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 registration dossiers. This procedure begins with the selection of a dossier for evaluation. This happens when a dossier containing one or more testing proposals has been submitted to ECHA or when a registration dossier has been selected as a potential candidate for compliance check.

3. Description

Dossier evaluation distinguishes compliance check and testing proposal examination. Both instances are based on the same principles, and follow the same decision-making procedure described in this document.

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

When an ECHA decision is prepared as a result, the registrant may comment on the draft document. Member State competent authorities and, where necessary, the Member State Committee and the European Commission, take part in the decision-making process and are informed on the status and outcome of the evaluations during the process.

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 registrant in an updated dossier.

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 adequate, enforcement actions or additional information requirements follow.

Dossier evaluation is divided into four stages:

1. Selection

In this stage, dossiers are selected for processing. All valid testing proposals are selected for examination. ECHA has established selection criteria for compliance check, which aim to improve safe use of chemicals. Selection criteria are agreed with the Member States.

Further information can be found at: https://newsletter.echa.europa.eu/home/-/newsletter/entry/5_14_new-compliance-check-strategy

2. Scientific and legal assessment

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

Scientific and legal assessment produces:

- a conclusion with no action; or
- a draft decision requesting to provide information.

The draft decision is made available to the registrant 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 decision is taken by the European Commission.

4. Follow-up

The decision specifies by when the registrant must deliver the required information in an updated registration dossier. Once this deadline has passed, ECHA checks whether the information requested has been provided or not. This can lead to different actions:

- information has not been submitted or is inadequate: ECHA informs the relevant Member State and the registrant about non-compliance;
- information complies with the request in the decision but the respective information requirement is nevertheless not fulfilled: ECHA drafts a new decision according to Stage 2;
- information meets the requirement; Member State competent authorities, the registrant and the Commission are notified that the process of dossier evaluation is completed.
- In the notification, ECHA also draws conclusions recommending further action where it appears necessary.

Stage 1: Selection

1-1. Selection: identify dossiers for evaluation

All registration dossiers containing testing proposals are assigned for examination of the said testing proposal upon arrival.

Dossiers are selected for compliance check according to the priority setting and according to the annual Work Programme. These programmes are published on the ECHA website at https://echa.europa.eu/about-us/the-way-we-work/plans-and-reports.

Selection is based on screening of the database by IT tools and a manual verification is performed to ensure that the cases selected fit the current selection strategy, i.e. priority setting.

1-2. Inform Member States competent authorities

Member States competent authorities are informed of the initiation of the evaluation of the selected dossier.

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 for testing proposals involving vertebrate animals

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 evaluation

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

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 registrant 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 registrant 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 ECHA decision containing a request to provide additional information.

2-6. Notify the draft decision to the registrant

The draft decision is sent to the registrant. It is accompanied by any third party information received. The registrant is informed in the notification letter of the right to comment on the draft decision and the means to do so are explained.

2-7. The registrant's comment is received

The registrant has 30 days starting from the date of receipt of the draft decision to comment on the decision.

2-8. Consider registrant's comment

Comment provided by the registrant is 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 comment provided.

If no comment is received from the registrant 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 or consultation. Information obtained from the consultation of third parties on proposed testing involving vertebrate animals, comments from the registrant and ECHA's responses to these comments are made available to the competent authorities.

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 3-8.), *i.e.* the draft decision becomes an ECHA decision.

3-3. Notify the registrant on 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 registrant immediately after the commenting period. A cover letter notifies the registrant of the right to comment on the proposals for amendments over a 30-day period and the deadline thereof.

3-4. Amend the draft decision

ECHA may amend the draft decision on the basis of a proposal made by a Member State.

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 registrant's comment, 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 registrant on the proposal for amendment to the MSC for consideration.

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

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

3-7. 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 registrant about this outcome.

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.

3-8. Take the ECHA decision

ECHA takes the decision either when none of the Member States proposed an amendment to the draft decision during Step 3-2 (above) or when a unanimous agreement on the proposed amendment is reached by the Member State Committee in Step 3-6. (above). In practice, the draft decision becomes an ECHA decision.

This ECHA decision is notified to the registrant. The ECHA decision is also notified to the Member State competent authorities and a non-confidential version is published on ECHA's website. The ECHA decision contains an exact date by which the registrant must provide the requested information in an updated dossier.

Stage 4: Follow-up of dossier evaluation decisions

4-1. ECHA decision becomes effective

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

If the registrant does not file an appeal against the decision, it becomes effective.

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

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 information provided in the updated registration dossier now meets the information requirement addressed in the respective ECHA decision.

4-3. Inform the relevant Member State about the continuing non-compliance

When no relevant information has been submitted and, therefore, the requested information is still missing, ECHA informs the relevant Member State about the continuing non-compliance. The registrant receives a copy of the document.

Herewith, ECHA invites the respective national enforcement authority to consider enforcement actions towards the registrant to secure the implementation of the decision. ECHA expects to receive the requested information in an updated registration dossier following the action of the respective Member State.

4-4. Prepare a new draft decision

When the registrant provides new and substantial information corresponding to the requests of the ECHA decision, but there are remaining or new concerns that need to be clarified with additional information by the registrant, ECHA may prepare a new draft decision and notifies the registrant of it accordingly. The follow-up 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 meets the information requirement addressed in the ECHA decision, ECHA informs the Member State competent authorities, the registrant 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.

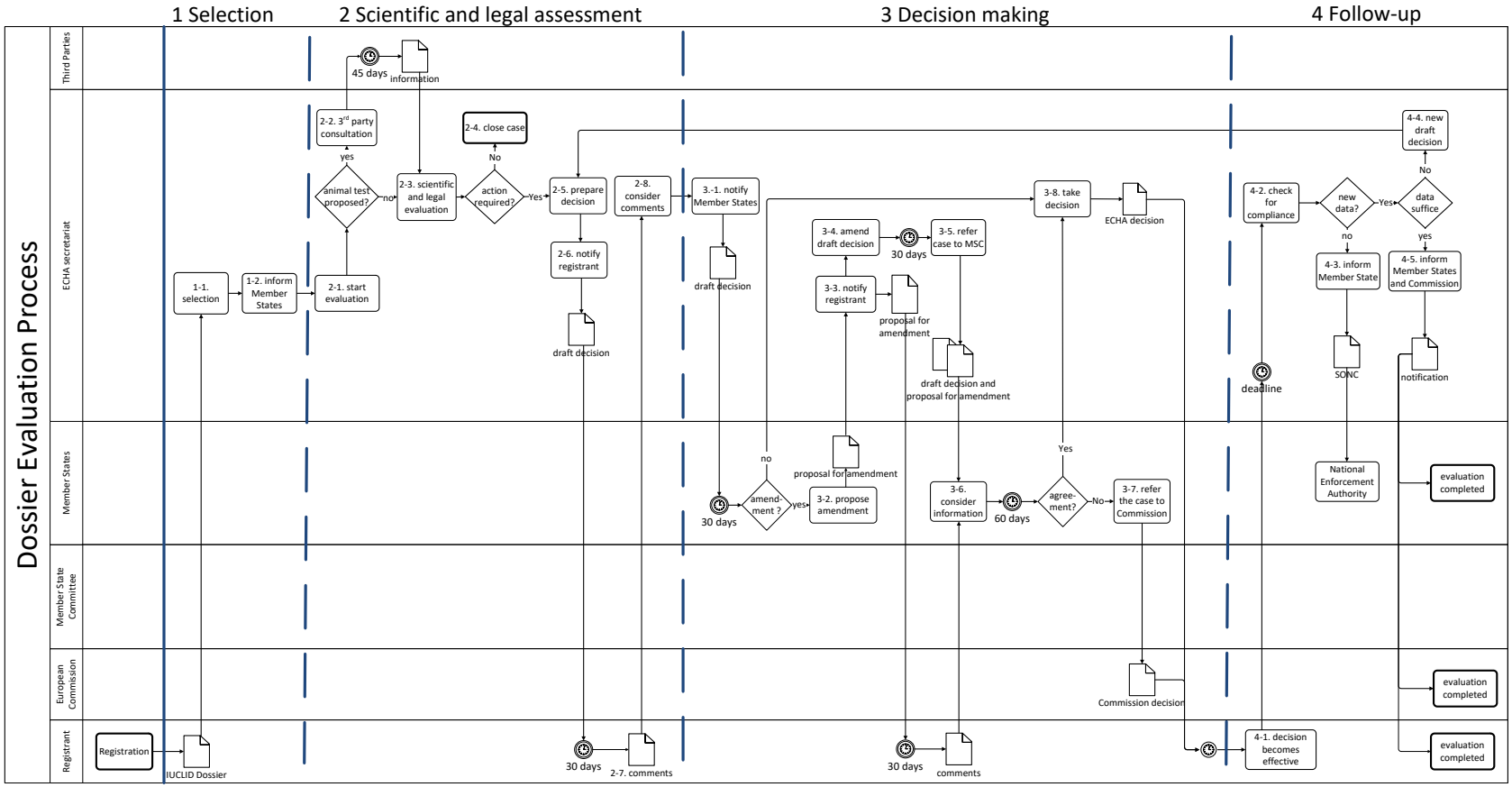
Based on the information in the notification, competent authorities may trigger the application of other REACH processes for the substance in question, *e.g.* identification as a candidate for substance evaluation, authorisation, restriction, or harmonised classification and labelling.

3.1. Supporting Documentation

The process described in this procedure is described in more detail in related working 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 given in PRO-0001 “Control of IQMS Documents”. The respective document owner is responsible for keeping the document up-to-date.

The flowchart below gives an overview on the process stages and steps.

4. Flowchart


1 Selection
2 Scientific and legal assessment
3 Decision making
4 Follow-up
Dossier Evaluation Process
Third Parties
ECHA secretariat
Member States
Member State Committee
European Commission
Registrant
45 days
information
2-2. 3rd party consultation
yes
animal test proposed?
no
2-3. scientific and legal evaluation
2-4. close case
No
action required?
Yes
2-5. prepare decision
2-8. consider comments
3.-1. notify Member States
1-1. selection
1-2. inform Member States
2-1. start evaluation
2-6. notify registrant
draft decision
draft decision
30 days
amend-ment ?
no
yes
proposal for amendment
3-2. propose amendment
3-4. amend draft decision
30 days
3-5. refer case to MSC
3-3. notify registrant
proposal for amendment
draft decision and proposal for amendment
3-8. take decision
ECHA decision
Yes
3-6. consider information
60 days
agree-ment?
No
3-7. refer the case to Commission
Commission decision
4-2. check for compliance
deadline
new data?
Yes
no
4-3. inform Member State
SONC
National Enforcement Authority
data suffice
No
yes
4-4. new draft decision
4-5. inform Member States and Commission
notification
evaluation completed
evaluation completed
evaluation completed
Registration
IUCLID Dossier
30 days
2-7. comments
30 days
comments
4-1. decision becomes effective

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	
SONCs_reporting_[upload_date]	Internal	Statement of non-compliance following a dossier evaluation decision

7. References

Associated document code	Document name
Regulation (EC) No 1907/2006	REACH Regulation
Regulation (EC) No 1272/2008	Regulation on Classification, Labelling and Packaging of substances and mixtures (CLP Regulation)
Regulation (EC) No 440/2008	Test Methods Regulation
	Guidance on information requirements and chemical safety assessment
	Guidance for intermediates
	ECHA Practical guide 12: how to communicate with ECHA in dossier evaluation

Associated document code	Document name
MB/45/2011	Policy for Managing potential Conflicts of Interests (CoI)
	New strategy on Compliance Check: https://echa.europa.eu/documents/10162/13608/echa_compliance check_strategy_en.pdf
	(Multi-)annual Work Programmes: https://echa.europa.eu/about-us/the-way-we-work/plans-and-reports
Regulation (EC) No 771/2008	Rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency

8. Annexes

N/A