

# How to communicate with ECHA in dossier evaluation

Practical Guide 12

# ABC

## Legal Notice

This document contains guidance on REACH explaining the REACH obligations and how to fulfil them. 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. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

| VERSION      | CHANGES   |              |
|--------------|---|--------------|
| Version 1    | First edition   | January 2011 |
| Version 1.1. | The update includes the following: <ul style="list-style-type: none"><li>• Updating the guide in accordance with changes in procedures and practices;</li><li>• Inclusion of information on communication with the registrant during and after the follow up process.</li><li>• Clarifying the information regarding technical dossier updates:</li><li>• Inclusion of information on communication with the lead registrant after issuing the draft decision.</li><li>• Links checked and updated.</li><li>• Editorial corrections</li></ul> | July 2015    |

## How to communicate with ECHA in dossier evaluation Practical Guide 12

**Reference:** ECHA-15-B-12-EN  
**Cat. number:** ED-02-15-542-EN-N  
**ISBN:** 978-92-9247-464-5  
**DOI:** 10.2823/43543  
**Date:** July 2015  
**Language:** English

© European Chemicals Agency, 2015

This document will be available in the following 23 languages: Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovakian, Slovenian, Spanish and Swedish.

If you have questions or comments in relation to this document please send them (quoting the reference and issue date) using the information request form. The form can be accessed via the 'Contact ECHA' page at: <http://echa.europa.eu/contact>

### European Chemicals Agency

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland  
Visiting address: Annankatu 18, Helsinki, Finland

# Table of Contents

|   |           |
|---|-----------|
| <b>THE PURPOSE AND NATURE OF PRACTICAL GUIDES</b>   | <b>3</b>  |
| <b>1. INTRODUCTION</b>  | <b>5</b>  |
| <b>2. WHO SHOULD READ THIS PRACTICAL GUIDE?</b>   | <b>6</b>  |
| <b>3. WHAT IS DOSSIER EVALUATION?</b>   | <b>6</b>  |
| 3.1 Compliance check  | 6         |
| 3.2 Testing proposal examination  | 7         |
| <b>4. WHAT DUTIES DO REGISTRANTS HAVE REGARDING THE CONTENT OF THEIR REGISTRATION DOSSIERS?</b> | <b>8</b>  |
| 4.1 Information requirements  | 8         |
| 4.2 Good laboratory practice and test guidelines  | 12        |
| 4.3 Chemical safety assessment  | 12        |
| <b>5. HOW ARE DOSSIERS EVALUATED?</b>   | <b>13</b> |
| 5.1 Who evaluates the dossiers?   | 13        |
| 5.2 When are the dossiers evaluated?  | 13        |
| 5.3 What is evaluated?  | 14        |
| 5.4 What are the possible outcomes of dossier evaluation?                                       | 17        |
| 5.4.1 Further data needed   | 17        |
| 5.4.2 No further data needed  | 18        |
| <b>6. WHAT HAPPENS AFTER ECHA ISSUES A DRAFT DECISION?</b>                                      | <b>19</b> |
| <b>7. WHAT HAPPENS AFTER ECHA ISSUES THE DECISION?</b>  | <b>20</b> |
| 7.1 Follow up to dossier evaluation   | 23        |
| <b>8. HOW AND WHEN CAN OTHER STAKEHOLDERS CONTRIBUTE TO THE DECISION-MAKING PROCESS?</b>        | <b>23</b> |
| <b>9. SUMMARY</b>   | <b>24</b> |
| <b>10. FURTHER INFORMATION</b>  | <b>26</b> |

## THE PURPOSE AND NATURE OF PRACTICAL GUIDES

Practical guides aim to help duty holders 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 (which is established under the formal guidance consultation process involving stakeholders) that provides the principles and interpretations needed for a thorough understanding of the requirements of REACH. However, they explain, in a practical way, specific issues presented in the Guidance.

ECHA invites interested parties to submit experiences and examples to be incorporated in future updates of this document. These can be submitted to the ECHA Information Desk at: <http://echa.europa.eu/contact>

## 1. INTRODUCTION

The purpose of this Practical Guide 12 is to explain, in simple terms, what dossier evaluation is, how the dossiers are processed under dossier evaluation and to highlight the opportunities and obligations that registrants have in making sure that their dossiers are compliant with the REACH Regulation. This guide also explains what kind of different administrative outcomes of dossier evaluation can be expected and how and when the registrants can react to communications received from ECHA.

In brief, the REACH Regulation<sup>1</sup> requires EU companies to submit registration dossiers for substances manufactured in or imported to the EU in quantities of one tonne or more per year. When a registration dossier is submitted, the European Chemicals Agency (ECHA) assigns a registration number once it has been confirmed that the dossier is complete. This completeness check of the registration dossier does not include an examination of the quality or the adequacy of the data submitted. The REACH Regulation states that such an assessment is carried out independently from the registration process, through a process called Evaluation (Title VI, Articles 40-54 of the REACH Regulation).

The REACH Regulation specifies three different evaluation processes<sup>2</sup>, which meet three distinct objectives:

- 1) **Compliance check in dossier evaluation** is used to assess whether or not the information submitted by a registrant is compliant with the legal requirements. The REACH Regulation requires that at least 5 % of the registration dossiers received by ECHA per tonnage band must be checked.
- 2) **Examination of testing proposals in dossier evaluation** aims to check that adequate and reliable data are produced and to prevent unnecessary animal testing. Registrants must seek permission from ECHA before conducting these higher-tier studies by submitting a testing proposal. Testing proposals which include (vertebrate) animal tests lead to a call for scientific information that is taken into account in the decision-making process. All testing proposals in registrations must be examined.
- 3) **Substance evaluation** assesses whether further information is necessary to decide if the use of a substance presents a risk to human health or the environment. The substances to be evaluated are selected by ECHA in cooperation with the Member States. Prioritised substances are evaluated by the Member States.

Registrants should ensure a high level of protection of human health and the environment by:

- Collecting and generating adequate information on the properties of the chemical substance;
- providing information on the potential exposure resulting from the use(s) of a substance;
- assessing the hazards and risks; and
- developing and recommending appropriate risk management measures.

The REACH process of **evaluation** contributes to making sure that registrants meet the REACH requirements in this regard. This practical guide focuses on the two dossier evaluation processes undertaken by ECHA, namely **compliance check** and the **examination of testing proposals**.

If, during compliance check, ECHA detects that the information provided in the registration dossier does not fulfil the necessary information requirements of the REACH Regulation, the registrant will be requested to fulfil the missing information requirements.

During the examination of testing proposals, third parties can also contribute by submitting additional

<sup>1</sup> Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of chemicals (REACH)

<sup>2</sup> Dossier evaluation processes do not apply for on-site isolated intermediates used under strictly controlled conditions

information that is relevant to the proposed animal tests and which is then taken into account in the decision-making. The conclusions from dossier evaluation may be used under 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, and they are responsible for enforcement activities.

Ultimately, it is only possible for the registrant to make a proper risk assessment and to give guidance on the safe use of the substance, whether it is on its own, in a mixture and/or in an article after assembling all the necessary information available for a substance. Non-confidential information included in the dossiers is published on the ECHA website<sup>3</sup> and it is in our common interest that this information is reliable and of good quality. The dossier evaluation processes contribute to this goal.

This guide does not concern substance evaluation. Other information on dossier<sup>4</sup> and substance<sup>5</sup> evaluation is provided, in brief, on the ECHA website.

## 2. WHO SHOULD READ THIS PRACTICAL GUIDE?

This document is intended for registrants, i.e. **manufacturers** and **importers** of substances as well as for **only representatives**. This document may also be useful for companies outside the EU who want to make sure that companies importing their substances into the EU are compliant with the information requirements that the REACH Regulation places on registrants.

This practical guide may also be useful as an introduction to readers who are new to the subject and to point them to more detailed information necessary to prepare registration dossiers.

This guide also provides useful information to other interested stakeholders, who are invited to provide additional information on the properties of substances during consultation periods on testing proposals.

## 3. WHAT IS DOSSIER EVALUATION?

REACH provides for two dossier evaluation processes, namely the **compliance check** and the **examination of testing proposals**. The decision-making process is described later in this practical guide and is the same for both of these dossier evaluation processes.

### 3.1 COMPLIANCE CHECK

A compliance check is an assessment of the quality and adequacy of the information provided in the registration dossiers. This assessment is focused on the requirements specified in the annexes of REACH, in particular Annexes I and VI-XI. The Good Laboratory Practice (GLP) status of the toxicological and environmental studies and opt-outs from joint submission of registration data for the same substance may

<sup>3</sup> <http://echa.europa.eu>

<sup>4</sup> <http://echa.europa.eu/regulations/reach/evaluation>

<sup>5</sup> <http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation>

also be checked. If a registrant has 'adapted' the standard information requirements<sup>6</sup>, ECHA will check the legal and scientific validity of the given justifications.

If ECHA considers that the dossier is not compliant with the information requirements, it will issue a draft decision requiring the registrant to submit any information needed to bring the registration into compliance with the relevant information requirements. In the draft decision, ECHA will also specify an adequate time limit for the submission of the missing information.

### 3.2 TESTING PROPOSAL EXAMINATION

For substances registered for quantities of 100 tonnes per year or more, more information on possible hazards is required and therefore more long-term studies on various animals might be needed to assess potential hazardous properties of the substances.

Consequently, the registrants have to address these information requirements, as specified in Annexes IX and X either by providing available data or, in cases where the necessary information is missing, by submitting a testing proposal.

Under certain circumstances, this may also apply for substances registered in quantities up to 100 tonnes per year (i.e. for which the information requirements of Annexes VII and VIII apply), where according to the REACH Regulation a need may be identified for further testing required in accordance with Annexes IX and/or X.

This may, for example, be the case where the physical-chemical properties of the substance or the results of the studies conducted identify the need for further testing which is a standard information requirement only under Annexes IX and/or X (e.g. short-term toxicity on fish is a requirement at Annex VIII; however, testing on long-term toxicity on fish must be considered if the substance is poorly water soluble).

Registrants are not allowed to undertake new Annex IX or Annex X studies before ECHA has taken a decision requiring the registrant to carry out a proposed test.

Registrants are reminded that testing on vertebrate animals is the last resort for obtaining missing information on a substance to be able to meet the information requirements of REACH.

The registration dossier should include a justification for the need for each new test. When a testing proposal concerns a study involving vertebrate animals, ECHA publishes the name of the substance<sup>7</sup> and the hazard endpoints for which testing is proposed.

Third parties are invited to submit scientifically valid information and reports of studies that address the hazard endpoints. This consultation is essentially a call for data to identify specific studies on the substance that might already have been conducted but not available to the registrant, or relevant information on close chemical analogues that can be used for read-across.

Data submitters are invited to include a scientific justification supporting how their data can address the data need specified in the testing proposal. This information from the third party consultation period is

<sup>6</sup> Column 2 in Annexes VII to X of the REACH Regulation set the specific adaptation rules for each end-point and Annex XI sets the general rules for adaptation of the standard testing regime set out in Annexes VII to X.

<sup>7</sup> A substance name can in some cases be a partial name instead of the full chemical structure to preserve commercially sensitive information.

disseminated on our website in published non-confidential ECHA decisions<sup>8</sup>.

If it is not possible to publish the full chemical name of the substance, registrants 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 the prospects of receiving meaningful information from third parties. ECHA has prepared further guidance for registrants on masking the substance name "*REACH-IT Data Submission Manual Part 17 - How to derive a Public Name for a substance for use under the REACH Regulation*"<sup>9</sup>.

Following this consultation period, ECHA examines the testing proposal and issues a draft decision on the proposal taking into account the information contained in the registration dossier as well as any scientifically valid information obtained from the public call for data or otherwise available to ECHA, such as the information received from other registrants of the same substance.

## 4. WHAT DUTIES DO REGISTRANTS HAVE REGARDING THE CONTENT OF THEIR REGISTRATION DOSSIERS?

### 4.1 INFORMATION REQUIREMENTS

The standard information requirements for substances are specified in Annexes VI and VII-X of the REACH Regulation. The requirements are tonnage dependant; the higher the imported or manufactured amount of the substance, the more information is needed to establish the hazard profile and any potential risks resulting from the use of that substance. The registration obligation, as well as the tiered information requirements, starts when a substance is manufactured or imported at or above 1 tonne per year. The other tonnage limits which trigger the need for submitting further information are 10, 100 and 1 000 tonnes per year.

The dossier must contain study summaries, and also robust study summaries for registration above 10 tonnes per year (See *Practical guide 3 How to report robust study summaries*<sup>10</sup>). The information in robust study summaries must be detailed enough to allow an independent assessment of the study without having to refer back to the full study report. If registrants want to they can also provide full study reports as outline attachments to the IUCLID dossier.

Column 2 of Annexes VII-X of REACH outlines rules for 'adapting' the standard tests specified in column 1. These rules define the circumstances in which a particular test does not have to be conducted or can be deferred to a higher tonnage level. Therefore, it is of the utmost importance for registrants to check these rules and the associated detailed *Guidance on Information Requirements and Chemical Safety Assessment*<sup>11</sup>.

Where a registrant chooses to apply such adaptations for a specific endpoint, the quality of the justifications provided in the technical dossier should allow an independent assessment of whether the Column 2 rules for that endpoint are met. Registrants must consider the adaptation possibilities and only generate new information using animal tests as a last resort.

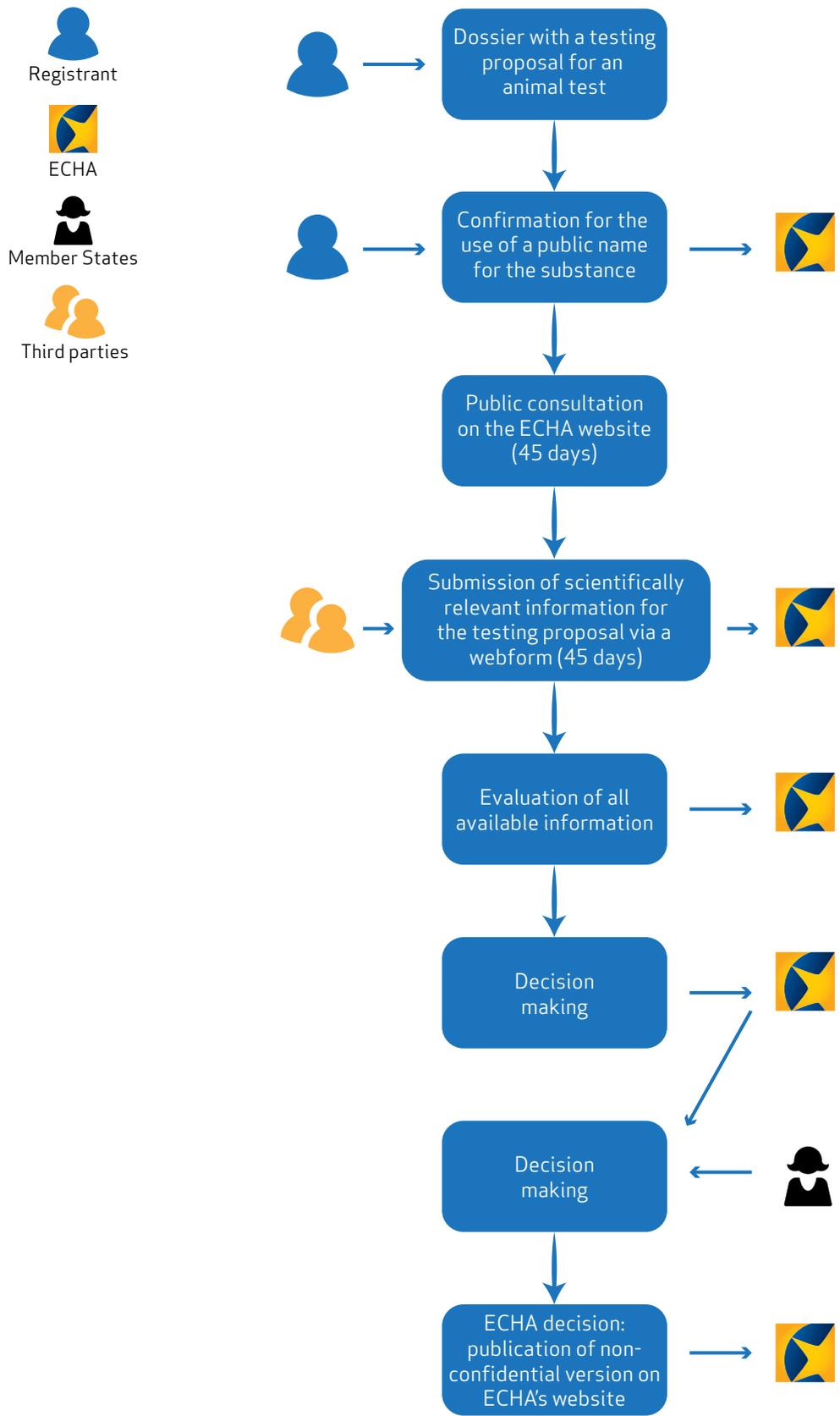
8 <http://echa.europa.eu/information-on-chemicals/dossier-evaluation-decisions>

9 <http://echa.europa.eu/support/dossier-submission-tools/reach-it/data-submission-manuals>

10 <http://echa.europa.eu/practical-guides>

11 <http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

Figure 1: Third party consultation for a testing proposal



Furthermore, Annex XI of REACH lays down the general rules for adapting the standard testing regime set out in Annexes VII-X. It is therefore sometimes also possible to adapt the standard information requirement for scientific, technical or exposure-based reasons.

Of course, available data of sufficient quality should also be used. Even if the provisions of current test guidelines or good laboratory practice (GLP)<sup>12</sup> are not met, such information may still be adequate for the purposes of classification and labelling and risk assessment and thus fulfil the standard information requirements of REACH. Other approaches and the conditions to be met when applied are described in Annex XI of the REACH Regulation.

Registrants must always provide comprehensive, scientifically-sound and transparent justifications for Annex XI adaptations to show that the non-standard data provides adequate information for the purposes of risk assessment and classification and labelling. ECHA underlines the importance of providing sufficient information on the substance identity of the tested substance in cases where it is not exactly the same as the registered substance.

When registrants submit a testing proposal, they should always indicate this by ticking the appropriate 'check-box' (i.e. 'experimental study planned') in the IUCLID dossier header and under the specific endpoint study summary.

The testing proposal should also be mentioned in the hazard assessment part of the chemical safety report (CSR). If mentioned only in the CSR, ECHA will not identify and examine the testing proposal.

Only once the registrant has confirmed by ticking the appropriate 'check-box', will the examination of the testing proposal start. As outlined above, it is not sufficient for a proposed test simply to be named: the testing proposal should include explanations as to why the study is necessary and what alternative methods have been considered, especially for vertebrate animal studies. Where a test is proposed to be conducted with a substance other than the registered substance to apply a category approach or use in a read-across strategy, a comprehensive scientifically-sound and transparent justification must be provided on why the registrant considers that this category or read-across approach can be applied to the registered substance for the endpoint in question.

## SUBSTANCES USED AS INTERMEDIATES

For the use of a substance as a **non-isolated intermediate**, there are no specific obligations under REACH. Manufacturers of **on-site isolated intermediates** in quantities of 1 tonne or more per year need to register their substances (if they are not otherwise exempted from registration).

Information requirements for on-site isolated intermediates are reduced according to Article 17(2) of the REACH Regulation provided that it is confirmed and documented in the registration dossier that the substance is manufactured and used under strictly controlled conditions during its whole lifecycle<sup>13</sup>.

Manufacturers or importers of **transported isolated intermediates** in quantities of 1 tonne or more per year need to register their substances if they are not otherwise exempted from registration. The information requirements in this case are also reduced according to Article 18(2) and (3) of REACH provided that the registrants confirm that they are manufacturing and/or using the substance under strictly controlled conditions or if they state that they have received confirmation from the user(s) of that substance that it is

<sup>12</sup> Article 13(4) of the REACH Regulation and Directive 2004/10/EC

<sup>13</sup> As described in Article 17(3) of the REACH Regulation.

used under strictly controlled conditions during its whole lifecycle<sup>14</sup>.

The specific *Guidance for intermediates*<sup>15</sup> describes when and how the specific provisions for the registration of intermediates under REACH can be used.

It should be noted that according to Article 49 of the REACH Regulation for on-site isolated intermediates that are used under strictly controlled conditions, neither dossier nor substance evaluation applies.

### PREVIOUSLY NOTIFIED SUBSTANCES (NONS)

Substances notified under the respective national law implementing Directive 67/548/EEC are considered as registered substances under the REACH Regulation. Such notifiers can claim a registration number from ECHA, and the substances will be legitimately on the EU market without the need to submit a new registration.

If the production or import of a notified substance exceeds the previously-notified tonnage level, the registrant must submit an update to the dossier providing additional information or testing proposals as required at the upper tonnage level according to the REACH Regulation (See *Questions and Answers for the registrants of previously notified substances*<sup>16</sup>).

### VERTEBRATE ANIMAL STUDIES

Testing on vertebrate animals for the purpose of the REACH Regulation “shall be undertaken only as a last resort”<sup>17</sup>. This means, in line with the guidance note in Annex VI of REACH, that all available existing information must be used if considered to be of sufficient scientific quality and/or if it provides as a whole sufficient proof for the approaches specified in Annex XI of the REACH Regulation/fulfils specific adaptations laid down in Annexes VII-X of the REACH Regulation.

However, omitting testing on vertebrate animals must not compromise the safe use of substances. In all cases, it is up to the registrant to justify that the data obtained by non-animal testing approaches are adequate for the purpose of classification and labelling and for risk assessment.

More information can be found in ECHA's reports on the use of alternatives to animal testing for REACH<sup>18</sup> and in *Practical guide 10: How to avoid unnecessary testing on animals*<sup>19</sup>.

Regarding tests in Annexes IX and X involving vertebrate animals which were conducted after 2008 (i.e. entry into operation of the REACH Regulation) for which no testing proposal has been made, ECHA expects the registrant to appropriately justify in the respective endpoint study records why the test has been conducted without a testing proposal under REACH.

When identifying cases where no justification or no appropriate justification are given, ECHA may contact the registrants and invite them to provide an explanation in the updated dossier. ECHA informs the national authorities for any suspected omission of the obligation to submit a testing proposal involving vertebrate animals.

<sup>14</sup> As described in Article 18(4) of the REACH Regulation.

<sup>15</sup> <http://echa.europa.eu/guidance-documents/guidance-on-reach>

<sup>16</sup> <http://echa.europa.eu/support/qas-support/qas>

<sup>17</sup> Article 25(1) of the REACH Regulation

<sup>18</sup> <http://echa.europa.eu/about-us/the-way-we-work/plans-and-reports>

<sup>19</sup> <http://echa.europa.eu/practical-guides>

## 4.2 GOOD LABORATORY PRACTICE AND TEST GUIDELINES

Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP). The GLP requirement applies to tests that have been performed after 1 June 2008. For physicochemical testing, GLP is desirable but not mandatory. Tests required to generate information on intrinsic properties of substances must also be conducted in accordance with the official EU test methods<sup>20</sup> or in accordance with other international test methods recognised as being equivalent.

In addition, in Annexes VII-X of REACH, the use of various OECD<sup>21</sup> test methods is required when no EU test method exists (e.g. OECD TG 421 and 422). However, for existing data, data from experiments not carried out according to GLP or using non-standard test methods may be acceptable provided that the criteria set out in Annex XI Section 1.1 are met and the data is adequate for the purposes of classification and labelling and/or risk assessment.

Due to scientific and regulatory developments, test guidelines are updated and new ones introduced. In March 2014, ECHA launched a new web page addressing OECD Test Guidelines and the EU Test Methods<sup>22</sup>. With this web page, ECHA supports registrants by showing how these may be used to meet certain standard information requirements under the REACH Regulation. For example, the role of some new test guidelines within testing strategies is described, when appropriate. This information is provided before ECHA's guidance is formally updated.

## 4.3 CHEMICAL SAFETY ASSESSMENT

Registrants must perform a chemical safety assessment (CSA) and prepare a chemical safety report (CSR) for all substances subject to registration in quantities of 10 tonnes or more per year.

The format and the requirements for the CSR are specified in Annex I of the REACH Regulation. Annex I sets out the provisions on how to assess and document that the risks that may arise from the substance are adequately controlled.

The CSR must also include an exposure assessment if the substance is classified or is considered to be a PBT<sup>23</sup> or vPvB<sup>24</sup> substance. The risk characterisation ratio (ratio of potential exposure to predicted or derived no effect level) must be below 1.

This could be achieved in a situation where the potential exposure does not exceed the relevant (eco) toxicological threshold values, i.e. DNEL<sup>25</sup> and PNEC values. This indicates that the risks are adequately controlled. For PBT and vPvB substances, the CSR must include measures to minimise emissions and exposure.

ECHA has created an IT-tool, Chesar, to help companies carry out their chemical safety assessments and prepare their CSRs. This tool provides industry with an efficient way to produce a full chemical safety assessment for the different uses of the substance. It will particularly help structure the information for the exposure scenarios. The principles for carrying out the chemical safety assessment described in the updated

20 Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006

21 Organisation for Economic Co-operation and Development

22 <http://echa.europa.eu/support/oecd-eu-test-guidelines>

23 PBT = persistent, bioaccumulative and toxic

24 vPvB = very persistent and very bioaccumulative

25 DNEL = derived no effect level, PNEC = predicted no effect concentration

Guidance on Information Requirements and Chemical Safety Assessment have been converted into this IT application. Chesar is also built to facilitate the re-use of all or part of the assessments already carried out by the registrant or other parties. There will be further updates to Chesar as more experience is gained.

The Chesar tool and user manuals are available from the ECHA website<sup>26</sup>.

## 5. HOW ARE DOSSIERS EVALUATED?

### 5.1 WHO EVALUATES THE DOSSIERS?

ECHA is responsible for dossier evaluation. ECHA initiates the evaluation process and prepares all the necessary document outputs such as draft decisions and letters to the registrant (see Sections 5 and 7). ECHA notifies the draft decisions to the Member States, which can contribute by proposing amendments (see Section 6). When the Member States submit proposals for amendments, the draft decision is turned into a formal decision only after the draft decisions are scrutinised by the Member State Committee.

Where there is disagreement amongst the Member State Committee members with regard to the draft decision, the matter is referred to the European Commission. Where no Member State submits proposals for amendments, the draft decisions request for further information is turned into a formal decision by the ECHA Secretariat.

### 5.2 WHEN ARE THE DOSSIERS EVALUATED?

#### COMPLIANCE CHECK

ECHA performs compliance checks on at least 5% of all registration dossiers received within each tonnage band. 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. There are provisions in the legal text<sup>27</sup> as to which dossiers should be prioritised for compliance checks. However, these criteria are not exclusive and ECHA can in principle check any dossier. In practice, the selection can be based on a mixture of risk considerations (exposure and hazard profile), on the number of adaptations to the standard information requirements, and on random pick-up.

ECHA uses IT-tools for screening all incoming dossiers for detecting potential non-compliance. ECHA can also start the compliance check at any time. From 2015 onwards, ECHA is implementing a revised compliance check strategy<sup>28</sup>. The goal is to increase efficiency and transparency in dossier evaluation and focus on those substances that matter the most for human health and the environment. The compliance check will mainly focus on eight key/super endpoints which are outlined in the new compliance check strategy. These are genotoxicity, repeated-dose toxicity, pre-natal developmental toxicity, reproduction toxicity, carcinogenicity, long-term aquatic toxicity, biodegradation and bioaccumulation endpoints.

In addition, ECHA has started to publish a list of substances for which a compliance check would in all probability be conducted<sup>29</sup>. This gives the registrants the possibility for early dossier updates before the

<sup>26</sup> <http://chesar.echa.europa.eu>

<sup>27</sup> Article 41(5) of the REACH Regulation

<sup>28</sup> [http://echa.europa.eu/documents/10162/13608/echa\\_cch\\_strategy\\_en.pdf](http://echa.europa.eu/documents/10162/13608/echa_cch_strategy_en.pdf)

<sup>29</sup> <http://echa.europa.eu/regulations/reach/evaluation/compliance-checks>

compliance check starts. However, the list is indicative and non-exhaustive: ECHA reserves the right to open further compliance checks on any dossier at any time and without prior notice to the registrants.

Dossiers subject to testing proposal examinations will not be automatically opened for a compliance check, but a preceding compliance check may be started if the description of the substance identity in the registration dossier is not sufficient; the assessment of a testing proposal needs to be suspended until the identity of the registered substance is clarified.

Registrants will not be informed of the start of a compliance check on their dossier. If the dossier is considered to meet the REACH requirements, the case will simply be closed without further notification to the registrant. When a draft decision is necessary to require further information, the draft decision should be prepared within one year from the start of the compliance check. A concluded compliance check does not prevent ECHA from making a further compliance check on the same dossier at a later stage.

Outside the compliance check process, ECHA may also send letters, inviting the registrant to update and improve their dossier by a certain date. If not adequately responded to, these letters may be followed up, under a formal compliance check process.

## TESTING PROPOSALS

All testing proposals have to be examined by ECHA. As there are time limits specified under REACH, 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. However, proposals for non-phase-in substances take priority over phase-in substances<sup>30</sup> due to the stricter deadline applicable for non-phase-in substances. The deadline for issuing a draft decision for non-phase-in substances is 180 days from receipt of the dossier, i.e. after successfully passing the completeness check.

Regarding the phase-in substances, there are three different deadlines for ECHA to issue draft decisions: 1 December 2012, 1 June 2016 and 1 June 2022. This means that all testing proposals for phase-in substances received by 1 December 2010 or 30 May 2013 have to be examined before 1 December 2012<sup>31</sup> and 1 June 2016, respectively. Dossiers with testing proposals for studies on vertebrate animals are prioritised as it is necessary to launch consultations on the website to find out if additional data is available from third parties, to avoid conducting a new test.

### 5.3 WHAT IS EVALUATED?

As part of the compliance check, ECHA can either examine all the endpoints in the dossier including the chemical safety report, or it can target the examination on certain parts of the dossier. Under a testing proposal examination, ECHA will always evaluate the grounds for conducting the proposed test. In the same context, other closely related endpoints to the test proposed may be examined.

Under dossier evaluation, ECHA pays particular attention to the following issues:

#### SUBSTANCE IDENTITY

<sup>30</sup> The REACH Regulation distinguishes between old (phase-in) and new (non phase-in) chemicals. Since 1 June 2008, new chemicals require a registration before manufacture or placing on the EU market. For old chemicals, a transitional regime provides for later registration deadlines depending on the tonnage band or specific hazard characteristics and conditional to a pre-registration made by 1 December 2008.

<sup>31</sup> [http://echa.europa.eu/view-article/-/journal\\_content/title/first-wave-of-proposals-to-test-substances-examined](http://echa.europa.eu/view-article/-/journal_content/title/first-wave-of-proposals-to-test-substances-examined)

The REACH Regulation requires a separate registration dossier for each substance that is submitted. Hence, it is essential that a complete, consistent and unambiguous description of the identity of the substance has been provided in the registration dossier to establish the legal right to manufacture, import or place the substance on the market in the EU. Each registrant must submit information on the substance identity according to Annex VI of REACH and this information must be specific and allow unambiguous identification of the manufactured or imported substance. This also concerns the substance identity of the test material used to produce the information in the dossier.

The non-compliant, i.e. inadequate and/or incorrect identification of a substance may not only lead to a decision requesting further information on the dossier but may also have as a consequence that any substances not considered to be within the scope of the registration, will be illegally on the market. This may lead to the imposition of penalties and may trigger the need to submit additional registrations for any substances that are not considered to be covered by the registration.

*(See Data Submission Manual Part 18: How to report the substance identity in IUCLID 5 for registrations under REACH)<sup>32</sup>*

## JUSTIFICATIONS FOR ADAPTATIONS

ECHA checks the dossier to make sure that any adaptations to the standard testing regime are sufficiently justified (see Section 4.1). Clear and robust justifications are needed for the regulator to independently assess their validity. The justifications must give scientific reasoning with any pertinent technical details as to why the REACH information requirement can be met by using an alternative method.

The justifications must also consider the specific rules for adaptation in column 2 of the testing requirements<sup>33</sup> and the general rules for adaptation<sup>34</sup>. Thus, ECHA checks that the registrant addresses the relevant adaptation rules of the legislation. Poor, scientifically incorrect or inadequate justifications will lead to an ECHA draft decision requesting the missing information.

For example, when using the read-across<sup>35</sup> or category approach the dossier must include explanations as to why the results gained from this approach are adequate for the purpose of classification and labelling and risk assessment, have adequate and reliable coverage of the key parameters addressed in the corresponding test method, and cover an exposure duration comparable to or longer than the corresponding test method.

In particular, these explanations should address how the rules provided in Annex XI, Section 1.5, which describe the permitted approaches to grouping and read-across, are met. The substance identities must also be specified and documented for all relevant members of the read-across or category, including their purity/impurity profiles.

## SELECTION OF KEY STUDIES

For each required endpoint an appropriate key study is needed. ECHA checks that the robust study summary of the key study provides sufficient information to allow independent assessment of the study and that the study is of sufficient quality to provide information on the intrinsic property of the substance (Klimisch score

<sup>32</sup> <http://echa.europa.eu/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals>

<sup>33</sup> Specific rules are in column 2 of Annexes VII–X to the REACH Regulation.

<sup>34</sup> Annex XI to the REACH Regulation: General rules for adaptation of the standard testing regime set out in Annexes VII to X.

<sup>35</sup> <http://echa.europa.eu/support/grouping-of-substances-and-read-across>

1 or 2<sup>36</sup>). ECHA also checks that the selected key study provides the adverse effects at the lowest dose or exposure level.

## CLASSIFICATION AND LABELLING

ECHA checks that any classification and labelling of the substance given in the registration dossier is consistent with the information provided in the dossier and is in line with the legal classification and labelling rules as defined in the CLP Regulation<sup>37</sup>.

## GOOD LABORATORY PRACTICE

ECHA checks whether ecotoxicological and toxicological tests and analyses have been carried out in compliance with the principles of good laboratory practice (GLP)<sup>38</sup>. However, existing information may also be acceptable even if it was conducted before 1 August 2008, and was not carried out according to GLP. In this case, the dossier should contain a reference to the criteria in Annex XI, Section 1.1 and provide an explanation on why the data available are adequate for the purposes of classification and labelling and risk assessment.

## TEST GUIDELINES

ECHA checks whether tests generating information on intrinsic properties of substances have been conducted in accordance with the codified EU test methods<sup>39</sup> or in accordance with other international test methods such as OECD test methods. However, existing data not fully in line with the relevant test method may be considered acceptable if the information is adequate for the purposes of classification and labelling and/or risk assessment. In this case, the dossier should contain a reference to the criteria in Annex XI Section 1.1 and an explanation of adequacy.

## CHEMICAL SAFETY REPORTS

ECHA may check that the information provided in the chemical safety report is consistent with the information in the registration dossier and is in compliance with Annex I to the REACH Regulation. In particular, ECHA may check that all identified uses are covered and, if an exposure assessment and risk characterisation is required, that a safe use has been demonstrated for the substance. Furthermore, ECHA checks that the risk assessment follows the recommendations in the *Guidance on Information Requirements and Chemical Safety Assessment*<sup>40</sup> in setting the relevant reference values such as DNELs and PNECs<sup>41</sup> and in preparing exposure scenarios. Any deviations from the guidance should be scientifically well justified.

## EVALUATION OF DOSSIERS REGARDING SUBSTANCES USED AS INTERMEDIATES

On-site isolated intermediates (Article 17) and transported isolated intermediates (Article 18) can benefit from reduced information requirements provided they are used under strictly controlled conditions. However, the REACH Regulation establishes strict criteria that registrants have to fulfil to benefit from this

<sup>36</sup> Klimisch score 1 = reliable without restrictions, Klimisch score 2 = reliable with restriction; H.J. Klimisch, M. Andreae and U. Tillmann (1997) A Systematic Approach for Evaluating the Quality of Experimental Toxicological and Ecotoxicological Data Regulatory Toxicology and Pharmacology Vol 25 pp 1-5

<sup>37</sup> Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures

<sup>38</sup> Article 13(4) of the REACH Regulation and Directive 2004/10/EC

<sup>39</sup> Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006

<sup>40</sup> <http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

<sup>41</sup> DNEL = derived no effect level, PNEC = predicted no effect concentration

derogation.

Firstly, the use of the substance must meet the definition of on-site and/or transported isolated intermediate set out in Article 3(15) of the REACH Regulation.

Secondly, this derogation must only apply if the strictly controlled conditions set out in Articles 17(3) and 18(4) of the regulation are ensured for manufacturing and/or identified uses of the substance.

The demonstration that the use of the substance satisfies these conditions is therefore a pre-requisite to the identification of the applicable information requirements. Therefore, in accordance with Article 36(1) of the REACH Regulation, ECHA may request a registrant to provide the information that would confirm the use of the substance as an intermediate under SCCs.

If any of the conditions are not fulfilled, ECHA may proceed to the compliance check and request all the information specified in Article 10 of the REACH Regulation to be provided in the registration dossier.

A Member State where the site using the substance is located may also take certain actions. This could apply if the Member State considers that a risk arising from the use of an on-site isolated and/or transported intermediate is not properly controlled. Where there is doubt about a registration dossier of an on-site isolated and/or transported intermediate qualifying under the requirements of an on-site isolated and/or transported intermediate as set out in the legal text, the factual basis will be clarified by informal communication or requesting available information according to Article 36 of the REACH Regulation.

## EVALUATION OF DOSSIERS REGARDING PREVIOUSLY NOTIFIED SUBSTANCES

In some cases, the national competent authorities acting under the national law implementing Directive 67/548/EEC did not finalise their assessments of the testing programme of notified substances before the relevant Article 135 of the REACH Regulation entered into force on 1 August 2008. This frequently applies to cases where the notifier exceeded the next tonnage level, but the competent authority did not issue a decision on the necessary additional information needed. Thus, such dossiers may therefore not yet include all the necessary higher-tier studies. In line with Article 24(1) of the REACH Regulation, previous notifications are regarded as registrations, i.e. being technically complete. However, this does not necessarily mean that the notifications comply with the information requirements. For these reasons, ECHA may perform compliance checks for some previously-notified substances.

In these cases, the registration dossier does not have to comply with all the information requirements of all relevant tonnage levels of the REACH Regulation. The regulatory framework (Directive 67/548/EEC or REACH) which requires less information, will be applied for notified substances.

Once a previously notified substance reaches the next tonnage threshold under the REACH Regulation, the registration dossier needs to comply fully with all REACH information requirements. For endpoints on Annexes IX and X, testing proposals have to be submitted where such data is not yet available.

## 5.4 WHAT ARE THE POSSIBLE OUTCOMES OF DOSSIER EVALUATION?

### 5.4.1 Further data needed

If the outcome of ECHA's evaluation is that further data or clarification is needed for the registration dossier then there are two methods to address the issue: a draft decision or a quality observation letter.

## DRAFT DECISION

A request for further data in the case of an incompliant dossier is done by formulating a draft decision. A draft decision specifies:

- the process steps taken;
- the missing information;
- the study or information that is needed to bring the dossier into compliance with the REACH requirements regarding the missing information;
- reasons for requesting the information; and
- the deadline (in months from the adoption of the decision) for fulfilling the information requirement to ECHA.

In the case of a testing proposal examination, the only outcome foreseen is a draft decision that becomes effective after the decision-making process. The options for the testing proposal draft decision are:

- a decision accepting the testing proposal;
- a decision accepting the testing proposal with modified conditions (e.g. test species, route of exposure, duration of the test);
- a decision rejecting the testing proposal; or
- any of the above options combined with a requirement of one or more additional tests relevant for the endpoint to be carried out.

The draft decision also includes a deadline for submitting the information to ECHA. Any decision also reminds the registrant that the data gap could also be filled by using valid adaptations according to Annex XI to the REACH Regulation.

## QUALITY OBSERVATION LETTER

As part of a compliance check, ECHA may identify shortcomings in the registration dossier which are not necessarily related to a direct lack of information. In such cases, ECHA will inform the registrant through a quality observation letter which invites the registrant to revise and/or update the dossier by a target date. These letters do not constitute a formal ECHA decision.

The quality observation letters are notified to the Member States and the reaction of the registrant is monitored. If no update to the registration dossier is received by the target date, ECHA may decide to start another compliance check and issue a draft decision on the matter. Furthermore, the Member States may decide on appropriate follow-up actions. For example, in the case of inappropriate risk management measures, a Member State may decide to start a process for national or EU-wide action.

### 5.4.2 No further data needed

If the dossier contains the information required by the REACH Regulation, the compliance check will be closed without further administrative action and the registrant will not be contacted. However, this does not necessarily mean that there are no shortcomings in the dossier as a whole since the examination might only concern a certain part of the dossier. Furthermore, ECHA will not address minor shortcomings that do not affect the safe use of the substance either.

## 6. WHAT HAPPENS AFTER ECHA ISSUES A DRAFT DECISION?

The decision-making process of ECHA involves consultation of the registrant, the Member State competent authorities (MSCAs) and, if necessary, ECHA's Member State Committee (MSC) or even the European Commission.

In the case of a joint submission, and when the draft decision relates to the jointly submitted information or testing proposals, ECHA addresses the draft decision only to the lead registrant. ECHA expects that the lead registrant of the joint submission for the registered substance will share the relevant requirements and reasoning of the draft decision with the members of their joint submission. ECHA also expects that the lead registrants will coordinate the response with the members of the joint submission and that ECHA will only receive coordinated comments from the lead registrant.

**Registrants can submit comments on ECHA's findings in the draft decision, but they must do so within the time frame and using the form communicated by ECHA:**

All registrants are given an opportunity to comment on a draft decision. Once ECHA has sent the draft decision to the registrant (through REACH-IT), the registrant has 30 days<sup>42</sup> to provide comments using a web form. The deadline for the comments and the address of the web form are specified to the registrants when they are notified of the draft decision.

Registrants comments may, for example, raise points of clarification, inaccuracies in the draft decision, requests for deadline extensions, etc.

In addition, ECHA offers, within the commenting period, an opportunity for an informal interaction with registrants to clarify the process and content of the draft decision. For that purpose, registrants need to contact ECHA, using the email address communicated in the notification letter, within 10 working days after the draft decision has been notified to the registrant.

Since 2015, if no reference is made in the registrant's comments submitted using the webform, ECHA does not normally take into account dossier updates in the process of adopting **compliance check decisions** to allow for efficient decision-making in the timelines set by the REACH Regulation. That means that after the draft decision has been notified to the registrant for comments no updates received will normally be taken into account for the adoption of the taken decision<sup>43</sup>.

For draft decisions on **testing proposals**, ECHA normally takes dossier updates submitted at the latest 30 calendar days after the end of the commenting period into account. To avoid unnecessary testing on vertebrate animals, ECHA may give more time to update, at the request of the registrant, testing proposals involving read-across and categories for two or more registered substances. The applicable deadline for considering an update of the dossier will be stated in ECHA's draft decision and the notification letter.

The above lines on the consideration of updates in the process of adoption of draft decisions apply without prejudice to the duties of registrants to update their registrations in accordance with Article 22(1) of the REACH Regulation.

<sup>42</sup> A communication (e.g. draft decision) sent by ECHA to the registrant is regarded as being received when it is opened, or, if it is not opened, seven days after its notification. In exceptional periods, such as Christmas holidays, 45 days are given to the registrant.

<sup>43</sup> See also ECHA's News Alert NA/15/02 published on 28 January 2015 at [http://www.echa.europa.eu/view-article/-/journal\\_content/title/echa-tightens-its-practice-on-dossier-updates](http://www.echa.europa.eu/view-article/-/journal_content/title/echa-tightens-its-practice-on-dossier-updates)

ECHA reminds that any adopted decision specifies a time limit for submission of new information that would bring the registration into compliance with the relevant information requirements. All information submitted by that date (including all updates submitted) will of course be taken into consideration by ECHA in the dossier evaluation following the expiry of the timeline set in the decision, which only then may lead to follow-up actions, as appropriate.

Once the draft decision, together with the comments of the registrants, are submitted to the MSCAs for consultation, the MSCAs will have 30 days to propose amendments to the draft decision. If ECHA does not receive any proposals for amendment, it will proceed and adopt the decision under Article 51(3) of the REACH Regulation.

**If an MSCA submits proposals for amendment, the registrant will be given the opportunity to submit its comments on the proposed amendments, but again they will need to do so within the timeframe and the form communicated by ECHA:**

If ECHA receives proposals for amendments from the MSCAs, it will assess whether the draft decision should be amended and the case will be referred to the MSC. At the same time, ECHA will send the MSCA proposals for amendments to the registrant for a commenting round on the proposals for amendments. The registrant has 30 days to provide comments on the MSCA's proposals for amendments using the web form.

The MSC will consider the (amended) draft decision as well as the registrant's comments on the proposals for amendments received using the web form within the commenting period. At this stage, the registrant's comments on the draft decision other than such on the proposals for amendment are not taken into consideration by the MSC.

ECHA would like to remind registrants that according to the rules of procedure for the MSC, a case-owner, i.e. a concerned registrant or a representative of a group of concerned registrants in the case of joint submissions, may be admitted as an observer when their specific case is addressed by the Committee. The case-owners must conform to the ECHA Code of Conduct for Case Owner Observers at MSC meetings. The rules can be found on ECHA's website<sup>44</sup>.

If the MSC reaches a unanimous agreement on the draft decision, ECHA will proceed and adopt the decision under Article 51(6) of the REACH Regulation. If the MSC does not reach a unanimous agreement, the MSC Secretariat will refer the draft decision to the European Commission. The decision-making then takes place in a Committee procedure (comitology) (See Figures 2 and 3).

## 7. WHAT HAPPENS AFTER ECHA ISSUES THE DECISION?

After adoption, the decision is communicated to the registrant. The decision will now include the date by when the dossier has to be updated with the requested information.

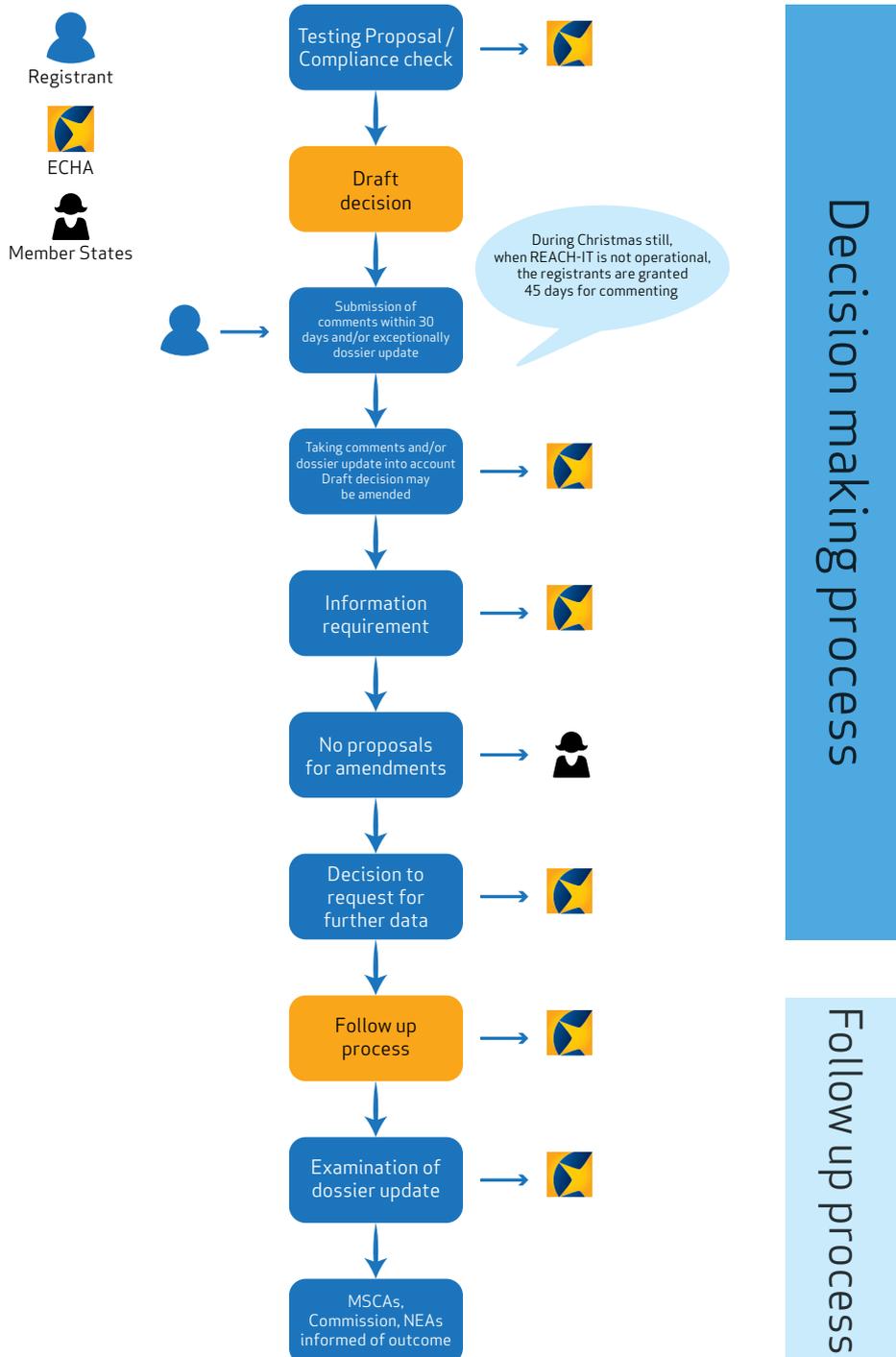
ECHA includes in the same sending a draft non-confidential version of the decision (based on the confidentiality claims in the latest registration dossier) and thereby launches a consultation of the registrant on this version. The registrant is given 21 days to inform ECHA, with justifications, if any other information in the decision should for confidentiality reasons, be removed from this version, which will be published on ECHA's website<sup>45</sup>.

<sup>44</sup> <http://echa.europa.eu/about-us/who-we-are/member-state-committee>

<sup>45</sup> <http://echa.europa.eu/information-on-chemicals/dossier-evaluation-decisions>

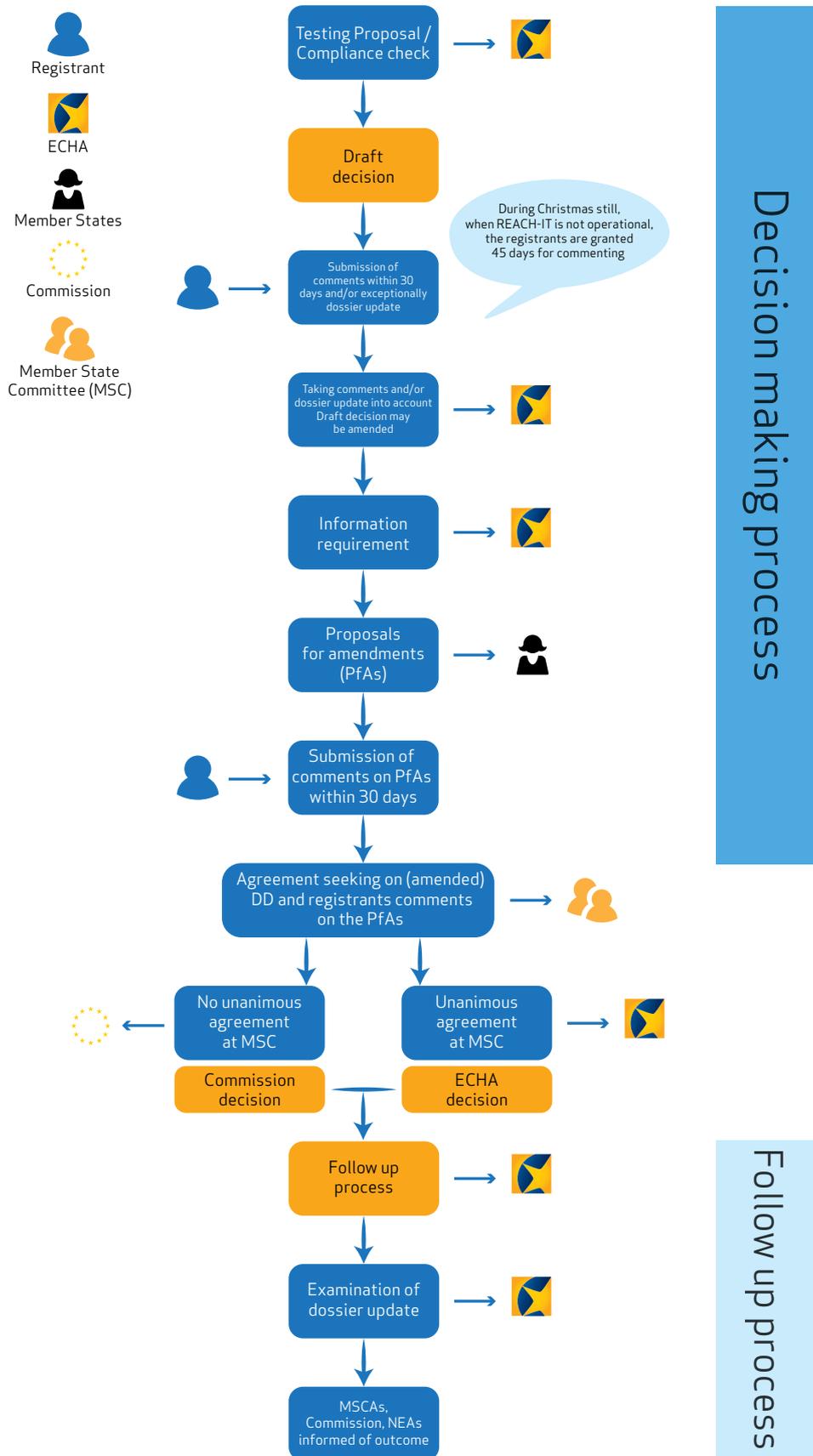
The decision always also includes the instructions for legal redress. If the registrant is unsatisfied with the decision, an appeal may be brought against the decision of ECHA. This has suspensive effect on the elements subject to the appeal. The appeal, together with the statements of the grounds thereof, must be filed in writing to ECHA within three months of the notification of the decision. An appeal is subject to a fee. Further information on the Board of Appeal can be found on ECHA's website<sup>46</sup>.

Figure 2: Decision making without involvement of the Member State Committee



46 <http://echa.europa.eu/about-us/who-we-are/board-of-appeal>

Figure 3: Decision making with the Member State Committee



## 7.1 FOLLOW UP TO DOSSIER EVALUATION

ECHA expects to receive the information requested, in the form of a registration dossier update, at the latest by the deadline set in the decision. ECHA will examine any information submitted as a consequence of a dossier evaluation decision. Once the dossier evaluation is completed, ECHA notifies the Commission and Member State competent authorities of the information obtained and conclusions made.

ECHA starts the follow-up step of the dossier evaluation process when the deadline set in the dossier evaluation decision has expired and investigates if the information requested in the decision is provided in the latest dossier update. More information on the process of follow up to dossier evaluation and advice to the registrants on how to communicate with ECHA at this stage of evaluation is available in ECHA's fact sheet published in 2013<sup>47</sup>.

## 8. HOW AND WHEN CAN OTHER STAKEHOLDERS CONTRIBUTE TO THE DECISION-MAKING PROCESS?

### NOMINATED STAKEHOLDERS

Nominated representatives of stakeholder organisations may be admitted by ECHA's MSC as regular observers to the meeting of the MSC or its working groups upon the request of members of the MSC or the Management Board. However, if the evaluation draft decision contains information considered as confidential, the case must be discussed in a closed session unless the case-owner registrant agrees to have an open session in the MSC. More information about stakeholders' role in the work of the MSC can be found on ECHA's website<sup>48</sup>.

### THIRD PARTY CONTRIBUTIONS

The website consultation on a testing proposal is a call for data. This means that third parties can submit to or notify ECHA of any existing studies or information. The information must be scientifically relevant for the data gap in question and for the substance mentioned in the testing proposal consultation. This information may also be data on chemical analogues to the substance, and in such a case the data submitters are invited to include a scientific justification to support the use of their data. The information is submitted to ECHA free of charge.

ECHA will open a third party consultation on its website each time a testing proposal including (vertebrate) animal tests is received. After publication, third parties have 45 days to submit relevant information.

ECHA will take into account all information provided and assess whether this information can be used instead of accepting the testing proposal. To make a proper evaluation, ECHA recommends that any information third parties provide contains as much detail as possible. It is also possible to attach individual study reports to the submission.

The submission can only be done electronically through a webform. It is important for data submitters to give their contact information in case ECHA needs to seek further clarifications. Data submitters are requested to provide a non-confidential version of the information which ECHA may make available to the registrant and the public.

<sup>47</sup> [http://echa.europa.eu/documents/10162/13628/factsheet\\_dossier\\_evaluation\\_decisions\\_followup\\_en.pdf](http://echa.europa.eu/documents/10162/13628/factsheet_dossier_evaluation_decisions_followup_en.pdf)

<sup>48</sup> <http://echa.europa.eu/about-us/who-we-are/member-state-committee>

Confidential details to support the non-confidential information may be submitted as well, but a justification must be given to explain why the information is confidential. Such confidential information will only be used by ECHA, including the MSCAs 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.

To improve the transparency of its decision-making process, ECHA is publishing non-confidential versions of all dossier evaluation decisions originating from compliance checks and examination of testing proposals on the Agency's website. 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 examinations<sup>49</sup>.

## 9. SUMMARY

This practical guide can be summarised with a few key messages to (potential) registrants:

- A. The quality and adequacy of information in the dossiers can be evaluated by ECHA after successful registration of a substance.
- B. ECHA examines all testing proposals and always issues a draft decision on admissible testing proposals. Third parties can submit information to ECHA about testing proposals concerning animal tests using a web-based form. The deadline for the submission is 45 days once the consultation is opened on ECHA's website.
- C. At least 5 % of dossiers in each tonnage band will undergo a compliance check.
- D. ECHA will open a compliance check to examine if information is missing from a dossier or if justifications provided are insufficient and prepare a compliance check draft decision requesting the information. Other shortcomings relevant for the safe use of the substance, which cannot be corrected by submitting new information but which would rather call for re-assessment of the existing data, may be addressed by a Quality Observation Letter (QOBL).
- E. In the case of a joint submission, ECHA sends a decision addressing the jointly submitted parts of the dossier only to the lead registrant. ECHA therefore expects that the lead registrant of the joint submission for the registered substance will share the relevant requirements and reasoning of the draft decision with the members of their joint submission. ECHA also expects that the lead registrants will coordinate the response ensuring ECHA receives only one coordinated response from the members of the joint submission.
- F. Registrants have the possibility to comment on ECHA's draft decisions within 30 days of receipt of the draft decision.
- G. Regarding the consideration of updates by ECHA in the decision-making process:
  - a) For compliance checks: In the process of adoption of the decision, ECHA will not normally take into account dossier updates after the draft decision on the compliance check has been notified to the registrant for comments. The change does not affect the commenting period given to registrants

<sup>49</sup> <http://echa.europa.eu/information-on-chemicals/dossier-evaluation-decisions>

to submit comments on the draft decision. ECHA will take into account comments in the decision making.

- b) For testing proposals: When the registrants receive a draft decision on a testing proposal, they will still have a commenting period. In addition, the registrants will receive 30 calendar days to update their dossier. The applicable deadlines will be stated in ECHA's draft decision and the notification letter. To avoid unnecessary testing on vertebrate animals, a more flexible time to update may be taken for testing proposals involving read-across and categories for two or more registered substances if the registrants justify their request in their comments.
  - c) If ECHA considers the dossier to be compliant, the decision process will be terminated and the examination closed with no further administrative action. In any other case, ECHA will continue the decision-making process and refer the decision to the Member State competent authorities.
- H. Member State competent authorities (MSCAs) can propose amendments to ECHA's draft decisions. If that happens, the case is referred to the Member State Committee (MSC) to seek agreement.
- I. Registrants can comment on the proposals for amendment provided by the Member States during a 30-day commenting period. Comments on the draft decision are not taken into account at this stage of the process by the MSC.
- J. Case-owners, i.e. concerned registrants or a representative of a group of concerned registrants in the case of joint submissions, may be admitted as observers when their specific case is addressed by the MSC.
- K. After adoption of the decision on a testing proposal, ECHA will publish the taken decision on its website. The follow-up step in the dossier evaluation process forms one of the interfaces between ECHA, the Member State competent authorities (MSCAs) and the national enforcement authorities (NEAs), respectively. The enforcement responsibility is attributed solely to the Member States
- a) ECHA cannot provide advice or comments on any alternative strategies or approaches that the registrant considers to use to fulfil the request in the decision.
  - b) Registrants may, under their own responsibility and risk, decide to fulfil the information requirements in an alternative way than requested in the decision.
  - c) The Agency will examine any information submitted as a consequence of a dossier evaluation decision. Once the dossier evaluation is completed, ECHA notifies the Commission and Member State competent authorities of the information obtained and conclusions made.
  - d) Once a case has been handed over to the national authorities, ECHA expects that any further communication on the case will be between the Member State authorities and the registrant.

## 10. FURTHER INFORMATION

### LEGAL TEXTS:

---

REACH Regulation

>> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R1907:EN:NOT>

CLP Regulation

>> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008R1272:EN:NOT>

### GUIDANCE:

---

>> <http://echa.europa.eu/support/guidance>

Evaluation web pages:

>> <http://echa.europa.eu/regulations/reach/evaluation>

Support:

>> <http://echa.europa.eu/support>

### PRACTICAL GUIDES:

---

>> <http://echa.europa.eu/web/guest/practical-guides>

### TECHNICAL MANUALS:

---

REACH-IT Supporting Documents:

>> <http://echa.europa.eu/support/dossier-submission-tools/reach-it>

IUCLID 5:

>> <http://iuclid.echa.europa.eu/>

Chesar:

>> <http://chesar.echa.europa.eu/>

EUROPEAN CHEMICALS AGENCY  
ANNANKATU 18, P.O. BOX 400,  
FI-00121 HELSINKI, FINLAND  
ECHA.EUROPA.EU

ECHA-15-B-12-EN - ED-02-15-542-EN-N - ISBN: 978-92-9247-464-5 - DOI: 10.2823/43543