ECHA
EUROPEAN CHEMICALS AGENCY

How to act in dossier evaluation

January 2019

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This document aims to assist users in complying with their obligations under the REACH Regulation. However, users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

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1. The purpose and nature of practical guides

Practical guides aim to help duty holders – manufacturers, importers of substances, and only representatives – to fulfil their obligations in relation to the REACH Regulation. They provide practical tips and advice and explain the Agency's processes and scientific approaches. Practical guides are produced by ECHA, under its sole responsibility. They do not replace the formal Guidance, established under the formal guidance consultation process involving stakeholders, which provides the principles and interpretations needed for a thorough understanding of the requirements under REACH.

The purpose of this practical guide is to explain in simple terms your duties regarding the content of your registration dossier and how the dossier is processed under dossier evaluation. The guide aims to give you and the other recipients of a draft or adopted decision information on how to act after receiving the decision. It also highlights the opportunities and obligations that you as registrants have in making sure that your dossier is compliant with the REACH Regulation. The guide also reminds you of your other obligations, such as data sharing, to make sure the information is generated in a reasonable manner and demonstrates the safe use of chemicals.

Finally, the practical guide also provides advice and recommendations based on ECHA's experience with the dossier evaluation processes.

Throughout the guide, you will find important messages and tips in boxes similar to this one.

Throughout the guide, you will find links to more information in boxes similar to this one.

2. Introduction

The REACH Regulation[1] requires EU companies to submit registration dossiers for substances they manufacture in or import to the EU in quantities of one tonne or more per year. Once you have submitted your registration dossier and it has passed the completeness check, the European Chemicals Agency (ECHA) will assign the substance a registration number. However, the completeness check of the registration dossier does not include an examination of the quality or adequacy of the data submitted. The REACH Regulation states that such an assessment is carried out independently through a process called Evaluation (Title VI, Articles 40 to 54). The evaluation of dossiers contributes to making sure that registrants meet the REACH requirements with regard to ensuring a high level of protection of human health and the environment.

This practical guide focuses on dossier evaluation, namely compliance check and the examination of testing proposals:

(i) **Compliance check of dossiers** assesses whether the quality and adequacy of information submitted in the registration dossiers is compliant with the legal

[1] Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of chemicals (REACH).

requirements of REACH Annexes I and VI to X, including possible adaptations according to Annex XI.

(ii) **Examination of testing proposals** in dossiers aims to ensure that adequate and reliable data are generated, and that testing is tailored to real information needs, in particular to prevent unnecessary testing on vertebrate animals. ECHA has the duty to examine all testing proposals in the registration dossiers. Registrants have the obligation to submit such proposals before conducting any studies listed in Annexes IX and X.

The conclusions from dossier evaluation may be used in other REACH processes, such as substance evaluation, authorisation and restriction.

Member States can start these processes or other EU-wide risk management measures, or impose national actions. Member States are also responsible for enforcement activities as a possible result of ECHA's decisions.

ADDRESSEES SUBJECT TO DOSSIER EVALUATION

Compliance of the information in a joint submission is the joint responsibility of all registrants of the same substance – whether you are the lead registrant, a member registrant, or have opted out for one or more endpoints. You will therefore receive a (draft) decision when ECHA finds that the information submitted in your registration, or in the registration submitted by the lead registrant on your behalf, is non-compliant.

Practical guide – How to act in substance evaluation: https://echa.europa.eu/practical-guides

Evaluation: https://echa.europa.eu/regulations/reach/evaluation

Authorisation: https://echa.europa.eu/substances-of-very-high-concern-identification-explained

Restriction: https://echa.europa.eu/regulations/reach/restriction

3. Duties regarding registration dossier content

3.1. Information requirements

The standard information requirements for substances are specified in Annexes VI to X to REACH and are tonnage-dependent.

Regarding Annex VI, you must provide a clear and accurate identification of your substance and of any relevant forms thereof, appropriately documented and correctly reported.

Also as a member of a joint submission you need to ensure that your compositional information (including impurities) is within the boundaries of the substance identity that the registrants agreed to cover with the data submitted jointly(according to a given substance identity profile). The lead registrant's dossier contains both the boundaries of the substance identity, technically reported as boundary composition(s) on behalf of all the other registrants, and the compositional information of the lead registrant. In addition, each registrant needs to report their compositional information individually.

It is important that you provide sufficient information on the identity of the test material used

in the studies reported in the dossier, to confirm it is representative for the registered substance.

During assessment, ECHA may contact you to resolve any uncertainties regarding the information submitted in your dossier, and you may be given, where needed, a relatively short deadline for updating the dossier. If you do not respond, or if you fail to update your dossier within a reasonable timeframe, ECHA will normally issue a (draft) decision targeting substance identity.

Regarding the endpoints listed in Annexes VII to X, a dossier must contain robust study summaries or study summaries of the required studies. These study summaries must be detailed enough to allow an independent assessment of the study without having to refer back to the full study report.

For adaptations for a specific endpoint[2], you must always provide a scientifically-sound and transparent justification so that ECHA can independently assess whether the rules for adapting that endpoint are met. It is up to you to demonstrate that the data you submit instead of standard study results fulfil the standard information requirements for the purpose of risk assessment and/or classification and labelling.

If you are subject to information required under Annexes IX and X to REACH, you must first submit a testing proposal to ECHA. Testing proposals may be required also for substances registered in quantities up to 100 tonnes per year if: (i) the results of studies conducted according to Annex VII or VIII require further testing under Annex IX or X, as described in column 2 of the relevant endpoints; or (ii) the physico-chemical properties of the substance require different information requirements to be addressed. For example, after a positive result in an *in vitro* genotoxicity test, further testing may be needed, or long-term toxicity testing on fish must be considered if the substance is poorly soluble in water.

When you propose to conduct a test with a substance other than the registered substance, that is, you want to use a category approach or a read-across strategy, you will need to (i) include a comprehensive and scientifically-sound justification and (ii) provide supporting data to confirm why you apply the alternative approach for the endpoint.

SUBSTANCE IDENTIFICATION

Non-compliance or inconsistencies regarding substance identity within the joint submission need to be solved before the other parts of the dossier are assessed.

ECHA normally seeks to solve substance identity issues first through informal communication with the registrants. **Engage** in this informal cooperation and update your dossier within the timeframe set by ECHA.

SUBSTANCES USED AS INTERMEDIATES

Dossier evaluation processes do not apply to **on-site isolated intermediates** used under strictly controlled conditions. Therefore, registrants of such intermediates will not be addressees of dossier evaluation decisions.

By contrast, registrants of **transported isolated intermediates** manufactured in quantities above 1000 tonnes per year, for which Annex VII requirements apply,

[2] Column 2 in Annexes VII to X to REACH set the specific adaptation rules for each endpoint, and Annex XI sets the general rules for adaptation of the standard testing regime set out in Annexes VII to X.

may be recipients of dossier evaluation decisions.

Registrants of on-site isolated intermediates and transported isolated intermediates can benefit from reduced information requirements if they demonstrate that their substance is used under strictly controlled conditions. To that aim, you have to fulfil the prescribed criteria of strictly controlled conditions[3] for the manufacture and/or identified uses of the substance. If any of the conditions are not fulfilled, the substance must comply with the registration requirements for the relevant tonnage. A Member State where the site manufacturing or importing the substance is located may also take certain actions to verify your information.

Information to provide in your own registration dossier:

https://echa.europa.eu/support/registration/what-information-you-need

https://echa.europa.eu/regulations/reach/registration/information-requirements.

Information on substance identification and the substance identity profile (SIP):

https://echa.europa.eu/support/substance-identification/how-to-characterise-and-identify-your-substance

Guidance for identification and naming of substances under REACH and CLP: https://echa.europa.eu/guidance-documents/guidance-on-reach

Practical guidance on how to prepare and develop a substance identity profile (SIP): https://echa.europa.eu/documents/10162/13655/practical_guide_how_to_develop_prepare_sip_en.pdf

Information on intermediates:

Guidance on intermediates: https://echa.europa.eu/guidance-documents/guidance-on-reach

Practical guide – How to assess whether a substance is used as an intermediate under strictly controlled conditions and how to report the information for the intermediate registration in IUCLID: https://echa.europa.eu/practical-guides

3.2. Vertebrate animal studies

The REACH Regulation foresees that testing on vertebrate animals for the purposes of the regulation "*shall be undertaken only as a last resort*"[4]. You have the obligation to avoid duplication of animal testing in accordance with the data and cost sharing provisions. This means that when a study involving vertebrate animal testing is available in a registration, it must be shared between all registrants. In addition, you must take all available existing information into account, prior to proposing and conducting any vertebrate animal testing.

Your assessment of the existing information should include considerations such as whether the information:

- is of sufficient scientific quality;
- fulfils the adaptation criteria specified in Annex XI to REACH;
- fulfils the specific adaptations laid down in Column 2 of Annexes VII to X to REACH.

[3] Set out in Articles 17(3) and 18(4) of REACH.
[4] According to Article 25(1) of REACH.

However, keep in mind that not testing on vertebrate animals must not compromise the safe use of your substance.

Once you have ascertained that you need to perform a new test involving vertebrate animals, you need to consider which Annex requirement you need to fulfil:

- you can start conducting a test listed under Annex VII or VIII to REACH at any time;
- you must first submit a testing proposal for tests listed under Annexes IX and X, and include your explanation as to why the study is necessary and which alternative methods have been considered. You can only start testing once you have received the adopted decision from ECHA, which also confirms the test design you must follow.

ECHA's reports on alternatives to animal testing for REACH: http://echa.europa.eu/about-us/the-way-we-work/plans-and-reports

Practical guides at https://echa.europa.eu/practical-guides:

How to use alternatives to animal testing to fulfil your information requirements for REACH registration

Practical guide for SME managers and REACH coordinators - How to fulfil your information requirements at tonnages 1-10 and 10-100 tonnes per year

3.3. Other duties and recommendations

3.3.1. Follow GLP and the most recent test methods

Eco-toxicological and toxicological tests and analyses performed after 1 June 2008 need to be carried out in compliance with the principles of good laboratory practice (GLP). For physicochemical testing, GLP is desirable but not mandatory.

Tests to generate new information on intrinsic properties of substances must be conducted in accordance with the official EU test methods[5], or in accordance with other international test methods recognised as being equivalent, such as OECD[6] test methods. Due to scientific and regulatory developments, test guidelines are regularly updated and new ones introduced.

Finally, in Annexes VII to X to REACH, when no EU test method exists, the reference is made to OECD test guidelines (TGs) instead (e.g. OECD TG 421 and 422 for reproductive toxicity screening studies).

It is your responsibility to conduct testing according to the most recently updated guideline, e.g. an OECD test guideline (TG) when it is updated before the EU test method has been adopted.

Existing data (i.e. studies conducted before 2008) from experiments not conducted according to GLP or standard test methods may be accepted by ECHA if the criteria set out in Annex XI, Section 1.1 are met. Take special care in documenting that the test material is representative for your registered substance. You also need to provide a valid justification that the existing data are adequate for the purpose of classification and labelling and/or risk assessment.

[5] Regulation (EC) No 440/2008 laying down test methods to be used under REACH.
[6] Organisation for Economic Co-operation and Development.

3.3.2. Perform a chemical safety assessment

Registrants must perform a chemical safety assessment and prepare a chemical safety report (CSR) for all substances registered in quantities of 10 tonnes or more per year. The format and the requirements for the CSR are specified in Annex I to REACH. The CSR must also include an exposure assessment if the substance is classified or is considered to be a PBT (persistent, bioaccumulative and toxic) or vPvB (very persistent and very bioaccumulative) substance.

For each endpoint, you need to provide a risk characterisation ratio (RCR) – the ratio of potential exposure to predicted or derived no-effect level – and demonstrate that measures are taken to maintain its value below 1.

Chemical safety assessment: https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

Chemical safety report: https://echa.europa.eu/regulations/reach/registration/information-requirements/chemical-safety-report

Chesar website: http://chesar.echa.europa.eu/

Practical guide for SME managers and REACH coordinators - How to fulfil your information requirements at tonnages 1-10 and 10-100 tonnes per year: https://echa.europa.eu/practical-guides

3.3.3. Keep your dossier up to date

Your registration has to reflect the most up-to-date knowledge on how a substance can be used safely at production sites and through the supply chain all the way down to the end user. This is not only good practice, but also a legal requirement. This concerns all registrants, even the ones that have submitted opt-outs.

Although the lead registrant has the duty to submit (and to update, if agreed within the joint submission) the joint part of the registration dossier, all registrants of the same substance share the responsibility for the data submitted jointly in the dossier. The registrants of the joint submission must ensure that the data on their substance are appropriate, fulfil the information requirements, inform adequately on the safe use of their substance, reflect the actual human and environmental exposure, and that the substance is appropriately classified.

To efficiently update your dossier, you need to have a mechanism in place to coordinate the work within your company and with all registrants of the same substance.

Finally, the registrants of the same substance are collectively responsible for responding to requests for further information they may receive in an ECHA decision. To this end, you should maintain a cooperation platform with all members of your joint submission.

Be sure to review and update your registration dossiers, without undue delay, paying special attention to the following:

- changes in production or import volumes (increase or decrease);
- new or obsolete uses (also from your customers);
- new or changed measures to ensure the safe use of your substance;
- registration type, i.e. transported or on-site isolated intermediate;
- new data on the intrinsic properties of your substance;

- your justification for relying on waivers for the required information, or on adaptations such as category or read-across approaches;
- new information about the composition of your substance;
- contact details both in REACH-IT and in your joint submission, so that you can always be reached regarding your registration.

Note that tonnage and uses are information relevant for priority setting and compliance check.

Dossier evaluation status: https://echa.europa.eu/information-on-chemicals/dossier-evaluation-status

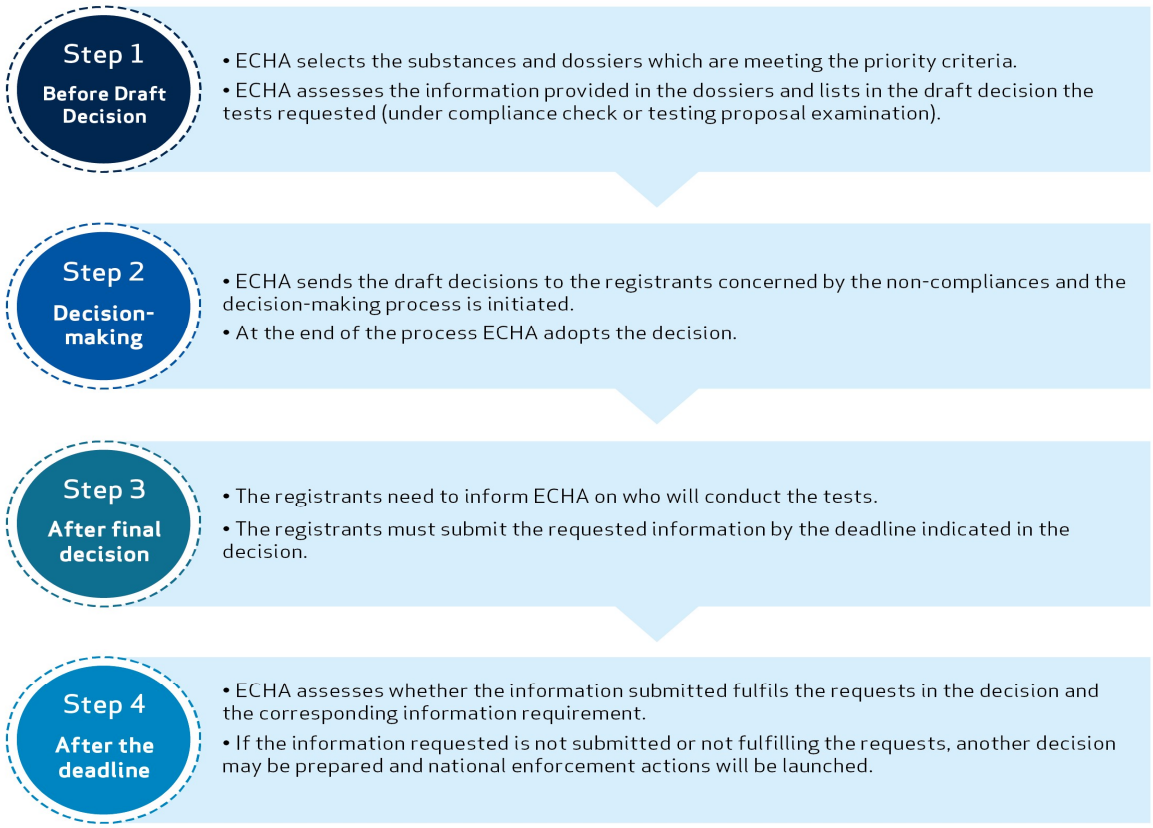
Update your dossier: https://echa.europa.eu/-/more-information-on-dossier-evaluation-processes-available

4. Dossier evaluation process

4.1. Dossier evaluation in a nutshell

ECHA is responsible for the dossier evaluation processes. ECHA will consider the information submitted in all individual and joint registration dossiers from all registrants of the same substance, including where registrants have used the provisions of Article 11(3) ('opt-out') for one endpoint or more. The dossier evaluation processes comprise several steps (Figure 1).

Figure 1: Main steps of the dossier evaluation process



Note: prioritisation (Step 1) is only for CCH.

Under the compliance check process, ECHA has 12 months from the start of its evaluation to issue a decision requesting further information to fill the data gaps. The outcome of ECHA's assessment may be either a draft decision or a conclusion.

Under the testing proposal process, although ECHA shall examine all testing proposals, different timelines apply: ECHA has 180 days from the start of its evaluation to issue a decision on whether testing on a non phase-in substance can be conducted. Regarding the phase-in substances from the last registration deadline in 2018, the deadline for ECHA to issue draft decisions is 1 June 2022.

To reduce the chance of receiving a dossier evaluation decision from ECHA:

- Check ECHA's recommendations to registrants and the information requirements for your tonnage band: https://echa.europa.eu/recommendations-to-registrants
- Review and update your dossier regularly: https://echa.europa.eu/-/keep-your-registration-up-to-date
- Check whether ECHA is evaluating your substance under compliance check, or which stage your testing proposal is at in the evaluation process: https://echa.europa.eu/information-on-chemicals/dossier-evaluation-status

4.2. How ECHA evaluates dossiers

4.2.1. Check if ECHA has started to assess your substance

ECHA does not inform you of the start of a compliance check on your dossier. You can nevertheless find out whether ECHA has started to evaluate dossiers for a particular substance.

1. Consult ECHA's Dossier Evaluation status web page.

By using the filtering options, you can find out, whether ECHA has started its assessment of a given dossier:

- these are marked as 'Under assessment' in the 'Status' column,
- the start date is displayed in the 'Latest update' column.

Once the dossier moves forward to another stage of the evaluation process, the date in the 'Latest update' column changes with each change in the data, or if additional data was included in the table.

2. Consult the Infocard[7] page for your substance.

If a 'Dossier evaluation status' entry is published under the 'REACH' activity on the Infocard page, a dossier evaluation process has been initiated.
By clicking on this entry, you can see the stage of the evaluation process for your substance.

ECHA takes into account any dossier update submitted before a draft decision is issued. Therefore you can still consider updating your dossier, especially with regard to tonnage and uses, before that time (see below section 5.4 for updates after the draft decision is issued).

[7] Infocards are automatically generated based on industry data.

Check if ECHA assesses your substance: https://echa.europa.eu/-/more-information-on-dossier-evaluation-processes-available

What is an Infocard?: https://www.echa.europa.eu/documents/10162/22177693/what_is_an_infocard_en.pdf/4960b3a4-a84f-461d-926c-b4a683b2f98f

Dossier Evaluation status: https://echa.europa.eu/information-on-chemicals/dossier-evaluation-status

4.2.2. Compliance check

ECHA can decide which dossiers to check for compliance and whether the evaluation should cover all submitted information or only certain parts of the dossier. ECHA can start a compliance check at any time, and reserves the right to open further compliance checks on any dossier at any time and without prior notice to the registrants.

ECHA prioritises dossiers according to both the provisions in REACH[8] and the Agency's regulatory strategy on compliance check (see in information box below), using a combination of selection criteria such as suspected data gaps in the higher-tier human health or environment endpoints, widespread uses and high tonnages.

Compliance checks may be performed on individual substances as well as on groups of substances (including categories submitted by registrants).

ECHA opens a compliance check to examine whether the standard information requirements are fulfilled and prepares a draft decision requesting the missing information, if necessary.

Screening: https://echa.europa.eu/screening

Strategy on compliance check: https://echa.europa.eu/regulations/reach/evaluation/compliance-checks

4.2.3. Testing proposal examination

ECHA has to examine all testing proposals submitted and needs to do so within the time limits specified under REACH. This means that the evaluation process for dossiers containing a testing proposal will start as soon as practically possible after the registration number is assigned or an updated dossier confirmed.

Public call for scientific information

For any testing proposals involving testing on vertebrate animals, ECHA will start the examination of your testing proposal after the public call for scientific information (third party consultation) is completed (see Figure 2). This consultation aims at identifying any relevant study on the substance that may have already been conducted but is not available to the registrants, or any other relevant scientific information.

[8] Article 41(5) of REACH.

Figure 2: Steps during the third party consultation

ECHA publishes on its website the name of the substance[9] and the hazard endpoint for which vertebrate animal testing is proposed.

Subsequently, third parties are invited to submit, using a webform and within 45 days, any scientifically valid information and studies that address the hazard endpoints, as well as a scientific justification supporting how their data can address the proposed endpoint for the registered substance. ECHA recommends that any information third parties provide contains as much detail as possible, including individual study reports. ECHA may make them available to the registrant and the public. If data submitters provide confidential information, they need to justify why the information is confidential. Such confidential information will only be used by ECHA, including the Member State competent authorities and the Member State Committee. However, following the prior consent of the data submitter, the registrant may contact the data submitter to find out if the missing data can be obtained for updating the dossier.

At the end of the consultation period, ECHA examines the testing proposal, and issues its draft decision taking into account the information from both the registration dossier and information from any third party or otherwise available to ECHA (e.g. information received from other registrants of the same substance).

If you conducted tests after 2008 for endpoints listed in Annexes IX and X involving vertebrate animals and without submitting any testing proposal, ECHA expects that you justify appropriately in the respective endpoint study records why the test has been conducted without a prior testing proposal. ECHA will inform national authorities of any situations where it finds that a testing proposal has been omitted, based on inappropriate or insufficiently justified scientific arguments

Third parties can submit information to ECHA on testing proposals involving animal tests within 45 days of the start of the consultation, using a webform on ECHA's website.

You are not allowed to undertake new studies listed under Annex IX or Annex X to REACH before ECHA has taken a decision on the proposed tests. This is because testing on vertebrate animals is the last resort for obtaining missing information.

ECHA examines all testing proposals and always issues a draft decision on admissible testing proposals.

[9] A substance name can be a partial name instead of the full chemical structure to preserve commercially sensitive information. If you do not want the full chemical name of your substance to be published, you should provide ECHA with a name that is illustrative and can be considered useful in the third party consultation. The closer the name is to the exact name of the registered substance, the greater are the prospects of receiving meaningful information from third parties.

Current public consultations on testing proposals:
https://echa.europa.eu/information-on-chemicals/testing-proposals/current

Information from third party consultations provided in the non-confidential ECHA decisions published on the Agency's Dossier evaluation status web page:

https://echa.europa.eu/information-on-chemicals/dossier-evaluation-status

4.3. What is evaluated

4.3.1. Check of identification of your substance

Prior to hazard assessment, ECHA checks that the substance has been identified appropriately.

If your substance is not identified correctly, ECHA may send you a decision requesting further information. In addition, if a substance is not considered to be within the scope of the registration, it is not legally on the market and has to be registered separately.

This may lead to penalties from national enforcement authorities and may trigger the need to submit additional registrations for any substances that are not considered to be covered by the registration.

4.3.2. Compliance check

Under compliance check, ECHA verifies whether the information submitted fulfils the requirements in Annexes I and VII to X or the general rules for adaptation as described in Annex XI. You need to submit sufficient information in your dossier to allow an independent assessment by ECHA for each endpoint. ECHA can examine the full dossier, or target the examination to certain parts of the dossier or certain endpoints.

ECHA checks that the classification and labelling of the substance reported in the registration dossier is consistent with the information provided in the dossier and in line with the legal classification and labelling rules defined in the CLP Regulation[10]. ECHA may also check whether the information provided in the chemical safety report is consistent with the information in the registration dossier and in compliance with Annex I to REACH. In particular, the chemical safety report must cover all identified uses of the substance and, if an exposure assessment and risk characterisation is required, the safe use must be demonstrated.

Strategy on compliance check:
https://echa.europa.eu/regulations/reach/evaluation/compliance-checks

ECHA's Integrated Regulatory Strategy: https://echa.europa.eu/echa-irs

4.3.3. Testing proposal examination

ECHA will always evaluate the justification for conducting the proposed test, as well as the test design you have submitted.

[10] Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures.

If ECHA finds your dossier subject to testing proposal examination to be non-compliant, you may be sent a compliance check decision. The assessment of the testing proposal may need to be suspended until you submit the information required to fulfil your information requirements.

ECHA may also perform further compliance checks on the dossier if it identifies other non-compliances to information requirements in the dossier.

4.3.4. Justification for adaptations

ECHA checks that adaptations to the standard testing regime – whether used for a testing proposal or for fulfilling an information requirement – are sufficiently justified and comply with either the specific rules for adaptation provided in column 2 of the relevant endpoint or the general rules for adaptation of Annex XI. This means that any adaptation must be supported by a justification that includes the scientific reasoning and any pertinent technical details as to why the REACH information requirement can be met by using an alternative information.

Poorly reported, scientifically incorrect or inadequate justifications will lead to an ECHA (draft) decision requesting the missing information.

For example, if read-across or the category approach are used, ECHA checks whether the dossier provides an adequate justification for why the results gained from this approach:

- have adequate and reliable coverage of the key parameters addressed in the corresponding test method;
- cover an exposure duration comparable to or longer than the corresponding test method; and
- are adequate for the purpose of classification and labelling and risk assessment.

In particular, these explanations are expected to address how the information in the dossier meets the rules for permitted approaches provided in Annex XI, Section 1.5 (grouping and read-across). ECHA also checks the substance identities (in terms of identification and quantification of the constituents) for all relevant members of the read-across or category, including their purity/impurity profiles.

Practical guide – How to use alternatives to animal testing to fulfil your information requirements for REACH registration: https://echa.europa.eu/practical-guides

Grouping of substances and read-across: https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

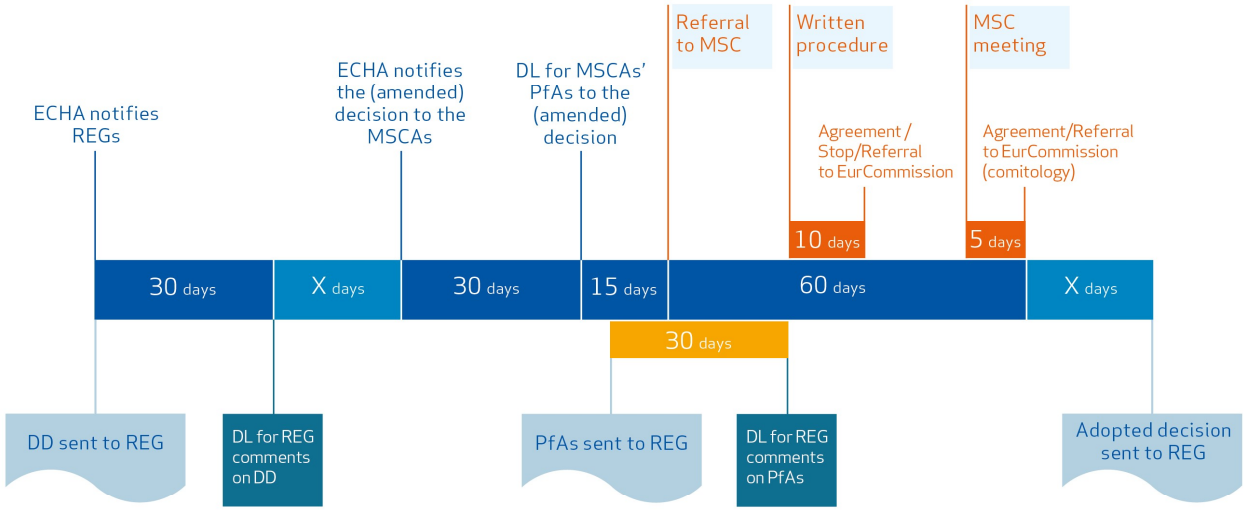
Recommendations for adaptations: https://echa.europa.eu/adaptations-recommendations

5. WHAT HAPPENS AFTER ECHA ISSUES A DRAFT DECISION

5.1. Decision-making in a nutshell

Once ECHA sends its draft decision to all recipients, the decision-making process starts and the subsequent steps fall within strict timeline, as described below (Figure 3).

Figure 3: Steps and timeline in decision-making - from draft to adopted decision



NB: A decision can be adopted directly if no PfAs are received.

(a) ECHA sends the draft decision (DD) to all relevant registrants (REGs).

(b) You have 30 days to provide your (consolidated set of) comments.

(c) ECHA evaluates your comments and amends (or not) the draft decision. ECHA does not have a defined time period over which to review your comments.

(d) Subsequently, ECHA notifies the Member State competent authorities (MSCAs) of the (amended) decision, which generally occurs within 3-9 months from receipt of your comments.

(e) MSCAs are invited to propose amendments within 30 days.

(f) If no proposal to amend the draft decision is received, ECHA formally adopts the decision and you are informed accordingly. If MSCAs submit proposals for amendment (PfAs), the draft decision is referred to the Member State Committee (MSC) in order to seek unanimous agreement.

(g) You are notified of the PfAs received. You also receive, for information, the decision as notified to the MSCAs (i.e. including response to your comments, if any). You then have 30 days to provide any (consolidated set of) comments to the PfAs.

(h) The MSC will seek unanimous agreement, either in a plenary meeting or in written procedure, considering the various inputs: the (amended) notified draft decision, the PfAs as well as your (consolidated) comments on the PfAs received within the commenting period.

Scenario 1: A decision can be agreed by the MSC via written procedure, during which MSC members indicate their agreement or disagreement to the (amended) notified draft decision, or their wish to stop the written procedure.

- If there is a unanimous agreement, no discussion needs to take place thereafter and the decision is adopted by ECHA.
- If one or more MSC members request the written procedure to be stopped, the (amended) notified draft decision will be discussed at the MSC meeting, and will only be addressed in closed session.

Scenario 2: If your substance is subject to a plenary meeting discussion (without preliminary written procedure), your representative who submitted comments on the PfAs on behalf of all addressees (see sections 5.3.1 and 5.5.2) is informed about the meeting and invited to participate in this specific session (open session) with up to two

participants. Reminder: According to the rules of procedure for the MSC, the representative of the registrants may be invited as an observer[11] when the Committee discusses their decision.

(i) If the MSC reaches unanimous agreement on the draft decision, either in written procedure or after discussion at the meeting (closed session), ECHA proceeds to formally adopt the decision.

(j) If the MSC does not reach a unanimous agreement, either in written procedure or at the MSC meeting, ECHA refers the draft decision to the European Commission. The further decision making takes place under a committee procedure ('comitology').

Finally, the decision becomes effective **only** after completion of the decision-making procedure.

5.2. Structure of the (draft) decision

If the outcome of ECHA's assessment from all relevant dossiers of a particular substance is that the dossier submitted does not comply with one or more information requirements, then ECHA will issue one draft decision to all registrants subject these information requirements. Each recipient of the decision is bound by the requests for information corresponding to the REACH Annexes applicable to their own registered tonnage at the time of evaluation.

To help you identify your legal obligations, the requests are structured in different appendices corresponding to the respective REACH Annexes containing the requirements concerned.

You have to comply with the requirements in:

- Annex VII to REACH if you registered a substance at 1-10 tonnes per year, or as a transported isolated intermediate in quantity above 1000 tonnes per year;
- Annexes VII and VIII to REACH if you registered a substance at 10-100 tonnes per year;
- Annexes VII, VIII and IX to REACH if you registered a substance at 100-1000 tonnes per year;
- Annexes VII to X to REACH if you registered a substance at above 1000 tonnes per year.

In the (draft) decision, ECHA lists the information requests and sets the deadline by which the requested data must be submitted.

All requests are included in one decision and the deadline is set to allow all tests to be performed. In some cases, ECHA chooses to set different timelines for different requests to allow that the tests may be conducted in sequence, one after the other (so that the first study provides information necessary for the second) to avoid unnecessary animal testing. This approach aims to ensure that the decision-making process is efficient.

If you want to follow a substance-specific testing strategy, it is your own responsibility and ECHA will not provide any opinion until the deadline in the adopted decision has expired. Once a decision is adopted, ECHA will not provide any guidance on possible strategies for testing.

[11] The attendees must conform to the code of conduct for case owners of evaluation draft decision as observers at meetings of the MSC: https://echa.europa.eu/about-us/who-we-are/member-state-committee

In the various appendices justifying its requests for information, ECHA addresses in a preliminary appendix the aspects of its assessment that are relevant for several incompliances (e.g. read-across adaptation, strategy for aquatic testing or PBT assessment).

All the registrants addressed by the decision are required to jointly ensure that requested information are generated by only one of them. In addition, according to Article 53 of REACH, the registrants are subject to data sharing rules.

5.2.1. Addressees of dossier evaluation decisions

You will receive a (draft) decision when ECHA finds that the information submitted in your registration (or in the registration submitted by the lead registrant on your behalf) is non-compliant. You will be required to comply with the requests listed in the decision according to the quantity you have manufactured or imported.

ECHA advises that you inform the other members of your joint submission that are not affected by the identified non-compliance but may be interested by the content of the decision as they may be able to contribute constructively to the comments on the draft decision. In any case, ECHA will inform these interested parties once the adopted decision is published on its website (see section 6.1).

5.2.2. Members of the joint submission as recipients of a draft decision

While substance information exchange forums (SIEFs) ceased to exist as of 1 June 2018, the registrants of the same substance are nonetheless bound by the obligation to submit the information on their substance jointly.

By setting out clearly how the information requirements apply at each tonnage band, ECHA gives the registrants better legal certainty as to what their individual legal obligations are, which helps ensure the same level-playing field among all the registrants within the joint submission. All recipients are required to comply with their respective information requirements, and will need to share existing/new data while respecting their legal obligation to avoid unnecessary (vertebrate animal) testing.

5.2.3. If you have opted out from the jointly submitted information

If you have opted out for one or more endpoints from the joint registration dossier on the same substance, you will receive your own (draft) decision addressing the specific endpoint.

The request made by ECHA may be:

(i) for a new study to be performed, which can be the same as one required from the other members of the joint submission In that case, only one test will have to be performed and shared among all registrants concerned for the same endpoint; or

(ii) for you to share the information for the specific endpoint, which was submitted in the jointly submitted registration dossier, with the other members of the joint submission. The data sharing rights and obligations set out in Title III must apply in this case

In any case, ECHA will require you to collaborate and coordinate with the other registrants to address the information requested in the decision.

5.3. Commenting the draft decision

5.3.1. Submitting comments during the commenting period

Once ECHA has sent the draft decision to all recipients through REACH-IT[12], you are invited to submit comments within 30 days of receipt on ECHA's findings in the draft decision. The deadline for comments and the address of the webform to be used are specified in the notification letter accompanying the draft decision.

All registrants concerned have the opportunity to comment on a draft decision. However, to ensure consistent comments and their successful consideration during decision-making, ECHA recommends that all recipients collectively identify a representative who can then coordinate and collect the comments, so as to submit one set of consolidated comments to ECHA. The webform for submitting comments provides a specific checkbox that the chosen representative can select to confirm that they submitted the comments on behalf of all recipients of the draft decision.

REACH foresees tight decision-making timelines. Hence, the deadline for delivering the comments on the draft decision cannot be extended, unless there are technical reasons (e.g. malfunction of the submission tools) or the commenting period falls during closure periods of the Agency. For example, during the Christmas break, ECHA grants a 45-day deadline to take into account the end-of-year closure.

Registrants may submit comments on ECHA's findings in the draft decision, **preferably jointly**, within the prescribed timeframe and using the form communicated by ECHA.

5.3.2. Scope of the comments

Comments on the draft decision should be concise and related to the content of the decision, flagging whether ECHA made an error in its assessment, e.g. raise points of clarification or inaccuracies in the draft decision.

While comments on the requests should be valid for all recipients of the draft decision, ECHA acknowledges that some comments may be registrant-specific and will have to be submitted separately (e.g. when you raise a confidentiality issue or a specific use consideration).

Prior to submitting comments, you are advised to consult ECHA's recommendations to registrants from evaluation on the Agency's website.

Recommendations to registrants: https://echa.europa.eu/recommendations-to-registrants

Extension of the deadline identified in the draft decision

ECHA may extend the deadline indicated in the draft decision only in exceptional circumstances, such as if in your comments to the draft decision you provide appropriate justification from a contracted laboratory that the specified study cannot be performed within the timelines set by ECHA.

[12] A communication (e.g. draft decision) sent through REACH-IT is regarded as having been received by the registrants either when it is opened or, at maximum, by seven days after notification, even if the communication was not opened.

Note that if you wish to perform preliminary studies (e.g. palatability studies, dose range-finding studies), you do not need to wait to receive the adopted decision and can already initiate them.

> Registrants have the possibility to comment on ECHA's draft decisions within 30 days of receipt of the draft decision.
>
> Registrants should coordinate their response to the draft decision and avoid diverging comments.

Identification of the legal entity who shall perform the test(s)

The adopted decision will contain a formal request to identify who shall perform the requested test(s) (see section 6.3) on behalf of the other addressees of the decision. You may already agree upon receipt of the draft decision on the legal entity that will perform the requested test(s) on behalf of the other addressees of the decision for each study requested in a decision. You can request your representative to provide that information as part of the consolidated set of comments.

5.4. Updates after receiving the draft decision

ECHA will not take into account an update of your registration dossier that is received after the draft decision has been sent. Consequently, ECHA expects that the dossiers under assessment, to the best knowledge of the registrants, contain the most up-to-date information[13].

Nonetheless, you remain legally bound to update your dossier without undue delay with any new information (Article 22 of REACH). If you make an update during the decision-making process, the information will be reviewed and considered only after the deadline for submitting the requested information has passed.

If you decrease the tonnage upon receipt of a draft decision, you still need to comply with the requests as per your tonnage indicated in the decision. This is because ECHA uses the information provided for registration purposes, as the basis for further processing (including dossier evaluation). It is the joint responsibility of the members within the joint submission to keep ECHA informed of their latest status.

Under exceptional circumstances where duplication of (animal) testing can be avoided, ECHA will consider information submitted in an update, for example if an experimental study with the registered substance becomes available and would remove the request in the decision.

> After the draft decision has been notified to the registrants for comments, no dossier updates will be taken into account for the decision-making and the adoption of the decision.
>
> The recipients listed in the draft decision will have to comply with the requests indicated by ECHA based on the registration submission available to ECHA at the time of evaluation and preparation of the draft decision.

Cease of manufacture or import upon receipt of the draft decision

If you decide to cease the manufacture or import of your substance **upon receipt of the**

[13] https://echa.europa.eu/-/member-registrants-will-start-receiving-dossier-evaluation-decisions-in-2019

draft decision, you should inform ECHA of your intention using REACH-IT. When you confirm that you have ceased/are ceasing manufacture or import, ECHA proceeds by invalidating your registration number in line with Article 50(3). You are then no longer allowed to manufacture or import the substance into the EU/EEA market.

If you start to manufacture or import the substance again, you will have to register the substance again and you may have to share the costs accrued for the maintenance and update of the registration dossier due to an evaluation process or for other reasons.

If you inform ECHA of cease of manufacture or import upon receipt of a draft decision, your registration will be invalidated, and you will no longer be allowed to manufacture or import that substance in the EU/EEA.

Subsequently you will not be a recipient of the adopted decision and will not be subject to the obligation to submit further information.

You are advised to inform the other members of the joint submission, as this may impact their organisation and discussions.

Note: If you cease manufacture or import upon receipt of the adopted decision, being an addressee of the adopted decision, you will still have to comply with the information requested.

5.5. Processing of the draft decision

As described above (section 5.1), after ECHA has reviewed your consolidated comments, the draft decision together with your comments are submitted to the Member State competent authorities (MSCAs) for consultation. The MSCAs have 30 days to propose amendments to the draft decision.

5.5.1. ECHA does not receive proposals for amending the draft decision

If MSCAs do not submit any proposals for amendment, ECHA proceeds and adopts the decision under Article 51(3) of REACH.

5.5.2. ECHA receives proposals for amending the draft decision

If MSCAs submit proposals for amendment, ECHA assesses whether the draft decision should be amended, and refers the draft decision to the Member State Committee (MSC). At the same time, ECHA sends you the proposals for amendment and provides you with 30 days to comment. The scope of your comments should only cover the proposals for amendment made by the MSCAs, not the other elements of the draft decision.

ECHA recommends that the representative of the registrants coordinates and submits, through a webform, a consolidated set of comments on the proposals for amendment within the 30-day commenting period.

5.5.3. Review of your comments by the Member State Committee

The MSC will consider the (amended) draft decision as well as the registrants' comments on the proposals for amendments received using the webform within the commenting period. At this stage, the registrants' comments on the draft decision itself are no longer considered.

Comments on the draft decision submitted when requested to comment on the PfAs will not be considered by the MSC in its decision-making.

5.5.4. Attending the Member State Committee meeting

Meeting schedule

The MSC meets on average five times a year. The annual schedule is published in advance so that you can prepare and better anticipate the time of the latest commenting round.

Meetings of the Member State Committee: https://echa.europa.eu/about-us/who-we-are/member-state-committee/meetings-of-the-member-state-committee

Meeting structure

The discussion on draft decisions at the MSC meeting occurs in two sessions:

- an open session, where the proposals for amendment (PfAs) and registrants' comments on them are presented and where the scientific discussion takes place; and
- a closed session, where agreement-seeking takes place.

Besides Committee members, invited experts, nominated representatives of stakeholder organisations and your representative(s) may attend the open session during which the draft decision is initially discussed. Your representative, like any other meeting participant, is bound by a confidentiality declaration.

Note that participating in the meeting is not a legal requirement. Your representative's attendance is meant to provide the MSC with further clarifications on scientific and technical issues. Such attendance has to be in line with the MSC's working procedures and must conform to ECHA's "code of conduct for case owners"[14]. Following a presentation by ECHA on any unresolved PfAs (and the comments you submitted on these), your representative will be given a few minutes to highlight orally the main points of your comments on the PfAs before the MSC starts its discussion in the open session.

If your draft decision is processed for agreement-seeking through written procedure and the process is stopped, the decision is then discussed only in a closed session of the MSC meeting. Your representative is not invited to attend this closed session.

If you attended the MSC meeting in its open session, you will normally receive an email from the MSC Secretariat with the outcome of the MSC discussion.

As a result of the written procedure or the MSC meeting agreement, ECHA proceeds and adopts the decision under Article 51(6) of REACH. If the MSC could not reach a unanimous agreement, the European Commission will send you the decision it adopted (see Figure 3).

6. After ECHA issues the adopted decision

After ECHA has adopted the decision, all recipients will receive it through REACH-IT. The decision includes the date by which the dossier has to be updated with the requested information. The decision always also includes the instructions for legal redress.

[14] https://echa.europa.eu/about-us/who-we-are/member-state-committee

The notification starts both the three-month period to appeal the decision and the 90-day period to inform ECHA of the legal entity, which will perform the requested test(s) on behalf of the other registrants.

If you cease manufacture or import upon receipt of the adopted decision, being an addressee of the adopted decision, you still have to fulfil all requests in the decision.

6.1. Commenting the non-confidential version of the decision

For transparency purposes, ECHA publishes a non-confidential version of all dossier evaluation decisions. By doing this, ECHA offers registrants and third parties an opportunity to follow and increase their insight into the outcome of the evaluation processes of compliance check and testing proposal examination.

Before publication, ECHA sends to all the recipients of the decision a draft of the non-confidential version of the decision, where any confidential business information and company-specific information has been redacted. Your representative is invited to coordinate the consolidated input and comment within 21 calendar days, using a webform link, on whether any further information in the decision should be redacted. If you request additional redaction, you need to justify such requests with documentary evidence.

You are invited to respond also when you agree on the non-confidential version of the decision you received. Nevertheless, in the case of no response, ECHA considers that you have no objection to the publication of the non-confidential decision.

ECHA will also send the non-confidential version of the adopted decision, for information, to the other members of the joint submission that have no legal obligation to comply with the information requested (see section 4.3.4).

Dossier evaluation status (and decisions): https://echa.europa.eu/information-on-chemicals/dossier-evaluation-status

6.2. Right to appeal

The decision always includes the instructions for legal redress.

Any addressee of a decision has the right to appeal against the decision to ECHA's Board of Appeal[15]. Also the non-addressees that are directly and individually concerned by the decision are entitled to lodge an appeal. The appeal, together with a statement of grounds, must be lodged in writing to ECHA within three months of the notification of the decision. An appeal is subject to a fee, due only if the notice of appeal is formally filed.

The appeal has a suspensive effect only on the elements of the decisions that are appealed by the appellant. All other elements of the decision need to be provided by the deadline(s) set in the decision.

If the Board of Appeal confirms the decision taken by ECHA (fully or partially), it issues a new

[15] https://www.echa.europa.eu/regulations/appeals

deadline for the submission of the information and the registrants must inform ECHA of the legal entity which is to perform the tests on behalf of the others (see section 6.3).

Board of Appeal: https://echa.europa.eu/regulations/appeals

6.3. Identifying who shall perform the test(s)

Within 90 days of receiving an adopted decision, you must collectively agree on and inform ECHA of the legal entity which will perform the requested test(s) on behalf of the other recipients of the decision, as required by Article 53(1) REACH. This should be done using the webform link provided in the notification letter accompanying the adopted decision.

If you cannot reach an agreement, you must contact ECHA, who will then designate one of the recipients of the decision to perform the test(s) on behalf of all registrants concerned. All registrants will be informed of the designation decision.

ECHA will also make such a designation decision if it receives no information from you by the end of the 90-day period.

Within 90 days of receipt, recipients of the adopted decision must inform ECHA about the legal entity (one or more) that is taking the responsibility to perform the requested test(s) on behalf of all registrants impacted by the decision.

6.4. Agreeing on sharing of data and costs

6.4.1. 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[16]". 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 in principle required to share only the costs of information that they are required to submit to satisfy their own registration requirements.

Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data sharing: https://echa.europa.eu/regulations/reach/legislation

Where multiple registrants of the same substance or participants in a Substance Information Exchange Forum (SIEF) are obliged to share information in accordance with their duties under REACH, they shall make every effort to reach an agreement

[16] Title III of REACH, Articles 27(3) and 30(1).

on the sharing of the information. To ensure that data is shared in a transparent and effective manner, all agreements to share data should be structured in a way that all relevant costs are clearly described and identifiable in order to determine the conditions under which you are to pay a share of the costs, including the proportion of your contribution.

The rules for sharing data apply both to new registrants joining a data-sharing agreement that has already been concluded and to registrants setting up a new data-sharing agreement. Therefore, the members in a joint submission must agree on a cost-sharing model, including a reimbursement mechanism[17].

If no agreement can be found, each registrant needs to pay an equal share of the costs required for their contribution[18].

A potential reimbursement mechanism shall apply equally to existing and future registrants.

Provisions for possible future costs shall be foreseen, namely related to those following ECHA decisions for the registered substance[19].

6.4.2. Sharing information on analogue substances

The Implementing Regulation also explicitly encourages the sharing of relevant studies that are conducted on an analogue substance, a substance which is structurally similar to the substance being registered. This is significant in promoting the development and use of alternative methods for the assessment of hazards of substances and in minimising animal testing. The data sharing agreement should also take into consideration how to facilitate responding to such requests for information in practice.

6.4.3. If you register a substance or increase your tonnage after ECHA has sent the (draft) decision

If you register a substance after the draft decision has been issued (i.e. after the start of the decision-making process, Figure 3), you will not be a recipient of the (draft) decision and will not be considered during the decision-making process.

Similarly, if you increase your tonnage or if you expand your registration from intermediate uses to full registration, you will know from the adopted decision which requirements you will need to comply with, for your actual tonnage, unless you have already opted out for some of the requests listed in the adopted decision.

Consequently, the same data-sharing rules as explained above will apply to you.

Cost sharing aims to share the actual expenses and costs related to the registration under REACH in a fair, transparent and non-discriminatory manner. It is not designed to generate profits for any party. The data sharing agreement should also determine to what extent a future registrant must contribute to the cost of a study.

All registrants, including future registrants, have to agree on a cost-sharing mechanism which addresses potential costs resulting from a dossier evaluation decision.

[17] Article 2(1)(c) of the Implementing Regulation (EU) 2016/9.
[18] Article 4(3) of the Implementing Regulation (EU) 2016/9.
[19] Article 4(2) of the Implementing Regulation (EU) 2016/9.

Data sharing: https://echa.europa.eu/regulations/reach/registration/data-sharing

Guidance on data sharing: https://echa.europa.eu/guidance-documents/guidance-on-reach

6.5. Submitting requested information by the set deadline

ECHA reminds that every adopted decision specifies a calendar date by which you have to submit the new information requested, or to adapt the information requirement (under your own responsibility) to bring the registration into compliance with the relevant information requirements.

As recipients of an adopted decision, you are collectively responsible of the following:

- the designated registrant(s) conduct the testing in a timely fashion, according to the appropriate test method and with a test material relevant for all registrants;
- the information requested is submitted in an updated registration dossier with the data and format (i.e. with adequate robust study summaries) requested, at the latest by the deadline(s) indicated in the decision;
- the lead registrant submits the requested information on behalf of the other registrants;
- the chemical safety reports, are updated, including classification and labelling, where relevant.

6.6. Follow up to dossier evaluation

ECHA starts the follow-up step of the dossier evaluation process when the deadline set in the dossier evaluation decision has expired.

ECHA will examine any information submitted on account of a dossier evaluation decision. ECHA will consider whether each registrant has complied with the information requirement requested in the decision, and whether further regulatory actions are required. If one or several registrants submit information that is different from that submitted by the others in response to the draft decision, this opt-out will be analysed.

If the submitted data comply with the relevant information requirement, ECHA notifies the Member States and the Commission of the information obtained and conclusions made, and informs all recipients of the decision.

If one or more of the requests in the decision are not met, either (i) you receive a new (draft) decision confirming the continued non-compliance or (ii) ECHA notifies the relevant Member States and informs the concerned registrants. In both cases, ECHA invites the Member State enforcement authorities to consider enforcement actions, where appropriate.

After adoption of the decision, ECHA publishes the decision on its website.

If you, the recipients of the decision, choose to adapt the information rather than submit the requested tests, it is at your own responsibility and risk. ECHA cannot provide any informal advice or comments on any alternative strategies once the decision has been issued.

If the information provided is not compliant, the enforcement responsibility is attributed solely to the Member States competent authorities and the national

enforcement authorities. Nonetheless, the registrant must still deliver their updated dossier to ECHA at any time when requested.

ECHA's recommendations to registrants receiving a decision under dossier evaluation: https://echa.europa.eu/decision-under-dossier-evaluation-recommendations

Steps of the evaluation procedure: https://echa.europa.eu/regulations/reach/evaluation/steps

Public versions of adopted decisions: https://echa.europa.eu/information-on-chemicals/dossier-evaluation-status

7. Useful links

LEGAL TEXTS

REACH Regulation: https://echa.europa.eu/regulations/reach/legislation

CLP Regulation: https://echa.europa.eu/regulations/clp/legislation

SUPPORT

Evaluation: http://echa.europa.eu/regulations/reach/evaluation

Recommendations to registrants: https://echa.europa.eu/recommendations-to-registrants

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

Support: http://echa.europa.eu/support

Contact – ECHA Helpdesk: https://echa.europa.eu/contact/reach

TOOLS

REACH-IT: http://echa.europa.eu/support/dossier-submission-tools/reach-it

IUCLID: http://iuclid.echa.europa.eu/

Chesar: http://chesar.echa.europa.eu/

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