ECHA
EUROPEAN CHEMICALS AGENCY

Dossier Evaluation Handbook

May 2022

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1. Introduction

The Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) requires EU companies manufacturing and importing chemicals to assess their chemicals and propose risk management measures. This assessment needs to be documented in a registration dossier which companies need to prepare and submit to ECHA.

The REACH evaluation provisions give ECHA the responsibility to check whether registrations are in compliance with the requirements of this Regulation.
ECHA and the Member States evaluate the information submitted by companies to examine the quality of the registration dossiers and the testing proposals and to clarify if a given substance constitutes a risk to human health or the environment.

Links: Evaluation - ECHA (europa.eu) and Guidance on REACH and Practical guides (especially How to act in dossier evaluation) and REACH Legislation

2. Actors

Before describing all the procedure, it is helpful to understand who the protagonists of this process are:

- **Registrants**
  - A natural or legal person established within the European Economic Area (EEA), manufacturing or importing a substance into the EEA at quantities of one tonne or more per year
  - Only representative appointed by the subjects mentioned above, according to Article 8 of the REACH Regulation

  They must provide information on the intrinsic properties of a substance and prove that their substance is used safely. The information required depends on the tonnage manufactured or imported: the higher the tonnage, the more information needs to be submitted.
  Links: Registration under REACH and Guidance on Information Requirements and Chemical Safety Assessment and Practical guides: How to act in dossier and substance evaluation

- **ECHA**
  ECHA intervenes in the process through the:
  - Secretariat: all employees that undertake work on registration and evaluation processes as well as the preparation of guidance, maintenance of databases and provision of information. It supports the Committees and the Forum.
  - Member state Committee: body to which each Member State appoints one member for a renewable term of three years. It seeks unanimous agreement on the draft evaluation decisions

  Links: Hazard Assessment Directorate and Units and Member State Committee

- **Third Parties**
  These subjects are citizens, organisations, academics, companies or authorities other than a registrant. They may provide information on testing proposals involving vertebrate animals.
  Links: Consultations on testing proposals and Member State Committee

- **Member States**
  They are representatives of the Member State competent authorities appointed by the EU Ministries. They can comment on and propose amendments to ECHA's draft decisions and propose substances for substance evaluation.

- **European Commission**
  All evaluation decisions made by ECHA must be unanimously supported by the Member States. If unanimous agreement cannot be reached, the European Commission has to prepare the draft decision to be taken according to the examination procedure [under Articles 5 and 13(1)(c) of Regulation 182/2011].

Link: Actors - ECHA (europa.eu)

3. The Evaluation Phasis

REACH aims to protect human health and the environment, and its evaluation process ensures that there is sufficient information available on the chemicals placed on the EU market.
The evaluation process focuses on two different areas:

1. Compliance check of the dossiers submitted to ECHA and examination of testing proposals submitted by registrants
2. Substance evaluation

The phasis of the check are detailed below.

Links: Evaluation Process - ECHA (europa.eu) and Dossier Evaluation status

3.1. Assessment

3.1.1. Dossier Evaluation

Ex art. 41 REACH, at any time ECHA can check that the information submitted by registrants is compliant with the legal requirements. This information is crucial for understanding whether a chemical may pose a risk to human health and the environment.

Two processes under dossier evaluation:
- Compliance check
- Examination of testing proposals

Links: Dossier Evaluation - description and procedures

3.1.1.1.1. Compliance Check

Verification of **legal requirements** fulfilment under REACH. Requirements are cumulative and vary depending on the tonnage band. Registrants must proactively review their registration dossiers and update them whether new relevant information is available.

Tonnage per year (manufactured/imported)	Standard information required under REACH (minimum to meet the registration obligations of REACH)
1 < 10	Annex VII
10 to< 100	Annex VII-VIII
100 to < 1000	Annexes VII-IX
1000 or more	Annexes VII-X

Compliance check focuses on **eight key endpoints**: genotoxicity, repeated-dose toxicity, pre-natal developmental toxicity, reproduction toxicity, carcinogenicity, long-term aquatic toxicity, biodegradation and bioaccumulation.

ECHA may open a compliance check on any registration dossier at any time, it evaluates the information in a dossier on substance identity, substance properties and chemical safety assessment.

OUTCOMES:

1. No action towards the registrants
2. Decision to request additional information

Links: Compliance checks - ECHA (europa.eu) and Addressing substances of concern

3.1.1.1.2. Examination of testing proposals

To avoid unnecessary tests on animals, every registrant must submit a testing proposal whether they foresee to perform one of the tests listed in Annexes IX and X of REACH. Proposals to test on vertebrate animals are always published on ECHA's website and opened for third parties who have 45 days after publication to submit any useful information.

OUTCOMES:

1. Acceptance of testing proposals with or without modifications to the testing conditions.
2. Acceptance or rejection of testing proposals, nevertheless some additional tests are required
3. Rejection

3.1.2. Substance Evaluation

The aim of this assessment is to clarify whether the use of a substance may cause harm to human health or to the environment. ECHA together with Member States define the risk-based criteria according to which substances are prioritised for evaluation and select the substances to be included in the Community rolling action plan (CoRAP).

Each substance listed in the CoRAP is assigned to a Member State for evaluation. **In many cases, the registrants are not based in the territory of the evaluating Member State**. The evaluating Member State competent authority (eMSCA) has 12 months from the publication of the CoRAP to evaluate whether further information is needed to clarify the identified concern.

OUTCOMES:

1. eMSCA prepares a draft decision requesting further information
2. no further information needed

If, after review of the available and new data, the evaluating Member State considers that the use of the substance poses a risk, it may then proceed with follow-up actions to substance evaluation. The possible options are available here.

Links: Substance Evaluation - ECHA (europa.eu) and Interaction between the Evaluating member State and the Registrants and Addressing substances of concern and Public activities coordination tool and CoRAP List

3.2. Decision Making

Once the evaluation has been completed, the decision making takes over. The steps of the process are described below.

3.2.1. Drafting a decision

When further information is needed, ECHA or eMSCA prepare a draft decision to be addressed to the registrants who have 30 days to comment it. ECHA or eMSCA may amend the draft decision following the submitted comments.

3.2.2. Member States involvement

Since the decisions taken by the eMSCA or ECHA must be agreed unanimously by all Member States, the original or amended draft decision and the registrants' comments are notified to the Member State competent authorities and ECHA for review. They have 30 days from the notification to propose amendments to the draft decision.

OUTCOMES:

1. If no proposals are received, the decision is adopted by ECHA
2. If proposals of amendments are received, the draft decision needs to be referred by ECHA to the Member State Committee.

3.2.3. ECHA's decision

In no amendments are proposed, ECHA adopts the decision; otherwise the Member State Committee has 60 days from the date of referral to reach unanimous agreement on the draft decision.

N.B. If the Member State Committee cannot reach unanimous agreement, ECHA refers the case to the European Commission for decision making.

The decision is **legally binding and notified** to registrants and National Competent Authorities. It contains the deadline which registrants have to comply with in order to satisfy all the legal

requirements. The non-confidential version is published on ECHA's website.

Link: Flowchart and Evaluation process - ECHA (europa.eu)

3.2.4. After the adoption of the decision – appeal

The registrants must inform ECHA within 90 days of receipt about who will perform the requested tests. The **registrants can appeal against ECHA's decision** within three months of receiving the decision, following art. 91 and 77 REACH. The independent competent body to decide on the appeals is the Board of Appeals.

Link: Appeal procedure - ECHA (europa.eu)

3.3. Follow-up to ECHA's decision

After the adoption of a decision, ECHA controls that the registrants comply with it. The follow-up involves both the Dossier Evaluation and the Substance Evaluation decisions.

3.3.1. Dossier Evaluation

This assessment starts once the deadline for updating the registration dossier with the requested information has passed. ECHA evaluates whether the information requested in the decision has been provided.

OUTCOMES:

1. If the requirements are met, ECHA informs the registrants, the Member State competent authorities and the European Commission.
2. If the requirements are missing, ECHA informs the relevant Member States and national enforcement authorities. **If necessary**, the Member States and **enforcement authorities** will address non-compliance by applying **enforcement measures**, communicated afterwards to ECHA.

3.3.2. Substance Evaluation

The follow-up assessment by the eMSCA of the substance evaluation decision starts once all information is submitted or when the deadline set in ECHA's decision for updating the dossier has passed.
ECHA informs the eMSCA when the registrant provides an updated version of the registration dossier.

Within 12 months of the submission of the update:

1. If the available information is sufficient to address the concern, the eMSCA ends the substance evaluation by preparing a conclusion document.
2. If the concern is still not clarified the eMSCA prepares a new draft decision requesting additional information.

The eMSCA notifies ECHA if registrants provide irrelevant studies or manifestly unreasonable adaptations or do not transmit the requested information. ECHA then informs the enforcement authorities of the relevant Member States which, if necessary, will address non-compliance by applying enforcement measures.

The eMSCA is informed of the enforcement measures, then it can either consider the enforcement measures suitable to obtain the missing information or confirm the concerns about the substance. In this case further **regulatory risk management measures** can be proposed.

Links: Evaluation process - ECHA (europa.eu) and Regulatory management option analysis - ECHA (europa.eu)

3.3.3. Support material: "In brief: Follow-up to dossier evaluation decisions"

The document 'In brief: Follow-up to dossier evaluation decisions' was published on ECHA website in April 2021, including the translated versions into all EU languages. This paper replaces the old "Follow-Up Factsheet" which was withdrawn in 2018 after the revision of the Follow-Up process.

This file contains all essential information on the follow-up process and also it summarises how the Agency deals with specific and recurring scenarios.

Links: English version In brief: Follow-up to dossier evaluation decisions and Translated versions available here

4. Progress in evaluation

Article 54 of REACH requires ECHA to report on the progress made (over the previous year) in dossier and substance evaluation, by 28 February each year.

This reporting consists of numerical data on compliance checks, testing proposal examinations, follow-up assessments and substance evaluations carried out during the previous year.

Each year in spring, ECHA also publishes its Integrated Regulatory Strategy report which explains the impact of these outputs on chemical safety.

Links: Progress in evaluation - ECHA (europa.eu) and Progress in evaluation in 2018, 2019, 2020 and 2021.

5. Sharing obligations apply to all registrants of the same substance

Registrants of the same substance must make "*every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way*". The main aim of data sharing is to avoid unnecessary animal testing and to reduce costs for the registrants of the same substance. Consequently, the data sharing obligations apply after the registration has been submitted, and when new information has to be generated as a result of a decision following

(i) ECHA's assessment of testing proposals,

(ii) a compliance check or

(iii) a substance evaluation by an evaluating Member State competent authority. In addition and as confirmed in the Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data sharing, registrants are required to share only the costs of information that they are required to submit to satisfy their own registration requirements.

Link: How to act in dossier evaluation

6. Questions and Answers

Here a list of the most common questions about the evaluation procedure.

6.1. Compliance check

https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/REACH/Evaluation

- What is the impact of the Integrated Regulatory Strategy on ECHA's compliance checks? Answer
- How are dossiers selected for compliance check? Answer
- What happens if my dossier is selected for compliance check? Answer
- If I get a draft decision from ECHA, does that mean that ECHA has checked the entire dossier and found it non-compliant? Answer
- When can we provide the (new) data ECHA has requested? Answer
- What are the target endpoints that ECHA is checking in the dossiers? Answer
- How do I know, if any of my registrations is undergoing a compliance check? Answer
- I have received a draft decision. What should I do? Answer
- I have a dossier containing information requirements which I have opted out from and I have received a (draft) decision. What are my obligations to bring my dossier into compliance? Answer
- Where can I find support material on the evaluation processes under REACH? Answer
- I am a member of the joint submission. Why have I received a draft decision? Answer
- Until when can I update my dossier so that the update is considered in the dossier evaluation process? Answer
- We cannot provide comments by the deadline set in the notification letter accompanying the draft decision. Can we have more time? Answer
- What happens if I decide to cease manufacture or import after I have received a draft decision? Answer

6.2. Follow up to dossier evaluation decisions

- Can the deadline of the dossier evaluation decision be extended if we cannot provide the requested information on time? Answer
- Is it possible to have a teleconference/meeting with ECHA to discuss the request in the (draft) decision? Answer
- Is it possible to discuss (in writing) with ECHA the scientific arguments an adopted decision was based on? Answer
- Is it possible to adapt the standard information requirements requested in a decision by using read-across, weight-of-evidence or alternative tests instead of the study requested? Answer
- What if the information submitted is not sufficient? Answer
- What happens if I decide to cease manufacture, or import, or downgrade tonnage band after I have received an adopted decision? Answer
- I am a member and I have received an adopted decision. What should I do? Answer
- How do we inform ECHA of the name of the registrant(s) who will perform the test(s) listed in the adopted decision? Answer
- Who is responsible for generating the requested data and submitting the information to ECHA? Answer

- Who enforces ECHA's adopted decision if I cease manufacture, or import, or downgrade tonnage band after receiving it? Answer
- Who is responsible for submitting the requested information if there is a change of lead registrant after the decision has been received? Answer
- Can ECHA let me know whether my proposed adaptation is acceptable before the deadline in the decision expires? Answer
- What happens if we do not update the registration dossier by the deadline in the decision? Answer
- The global situation due to Covid-19 has caused delays and we cannot provide the information requested in the adopted ECHA decision by the set deadline. Can ECHA grant an extension? Answer

Link: list of all questions

7. Recommendations

The following recommendations are based on findings from the evaluation activities. They fulfil ECHA's obligation to publish recommendations from this process as set out in Article 54 of REACH and they represents a useful guide to comply with all the requirements assessed during the evaluation procedure.

7.1.1. General recommendations Useful to keep registrations up to date and take actions to proactively improve them. **Link:** here	**7.1.2. Registration** If your company manufactures or imports substances in quantities of more than one tonne per year **Link:** here	**7.1.3. Substance Identification** Companies need to clearly identify the substances they manufacture or import following the 'one substance, one registration' principle. **Link:** here
7.1.4. Standard information requirements To fulfil the obligation of registration, registrants must meet the minimum standard information requirements depending on the manufactured/imported tonnes. **Link:** here	**7.1.5. Adaptations** An adaptation to a standard information requirement means that instead of performing a test, you provide a justification. (Cfr. Annex IX and/or Column 2 Annexes VII-X REACH) **Link:** here	**7.1.6. Exposure assessment and risk characterisation** For substances registered at or above 10 tonnes per year, if they are classified as dangerous or as having persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) properties. **Link:** here
7.1.7. Classification and labelling Starting point for hazard communication and prerequisite for free movement of substances, mixtures and articles. **Link:** here	**7.1.8. Dossier evaluation decisions** How to deal with a draft and final ECHA's decision. **Link:** here	**7.1.9. Substance evaluation decision** Process and follow-up of a substance decision. **Link:** here