision
15 days
3.5 Refer case to MSC
Draft decision and Proposal for Amendment
3.7 Take decision
ECHA decision
3 months
Yes
3.6 Consider all information
60 days
Agreement?
No
3.8 Refer the case to the Commission
Commission decision
Registration
IUCLID Dossier
30 days
Comments
30 days
Comments
Appeal?
No
Decision becomes effective
Yes
3.9 Examination of case by BoA
4.1 Identify for FUP
4.2 Check for compliance
New information ?
Yes
No
Data sufficient?
No
Yes
4.4 New draft decision
4.3 Inform Member States
4.5 Inform Member States and Commission
FTR
Notification
Deadline
National Enforcement Authority
Evaluation completed
Evaluation completed
Evaluation completed

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