

Guidance on registration

Draft version 4.0

September 2020



1 LEGAL NOTICE

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

| Version | Changes | Date |
|-------------|---|----------------|
| Version 0 | First edition | June 2007 |
| Version 1 | First revision | February 2008 |
| Version 1.1 | Warning added on Only Representative issue | April 2008 |
| Version 1.2 | "Only Representative" and the "Assigning a registration number" chapters amended | May 2008 |
| Version 1.3 | Clarification on "Only Representative" added | September 2008 |
| Version 1.4 | Clarification on "Only Representative" added | November 2008 |
| Version 1.5 | Clarification on information that needs to be submitted for updating dossiers of previously notified substances (NONS) | November 2009 |
| Version 1.6 | <p>Corrigendum covering the following:</p> <ul style="list-style-type: none"> - Amendment of Annex IV and Annex V of REACH by Commission Regulation (EC) No 987/2008 of 8 October 2008. - Amendment of Annex XI of REACH by Commission Regulation (EC) No 134/2009. - Amendment of REACH by the CLP Regulation ((Regulation (EC) No 1272/2008 of 16 December 2008). - Amendment of Annex II of REACH by Commission Regulation No 453/2010 of 20 May 2010. - Ratification of REACH under the EEA Agreement. - Clarification on the registration, updating and classification and labelling notification processes. - Reference to the Data Submission Manuals, REACH-IT Industry User Manuals and Practical Guides published by ECHA. - Editorial corrections. | January 2011 |

| Version | Changes | Date |
|-------------|--|---------------|
| Version 2.0 | <p>Revision of the document covering the following:</p> <ul style="list-style-type: none"> - Restructuring of the content of the guidance: <ul style="list-style-type: none"> - Part I focuses on the explanation of the regulatory requirements. - Part II provides practical information for registrants. - Further clarifications and examples of the registration requirements added. <p>The changes are listed in Appendix 3 of the guidance.</p> | May 2012 |
| Version 3.0 | <p>Revision of the document addressing the content and structure. Main changes include the following:</p> <ul style="list-style-type: none"> - Removal of Part II and Appendix 3; - Clarification of the registration scope in section 2.2.1; - Update of the text on substances regarded as registered (section 2.2.4.1 and 2.2.4.2); - Clarification of the text and addition of new examples on calculation of tonnage in section 2.2.3; - Change in the sequence of chapters 3 and 4; - Update of information on data sharing procedures (chapter 3); - Update of the information on the inquiry process (section 3.4); - Update of the text on standard information requirements in section 4.1.1; - Update of the text about joint submission of data in section 4.3; - Clarification of opt-out possibilities (section 4.3.2); - Explanation of 'one substance – one registration' principle and of the SIP concept (section 5.2.1); - Inclusion of special considerations for 1-10 tonnes dossiers in section 5.2.4; - Update of the information about CHESAR in section 5.3.2; - Addition of a new section 6.1.3; | November 2016 |

| Version | Changes | Date |
|-------------|---|------------|
| | <ul style="list-style-type: none"> – Revision of Appendix 1 and 2 in relation to outdated, incorrect or missing information; – Inclusion of references to updated technical manuals with practical instructions on how to prepare, submit and update registration dossiers. | |
| Version 4.0 | <p>Revision of the document addressing the content and structure. Main changes include the following:</p> <ul style="list-style-type: none"> – Alignment with the <i>Implementing Regulation on the application of certain registration and data-sharing provisions of REACH after the expiry of the final registration deadline for phase-in substances</i>: <ul style="list-style-type: none"> o Changes in the whole document related to the deadlines for registration of phase-in substances; o Removal of references to pre-registration of substances; o Clarification of the calculation of tonnages after the end of phase-in; o Removal of the obsolete sections as the one on non phase-in substances or the one on deadlines for registration of phase-in substances; o Clarification on when it is needed to declare the phase-in status of a substance (section 2.3.2); o Clarification on when the IUPAC name can be claimed confidential (section 4.4) after the end of phase-in; o Clarification of when reduced information requirements for low tonnage dossiers can be provided (section 5.2.4); – Alignment with the Implementing regulation on dossier updates (section 7.2) <ul style="list-style-type: none"> o Explanation and examples on the timelines to update a dossier on the registrants' own initiative; – Extended information on the notification of a cease of manufacture or import; – New section explaining when a registration is no longer valid (section 8) | Month 2021 |

| Version | Changes | Date |
|---------|---|------|
| | <ul style="list-style-type: none"> – Alignment with the Guidance on data sharing: <ul style="list-style-type: none"> ○ Data-sharing section has been reduced and instead references have been made to the Guidance on data-sharing that is being updated in parallel to this guidance (section 3); ○ Information on joint submission from the old Guidance on data-sharing such as joint submission of data, joint submission obligation and conditions for opting out from the joint submission, has been added and updated: (section 4.3). – Streamline of sections to make it more readable: <ul style="list-style-type: none"> ○ Removal of Annex V in section 2.2.3.4 and Annex VII in section 4.1. The reader is advised to consult the text directly in the REACH text; ○ Explanation of the examples for re-imported substances in section 2.2.3.6; ○ Chemical Safety Report section is more concise (section 5.3) ○ Further explanation of the technical completeness check step, in particular what makes reference to automated and manual checks (section 11.3.1) ○ – Adaptation of the text to a gender-inclusive language; – Links added to the cross-references within the document; – Definitions added to Appendix 1; – Roles and duties of only representatives added to Appendix 2. | |

Guidance on registration

Reference: ECHA-16-G-06-EN

Cat. Number: ED-01-16-445-EN-N

ISBN: 978-92-9495-072-7

DOI: 10.2823/969

Publ. date: XYZ 2021

Language: EN

© European Chemicals Agency, 2021

If you have questions or comments in relation to this document please send them contacting

1 echa at: <https://echa.europa.eu/contact>.

2 **European Chemicals Agency**

3 Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland

4 Visiting address: Telakkakatu 6, FI-00150 Helsinki, Finland

5

Preface

This document describes when to register a substance under REACH. It is part of a series of guidance documents that are aimed to help all stakeholders with their preparation for fulfilling their obligations under the REACH Regulation. These documents cover detailed guidance for a range of essential REACH processes as well as for some specific scientific or technical methods that industry and authorities need to make use of under REACH.

The guidance documents were drafted and discussed within the REACH Implementation Projects (RIPs) led by the European Commission services, involving all stakeholders: Member States, industry and non-governmental organisations. The European Chemicals Agency (ECHA) updates these guidance documents following the Consultation procedure on guidance. These guidance documents can be obtained via the ECHA website¹.

This document relates to the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006².

¹ <http://echa.europa.eu/guidance-documents/guidance-on-reach>

² Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, corrected version in OJ L136, 29.5.2007, p.3). Most recent REACH version (i.e. aggregated text with successive amendments and corrigenda) is accessible at: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1907-20150601>

| | | |
|----|--|-----------|
| 1 | Table of Contents | |
| 2 | | |
| 3 | 1. General Introduction..... | 12 |
| 4 | 1.1 Aim of this guidance | 12 |
| 5 | 1.2 Aim of registration | 13 |
| 6 | 1.3 Substances, mixtures and articles | 14 |
| 7 | 2. Registration obligations..... | 16 |
| 8 | 2.1 Who has to register?..... | 16 |
| 9 | 2.1.1 Roles under REACH..... | 16 |
| 10 | 2.1.2 Actors with registration obligations | 17 |
| 11 | 2.1.2.1 Legal personality..... | 18 |
| 12 | 2.1.2.2 Customs boundaries for manufacturing and import | 19 |
| 13 | 2.1.2.3 Who is responsible for the registration in case of manufacturing?..... | 19 |
| 14 | 2.1.2.4 Who is responsible for the registration in case of import? | 20 |
| 15 | 2.1.2.5 Only representative of a 'non-EU manufacturer' | 21 |
| 16 | 2.1.2.6 Role of industry associations and other types of service providers..... | 26 |
| 17 | 2.2 What to register?..... | 26 |
| 18 | 2.2.1 Overview of the registration scope..... | 26 |
| 19 | 2.2.2 Substances exempted from the REACH Regulation | 27 |
| 20 | 2.2.2.1 Radioactive substances | 27 |
| 21 | 2.2.2.2 Substances under customs supervision | 27 |
| 22 | 2.2.2.3 Substances used in the interest of defence and covered by national exemptions..... | 28 |
| 23 | 2.2.2.4 Waste | 29 |
| 24 | 2.2.2.5 Non-isolated intermediates..... | 29 |
| 25 | 2.2.2.6 Transported substances | 30 |
| 26 | 2.2.3 Substances exempted from registration | 30 |
| 27 | 2.2.3.1 Food or feedingstuffs | 30 |
| 28 | 2.2.3.2 Medicinal products..... | 31 |
| 29 | 2.2.3.3 Substances included in Annex IV of the REACH Regulation..... | 32 |
| 30 | 2.2.3.4 Substances covered by Annex V of the REACH Regulation..... | 32 |
| 31 | 2.2.3.5 Recovered substance already registered..... | 32 |
| 32 | 2.2.3.6 Re-imported substance | 34 |
| 33 | 2.2.3.7 Polymers | 37 |
| 34 | 2.2.3.8 Substances used in product and process orientated research and development (PPORD) | 38 |
| 35 | 2.2.4 Substances regarded as registered | 39 |
| 36 | 2.2.4.1 Substances for use in biocidal products | 40 |
| 37 | 2.2.4.2 Substances for use in plant protection products..... | 41 |
| 38 | 2.2.4.3 Notified substances according to Directive 67/548/EEC | 42 |
| 39 | 2.2.5 Obligations related to registration of intermediates..... | 43 |
| 40 | 2.2.6 Calculation of the volume to be registered..... | 44 |
| 41 | 2.2.6.1 Calculation of the volume in case of exemptions..... | 45 |
| 42 | 2.2.6.2 Calculation of the volume for intermediates | 45 |
| 43 | 2.2.6.3 Calculation of the total volume | 46 |

| | | |
|----|---|-----------|
| 1 | 2.2.6.4 Calculation of the amount of substance in a mixture or in articles | 47 |
| 2 | 2.3 When to register? | 48 |
| 3 | 3. The sharing of data | 49 |
| 4 | 4. The registration process | 50 |
| 5 | 4.1 Information requirements | 50 |
| 6 | 4.1.1 Fulfilling the information requirements | 51 |
| 7 | 4.1.2 Use of information from other assessments | 52 |
| 8 | 4.2 Registration dossier | 53 |
| 9 | 4.2.1 Structure of the registration dossier | 53 |
| 10 | 4.2.2 Format and submission of the registration dossier | 54 |
| 11 | 4.3 Joint submission of data | 55 |
| 12 | 4.3.1 Mechanisms of joint submission | 56 |
| 13 | 4.3.2 Jointly submitting data | 58 |
| 14 | 4.3.3 Conditions for opting out from the jointly submitted data | 59 |
| 15 | 4.3.3.1 Disproportionate costs | 60 |
| 16 | 4.3.3.2 Protection of confidential business Information (CBI) | 61 |
| 17 | 4.3.3.3 Disagreement on the selection of information to be included in the lead dossier | 61 |
| 18 | 4.4 Confidentiality and electronic public access to registration information | 62 |
| 19 | 4.5 Access to documents | 64 |
| 20 | 5. Preparation of the registration dossier | 65 |
| 21 | 5.1 Introduction | 66 |
| 22 | 5.2 Preparation of the technical dossier | 68 |
| 23 | 5.2.1 General information on the registrant and on the registered substance | 68 |
| 24 | 5.2.2 Classification and labelling | 69 |
| 25 | 5.2.3 Manufacture, use and exposure | 70 |
| 26 | 5.2.3.1 Information on manufacture and uses of the substance (section 3 of Annex VI of REACH) | 70 |
| 27 | 5.2.3.2 Information on exposure for substances > 10 tonnes | 71 |
| 28 | 5.2.3.3 Information on exposure for substances < 10 tonnes (section 6 of Annex VI) | 71 |
| 29 | 5.2.4 Information requirements on intrinsic properties (Annexes VII to X) | 72 |
| 30 | 5.2.5 Guidance on safe use | 73 |
| 31 | 5.2.6 Review by an assessor | 74 |
| 32 | 5.2.7 Confidential information | 74 |
| 33 | 5.3 Chemical Safety Report | 74 |
| 34 | 5.3.1 Steps of the chemical safety assessment | 76 |
| 35 | 5.3.1.1 Hazard assessment | 76 |
| 36 | 5.3.1.1.1 Human health hazard assessment | 76 |
| 37 | 5.3.1.1.2 Physicochemical hazard assessment | 77 |
| 38 | 5.3.1.1.3 Environmental hazard assessment | 77 |
| 39 | 5.3.1.1.4 PBT/vPvB assessment | 77 |
| 40 | 5.3.1.2 Exposure assessment including risk characterisation | 77 |
| 41 | 5.3.2 Chesar tool | 78 |
| 42 | 6. Duty of communication in the supply chain | 80 |

| | | |
|----|--|------------|
| 1 | 6.1 Provide a safety data sheet (SDS) to customers..... | 80 |
| 2 | 6.2 Provide other information to customers..... | 81 |
| 3 | 6.3 Include identified uses in the dossier | 81 |
| 4 | 7. When and how to update a registration | 83 |
| 5 | 7.1 Duty to keep information up to date | 84 |
| 6 | 7.2 Update on the registrant's own initiative | 85 |
| 7 | 7.3 Update as a consequence of an ECHA or a Commission decision | 97 |
| 8 | 7.4 Update of registration dossier for substances regarded as being registered under REACH | 98 |
| 9 | 8. When is a registration no longer valid? | 101 |
| 10 | 9. Appeal procedures | 103 |
| 11 | 10. Fees | 104 |
| 12 | 10.1 Calculation of applicable fees | 104 |
| 13 | 10.2 Fee for updating a registration dossier | 105 |
| 14 | 11. Duties of ECHA..... | 106 |
| 15 | 11.1 Initial verification..... | 106 |
| 16 | 11.2 Assigning submission number | 107 |
| 17 | 11.3 Completeness check and invoicing procedures | 107 |
| 18 | 11.3.1 Technical completeness check (TCC) | 107 |
| 19 | 11.3.2 Financial completeness check | 108 |
| 20 | 11.4 Rejection of the registration dossier..... | 108 |
| 21 | 11.5 Assigning a registration number | 109 |
| 22 | 11.6 Informing the relevant Member State Competent Authority | 109 |
| 23 | 11.7 ECHA procedure in case of a registration update | 109 |
| 24 | Appendix 1. Glossary/List of acronyms | 111 |
| 25 | Appendix 2. Roles and duties of the main actors of REACH..... | 117 |
| 26 | | |
| 27 | | |
| 28 | | |
| 29 | | |
| 30 | | |
| 31 | | |
| 32 | | |
| 33 | | |
| 34 | | |
| 35 | | |
| 36 | | |
| 37 | | |
| 38 | | |
| 39 | | |
| 40 | | |

Table of Figures

| | |
|---|----|
| Figure 1: Steps within the registration process and link to the structure of this document | 13 |
| Figure 2: Role and registration obligations of different actors in case of import..... | 21 |
| Figure 3: Example of roles and registration obligations of different actors when an only representative is appointed | 25 |
| Figure 4: Structure and format of the registration dossier | 67 |
| Figure 5 - Deadlines to update dossier in case of change in tonnage band..... | 89 |
| Figure 6 - Deadlines for updating member dossiers..... | 96 |

Table of Tables

| | |
|--|----|
| Table 1: Information requirements for data submitted jointly within a joint submission..... | 58 |
| Table 2: Relation between the information requirements in Article 10 and the corresponding sections in a IUCLID file..... | 66 |
| Table 3: Short summary of the CSR format..... | 75 |
| Table 4 – Updates pursuant to Article 22(1) and relevant maximum deadlines | 85 |
| Table 5 - Examples of update reasons falling under Art 22(1)(a)..... | 87 |

1. General Introduction

1.1 Aim of this guidance

The aim of this guidance is to assist industry in determining which tasks and obligations have to be complied with to fulfil their registration requirements under REACH.

This document guides potential registrants to answer the following questions:

- Who has registration obligations?
- Which substances are within the scope of REACH?
- Which substances need to be registered?
- What is a registration dossier?
- When does a registration dossier have to be submitted to ECHA?
- What is a joint submission?
- Which data must be submitted jointly and in which circumstances can a registrant submit data separately?
- When and how to update the registration dossier?
- What is the registration fee?
- What are the duties of ECHA once the registration dossier is submitted?

The guidance is based on descriptions of obligations supplemented by explanations and practical advice, which whenever possible are illustrated by examples. Throughout the text, explanations of the REACH processes are offered, providing references to relevant guidance documents, manuals and other useful tools.

Whenever in the text of this guidance an 'Annex' or an 'Article' is mentioned what is meant is an Annex or an Article of the REACH Regulation. Whenever the EU is referred to in the text of this guidance, Iceland, Liechtenstein and Norway are also covered.

The guidance is addressed to all potential registrants with or without an expert knowledge in the fields of chemicals and chemicals assessment. It explains what the registration requirements are, who is responsible for them and how and when they must be fulfilled.

Figure 1 guides the reader through this guidance helping them to identify their registration obligations.

Practical instructions for submitting a registration are available in the ECHA manual *How to prepare registration and PPORD dossiers* accessible at: <http://echa.europa.eu/manuals>. The manual is also available via the help system built into IUCLID.

A tool, called the Navigator is also available in 23 languages to help the users identify their obligations under REACH. It can be found at <https://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/identify-your-obligations/navigator>.

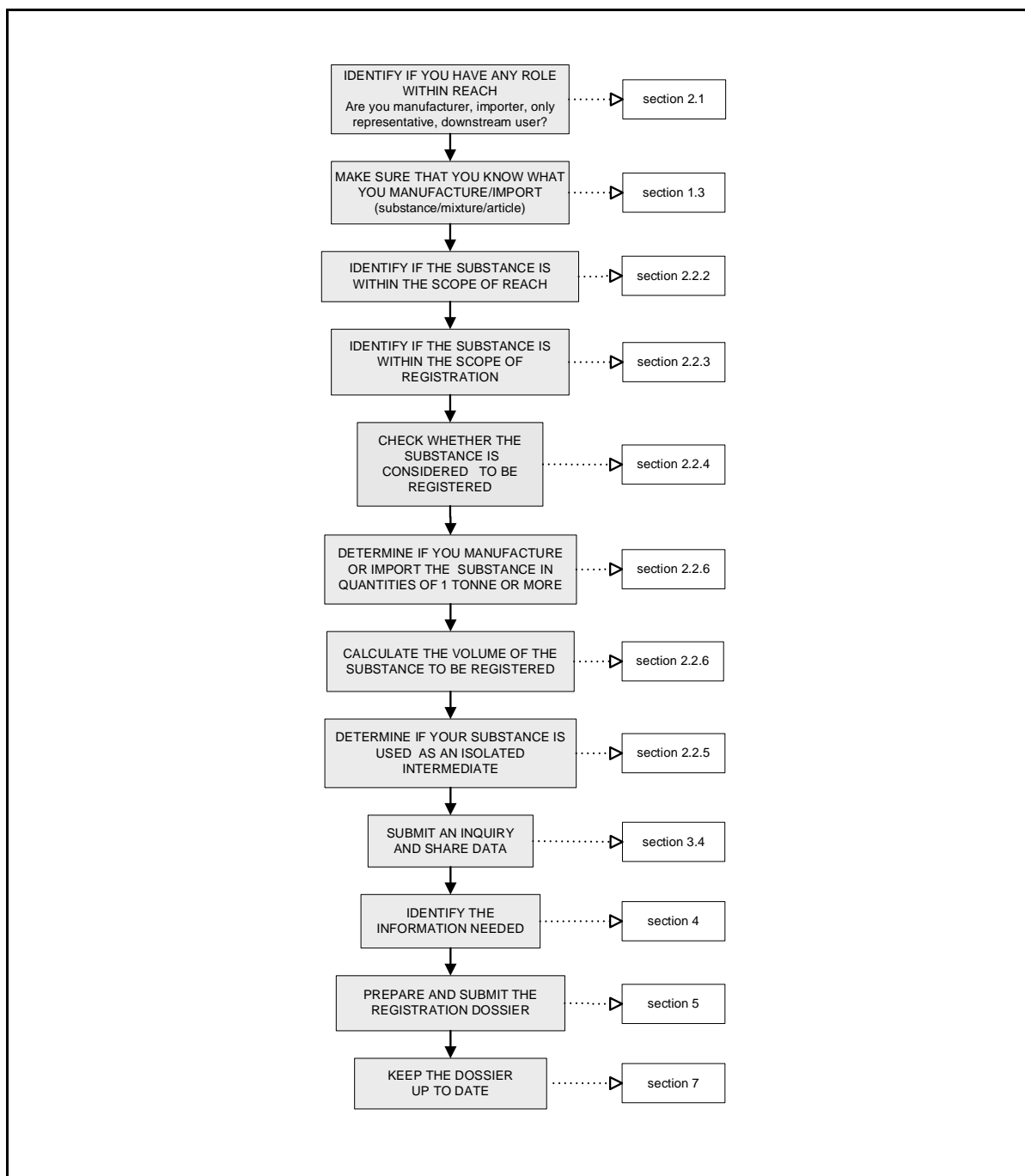


Figure 1: Steps within the registration process and link to the structure of this document

1.2 Aim of registration

REACH is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. The responsibility for the management of the risks of substances lies therefore with the natural or legal persons that manufacture, import, place on the market or use these substances in the context of their professional

1 activities.

2 The registration provisions require manufacturers and importers to collect or generate data on
3 the substances they manufacture or import, to use these data to assess the risks related to
4 these substances and to develop and recommend appropriate risk management measures to
5 control these risks. To ensure that they actually meet these obligations, as well as for
6 transparency reasons, manufacturers and importers are required to prepare a registration
7 dossier in IUCLID format and submit it to ECHA via REACH-IT portal (see sections 4.2.2
8 Format and submission of the registration dossier and Preparation of the registration dossier).

9 When a substance is intended to be or is being manufactured or imported by more than one
10 manufacturer or importer, certain data must be shared (please consult the *Guidance on data-*
11 *sharing* at <http://echa.europa.eu/guidance-documents/guidance-on-reach> and submitted
12 jointly (see section 4.3 Joint submission of data) with the purpose of increasing the efficiency
13 of the registration system, saving costs and reducing testing on vertebrate animals.

14 A joint submission³ allows registrants of the same substance to submit their dossier jointly in
15 REACH-IT. Being part of the same joint submission in REACH-IT does not mean that
16 registrants shared data on the substance, but only that they consider that they are
17 manufacturing or importing the same substance.

18 While still being a part of the joint submission, a registrant may opt out from some or all the
19 information requirements and submit the information separately to ECHA in certain specified
20 cases (see section 4.3.3 Conditions for opting out from the jointly submitted data).

Unless the REACH Regulation indicates otherwise, registration obligations apply to substances manufactured or imported in quantities of one tonne or more per year per manufacturer or importer (see section 2.2 What to register?). The registration must be successfully completed and a registration number assigned to the registrant before a substance can be manufactured, imported or placed on the market. Registered substances can in principle circulate freely on the internal market.

21

22 **1.3 Substances, mixtures and articles**

23 REACH lays down obligations which apply to the manufacture, import, placing on the market
24 and use of substances on their own, in mixtures or in articles. Before continuing to explain
25 which substances require registration it is important to have a clear understanding of these
26 terms and how mixtures and articles are dealt with.

27 **Substance** means a chemical element and its compounds. The term substance includes both
28 substances obtained by a manufacturing process (for example formaldehyde or methanol) and
29 substances in their natural state. The term substance also includes its additives and impurities
30 where these are part of its manufacturing process, but excludes any solvent which can be
31 separated without affecting the stability of the substance or changing its composition. Detailed
32 guidance on substances and substance identity can be found in the *Guidance on identification*

³ For consistency with the terminology used in REACH-IT and in other ECHA's documents, the word 'joint submission' is used in the present Guidance to reflect the concept of being part of the same registration in the Implementing Regulation 2016/9. This must be distinguished from the actual joint submission of data, or references to the jointly submitted data, which address the situation where a lead registrant jointly submits data on behalf of other assenting registrants, as per Article 11(1) and 19(1) of REACH.

and naming of substances under REACH and CLP at: <http://echa.europa.eu/guidance-documents/guidance-on-reach>.

Mixture means a mixture or solution composed of two or more substances. Typical examples of mixtures under REACH include paints, varnishes and inks. REACH obligations apply individually to each of the substances contained in the mixture depending on whether the individual substances are within the scope of REACH.

When contained in a mixture, each individual substance needs to be registered if the threshold of one tonne per year is reached (for additional information on how to calculate the tonnage for registration for substances in mixtures please refer to sections 2.2.6.3 Calculation of the total volume and 2.2.6.4 Calculation of the amount of substance in a mixture or in articles). The registration obligation applies to the manufacturer or importer of each individual substance, or in case that the mixture is imported as such, to the importer of the mixture. The formulator, i.e. the natural or legal entity that mixes the individual substances to produce the mixture, does not have registration obligations under REACH unless they are at the same time a manufacturer or importer of the individual substances contained in the mixture or an importer of the mixture itself.

The REACH Regulation refers to alloys as “special mixtures”. Therefore, an alloy is to be treated in the same way as other mixtures under REACH. This means that although the alloy is not subject to registration, the alloying elements (e.g. metals) must be registered. The obligation to register the alloying elements applies irrespectively of the production process involved in the manufacturing of the alloy. Constituents which are not intentionally added to the alloy should be considered as impurities (i.e. they are part of one of the substances in the mixture) and therefore do not need to be registered separately.

An **article** is an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition (e.g. manufactured goods such as textiles, electronic chips, furniture, books, toys, kitchen equipment). An individual substance in an article is subject to the registration obligations in case it is present in the article in quantities over one tonne per year and the substance is intended to be released under normal or reasonably foreseeable conditions of use. The registration obligation applies to the producer of the article or, in case the article is imported, to the importer, insofar as the substance has not been registered for that use. Detailed guidance on articles and how they are dealt with under REACH can be found in the *Guidance on requirements for substances in articles* available at: <http://echa.europa.eu/guidance-documents/guidance-on-reach>

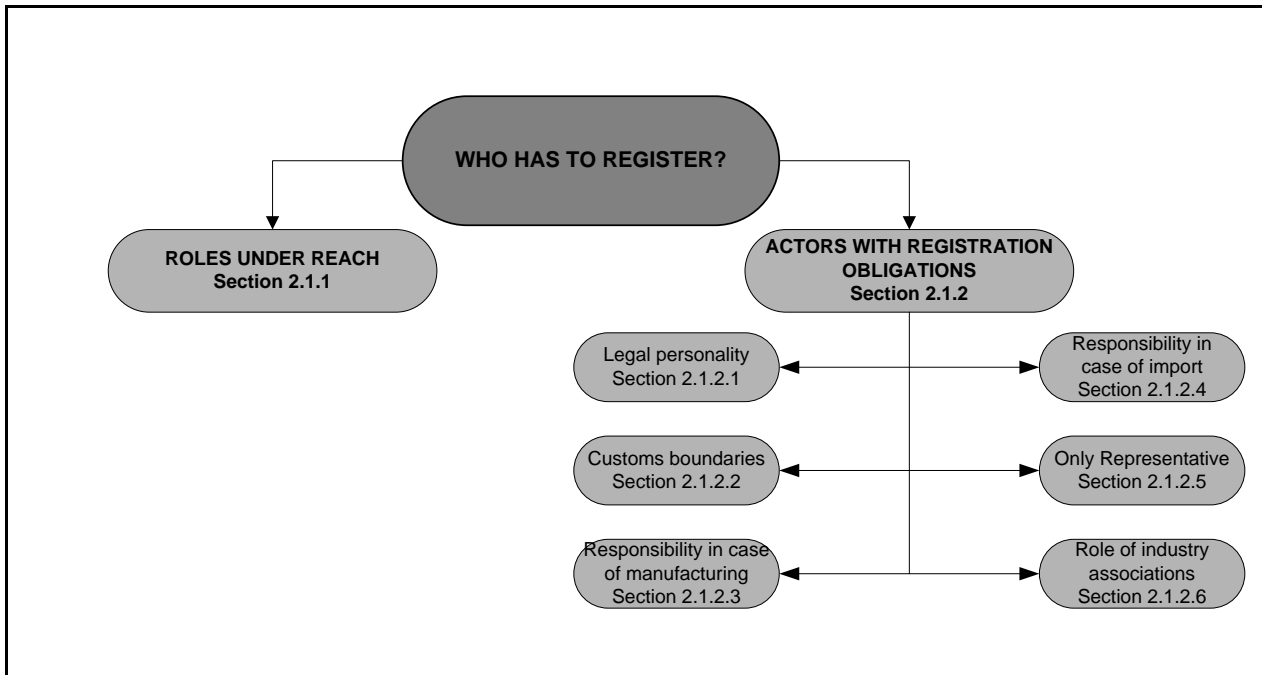
The registration obligations apply to the individual substances themselves, independently of whether they are on their own, in a mixture or in an article. In other words, only substances must be registered under REACH, mixtures or articles do not.

1 **2. Registration obligations**

2 **2.1 Who has to register?**

3 **Aim:** The aim of this chapter is to explain which actors have registration obligations
4 and responsibilities under REACH.

5 **Structure:** The structure of this chapter is as follows:



6 **2.1.1 Roles under REACH**

7 The obligation to register a substance applies only to certain actors established in the EU.

8 One legal entity (see section 2.1.2.1 Legal personality) may have various roles depending on
9 its activities, even for the same substance. **Therefore, it is very important that companies**
10 **correctly identify their role or roles in the supply chain for each substance they**
11 **handle**, because this will be a decisive factor in determining their registration obligations.

12 The following roles may be adopted in the context of REACH:

Manufacturer: means any natural or legal person established within the EU who manufactures a substance within the EU (Article 3(9)).

Manufacturing: means production or extraction of substances in the natural state (Article 3(8)).

13

Importer: means any natural or legal person established within the EU who is responsible for import (Article 3(11)).

Import: means the physical introduction into the customs territory of the EU (Article 3(10)).

Placing on the market: means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market (Article 3 (12)).

Only Representative: means a natural or legal person established in the EU and appointed by a manufacturer, formulator⁴ or producer of an article established outside the EU to fulfil the obligations of importers (Article 8).

Downstream user: means any natural or legal person established within the EU, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities (Article 3(13)).

Use: means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation (Article 3(24)).

Producer of an article: means any natural or legal person who makes or assembles an article within the EU (Article 3(4)).

Distributor: means any natural or legal person established within the EU, including a retailer, who only stores and places on the market a substance, on its own or in a mixture, for third parties (Article 3(14)).

Supplier of a substance or a mixture: means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture (Article 3(32)).

An important point to bear in mind is that the terms used in REACH to describe the various roles have very specific definitions and meanings which do not always correspond with how they might be interpreted in other fora.

Example:

A company purchasing registered substances **from within the EU** and then formulating these into mixtures (e.g. paints) would be regarded as a downstream user under REACH. In layman's terms this company might be considered a *manufacturer* of paints. However, within the context of REACH the company would not be a *manufacturer of a substance* and so would have no registration obligations for these substances.

2.1.2 Actors with registration obligations

The only actors with registration obligations are:

- EU **manufacturers and importers of substances on their own or in mixtures** in quantities of one tonne or more per year.
- EU **producers and importers of articles** in case that the article contains a substance in quantities over 1 tonne per year and the substance is intended to be released under normal or reasonably foreseeable conditions of use.

⁴ A formulator is a producer of mixtures in the context of the REACH Regulation.

- 1 The registration obligations of importers can be taken over by an **only representative**
- 2 established in the EU and appointed by a manufacturer, formulator or article producer
- 3 established outside the EU to fulfil the registration obligations of importers (see section 2.1.2.5
- 4 Only representative of a 'non-EU manufacturer').

Examples of when registration is needed

- A manufacturer of a substance who uses the manufactured substance themselves has a duty to register each substance manufactured in quantities of 1 tonne or more per year, unless exemptions apply, and will have to include information on their own use(s) and any identified uses of their customers in their registration.
- An importer of a mixture must register those substances which are present in the imported mixture in quantities of 1 tonne or more per year unless exemptions apply. They will have to include information in their registration on the identified use(s) of the substances in the mixture. There is no obligation for importers of mixtures to register the mixtures as such, indeed mixtures cannot be registered.

Examples of when registration is not needed

- Any user of substances not manufactured or imported by themselves, is a downstream user and has no obligation to register these substances.
- An importer of a substance, a mixture or an article, who is importing from a non-EU company who has appointed an only representative will be considered as a downstream user if the quantities of the substance they import are covered by this registration. Therefore, the importer does not need to register. The non-EU company needs to inform the importer of the appointment. In addition, the only representative must have an up-to-date information on the importer's identity and quantity of imported substance.
- A manufacturer or importer of a substance which is exempted from registration under REACH has no obligation to register that substance.

5

6 2.1.2.1 Legal personality

7 Only a natural or legal person established in the EU can be a registrant. REACH-IT and IUCLID
8 as well as the current guidance use the term '**legal entity**' to refer to such a natural or legal
9 person having rights and obligations under REACH.

10 Although what constitutes a natural and a legal person is defined by the national laws of each
11 EU Member State, the following principles may be of interest:

- 12 • A 'natural person' is a concept applied in many legal systems to refer to human beings
13 who are capable and have the right to engage into contracts or commercial
14 transactions. These are usually people who have reached the age of legal maturity and
15 are in full possession of their rights (meaning that these rights have not been taken
16 away from them, for example due to a criminal conviction).
- 17 • A 'legal person' is a similar concept, applied in many legal systems to refer to
18 companies who have been endowed with legal personality by the legal system
19 applicable to them (the law of the Member State where they are established) and
20 therefore are capable of carrying rights and obligations, independently of the people or
21 other companies behind them (in the case of a 'société anonyme' or 'limited company',
22 their shareholders). In other words, the company usually has its own existence and its
23 assets do not coincide with those of its owners.

One legal person can work on different sites. It can also open so-called 'branch offices' which do not have separate legal personality from the main or head office. In such a case, it is the head office that has the legal personality and that must respect the provisions of REACH if it is established in the EU.

On the other hand, a legal person can also open 'daughter companies' or 'subsidiaries' in the EU in which it holds shares or another type of ownership. Such EU daughter companies have a different legal personality and therefore qualify as a 'legal person established in the Community' for the purposes of REACH. They are to be considered as different manufacturers and importers who each may be obliged to register for the respective quantities they manufacture or import. Often operators do not use the terms 'branch' and 'office' in this technical-legal sense and therefore it should be ascertained in detail whether the entity being referred to has legal personality or not.

In principle, each legal entity must submit its own registration for each individual substance. If a company group is composed of several legal entities (e.g. a parent company and its subsidiaries), each of those legal entities must submit its own registration. On the other hand, if one legal entity has two or more production plants which are not separate legal entities, then only one registration covering the different sites needs to be submitted by the legal entity.

Example:

International companies sometimes have several daughter companies in the EU acting as importers, often spread over several Member States. Each of those daughter companies, if they have legal personality, are legal persons within the meaning of REACH. Depending on the distribution of work within the group, each of them can be an 'importer' responsible for import. It is for the group or the individual companies to assign the tasks and the responsibilities to companies in the group.

2.1.2.2 Customs boundaries for manufacturing and import

REACH applies to the European Economic Area (EEA), i.e. the 27 EU Member States and Iceland, Liechtenstein and Norway. This means that imports from Iceland, Liechtenstein and Norway are not considered imports for the purposes of REACH.

Therefore, an importer of a substance from Iceland, Liechtenstein or Norway is not required to register the substance under REACH and is simply regarded as a distributor or downstream user. However, if the manufacturer of the substance is established in Iceland, Liechtenstein or Norway, they will be subject to the same registration obligations as all EU manufacturers.

Importers of a substance from Switzerland (a non-EU country not belonging to the EEA) will have the same obligations under REACH as any other importers.

Examples:

A formulator purchasing their substances in Germany or Iceland will be considered as a downstream user.

A formulator purchasing their substances in Switzerland or Japan and introducing them into the EU customs territory will be considered as an importer.

2.1.2.3 Who is responsible for the registration in case of manufacturing?

In case of manufacturing (see definition in section 2.1.1 Roles under REACH), the registration should be made by the legal entity who undertakes the process of manufacturing. Only manufacturers established in the EU are required to submit a registration for the substance they manufacture. The registration obligation also applies in the case that the substance is not marketed in the EU but exported outside the EU after manufacturing.

1 Who is the registrant in case of toll manufacturing?

2 A toll manufacturer (or subcontractor) is normally understood to be a company that
3 manufactures a substance in its own technical facilities following the instructions of a third
4 party in exchange for an economic compensation.

5 The substance is generally put on the market by the third party. Often this arrangement is
6 used for an intermediate step in the production process for which sophisticated equipment is
7 needed (distillation, centrifugation, etc.).

8 In this regard, the legal entity that manufactures the substance according to Article 3(8) on
9 behalf of the third party is to be considered a manufacturer for the purposes of REACH and is
10 required to register the substance they manufacture. If the legal entity practically undertaking
11 the manufacturing process is different from the legal entity owning the production facility, one
12 of these entities must register the substance.

13 For more details on the obligations of toll manufacturers under REACH please consult ECHA
14 fact sheet *Toll manufacturer under the REACH Regulation* available at:
15 <https://echa.europa.eu/publications/fact-sheets>.

16

17 2.1.2.4 Who is responsible for the registration in case of import?

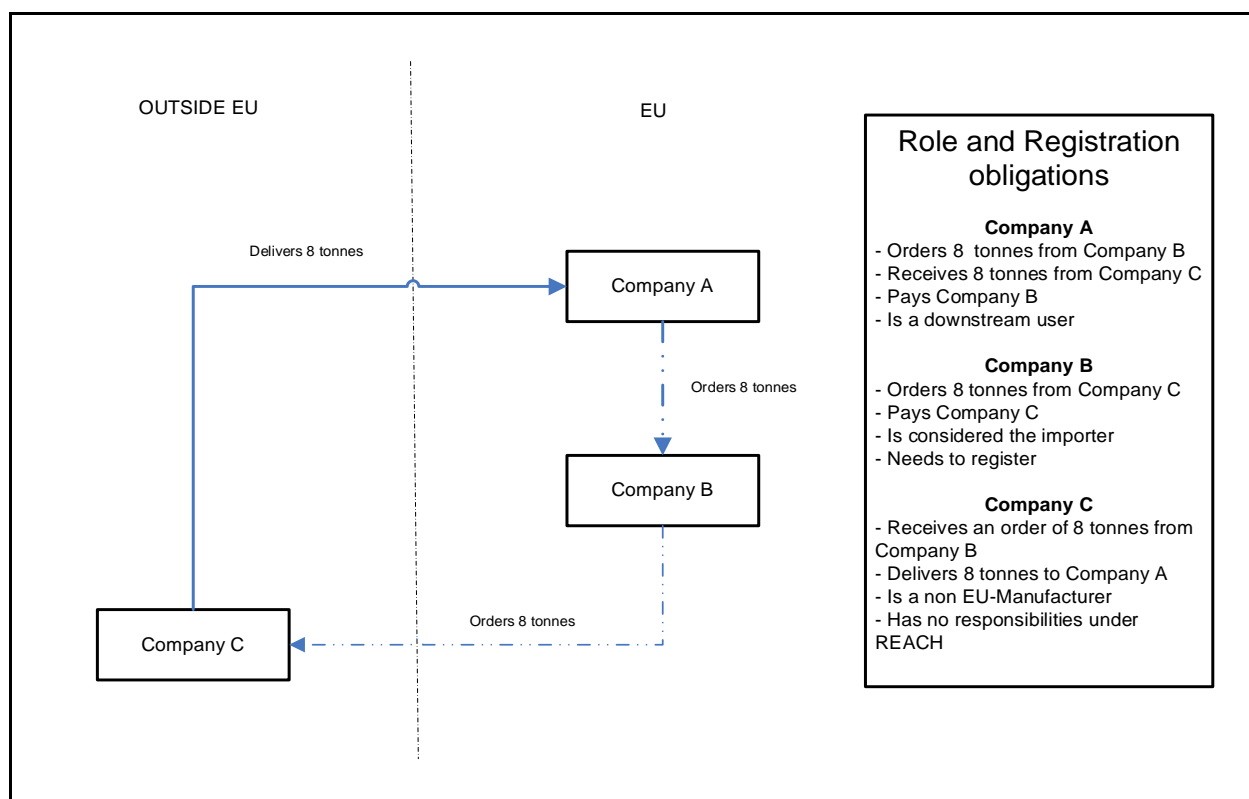
18 In case of import (see definition in section 2.1.1 Roles under REACH), the registration should
19 be made by the legal entity established in the EU who is responsible for the import. The
20 responsibility for import depends on many factors such as who orders, who pays, who is
21 dealing with the customs formalities or the 'INCOTERMS'⁵ chosen, but this might not be
22 conclusive on its own.

23 For example, in the case of a 'sales agency' established in the EU and acting as an
24 intermediary, i.e. transmitting an order from a buyer to a non-EU supplier (and being paid for
25 that service) but taking no responsibility whatsoever on the goods or the payment for the
26 goods and not having their ownership at any stage, then, the sales agency is not to be
27 considered as the importer for the purposes of REACH. The sales agency is not responsible for
28 the physical introduction of the goods.

29 When interpreting the term 'importer' according to the REACH Regulation, it is not always
30 possible to fall back upon the Regulation (EU) No 952/2013 laying down the Union Customs
31 Code (UCC). In many instances it will be the ultimate receiver of the goods (the consignee)
32 who is the legal entity that is responsible for the import. However, this is not always the case.
33 If for example company A (established in an EU country) orders goods from company B
34 (established in another EU country) who acts as a distributor, company A probably does not
35 know from where the goods originate. Company B may choose to order the goods from either
36 an EU manufacturer or from a 'non-EU manufacturer'. In case company B chooses to order
37 from a 'non-EU manufacturer' (company C) the goods may be delivered directly from company
38 C to company A to save on transportation costs. Because of this, company A will be stated as
39 the consignee on the documents used by the customs authorities and customs handling will
40 take place in company A's country. Payment for the goods is, however, settled between
41 companies A and B. In the present example company B is not a 'sales agency' as described
42 above, as the 'sales agency' does not choose the manufacturer from which to order the goods.
43 Because the decision whether to order goods from an EU or 'non-EU manufacturer' lies with
44 company B, this company (and not company A) should be considered the legal entity
45 responsible for the physical introduction of the goods into the customs territory of the EU,
46 while company A is a downstream user. The registration obligation consequently would lie with

⁵ International Commercial Terms - a set of international rules for the interpretation of trade terms.

- 1 company B. Company A on the other hand will have to be able to prove through
- 2 documentation to the enforcement authorities that it is a downstream user, for example by
- 3 showing that the order was placed to company B.



4

5 **Figure 2: Role and registration obligations of different actors in case of import**

6

- 7 The 'non-EU manufacturer' or supplier who is exporting a substance or mixture into the EU has
- 8 no responsibilities under REACH. The shipping company that is transporting the substance or
- 9 mixture normally has no registration obligation either. Exceptions may occur under specific
- 10 contractual arrangements if the shipping company is established in the EU and if it is
- 11 responsible for the introduction of the substance into the EU.

- 12 Typically, supply chains may include one or more companies who have the role of a distributor.
- 13 A company considering that it has the role of a distributor may actually qualify under REACH
- 14 as being the importer of the substance, following the guidelines above. If there is another
- 15 company that acts as an importer of the substance, then the distributor has mainly duties
- 16 related to the communication of information in the supply chain. The distributor duties are
- 17 explained in Appendix 1 of the *Guidance for downstream users* available at:
- 18 <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

- 19 In case an only representative has been appointed the only representative is responsible for
- 20 the registration (see next section) and the importers covered by this registration do not need
- 21 to register.

22

23 2.1.2.5 Only representative of a 'non-EU manufacturer'

- 24 Substances imported into the EU on their own, in mixtures or, under certain conditions, in
- 25 articles need to be registered by their EU importers. This implies that each individual importer

needs to register the substance(s) they import. However, under REACH, **a natural or legal person established outside the EU, who manufactures a substance, formulates a mixture or produces an article⁶ can appoint an only representative** to carry out the registration of the substance that is imported (as such, in a mixture or in an article) into the EU (Article 8(1)). This will relieve the EU importers importing from this non-EU entity and whose tonnage is covered by this registration from their registration obligations, as they will be regarded as downstream users.

An only representative is not the same as a third party representative (Article 4). A third party representative can be appointed by a manufacturer, importer or, where relevant, a downstream user to allow this potential registrant or data holder to remain anonymous in relation to other stakeholders in the data-sharing process. A third party representative cannot submit a registration dossier on behalf of the manufacturer or importer they represent. For more information on this see the Guidance on data-sharing at <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

Who can appoint an only representative?

According to Article 8(1), a 'non-EU manufacturer', being a natural or legal person who is manufacturing a substance, formulating a mixture or producing an article that is imported into the EU, can appoint an only representative to fulfil the registration obligations of the importers. 'Non-EU distributors'⁷ are not mentioned in Article 8(1) and can therefore not appoint an only representative.

REACH does not distinguish between direct and indirect imports into the EU. In other terms, REACH specifies which non-EU actors can appoint an OR, but it does not indicate that these non-EU actors must be the direct suppliers to the importer. Therefore, **it does not matter if there are other supply chain actors outside of the EU between the non-EU actor appointing an only representative and the importer**, as long as these have no impact on the substance. However, it is essential that there is a clear identification of who is the 'non-EU manufacturer' who has appointed the only representative and which imports the only representative covers with its registration.

Who can be an only representative?

An only representative is a legal entity established in the EU which has sufficient background in the practical handling of substances and the information related to them to be able to fulfil the obligations of importers.

What should a 'non-EU manufacturer' do when appointing an only representative?

A 'non-EU manufacturer' can only appoint one only representative per substance. The 'non-EU manufacturer' usually provides the only representative with up to date information on the EU importers which should be covered by the registration and the quantities imported into the EU. This information may also be supplied by other means (e.g. it may be notified directly to the only representative by the EU importers) depending on the arrangements made between the

⁶ For the cease of reference, the non-EU entities that are listed in Article 8(1) will be referred to in this document as 'non-EU manufacturer', even though they may be formulator of a mixture or producer of an article.

⁷ A 'non-EU distributor' is **not** a distributor for the purposes of REACH as they are not a natural or legal person **established in the EU** (as defined in Article 3(14)). An EU-based distributor cannot, of course, appoint an only representative.

1 'non-EU manufacturer' and the only representative.

2 The only representative registers the imported quantities depending on the contractual
3 arrangements between the 'non-EU manufacturer' and the only representative.

4 The 'non-EU manufacturer' needs to inform all the concerned EU importers in the same supply
5 chain that they have appointed an only representative to conduct the registration thus
6 relieving the importers from their registration obligations. The only representative's
7 registration should indicate the quantity of the imported substance it covers – be it the entire
8 import into the EU from a given 'non-EU manufacturer', or only specified quantities within that
9 total.

10 If a 'non-EU manufacturer' decides to change their only representative, they must
11 communicate this to ECHA. A change of only representative constitutes a change of legal
12 personality and the same obligations as described in section Update on the registrant's own
13 initiative of this guidance, apply. To prevent disputes, it is recommended to include clauses on
14 the eventuality of a later change of the only representative in the contracts between the 'non-
15 EU manufacturer' and the only representative. For more detailed information see the ECHA
16 practical guide *How to report changes in identity under REACH and CLP* available at:
17 <https://echa.europa.eu/practical-guides>.

18 **What are the consequences for the EU importers?**

19 When an importer receives information from a 'non-EU manufacturer' in their supply chain that
20 an only representative has been appointed to cover the registration obligations, this importer
21 will be regarded as a downstream user for the tonnage covered by the registration of the only
22 representative. This only concerns the tonnage imported from the 'non-EU manufacturer' that
23 is covered by the registration of the only representative. If this importer also imports the
24 substance from other non-EU suppliers, the importer still must register the tonnage imported
25 from these non-EU suppliers unless these have appointed only representatives to cover the
26 respective imports.

27 The appointment of an only representative by the 'non-EU manufacturer' creates the need for
28 importers to keep documentation on which imported quantities of the substance are covered
29 by the only representative registration and which imported quantities are not. In case of
30 import of mixtures, the importers will also need to know what quantity of the substance in a
31 mixture is covered by an only representative registration, as they would otherwise be subject
32 to a registration requirement themselves. This documentation will need to be presented to the
33 enforcement authorities upon request.

34 Although the importer will receive confirmation from the 'non-EU manufacturer' on the
35 appointment of the only representative, the importer should preferably also obtain
36 confirmation in writing from the only representative that their imported tonnage and use is
37 indeed covered by the registration submitted by the only representative. This would provide
38 the importer with the contact point to whom they, being regarded as a downstream user, can
39 make their use known, and would also give the importer a clear documentation that the
40 imports are indeed covered by the registration of the only representative. In addition, the
41 importer has an interest in obtaining sufficient information from the 'non-EU manufacturer' and
42 /or from the only representative in order to compile its safety data sheet, where relevant.

43 The importer, regarded as a downstream user, may decide to perform their own chemical
44 safety assessment (for further information see the *Guidance on downstream users* at
45 <https://echa.europa.eu/guidance-documents/guidance-on-reach>). This requires considerable
46 effort so it is advisable that the importer considers carefully the option of making its use
47 known.

| |
|--|
| The roles of only representative and importer are not interchangeable. Thus, it is not |
|--|

possible to update a dossier in order to change from one role to another.

The role of an only representative is substantially different from that of an importer, as the registration dossier submitted by an only representative ultimately belongs to the 'non-EU manufacturer'. While the registration of an only representative can cover multiple importers in the EU, it only covers imports from the one non-EU manufacturer that has appointed the only representative.

In contrast, an importer does not represent another legal entity but acts on their own behalf. An importer is physically introducing the substance into the EU customs territory and placing it on the market, and their registration covers all quantities of the substance imported in the EU, regardless of the non-EU source.

1

2 **Obligations of the only representative regarding the registration of substances**

3 The following paragraphs describe the role of the only representatives regarding their
4 registration obligations. An only representative is fully responsible and liable for fulfilling all
5 obligations of importers.

6 The registration dossier of the only representative should contain all uses of the importers
7 (now downstream users) covered by the registration. The only representative must keep an
8 up-to-date list of EU customers (importers) within the same supply chain of the 'non-EU
9 manufacturer' and the tonnage covered for each of these customers, as well as information on
10 the supply of the latest update of the safety data sheet.

11 Although the only representative is legally responsible for the registration, it can be anticipated
12 that it will be the 'non-EU manufacturer' that will provide them with all the necessary data for
13 the registration dossier.

14 An only representative must be able to document who they are representing and is advised to
15 attach a document from the 'non-EU manufacturer' appointing them as only representative in
16 their registration dossier. Although it is not mandatory to include this information in the
17 registration dossier, it needs to be presented to the enforcement authorities upon request.

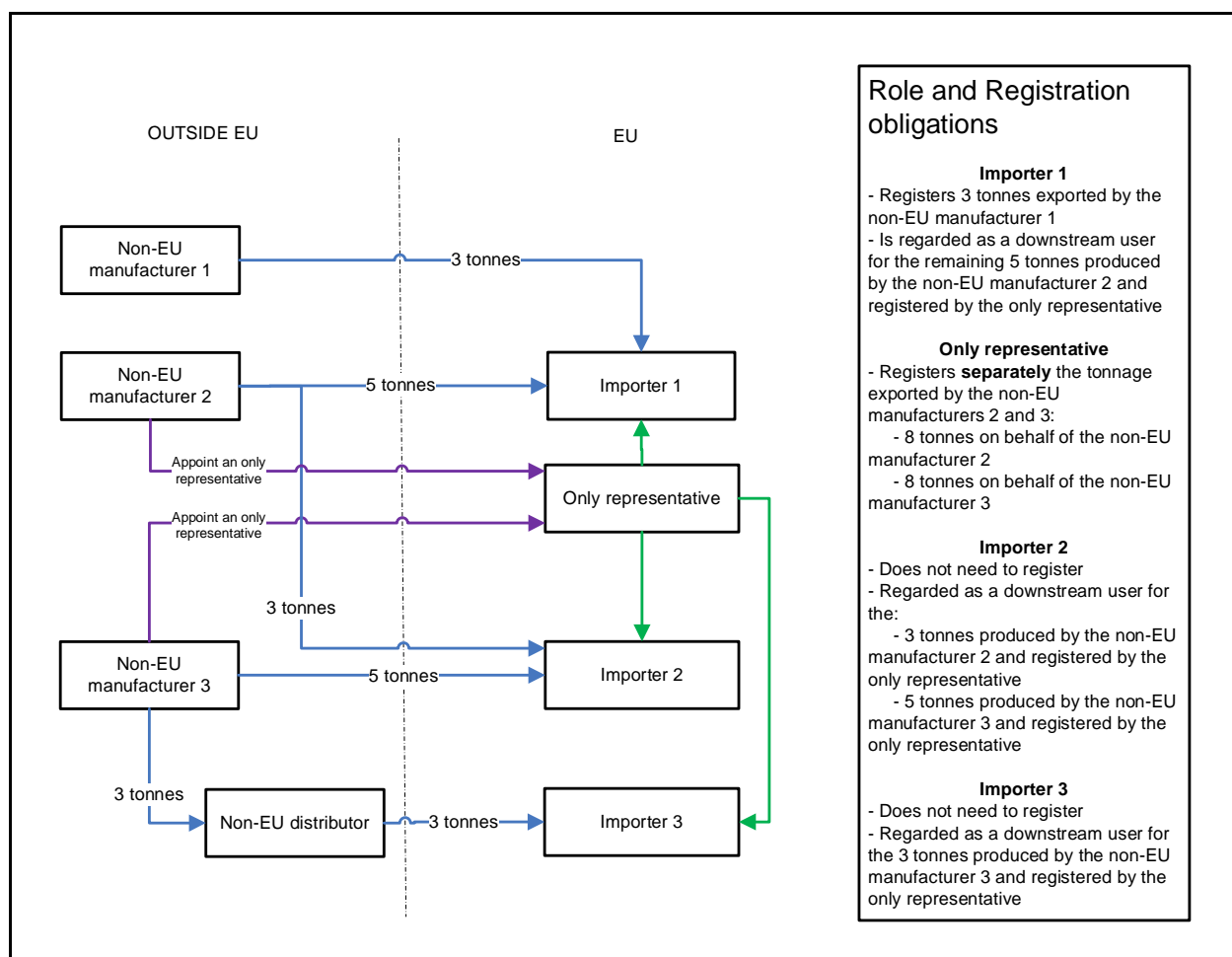
18 If several companies established outside the EU export substances into the EU, each company
19 constitutes a separate 'non-EU manufacturer' under REACH, even if they are part of the same
20 group, and may appoint an only representative. If the only representative acts on behalf of
21 several 'non-EU manufacturers', the only representative must submit a separate registration
22 for each of these manufacturers using separate **REACH-IT accounts**. One REACH-IT account
23 can cover only registrations from one 'non-EU manufacturer'. Separate registrations also
24 ensures the preservation of confidential business information (CBI) of the 'non-EU
25 manufacturer' and equal treatment with EU manufacturers can be ensured (EU manufacturers
26 must submit separate registration dossiers for each legal entity).

27 Each registration should cover the total tonnage of the substance included in the contractual
28 agreements between the only representative and the specific 'non-EU manufacturer'. The
29 information requirements for the registration dossier must be determined according to this
30 tonnage.

31 An only representative cannot declare to also be a manufacturer or importer in the same
32 registration dossier. If an only representative also manufactures or imports a substance, they
33 must submit a separate registration on their own behalf from a different REACH-IT account.

34 The only representative must declare the company size of the **non-EU company** that they
35 represent. The size of the non-EU company will determine the registration fee payable to
36 ECHA.

1



2

3 **Figure 3: Example of roles and registration obligations of different actors when an**
4 **only representative is appointed**

5

6 **Import of mixtures when an only representative is appointed**

7 An importer of mixtures is obliged to register the individual substances in the mixtures they
8 import and needs to know the chemical identity and the concentration of the substances in the
9 mixtures. If the 'non-EU manufacturer' of the mixture, or of the individual substances in the
10 mixture, appoints an only representative, it will be the only representative who will carry out
11 the registration of the individual substances instead of the importers.
12 The 'non-EU manufacturer' will inform the importers that an only representative has been
13 appointed. If the 'non-EU manufacturer' appoints separate only representatives for the
14 different substances in the mixture, or appoints only representatives for some of the
15 substances in the mixture, this information needs to be communicated clearly to the importers,
16 so that they are aware of which obligations they are relieved of and which obligations they still
17 have to fulfil regarding the registration of the substances.

18 In any case, the importers of the mixtures must be able to document which quantities of the
19 substances imported in the mixtures are covered by the registration dossier of the only
20 representatives and, where relevant, which quantities are covered by the registration dossier
21 of the importers themselves.

22

1

2 2.1.2.6 Role of industry associations and other types of service providers

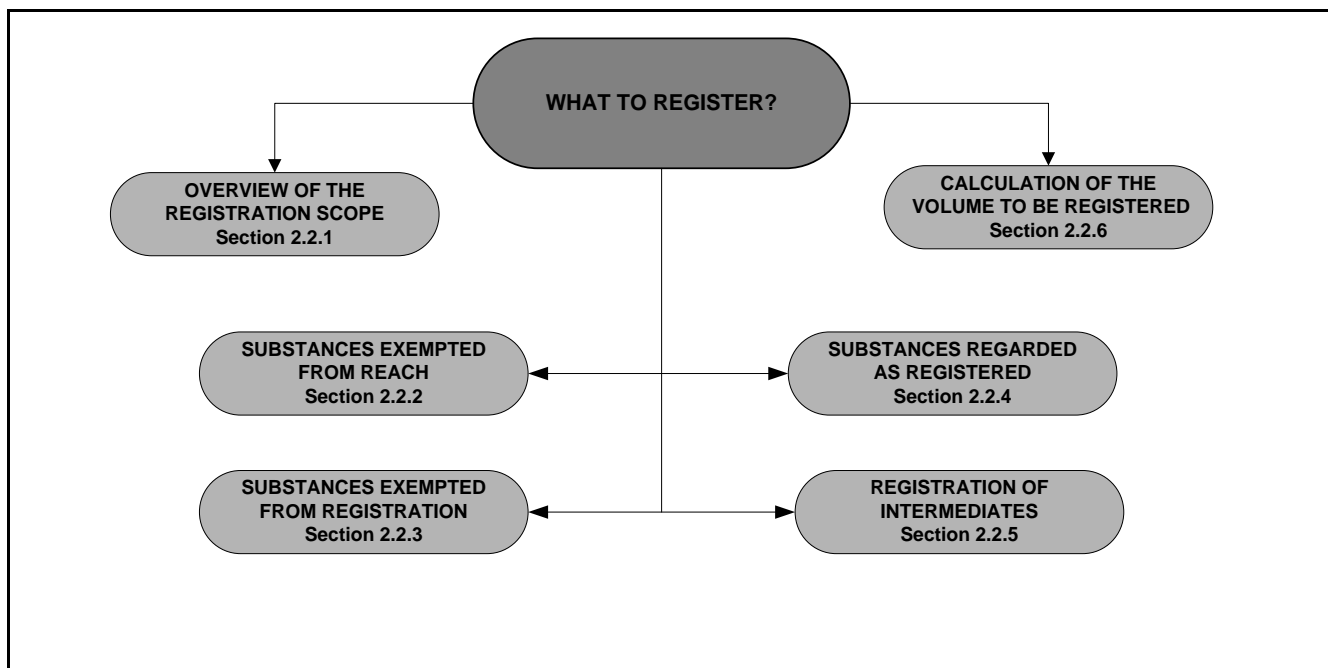
3 The actual registration of a substance can only be done by the manufacturer, importer or
 4 producer of an article, or by an only representative. It cannot be done by any third party
 5 including industry associations, unless they act as the only representative for a non-EU
 6 manufacturers.

7 However, industry associations can provide very valuable assistance to registrants for the
 8 preparation of registration dossiers and can help in co-ordinating the process. In addition, they
 9 may have valuable data on the substance, as well as information on chemical categorisation
 10 and read-across that can be used in the data-sharing process. They could also be appointed to
 11 represent a registrant in discussions with other registrants regarding preparation of the joint
 12 submission of hazard data and act as third party representative. They can include non-EU
 13 enterprises as members, who, even though having no direct registration obligations, can
 14 provide information and assistance through these associations.

15 **2.2 What to register?**

16 **Aim:** This chapter provides an outline of which substances are subject to registration
 17 requirements and a detailed explanation of the circumstances under which the
 18 various exemptions from registration are applicable. Because the tonnage of
 19 manufacture or import of each substance is critical in determining whether and
 20 how to register, this chapter also outlines methods for calculating the volume to
 21 be registered.

22 **Structure:** The structure of this chapter is as follows:



23 **2.2.1 Overview of the registration scope**

24 Each company that manufactures or imports a substance in quantities of one tonne or more
 25 per year must register it unless this substance is exempted from the scope of registration. The
 26 registration requirement applies to all substances irrespective of whether they are hazardous
 27 or not, and includes substances on their own, in mixtures or substances in articles when they
 28 are intended to be released under normal or reasonably foreseeable conditions of use.

For all registrations, a registration dossier must be prepared and submitted electronically to ECHA. The information that the registrant must provide in the registration dossier will depend on the volume i.e the tonnage of the substance that the registrant manufactures or imports per year.

The definition of a substance under REACH (see section 1.3 Substances, mixtures and articles) is very broad. It includes substances which are already closely regulated by other legislation such as radioactive substances, medicines, food or feedingstuffs, biocides or pesticides. These substances are completely or partially exempted from REACH or from the registration requirements (see the following sections below). Other substances within the scope of specific pieces of legislation, e.g. food-packaging and cosmetics, are subject to registration, even though they may have reduced risk assessment requirements under REACH (see section 4.2.1 Structure of the registration dossier) or are not subject to REACH provisions on communication in the supply chain (e.g. cosmetic products, mixtures in medical devices).

When the manufacturer or importer intends to register more than one composition of a substance in the same registration dossier, they would need to ensure that the relevant Annex VII-XI information takes into account all compositions or forms registered, and that this is transparently reported in the corresponding registration dossiers submitted to ECHA.

For specific advice on preparation of the registration dossiers for nanomaterials, please consult the Appendix for nanoforms applicable to the *Guidance on Registration and Substance Identification* available at: <http://echa.europa.eu/guidance-documents/guidance-on-reach>.

This guidance focuses on the registration requirements for substances on their own and in mixtures. For substances in articles the reader is advised to consult the *Guidance on requirements for substances in articles* available at <http://echa.europa.eu/guidance-documents/guidance-on-reach>, where the specific conditions and obligations that the REACH Regulation imposes on producers or importers of articles are explained in detail.

2.2.2 Substances exempted from the REACH Regulation

2.2.2.1 Radioactive substances

Radioactive substances are substances that contain one or more radionuclides of which the activity or concentration cannot be disregarded as far as radiation protection is concerned. In other words, they are substances which give off such a degree of radiation that there is a need to protect people and the environment against that radiation. Radioactive substances are covered by specific legislation⁸ and therefore exempted from REACH.

Legal reference: Article 2 (1) (a)

2.2.2.2 Substances under customs supervision

If substances (on their own, in a mixture or in an article) are in temporary storage, in a free zone or a free warehouse with a view to re-exportation, or in transit, and remain under customs supervision without undergoing any treatment or processing, they are not subject to

⁸ Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ L 13, 17.1.2014, p. 1)

1 the REACH Regulation.

2 Importers of substances who wish to rely on the exemption from REACH are therefore advised
3 to ensure that these substances meet all the following conditions:

- 4 • the substances are put in a free zone or free warehouse as defined under customs
5 legislation or placed under another relevant customs procedure (transit procedure,
6 temporary storage),
- 7 • the substances are kept under supervision of the customs authorities, and
- 8 • the substances do not undergo any form of treatment or processing during their stay in
9 the EU. A free zone or a free warehouse on the EU territory is part of the EU.

10
11 In case of doubt, it is recommended to contact the customs authorities, who can provide more
12 detailed clarification on the possible customs regimes established by Regulation (EU) No
13 952/2013 laying down the Union Customs Code (UCC) which may be applied to substances
14 merely passing through the EU.

15 *Legal reference: Article 2(1)(b)*

16

17 2.2.2.3 Substances used in the interest of defence and covered by national 18 exemptions

19 The REACH Regulation allows individual Member States to exempt in specific cases certain
20 substances (on their own, in a mixture or in an article) from the application of REACH, in the
21 interests of defence.

22 This exemption will only apply once a Member State has taken a formal measure, in
23 accordance with its national legal system, to exempt in specific cases certain substances from
24 REACH. The exemption will, naturally, only apply within the territory of the Member State
25 having fixed the exemption.

26 It can be expected that Member States who decide on such an exemption will inform the
27 suppliers concerned; however, if in doubt, manufacturers, importers and producers of mixtures
28 or articles which are used by Member State military forces or authorities in a defence context,
29 are advised to contact those forces or authorities to check if an exemption has been granted
30 which may cover their substance, mixture or article.

31 To further harmonise national practices towards REACH defence exemptions, a voluntary Code
32 of Conduct on REACH Defence Exemptions was adopted by European Defence Agency
33 participating Member States.

34 More information on national exemptions in the interest of defence in individual Member States
35 is available on the European Defence Agency website at <http://www.eda.europa.eu/reach>.

36 *Legal reference: Article 2(3)*

37

2.2.2.4 Waste

Waste is defined in the Waste Framework Directive 2008/98/EC⁹ as any substance or object which the holder discards or intends or is required to discard. This may be waste from households (e.g. newspapers or clothes, food, cans, bottles), from professional businesses or from industry (e.g. tyres, slag, window frames that are discarded).

The requirements of the REACH Regulation for substances, mixtures and articles do not apply to waste: waste operations are not downstream uses under REACH. This does not mean that substances in their waste stage are totally exempted from REACH. When a chemical safety assessment is required (see section 4.2.1 Structure of the registration dossier) it must cover the whole life cycle of the substance in the exposure assessment, including the waste stage. Additional information on this can be found in the *Guidance on waste and recovered substances* available at: <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

It is important to remark that once waste is recovered (the so called “end of waste status” under Directive 2008/98/EC) and, in this recovery process, another substance, mixture or article is produced, the REACH requirements will apply to the recovered material in the same way as to any other substance, mixture or article manufactured, produced or imported in the EU. In specific cases, where a substance recovered in the EU is the same as a substance which has already been registered, an exemption from the registration obligation may apply. More information on recovery is available in section 2.2.3.5 Recovered substance already registered.

Legal reference: Article 2(2)

2.2.2.5 Non-isolated intermediates

Intermediates are a type of use of substances for which specific provisions have been laid down under REACH for reasons of workability and because of their special nature. An intermediate is defined as a ‘*substance that is manufactured for and consumed in or used for chemical processing to be transformed into another substance*’ (Article 3 (15)).

REACH distinguishes between non-isolated intermediates and isolated intermediates. **Non-isolated intermediates are not covered by REACH.** REACH applies however to isolated intermediates, although they may benefit from reduced registration requirements under specific conditions. Isolated intermediates are discussed further in section 2.2.5 Obligations related to registration of intermediates.

A non-isolated intermediate is defined as ‘*an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipe work for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture (Article 3 (15) (a))*’. Intermediates falling within the above definition are therefore exempted from REACH.

Quantities of the same substance may be used in other operations or under other conditions, which implies that those quantities cannot be regarded as non-isolated intermediates. Only the quantities of the substance used under the conditions qualifying it as a non-isolated intermediate are exempted from REACH. For the remaining quantities, the relevant

⁹ Directive 2008/98/EC repeals and replaces Directive 2006/12/EC which is mentioned in Article 2(2) of the REACH Regulation.

1 requirements under REACH must be fulfilled.

2 Additional information on intermediates can be found in the *Guidance on intermediates*
3 (<https://echa.europa.eu/guidance-documents/guidance-on-reach>).

4 *Legal references: Article 2(1)(c), Article 3(15)(a)*

5 2.2.2.6 Transported substances

6 The REACH Regulation exempts from its provisions the carriage of dangerous substances and
7 dangerous substances in dangerous mixtures by rail, road, inland waterway, sea or air.
8 However, for all other activities (manufacture, import, use) related to the concerned
9 substances other than its transport, the REACH requirements apply (unless covered by another
10 exemption).

11 EU transport legislation (for example, Directive 2008/68/EC on the inland transport of
12 dangerous goods, with subsequent amendments) already regulates the safety conditions of
13 transport of dangerous substances by various means of transport and thus such transport is
14 exempted from the provisions of the REACH Regulation.

15 *Legal reference: Article 2(1)(d)*

16

17 2.2.3 Substances exempted from registration

18 Substances that present minimum risk because of their intrinsic properties (like water,
19 nitrogen, etc.) and substances for which registration is deemed inappropriate or unnecessary
20 (such as substances occurring in nature like minerals, ores and ores concentrates if they are
21 not chemically modified) are exempted from registration.

22 Polymers are exempted from the requirement to register while the monomer substances or
23 any other substances they consist of must be registered provided certain conditions are
24 fulfilled.

25 REACH also exempts from registration certain substances that are adequately regulated under
26 other legislations, like substances used in food or feedingstuffs or in medicinal products, where
27 the relevant criteria are met.

28 Additional exemptions from registration apply to substances that are already registered and
29 are either exported and re-imported into the EU or recovered through a recovery process in
30 the EU.

31 Substances exempted from the obligation to register may still be subject to authorisation or
32 restriction provisions under REACH. The specific conditions under which the exemptions from
33 registration under REACH apply are described in detail below.

34

35 2.2.3.1 Food or feedingstuffs

36 When a substance is used in food for humans or feedingstuffs for animals in accordance with
37 the Food Safety Regulation (EC) No 178/2002, the substance does not have to be registered.
38 This includes the use of the substance:

- 39
- 40 • as a food additive in foodstuffs within the scope of Regulation (EC) No 1333/2008;
 - 41 • as a flavouring in foodstuffs within the scope of Council Regulation (EC) No 1334/2008 and
Commission Implementing Regulation (EU) No 872/2012;

- as an additive in feedingstuffs within the scope of Regulation (EC) No 1831/2003;
- in animal nutrition within the scope of Regulation (EC) 767/2009.

The Food Safety Regulation already requires that food for humans cannot be placed on the market unless it is safe, i.e. not injurious to human health and fit for human consumption. Similarly, according to the Food Safety Regulation, feed is not to be placed on the market or fed to food-producing animals unless it is safe, i.e. not having an adverse effect on human or animal health and not making the food derived from food-producing animals unsafe for humans. Moreover, for food additives, food flavourings and their source materials, feedingstuff additives and animal nutrition, specific pieces of EU legislation already create a system for authorisation of substances for those particular uses. Therefore, registration under REACH would be considered as double regulation.

Accordingly, it is in the interest of manufacturers and importers to be aware if the substance that they manufacture/import is used in food or feedingstuffs in accordance with the Food Safety Regulation, both by themselves and their clients. In that case they will not have to register for the quantities of the substance which are used in this way.

Quantities of the same substance used for other uses than food and feedingstuffs are not exempted from registration. Only the quantities of the substance used in food and feedingstuffs are exempted from the registration obligation under REACH.

Example:

A manufacturer manufactures 100 tonnes of sulphuric acid in year X. 50 tonnes are used in foodstuffs in accordance with the Food Safety Regulation, 50 tonnes are used for the formulation of a non-food mixture. The 50 tonnes used for the formulation of the non-food mixture will be subject to the registration provisions of the REACH Regulation while the 50 tonnes used in foodstuffs are exempted.

Legal reference: Article 2(5)(b)

20

2.2.3.2 Medicinal products

When a substance is used in a medicinal product within the scope of:

- either Regulation (EC) No 726/2004 on Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;
- or Directive 2001/82/EC on the Community code relating to veterinary medicinal products;
- or Directive 2001/83/EC on the Community code for medicinal products for human use;

the substance does not have to be registered under the REACH Regulation for that use. The same exemption applies whether the substance is manufactured in the EU and used in the EU or exported to a third country. Imports of substances for that use from a third country are also covered by the same exemption and do not have to be registered under REACH.

Accordingly, it is in the interest of manufacturers and importers to be aware if the substance that they manufacture/import is used in pharmaceutical related uses, in accordance with the legislations indicated above, both by themselves and their clients. In that case they will not have to register under REACH to the extent that the substance is used in such medicinal products.

The exemption does not distinguish between active or non-active ingredients as it applies to

- 1 any substance used in medicinal products. Excipients used in medicinal products are therefore
2 also exempted from registration.
- 3 Quantities of the same substance used for other uses than pharmaceuticals are not exempted.
4 Only the quantities of the substance used in medicinal products are exempted from the
5 registration obligation.

Example:

A manufacturer manufactures 100 tonnes of salicylic acid in year X. 50 tonnes are used in medicinal products within the scope of Directive 2001/83/EC on the Community code relating to medicinal products for human use, 50 tonnes are used for the formulation of a non-medicinal mixture. The 50 tonnes used for the formulation of the non-medicinal mixture will be subject to the registration provisions, while the 50 tonnes used in medicinal products are exempted from registration.

6 *Legal reference: Article 2(5)(a)*

7

8 **2.2.3.3 Substances included in Annex IV of the REACH Regulation**

9 Annex IV lists a number of substances for which it is understood that sufficient information is
10 available to consider them as causing minimum risk to human health and the environment.
11 These substances are typically of natural origin and the list of exempted substances includes,
12 for example, water and nitrogen. Substances included in Annex IV are exempted from the
13 registration provisions.

14 The list is largely based on the exemptions from Regulation (EEC) No 793/93 on risk
15 evaluation of existing substances, although more substances were added. The registration
16 exemption applies to the substance as such, not to a particular use.

17 *Legal reference: Article 2(7)(a)*

18

19 **2.2.3.4 Substances covered by Annex V of the REACH Regulation**

20 Annex V lists thirteen broad categories of substances for which registration is deemed
21 inappropriate or unnecessary. The registration exemption applies to the substances as such,
22 provided that they meet the conditions for the exemption which are given in the particular
23 category of Annex V.

24 The reader is advised to consult Annex V directly on the REACH text available at
25 <https://echa.europa.eu/regulations/reach/registration/information-requirements> and the
26 *Guidance for Annex V* (<https://echa.europa.eu/guidance-documents/guidance-on-reach>) if in
27 need of more detailed information on any category of substances. The guidance provides
28 explanations and background information for applying the different exemptions and clarifies
29 when an exemption can be applied and when not.

30 *Legal reference: Article 2(7)(b)*

31

32 **2.2.3.5 Recovered substance already registered**

33 The REACH Regulation exempts from registration substances which are recovered **in the EU**,
34 provided a number of conditions are met. Recycling is a form of recovery and therefore
35 covered by this exemption.

'Recovery' is currently defined in EU law as any of the recovery operations provided in Annex II of the Waste Framework Directive 2008/98/EC. This non-exhaustive list covers the following operations:

- R1 Use principally as a fuel or other means to generate energy
- R2 Solvent reclamation/regeneration
- R3 Recycling/reclamation of organic substances which are not used as solvents (including composting and other biological transformation processes)
- R4 Recycling/reclamation of metals and metal compounds
- R5 Recycling/reclamation of other inorganic materials
- R6 Regeneration of acids or bases
- R7 Recovery of components used for pollution abatement
- R8 Recovery of components from catalysts
- R9 Oil re-refining or other reuses of oil
- R10 Land treatment resulting in benefit to agriculture or ecological improvement
- R11 Use of waste obtained from any of the operations numbered R1 to R10
- R12 Exchange of waste for submission to any of the operations numbered R1 to R11
- R13 Storage of waste pending any of the operations numbered R1 to R12 (excluding temporary storage, pending collection, on the site where the waste is produced).

For more information on the criteria for defining when waste is no longer considered to be waste, refer to the legislative framework of the Waste Framework Directive and the criteria developed at national and EU level. A recovered substance will only fall within the scope of the REACH Regulation if it meets the end of waste criteria and as such is no longer waste.

The REACH Regulation sets the following conditions which must be respected to benefit from the exemption from registration:

- (1) The same substance must have been registered. This means that if, for some reason, the same substance has not been registered at the manufacturing or import stage, the recovered substance must be registered.
The legal entity performing the recovery should check whether a registration exemption applies to the recovered substance. If this is the case, then that exemption can of course be invoked.
- (2) The substance must be the same (the sameness of the substance must be assessed according to the criteria defined in *Guidance for identification and naming of substances under REACH and CLP* available at: <https://echa.europa.eu/guidance-documents/guidance-on-reach>). If the substance is modified in the recovery and the modified substance has not been registered, then the exemption from registration for recovered substance does not apply.
- (3) The legal entity that did the recovery must have available:
 - the information that is contained in a safety data sheet (see section 6.1 Provide a safety data sheet (SDS) to customers); or

- if the substance is supplied to the general public, sufficient information to enable users to take the necessary protection measures; or
- if a safety data sheet is not required, the information on any authorisation or restriction on the substance and other relevant information necessary to identify and apply risk management measures, as applicable (see section 6.2 Provide other information to customers).

The form in which this information has to be available to the company carrying out the recovery is not specified in REACH. It is however important to remark that recovery operators, relying or not on this exemption from registration, must comply with their duties regarding the provision of information on the substance down the supply chain, as specified in sections Provide a safety data sheet (SDS) to customers and Provide other information to customers.

This exemption does not require that the substance has been registered by an actor of the supply chain leading to the waste generation. It is sufficient that the substance has been registered by any registrant.

More detailed information can be found in the *Guidance on waste and recovered substances* available at: <https://echa.europa.eu/guidance-documents/guidance-on-reach>. The guidance explains in detail the conditions under which recovered substances may be exempted from registration and provides advice on how to fulfil the different criteria. The guidance also presents the recovery process of specific materials such as paper, glass, and metals in relation with the requirements of the REACH Regulation. The reader is strongly advised to become familiarised with the guidance if they intend to register or claim an exemption from registration for a recovered substance.

Legal reference: Article 2 (7) (d)

2.2.3.6 Re-imported substance

In cases where a substance is first manufactured in the EU, then exported – for example, to be formulated into a mixture – and then brought back into the EU again – for example, to be marketed or for further processing – this could lead to a double registration obligation if it happens within the same supply chain: first at the stage of original manufacture, by the original manufacturer, and a second time at the stage of import back into the EU, by a re-importer down in the same supply chain (who may or may not be the original manufacturer). Therefore, substances which have been registered, exported and then re-imported are exempted from registration under certain conditions.

The following conditions must be fulfilled to benefit from this exemption:

- (1) The substance must have been registered before it was exported from the EU. This means that if, for some reason, the substance was not registered at the manufacturing stage, the substance must be registered upon re-import.
- (2) The substance already registered and exported must be the same, as the substance being re-imported, on its own or in a mixture (the sameness of the substance must be assessed according to the criteria defined in the *Guidance for identification and naming of substances under REACH and CLP* available at: <https://echa.europa.eu/guidance-documents/guidance-on-reach>). For example, if the exported substance itself was modified outside the EU and therefore it is not the same substance as that which is now being re-imported, the re-imported substance must be registered.

Again, the reason is clear: if the substance is not the same, it has not yet been registered (the registration information will be different), and therefore there will not be duplication of registrations.

(3) The substance must not only be the same but it must actually proceed from the same supply chain in which the substance was registered.

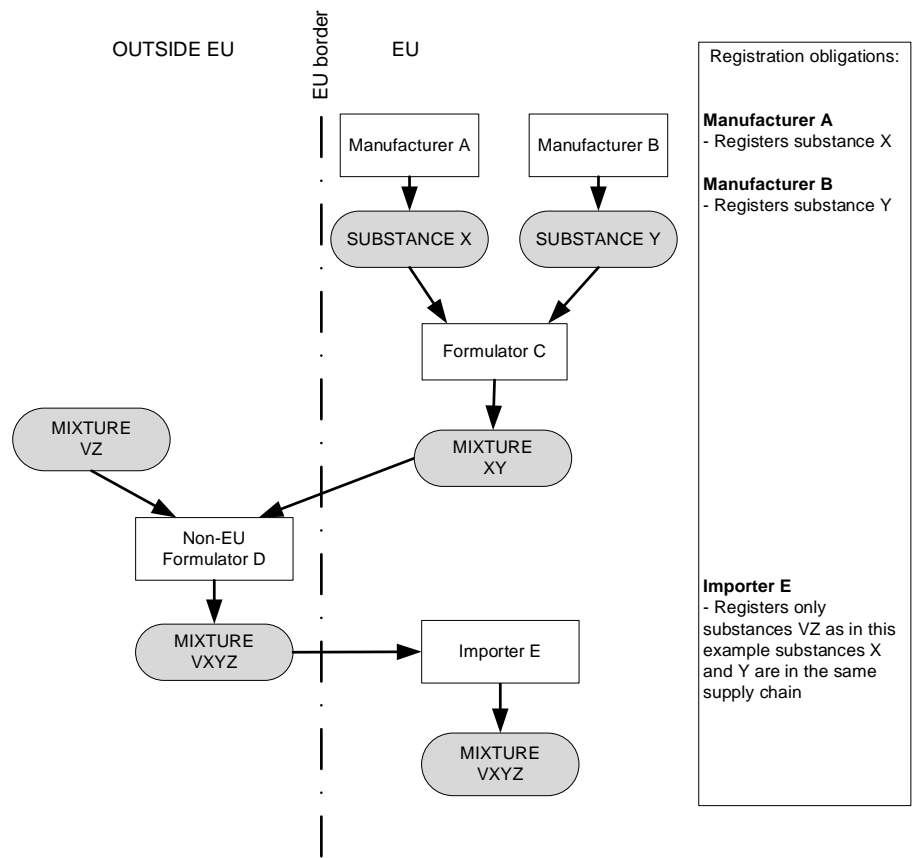
(4) The re-importer must have been provided with information on the exported substance, and that information must comply with the requirements established under REACH for the provision of information down the supply chain. The required information is described in detail in sections Provide a safety data sheet (SDS) to customers and Provide other information to customers.

The two examples below illustrate the application of this exemption.

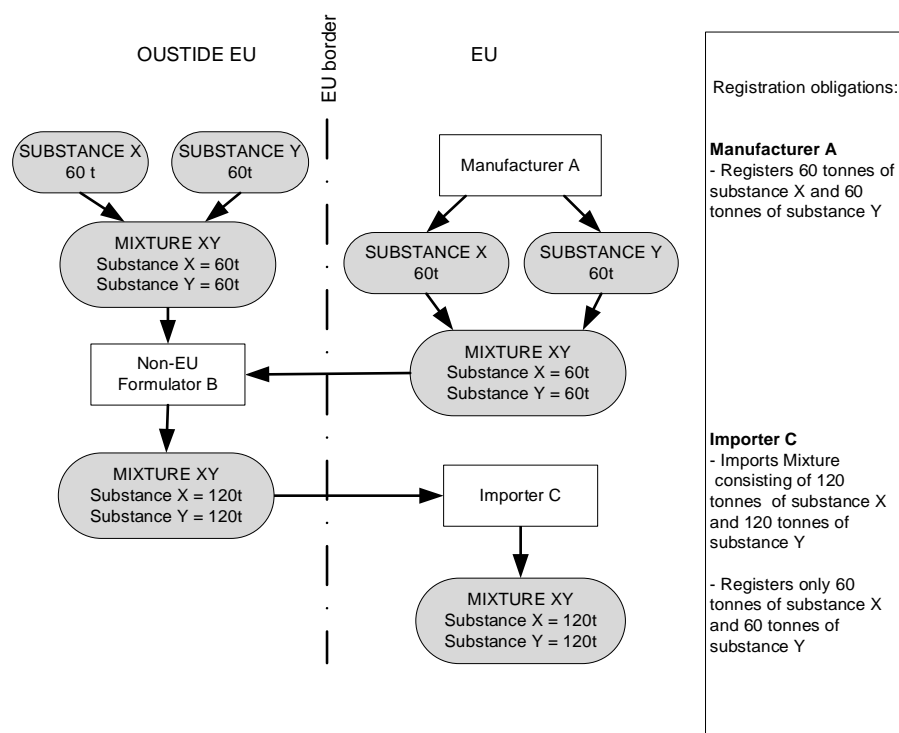
In Example 1 two substances are manufactured in the EU, and duly registered. These substances are then formulated to a mixture in the EU and exported. Outside the EU, the mixture is incorporated into another mixture with two more components. When this mixture is imported into the EU, only those substances in the mixture that have not yet been registered are subject to registration obligation.

In Example 2 the starting point is the same: two substances are manufactured in the EU, and duly registered. These substances are then formulated to a mixture in the EU and exported. Outside the EU, this mixture is formulated with volumes of the same two substances that are sourced from non-EU companies. This increased volume of the mixture is then imported to the EU. In this case, only the re-imported volumes of the substances that have already been registered, benefit from the registration exemption.

Example (1)



Example (2)



Legal reference: Article 2(7)(c)

2.2.3.7 Polymers

A polymer means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:

- a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;
- less than a simple weight majority of molecules of the same molecular weight.

In the context of this definition a monomer unit means the reacted form of a monomer substance in a polymer (Article 3(5)).

Owing to the especially extensive number of different polymer substances on the market, and since polymer molecules are generally regarded as representing a low concern in relation to their high molecular weight, this group of substances is exempted from registration. Manufacturers and importers of polymers must however register the monomer substances or other substances used for the manufacture of the polymers if all the following conditions are met:

- a) the monomer substances or other substances have not been already registered by their supplier or another actor up their supply chain;
- b) the polymer consists of 2% weight by weight or more of such monomer substances or other substances in the form of monomer units and chemically bound substances;
- c) the total quantity of such monomer substances or other substances makes up one tonne or more per year (for further information on how to calculate the total quantity in this context the reader should consult the *Guidance for monomers and polymers* available at: <https://echa.europa.eu/guidance-documents/guidance-on-reach>).

Therefore, the manufacturer or importer of a polymer will not need to register the monomer substance, or any other substance chemically bound to the polymer, if these have already been registered by the supplier or another actor up their supply chain. For most polymer manufacturers the situation will generally be that their monomers and other substances will be registered by the suppliers of these substances. However, for an importer of a polymer consisting of monomers or other substances fulfilling both the conditions (b) and (c) stated above, the monomers or other substances must be registered unless:

- an only representative has been appointed by the 'non-EU manufacturer' to fulfil the obligations of the importer. In this specific case, it is the duty of the only representative to proceed with the registration of the monomers;
- the monomer substances or any other substances used for the manufacture of the polymer have already been registered up the supply chain, e.g. if they have been manufactured within the EU and exported to a 'non-EU manufacturer';
- the monomer substances or any other substances used for the manufacture of the polymer are exempted from registration under Annex IV or V;
- the imported polymer is natural (i.e. it is the result of a polymerisation process that has taken place in nature, independently of the extraction process with which it has been extracted). In this case the monomer substances or any other substances in the form of monomeric units and chemically bound substances in natural polymer can, for practical reasons, be treated as 'non-isolated intermediates' and do not have to be registered.

More detailed information can be found in the *Guidance for monomers and polymers*. The guidance describes the provisions for monomers and polymers under REACH and provides clarification on how to deal with specific cases such as naturally occurring polymers and recycled polymers. The reader is advised to consult the document if in need of further information on these topics.

Legal references: Article 2(9), Article 6(3)

2.2.3.8 Substances used in product and process orientated research and development (PPORD)

One of the main objectives of REACH is to enhance innovation. To achieve this objective, REACH allows substances manufactured or imported at above 1 tonne per year to be exempted from registration under certain conditions, i.e. when they are used in product and process orientated research and development (PPORD).

Product and process orientated research and development is defined as *any scientific development related to product development or the further development of a substance, on its own, in mixtures or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance* (Article 3 (22)).

Substances manufactured or imported on their own or in mixtures, as well as substances

incorporated in articles or imported in articles¹⁰ for the purpose of PPORD in quantities of one tonne or more per year can be exempted from the registration obligation for a period of five years. To benefit from the exemption a company needs to submit a PPORD notification to ECHA according to Article 9(2). The notifier must pay a fee to ECHA when submitting the notification dossier in addition to providing certain information about the substances and the PPORD use.

The exemption applies only to the quantity of substance manufactured or imported only for the purpose of PPORD by a manufacturer, importer or producer of articles, themselves or in cooperation with listed customers referred to in Article 9(4). The notifier must identify these customers in their notification dossier including their names and addresses.

Upon request, ECHA may extend the exemption period for up to a further five years (or ten years in the case of medicinal products for human or veterinary use or substances that are not placed on the market). The notifier needs to present a sufficiently detailed research and development programme that allows to demonstrate that such an extension is justified.

ECHA will undertake a completeness check of the PPORD notification. The completeness check will verify whether all required information elements have been submitted and the payment of the fee has been received.

As detailed in Article 9(4), ECHA may decide to impose conditions to ensure that the substance will be handled only by staff of listed customers in reasonably controlled conditions and will not be made available to the general public and that remaining quantities will be re-collected for disposal after the exemption period. For this purpose, ECHA may ask a manufacturer or importer of a substance, who has submitted a PPORD notification, to provide additional information necessary to set conditions in accordance with Article 9(4). A manufacturer or importer must comply with any conditions imposed by ECHA according to Article 9(4).

Legal references: Article 3(22), Article 9

The REACH Regulation contains another notion related to research and development: scientific research and development. It concerns *any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume below 1 tonne per year*. As it concerns substances used in volume below 1 tonne per year, it is not relevant for the registration obligation.

Legal reference: Article 3(23)

For any detailed or specific issues on research and development see the *Guidance on Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD)* available at: <http://echa.europa.eu/guidance-documents/guidance-on-reach>.

2.2.4 Substances regarded as registered

Substances manufactured or imported for certain uses are regarded as being registered, and therefore no registration will be required for these substances for these uses. This applies to:

- substances in biocidal products as described below; and

¹⁰ Article 7(1) specifies the conditions under which the registration is required for substances contained in articles.

- substances in plant protection products as described below.

Similarly, a notification under Directive 67/548/EEC¹¹ (the so-called Notification of New Substances - NONS) that has been made before the entry into force of REACH is regarded as a registration.

2.2.4.1 Substances for use in biocidal products

According to Article 3(1)(c) of Regulation (EU) No 528/2012 (BPR) '**active substance**' means a substance or micro-organism that has an action on or against harmful organisms.

A biocidal product may be composed of only one active substance, with or without co-formulants, or it may be a mixture containing several active substances.

Active substances manufactured or imported for use in biocidal products are regarded as registered for the uses in biocidal products in the following situations:

- (1) The active substance has been approved in accordance with Regulation (EU) No 528/2012 (BPR), or
- (2) The active substance is under assessment in the review programme of existing active substances established under Article 16(2) of Directive 98/8/EC and continued under Article 89 of BPR.

The list of approved active substances is available on ECHA website at:

<http://echa.europa.eu/information-on-chemicals/biocidal-active-substances>

To check which active substances are in the review programme, the reader can consult Annex II, part I to Commission Delegated Regulation (EU) No 1062/2014. More information about the review programme is available at: <http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/existing-active-substance>

An exemption from REACH registration also applies in the following cases:

- The active substance is manufactured/imported for use in a biocidal product which has a simplified authorisation (Article 27 of BPR);
- The active substance is manufactured/imported for use in a biocidal product which has a provisional authorisation (Article 55(2) of BPR);
- The active substance is manufactured/imported for use exclusively in a biocidal product which is the subject of experiments or tests for the purposes of scientific or product and process-orientated research and development (Article 56 of BPR).

Only active substances can be regarded as registered: other substances used for producing the biocidal product are subject to registration.

If the substance is used in non-biocidal products it will have to be registered even if it fulfils the definition of an active substance according to Article 3(1)(c) of BPR and falls in the situation (1) or (2) mentioned above before it can be manufactured or imported in the EU for

¹¹ Directive 67/548/EEC was repealed by the CLP Regulation on 1 June 2015.

- 1 other than biocidal uses.
- 2 If a manufacturer or importer manufactures or imports the substance for biocidal and non-
- 3 biocidal uses, it will have to submit a registration for the quantities of the substance used in
- 4 non-biocidal products.
- 5 Once a decision is adopted that an active substance is not approved, the manufacture and
- 6 import of the substance is subject to the same registration requirements as any other
- 7 substance under the scope of REACH.

Example:

A manufacturer manufactured 100 tonnes of quaternary ammonium compounds in year X. 50 tonnes are used as active substances in biocides (e.g. wood preservatives) and the active substance is included in one of the acts mentioned under (2) above, the other 50 tonnes are used as surfactants in cleaning products. This latter use is in non-biocidal products and must be registered; the former use is in biocidal products and is regarded as registered.

8 *Legal references: Articles 15(2) and 16 of REACH, Article 57 of BPR*

9

10 2.2.4.2 Substances for use in plant protection products

An **active substance**¹² in the context of plant protection products is a substance, including micro-organisms¹³ having general or specific action against harmful organisms or on plants, parts of plants or plant products.

Co-formulants in the context of plant protection products are substances or mixtures which are used in a plant protection product or adjuvant but are neither active substances nor safeners or synergists.

Safeners are substances or mixtures that are added to a plant protection product to eliminate or reduce phytotoxic effects of the plant protection product on certain plants.

Synergists are substances or mixtures that can give enhanced activity to the active substance(s) in a plant protection product. A plant protection product may be composed of active substances, safeners or synergists with or without co-formulants.

11

12 Active substances manufactured or imported for use in plant protection products in accordance

13 with Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the

¹² Regulation (EC) No 1107/2009 repealed Directive 91/414/EEC with effect from 14 June 2011 while it provides for transitional measures to ensure the smooth transition to the new legislative regime. The references in the REACH Regulation to Directive 91/414/EEC and the legislation adopted thereunder should therefore be construed as references to Regulation (EC) 1107/2009 and its implementing legislation. For that reason, the Guidance refers to the definitions and the applicable legal requirements provided for in the Regulation (EC) 1107/2009. Please refer to Article 2(3) (a), (b), (c) and (d) of Regulation (EC) No 1107/2009 where the definitions of safeners, synergists, co-formulants and adjuvants are given.

¹³ Microorganisms are not included within the scope of the definition of a substance under REACH and are therefore outside the scope of the REACH Regulation.

1 market, are regarded as registered under REACH (for that use) if the active substance:

2 (1) is approved and included in the Commission Implementing Regulation (EU) No
 3 540/2011 (list of approved active substances), or

4 (2) where the application for approval of the active substance is deemed admissible in
 5 accordance with Article 9 of Regulation (EC) No 1107/2009.

6 Quantities of the same active substance used for other uses than in plant protection products
 7 are not regarded as being registered even if they are approved.

8 Under Regulation (EC) 1107/2009, synergists and safeners are subject to similar approval
 9 requirements as active substances. Thus, sufficient information on their use in plant protection
 10 products is obtained allowing them to be adequately controlled within the framework of the
 11 plant protection products legislation. Therefore, they should also be regarded as registered
 12 under Article 15 (1), if they meet the requirements set out therein.

13 Given that co-formulants in plant protection products cannot satisfy the requirements of Article
 14 15 (1), they cannot benefit from that provision and thus are subject to registration.

15 Adjuvants are not substances used in plant protection products, but they may be placed on the
 16 market to be mixed by the user with a plant protection product. Therefore, they cannot satisfy
 17 the requirements of Article 15 (1) and are subject to registration.

Example:

A manufacturer manufactured 100 tonnes of copper sulphate in year X. 50 tonnes are used as active substances in pesticides and the active substance is approved, the other 50 tonnes are used for other purposes. This latter use is in non-plant protection products and must be registered; the former use is in plant protection products and is regarded as registered.

18
 19 The Commission maintains an electronic list of the approved (and non-approved) active
 20 substances which is available at: [http://ec.europa.eu/food/plant/pesticides/eu-pesticides-](http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN)
 21 [database/public/?event=activesubstance.selection&language=EN](http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN)

22 *Legal references: Article 15(1), Article 16*

23
 24 **2.2.4.3 Notified substances according to Directive 67/548/EEC**

25 Directive 67/548/EEC introduced a notification requirement for so-called new substances,
 26 which were substances not appearing on the European Inventory of Existing Commercial
 27 Chemical Substances (EINECS). The EINECS list contains, in principle, all substances on the
 28 Community market on 18 September 1981.

29 Notifications made in accordance with Directive 67/548/EEC contain much of the technical
 30 dossier information which the REACH Regulation aims to have assembled by registrants
 31 through the registration requirement. This is the reason why such **notifications are**
 32 **regarded as registrations under REACH**. Notified substances according to Directive
 33 67/548/EEC are generally referred to as NONS (Notification of New Substances) in the context
 34 of REACH.

35 ECHA has assigned registration numbers to all notifications and distributes them electronically
 36 upon the notification owner's request through REACH-IT. Importantly, the registration is
 37 assigned for the tonnage band referred to in the notification of the substance. As soon as the
 38 actual volume differs from this initial tonnage band the registrant will have to update their
 39 registration dossier as described in section Update of registration dossier for substances
 40 regarded as being registered under REACH.

The process of requesting the notification registration number is done by claiming the registration number in REACH-IT. At this point, the user is asked to indicate the role they had under NONS:

- If they were a domestic manufacturer and/or importer, they will be manufacturers and/or importers under REACH;
- If they were a sole representative under NONS, they will be an only representative under REACH;

Notifications that covered several roles (e.g. manufacturers/importers and sole representatives) should be claimed separately. Additionally, there may have been several sole representatives covered by the same NONS notification. In this case, companies should claim separate registration numbers for each sole representative of the notification. This must be done from separate REACH-IT accounts.

Legal entities are advised to check whether they submitted a notification for their substance to a Member State competent authority in accordance with the national legislation implementing Directive 67/548/EEC. If this is the case, they have an official notification number on file which was allocated by the Member State competent authority. The substance will in that case also appear on the European List of Notified Chemical Substances (ELINCS).

Notification under Directive 67/548/EEC was only required if a substance was placed on the EU market or imported into the EU. If a substance was manufactured in the EU, but not placed on the market, a notification would not have been made. These substances must be registered under REACH.

Manufacturers or importers of polymers which were notified according to Directive 67/548/EEC are advised to read the [Guidance for monomers and polymers](http://echa.europa.eu/guidance-documents/guidance-on-reach) (<http://echa.europa.eu/guidance-documents/guidance-on-reach>) where the specific steps to claim a registration number for a notified polymer are explained in detail.

A notification under Directive 67/548/EEC is nominal and only the notifier benefits from being considered registered. Any other parties manufacturing or importing the substance who have not notified it, must register it, unless there is another exemption that applies to them.

Legal reference: Article 24

2.2.5 Obligations related to registration of intermediates

REACH establishes specific obligations for intermediates as previously explained in section 2.2.2.5 Non-isolated intermediates. While non-isolated intermediates are not covered by REACH, isolated intermediates may have reduced requirements, depending on the conditions of manufacture and use (i.e. if strictly controlled conditions apply).

The following types of isolated intermediates are defined under REACH:

- On-site isolated intermediate
- Transported isolated intermediates

An on-site isolated intermediate is an intermediate not meeting the criteria of a non-

1 *isolated intermediate and where the manufacture of the intermediate and the synthesis of*
2 *(an) other substance(s) from that intermediate take place on the same site, operated by one or*
3 *more legal entities (Article 3(15)(b)).*

4 **A transported isolated intermediate** *is an intermediate not meeting the criteria of a non-*
5 *isolated intermediate and transported between or supplied to other sites (Article 3(15)(c)).*

6 A manufacturer or importer of an isolated intermediate in quantities of one tonne or more per
7 year is required to register their substance under REACH. In doing so they have to confirm that
8 the substance is used as isolated intermediate according to the criteria set in article 3(15) of
9 REACH. A registrant of an isolated intermediate may benefit from reduced registration
10 requirements provided the manufacture and use of the substance takes place under strictly
11 controlled conditions. Requirements for registration of intermediates and strictly controlled
12 conditions are included in Article 17 of REACH for on-site isolated intermediates and in Article
13 18 for transported isolated intermediates. The requirements for registration vary depending on
14 whether the isolated intermediate is an on-site or a transported intermediate.

15 In case the registrant cannot demonstrate that the strictly controlled conditions are met, they
16 have to include in their registration dossier the standard information specified in Article 10 of
17 REACH.

18 For the sake of simplification, isolated intermediates will be referred to simply as intermediates
19 in the context of this document.

20 If in need of more detailed information, the reader is advised to consult the *Guidance on*
21 *intermediates* available at: <http://echa.europa.eu/guidance-documents/guidance-on-reach>.
22 This guidance is designed to support potential registrants of intermediates in assessing
23 whether the use of their substances fulfil the definition of intermediate and the conditions of
24 manufacture and use fulfil the requirements to be considered as strictly controlled conditions.
25 A detailed description of the registration requirements is also included.

26 *Legal reference: Article 3(15), Article 17, Article 18*

27

28 **2.2.6 Calculation of the volume to be registered**

29 The following sections describe how to calculate the volume (tonnes per year) to be used in
30 order to decide whether a registration must be submitted for a substance and what are the
31 information requirements that have to be fulfilled.

32 According to REACH, once a substance is manufactured or imported in quantities of one tonne
33 per year (or present in an article in quantities over one tonne per year under specific
34 conditions) it has to be registered, unless an exemption applies. The registration requirement
35 is therefore triggered by the volume of the substance manufactured or imported (or present in
36 an article, if applicable).

37 The volume of the substance will also determine the information to be submitted in the
38 registration dossier. REACH defines four tonnage bands (1 to < 10 tonnes, 10 to < 100 tonnes,
39 100 to < 1000 tonnes, 1000 tonnes or more per year) and the standard information
40 requirements for each of them. If the volume of the substance reaches the lower limit of a
41 tonnage band, the standard information requirements for that tonnage band apply. The
42 standard information to be submitted depending on the tonnage band is discussed in detail in
43 section Information requirements.

44

2.2.6.1 Calculation of the volume in case of exemptions

A potential registrant needs to calculate the total volume (tonnes per year) of the substance they manufacture or import and, based on that, determine whether a registration must be submitted and within which tonnage band. However **if certain exemptions to registration apply** (such as in food or medicinal products or for PPORD purposes as in the examples below) the potential registrant does not need to include those quantities in the calculation to determine the volume they have to register.

Information requirements for the registration are determined by the volume of the substance that is subject to registration.

For details on the different exemptions, please, refer to previous sections of this guidance.

Example 1: Use in medicinal products

If a company manufactures a substance to be used in a medicinal product, it does not need to register the substance for that use. However, the company or its customers may at the same time make other uses of the same substance. To determine the registration obligation under REACH, the quantities for the other uses must be determined.

E.g., company A manufactures 120 tonnes of magnesium hydroxide in year X. 70 tonnes are used in medicinal products and 50 tonnes are used for the formulation of a mixture. The 50 tonnes used for the formulation of the mixture will be subject to the provisions of the REACH Regulation, while the 70 tonnes used in medicinal products are exempted from registration under the REACH Regulation. The substance is to be registered according to the information requirements of the 10-100 tonnes per year tonnage band.

Example 2: Use for PPORD purposes

If a company manufactures 11 tonnes per year of a substance, of which 2 tonnes are for PPORD, the registration obligation is defined by the 9 tonnes per year which are not for PPORD. The company will also have to submit a PPORD notification dossier for the 2 tonnes used for PPORD purposes. The substance is to be registered according to the information requirements of the 1-10 tonnes per year tonnage band.

2.2.6.2 Calculation of the volume for intermediates

In addition to the exemptions from registration, the potential registrant should consider whether the substance they intend to register is used as an intermediate and if it is manufactured and used under strictly controlled conditions (see previous section 2.2.5 Obligations related to registration of intermediates). If this is the case, they can benefit from the limited information requirements defined for intermediates and need not comply with the full set of information required for a standard registration. If the manufacture or use of the intermediate does not take place under strictly controlled conditions, the potential registrant will have to submit a standard registration dossier and comply with the information requirements established for the tonnage band in which they intend to register the intermediate.

Where a dossier contains both the use of a substance as an intermediate under strictly controlled conditions and as an intermediate where strictly controlled conditions are not met, and/or as a non-intermediate, the information requirements will depend on the volume of the non-intermediate and of the intermediate use that is not taking place under strictly controlled conditions.

Example: Volume to consider for the registration dossier in the case of intermediates

A company manufactures 2300 tonnes per year of substance A, of which 1700 tonnes are used as intermediate in strictly controlled conditions and the other 600 tonnes are used for other purposes not exempted from registration. This company will submit only one registration dossier for substance A, covering the 1700 tonnes used as intermediates and the 600 tonnes for the other purposes. However, the information requirements of the registration dossier will be determined by the 600 tonnes, since for the intermediate use under strictly controlled conditions only a limited set of information is required. This means that the information requirements defined under REACH for the 100-1000 tonnes per year tonnage band will be used as a basis for this dossier. The fact that the substance is also used as an intermediate under strictly controlled conditions should be indicated in the dossier and the volume of 1700 tonnes used as intermediates will also need to be documented in it.

1

2 2.2.6.3 Calculation of the total volume

3 In a registration, the registrant must report in tonnes the volume they manufacture or import
4 per year. A registrant needs to calculate the total volume (tonnes per year) of the substance
5 that is intended to be manufactured and imported and that is not exempted from registration.
6 The tonnes per year to be reported in a registration dossier are the estimated quantity in
7 tonnes that is expected to be manufactured or imported in the calendar year of registration (1
8 January to 31 December). If the manufacturing starts only later in a particular calendar year,
9 the registration dossiers can cover the expected tonnes for a full calendar year rather than the
10 remaining months of the first calendar year, in order to avoid the need for a very quick update
11 of the registration dossier for the second year.

12 As stated before, this total volume will determine the information to be submitted in the
13 registration dossier. For combined registrations of substances used as intermediates under
14 strictly controlled conditions and for other uses, as in the example above, the volume to be
15 used as an intermediate will not be considered for the definition of the information
16 requirements.

17 If a registrant manufactures or imports the same substance at different sites which belong to
18 the same legal entity, then the volume of the substance to be registered is the total volume of
19 the substance manufactured or imported at the different sites, because the sites are not
20 separate legal entities.

21 If a substance is imported in several mixtures, the volume of the substance in each mixture
22 (calculated as defined in section 2.2.6.4 Calculation of the amount of substance in a mixture or
23 in articles) will have to be aggregated.

24 Moreover, if a substance is imported in several articles from which it is intended to be
25 released, the potential registrant needs to sum up all quantities of the substance present in
26 those articles. For this purpose, they need to count only those articles from which the
27 substance is intended to be released. Whenever a substance is intended to be released from
28 an article, the total volume present in that article needs to be counted and not only the volume
29 intended to be released. If the substance has already been registered for that use by any
30 registrant in the EU and the registration has covered the volume of the substance in the
31 article, the importer of the articles is relieved from the registration obligation.

Example

Company X imports per year three articles A, B, and C with 60 tonnes of the substance present in each but:

- in article A, the substance is not intended to be released
- in article B, the substance is intended to be released and 40 out of 60 tonnes are released under normal conditions
- in article C, the substance is intended to be released and 10 out of 60 tonnes are released under normal conditions

The company X will need to register the total volume of the substance in articles B and C: 120 tonnes, i.e. in the 100-1000 tonnes per year tonnage band, provided that the substance has not been registered before for that use by any registrant.

If the potential registrant manufactures or imports a substance and at the same time produces an article from which the substance is intended to be released, they are required to register the total volume of the substance they manufacture or import. In other words, all quantities of a substance that a company manufactures or imports must be added up and registered in one registration dossier, regardless whether the substance is on its own, in a mixture, in articles with the intention to be released or in combination of any of those. If the substance is imported in an article, the registration of the substance manufactured or imported must contain a description of the incorporation of the substance into the article as an identified use and this use needs to be assessed in the chemical safety assessment (see section 5.3 Chemical Safety Report). Additional information on the requirements for the registration of substances in articles is available in the *Guidance on requirements for substances in articles* at:

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

2.2.6.4 Calculation of the amount of substance in a mixture or in articles

Specific situations may occur for substances present in mixtures or in articles:

Amount of a substance in a mixture

In order to be able to calculate the amount of a substance in a mixture, the total volume of the mixture is multiplied by the fraction of the constituent substance. This value can, for example, be obtained from the safety data sheet of the mixture. When only a range of concentrations of a substance in a mixture is available, then the maximum volume of the substance is calculated using the highest possible content of that substance in the mixture. Without more precise information on the composition, this may be the only way to ensure that the registration requirements are being respected.

Amount of a substance in an article

In the case of articles which contain a substance that is intended to be released under normal or reasonably foreseeable conditions of use, then:

- If the weight by weight content of that substance is known, then this value is multiplied by the total mass of the produced or imported article; or
- If the weight of substance per unit article is known, then this value is multiplied by the total number of imported articles.

More detailed guidance can be found in the *Guidance on requirements for substances in articles* available at: <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

1 **2.3 When to register?**

2 The REACH Regulation created a special transition regime for substances which, under certain
3 conditions, were already being manufactured or placed on the market before the entry into
4 force of the REACH Regulation on 1 June 2007 and were not notified according to Directive
5 67/548/EEC. For these substances, manufacturers and importers could, if they had pre-
6 registered, submit their registration dossiers within deadlines foreseen by the REACH
7 Regulation.

8 Such substances were defined as **phase-in substances** because they were being subjected to
9 the registration system in different phases over time, rather than immediately in one go.
10 However, after the third registration deadline of May 2018, **all substances** must be registered
11 before they are manufactured or imported it into the EU.

12 The registration of any substance will first require the submission of an **inquiry dossier** to
13 determine whether a registration or another inquiry has already been submitted for the same
14 substance so that data-sharing mechanisms can apply. For more information on inquiry and
15 data-sharing processes, please consult the Guidance on data-sharing available at:
16 <http://echa.europa.eu/guidance-documents/guidance-on-reach>.
17
18
19

3. The sharing of data

The purpose of data-sharing is to increase the efficiency of the registration system as well as to reduce costs and to reduce testing on vertebrate animals. Duplication of animal testing has to be avoided and tests on vertebrate animals must only be undertaken as a last resort (Article 25).

The data-sharing provisions set out in REACH aim to facilitate the sharing of data between registrants, before and after the registration of a substance.

In order to put registrants into contact, the first step to the sharing of data is the submission of an inquiry to ECHA (Article 26).

In this context, the following principles apply:

- **Data must be shared for the same substance in the case of information involving tests on vertebrate animals.** Before testing is carried out on vertebrate animals, a potential registrant **must** request available data through the inquiry process from the previous registrant.
- **Information not involving tests on vertebrate animals must be shared if requested by a potential registrant of the same substance.** The potential registrant **may** request the study they need from the previous registrant.

The previous registrants and potential registrants must make every effort to reach an agreement on sharing the data and ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way.

In case the negotiations fail, the potential registrant may submit, as a last resort, a data-sharing dispute to ECHA (Article 27). In such case, ECHA will assess the parties' efforts to reach an agreement on the sharing of the data and their costs and may grant the potential registrant permission to refer to the data subject to the negotiations.

The inquiry and data-sharing procedures are described in detail in the Guidance on data-sharing available at <http://echa.europa.eu/guidance-documents/guidance-on-reach>. The history of the data-sharing process is also described in that Guidance.

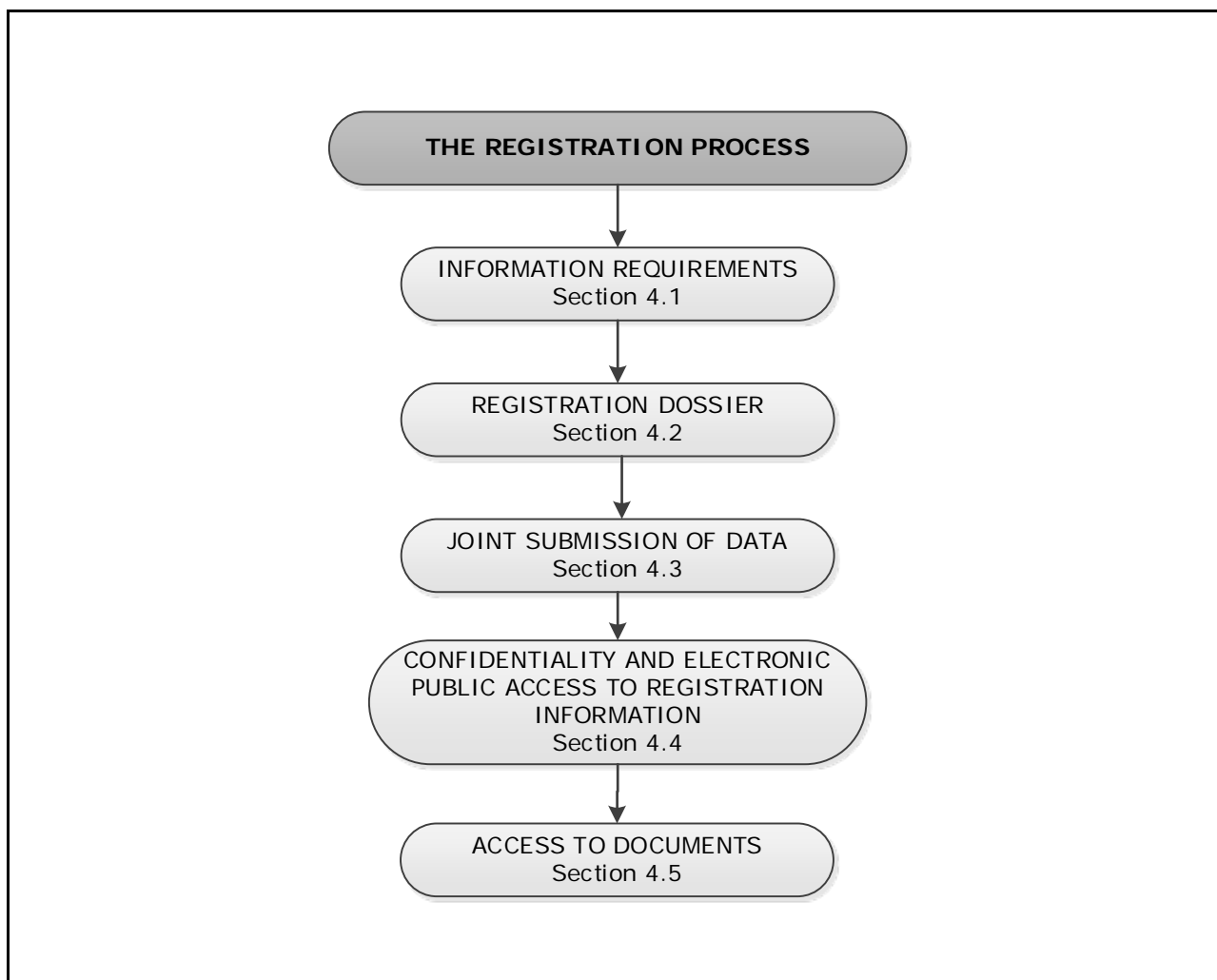
.....

1 4. The registration process

2 **Aim:** The aim of this chapter is to present the information that the registrant must
3 submit as part of his registration. It also describes how to jointly submit data.

4

5 **Structure:** The structure of this chapter is as follows:



6

7 Practical instructions for the preparation of a registration dossier are available in the ECHA
8 manual *How to prepare registration and PPORD dossiers* accessible at:
9 <http://echa.europa.eu/manuals>. The manual is also available via the help system built into
10 IUCLID.

11

12 4.1 Information requirements

13 Prior to registering, manufacturers and importers need to obtain information on the substance
14 they manufacture or import in order to (i) to assess the risks arising from the manufacture and
15 use of their substance and (ii) to ensure that the potential risks are controlled.

16 The information gathered and the assessment performed must be documented in the

1 registration dossier and submitted to ECHA for the registration of the substance.

2 For specific advice on preparation of the registration dossiers for nanomaterials, please consult
3 the Appendix for nanoforms applicable to the *Guidance on Registration and Substance*
4 *Identification* available at: <http://echa.europa.eu/guidance-documents/guidance-on-reach>.

6 4.1.1 Fulfilling the information requirements

7 Manufacturers and importers must collect **all available existing information** on the
8 properties of the substance for registration purposes, regardless of the tonnage manufactured
9 or imported. This information has to be assessed against the standard information
10 requirements set up by the REACH Regulation.

11 The information to be gathered may include:

- 12 • experimental data (*in vivo* and *in vitro*);
- 13 • non experimental 'alternative' data: e.g. from (Q)SARs models ((Quantitative) Structure
14 Activity Relationships), resulting from the grouping of substances and the related read-
15 across approach;
- 16 • information on manufacture, uses, risk management measures and resulting exposures.

17 For each tonnage band, REACH defines the minimum information that the registrant must
18 provide on the intrinsic properties of their substance. At the lowest tonnage level (1-10 tonnes
19 per year), the standard information requirements are defined in Annex VII. When a new
20 tonnage band level is reached, additional requirements must be fulfilled which are described in
21 the subsequent Annex.

22
23 An **overview of the standard information requirements** defined in REACH (Annex VII to
24 X) is available at [https://echa.europa.eu/regulations/reach/registration/information-](https://echa.europa.eu/regulations/reach/registration/information-requirements)
25 [requirements](https://echa.europa.eu/regulations/reach/registration/information-requirements).¹⁴

26
27 **The precise information requirements depend on the intrinsic properties as well as**
28 **on the tonnage, use and exposure of each substance. It can also depend on the**
29 **information on the substance and related analogues, which is already available.**

30
31 Where available data are not adequate to meet the requirements of REACH, additional testing
32 may need to be generated. Only tests required under Annexes VII and VIII can be performed
33 without ECHA's agreement.

34
35 Under Article 13, tests required to generate information on intrinsic properties of substances
36 must be conducted in accordance with the test methods laid down in Commission Regulation
37 (EC) No 440/2008 and its amendments, or in accordance with other international test methods
38 recognised by the Commission or ECHA. In addition, ecotoxicological and toxicological tests
39 and analyses must be carried out in compliance with the principles of good laboratory practice
40 (GLP) and with the provisions of Directive 2010/63 EU on the protection of animals used for
41 scientific purposes.

42
43 REACH foresees that the standard requirements may be adapted (or waived) if the registrant
44 can appropriately justify it as per the criteria set out in Annexes VII to X, column 2 or Annex
45 XI.

46
47 For further information about the process for information gathering and data generation please

¹⁴ The full information requirements can be found directly in the REACH legal text, available at
<https://echa.europa.eu/regulations/reach/legislation>

refer to the *Guidance on information requirements and chemical safety assessment* available at: <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

The following chapters of the guidance may be particularly useful for the reader:

- Part B: Hazard Assessment
- Chapter R.2: Framework for generation of information on intrinsic properties
- Chapter R.3: Information gathering
- Chapter R.4: Evaluation of available information
- Chapter R.5: Adaptation of information requirements
- Chapter R.6: QSARs and grouping of chemicals
- Chapter R.7: Endpoint specific guidance

Additional practical information on alternative methods to the generation of information can also be found in our practical guides (<http://echa.europa.eu/practical-guides>):

- *How to use alternatives to animal testing to fulfil your information requirements for REACH registration*
- *How to use and report (Q)SARs*
- *Practical guide for SME managers and REACH coordinators - How to fulfil your information requirements at tonnages 1-10 and 10-100 tonnes per year*

Important:

For information required to fulfil the information requirements **listed in Annexes IX and X** and that are not available or adequate, the registrant must first develop and submit a **proposal for testing** to ECHA and await that ECHA decides on whether the proposal is adequate.

Before proposing a new test involving vertebrate animals, the registrant must consider all relevant and available data sources as well as available testing methods (other than *in vivo* tests) to avoid unnecessary animal testing in accordance with Article 25.

For example, the registrant may use a variety of alternative methods such as *in vitro* or *in chemico* tests, (Q)SARs ((Quantitative) Structure Activity Relationships), a grouping/read-across approach, or rely on a weight of evidence approach. The registrant must be able to justify the use of such methods and thereby fulfil the requirements of Annex XI.

In addition, Article 25 states that **animal testing should only be performed as a last resort**. Therefore, instead of generating data by themselves, each registrant concerned by the respective information requirement must agree with the other registrants of the same substance if there are available data that can be used to reflect the intrinsic properties of their substance without the need to generate new information. If that is not the case, then the registrants must agree on the testing proposal which will be submitted in the registration dossier by the lead registrant on their behalf.

Registrants must clearly justify the need for testing in vertebrate animals in the registration dossier submitted by the lead, including a documented analysis of the alternative methods they have considered.

4.1.2 Use of information from other assessments

Under REACH, 'Available information from assessments carried out under other international and national programmes shall be included. Where available and appropriate, an assessment

carried out under Community legislation (e.g. risk assessments completed under Regulation (EEC) No 793/93) shall be taken into account in the development of, and reflected in, the chemical safety report. Deviations from such assessments shall be justified' (Annex I Section 0.5).

Therefore registrant must take into consideration existing assessments in meeting the information requirements given in the Annexes VIII to X **only if** (i) this information allows them to fulfil the relevant information requirement and (ii) they are in legitimate possession or have permission to refer to the full study reports which must also be summarised in the joint registration dossier. Therefore, registrants must take into account and use these already available assessments to prepare their registration dossier, in particular assessments carried out under other EU programmes, such as the Existing Substances Risk Assessment Programme, the assessments of active substances under the Biocidal Products Regulation or the Plant Protection Products Regulation, when such substances are covered by REACH.

The OECD HPV¹⁵ Chemicals Programme which bears a lot of similarities with REACH can be another important source of information which should be taken into account when preparing a registration dossier where the substance was assessed under the OECD HPV Chemicals Programme. To reduce duplicate testing and save the government and industry resources the OECD has developed the Mutual Acceptance of Data (MAD) system, which allows participating countries (including non-members) to share the results of various non-clinical tests done on chemicals using OECD methods and principles. Further information on MAD system is available at: <http://www.oecd.org/env/ehs/mutualacceptanceofdatamad.htm>.

4.2 Registration dossier

4.2.1 Structure of the registration dossier

The registration dossier is the set of information submitted electronically by a registrant for a particular substance. It consists of two main components:

- a **technical dossier**, always required for all substances subject to the registration obligations;
- a **chemical safety report**, required if the registrant manufactures or imports a substance in quantities of 10 tonnes or more per year.

The **technical dossier** contains a set of information about:

- (i) the identity of the manufacturer/importer;
- (ii) the identity of the substance;
- (iii) information on the manufacture and use of the substance;
- (iv) the classification and labelling of the substance;
- (v) guidance on its safe use;
- (vi) study summaries of the information on the intrinsic properties of the substance;
- (vii) robust study summaries of the information on the intrinsic properties of the substance, if required;
- (viii) an indication as to whether the information on manufacture and use, the classification and labelling, the (robust) study summaries and/or, if relevant, the chemical safety report has been reviewed by an assessor;

¹⁵ Organisation for Economic Co-operation and Development High Production Volume

- (ix) proposals for further testing, if relevant;
- (x) for substances registered in quantities between 1 and 10 tonnes, information on exposure;
- (xi) a request as to which information should be considered confidential, including a justification.

The **chemical safety report (CSR)** is the documentation of the registrant's chemical safety assessment (CSA) (see section 5.3 Chemical Safety Report). The requirement to prepare a CSA and document it in the CSR is triggered by the yearly tonnage manufactured or imported by the registrant (the threshold being 10 tonnes per year). The following exemptions apply:

- a CSR does not need to be performed for a substance present in a mixture if the concentration of the substance in the mixture is less than the lowest of the values defined in Article 14(2);
- for uses in food contact materials and cosmetics, the CSR does not need to address human health aspects because these are addressed under other legislation.

The obligations that apply to registrants regarding the information to be submitted in the registration dossier are explained in more detail in section Preparation of the registration dossier.

Legal references: Article 10, Article 14, Annex I, Annexes VI to X

4.2.2 **Format and submission of the registration dossier**

The format of the registration dossier must be IUCLID (International Uniform Chemical Information Database). Other IT tools can be used to prepare the dossier as long as they produce the exact same format.

IUCLID is a software application to capture, store, maintain and exchange data on the properties and uses of chemical substances. Although the design and build of IUCLID was triggered by the entering into force of REACH, the software tool can be used for many purposes. The data storage formats have been developed in co-operation with the OECD and have been accepted by many national and international regulatory authorities. IUCLID data can therefore be used in different chemical assessment programmes, such as the OECD HPV Chemicals Programme, US HPV Challenge Programme, the Japan Challenge Programme as well as in the EU Biocides Directive.

The IUCLID software can be downloaded free of charge by all parties, if used for non-commercial purposes, from the IUCLID website at: <https://iuclid6.echa.europa.eu/>. IUCLID is available either as part of a local installation or using the ECHA Cloud services. More information about ECHA Cloud services is available at: <https://echa.europa.eu/support/dossier-submission-tools/echa-cloud-services>.

Each manufacturer, importer or only representative is **individually obliged to submit a registration dossier** for each of their substances to ECHA in order to register them. The registration dossier must be submitted electronically via the REACH-IT portal accessible at: <https://reach-it.echa.europa.eu>. Practical instructions for the preparation of a registration dossier are available in the ECHA manual *How to prepare registration and PPORD dossiers* accessible at: <http://echa.europa.eu/manuals>. The manual is also available via the help system built-in IUCLID.

Legal reference: Article 111

4.3 Joint submission of data

The 'one substance, one registration' principle

If the registrants agree that they manufacture or import the same substance, they must register this substance jointly within the same joint submission.

All parties with registration obligations related to the same substance need to co-operate (discuss and agree) on their registration strategy. This includes discussion on the data itself (e.g. information on the hazardous properties of the substance in the form of studies and proposals for testing, its classification and labelling, etc.) and the sharing of its costs, but it also covers the obligation to submit jointly the information that is required under Articles 11(1) and 19(1) of REACH.

Submitting data jointly intends to minimise costs for registrants by co-operating on the preparation of the dossier and to have one set of information for the substance jointly submitted to ECHA. In addition, registrants submitting data jointly can benefit from a reduced registration fee.

Boundary composition

The boundary composition, as referred to in IUCLID, specifies the coverage of the jointly submitted data in the registration dossier. Thus, an unambiguous relation is created between the composition(s) identified for the substance in the registration dossier and the corresponding jointly submitted data.

By reporting the boundary composition(s) and ensuring that their own compositions are within the boundary composition(s), registrants confirm that the jointly submitted data covers their own substance (unless a member decides to opt out for part of their data). The boundary compositions should be reported in the dossier submitted by the lead registrant.

The number of boundary compositions provided in one dossier will depend on the variability of the compositions registered by the different members of the joint submission and the fate and hazard profiles of these compositions. The boundary composition is particularly important for UVCBs and multi-constituent substances, where the identifiers are often not characterising the substance in sufficient detail and variation exists between compositions of the members of the joint submission.

Registrants are required to submit jointly the following information:

- classification and labelling of the substance;
- (robust) study summaries and proposals for testing;
- indication as to which of the submitted information on classification and labelling study summaries and robust study summaries have been reviewed by an assessor chosen by the registrant and having appropriate experience (see section 5.2.6 Review by an assessor).

Under specific conditions (listed in Article 11(3) and 19(2)) which need to be justified in the dossier, separate submission of the above mentioned data is allowed by members of a joint submission (see section 4.3.3 Conditions for opting out from the jointly submitted data Conditions for opting out from the jointly submitted data where opt-out possibilities are described).

Registrants may decide to submit jointly or separately:

- 1 – guidance on safe use of the substance;
- 2 – chemical safety report (CSR) when required;
- 3 – indication as to which of the information submitted for the CSR has been reviewed by
- 4 an assessor.

5 **Registrants must submit separately in their own dossier:**

- 6 – their identity;
- 7 – the identity of the substance;
- 8 – information on the manufacture and uses;
- 9 – exposure information for substances in quantities of 1 to 10 tonnes;
- 10 – indication as to which of the information on manufacture and use has been reviewed by
- 11 an assessor.

12 Details on which information must be submitted jointly as part of the lead dossier, and which
13 must be submitted in each member dossier, is available in Table 1: Information requirements
14 for data submitted jointly within a joint submission of this guidance.

15 Regardless of whether the registrants of the same substance submit some information jointly
16 or separately with an opt-out, all registrants of the same substance must submit their
17 registration dossier within the same joint submission.

18 It is important to stress that in case an only representative has been appointed by a 'non-EU
19 manufacturer' to carry out the registration of the substance, the only representative must be
20 part of a joint submission together with the other manufacturers, importers and only
21 representatives for the same substance. Only representatives must join the joint submission
22 for each 'non-EU manufacturer' they represent separately and subsequently submit a
23 registration dossier for each of the 'non-EU manufacturer' they represent.

24 Due to the reduced information requirements applicable to intermediates (used under strictly
25 controlled conditions), registrants of intermediates may choose for practical reasons to either
26 be part of the 'full' joint submission together with the registrants with non-intermediate uses
27 or to form one parallel joint submission for registrants with intermediate use only. However, it
28 is recommended to exercise this possibility only when accommodating intermediate uses into
29 the 'full' joint submission is not possible. In case a separate joint submission for intermediate
30 use only is created, it is recommended to bring all existing, available information together
31 (especially the information necessary for the classification of the substance).

32 The Implementing Regulation (EU) 2016/09 on joint submission and data-sharing establishes
33 the rules to ensure an efficient implementation of the data-sharing and joint submission
34 obligations. For more information, please refer to the *Guidance on data-sharing* at
35 <http://echa.europa.eu/guidance-documents/guidance-on-reach>.

36 *Legal reference: Article 11*

37 **4.3.1 Mechanisms of joint submission**

38 When a potential registrant prepares to register a substance, they will start by submitting an
39 inquiry to ECHA (consult the *Guidance on data-sharing* at [http://echa.europa.eu/guidance-](http://echa.europa.eu/guidance-documents/guidance-on-reach)
40 [documents/guidance-on-reach](http://echa.europa.eu/guidance-documents/guidance-on-reach)). If the inquiry results in finding that one (or several)
41 registration have previously been submitted for the same substance, the potential registrant

1 may need to share data with the previous registrants and will have to submit its registration
2 dossier as part of the existing joint submission.

3 Where the same substance has previously been registered by only one other company who did
4 not create a joint submission in REACH-IT, the potential registrant will need to contact this
5 previous registrant. They must then agree on who will be the lead registrant. In most cases, it
6 may be most sensible if the previous registrant takes over the role of the lead registrant, as
7 they have already submitted a dossier. However, the previous registrant and the potential
8 registrant are also free to agree that the potential registrant will be the lead registrant and will
9 create the joint submission. In that case, the potential registrant must create the joint
10 submission and submit the lead dossier with the information requirements for the agreed
11 jointly submitted data. The previous registrant will subsequently need to join the joint
12 submission and submit an update of its registration dossier.

13 The obligation to be part of the same joint submission also applies to previous notifications
14 under Directive 67/548/EEC. Given that this obligation did not exist prior to REACH and to ease
15 the previous notifications into the registration system, they are regarded as registrations under
16 REACH that are outside a joint submission. Therefore, such registrations are not linked to any
17 joint submission. If a potential registrant wants to register the same substance, a joint
18 submission will have to be created in REACH-IT. In this case the potential registrant will also
19 need to contact the previous registrant and they will need to agree together on who will be the
20 lead registrant.

21 When a lead registrant ceases to manufacture or import the substance, the other registrants
22 must appoint a new lead registrant. If ceasing of manufacture or import of the substance
23 occurs upon receipt of a draft decision on evaluation, the lead registrant cannot continue to act
24 as a lead registrant as their registration is no longer valid (Article 50(3)). A new lead registrant
25 must be selected and the lead role be transferred to them.

26 In other cases of ceasing of manufacture or import of the substance by the lead registrant (not
27 upon receipt of a draft evaluation decision), the existing lead registrant may continue to carry
28 out their duties, as their registration for the substance is still valid (although the tonnage is set
29 to zero). However, the transfer of the lead registrant role may still be preferable so as to
30 facilitate the communication (both current and future) with ECHA and other members of the
31 joint submission by ensuring that the new lead registrant continues to manufacture/import the
32 substance.

Registrants have been subject to the joint submission obligation since the entry into force of REACH, i.e. 1 June 2007. Thus, all registrants of the same substance have been required to submit jointly the information for the substance. The entry into force of the Implementing Regulation (EU) 2016/9 on joint submission and data-sharing, has given ECHA the practical tools to ensure that all submissions of information regarding the same substance are part of a joint submission.

Where registrants of the same substance have submitted before the entry into operation of the Implementing Regulation their dossiers in parallel, i.e. not as part of one joint submission, this is not in line with Articles 11 or 19. These registrants will have to agree to create a joint submission and all of them will have to join this joint submission. Once a joint submission is created, registrants that are not part of this joint submission will not be able to update their dossier until they join the joint submission.

If the registrant cannot agree on the conditions for the access to a joint submission despite every effort having been made, they can inform ECHA that they intend to submit a full opt-out dossier under Articles 11(3) or 19(2) of REACH. ECHA will provide them with a token to join the joint submission that only allows the registrant to submit a full opt-out dossier. By

doing so ECHA ensures that the registrants remain part of the joint submission, including where an opt-out is submitted in accordance with Article 11(3)(c) of REACH.

1

2

3 4.3.2 Jointly submitting data

4 The lead registrant is defined as the registrant acting with the agreement of the other

5 assenting registrants under Article 11(1) to submit first the joint data. However, REACH does

6 not specify the rules as to how the lead registrant should be selected. The lead registrant may,

7 for example, be the registrant who has most data on the substance already available or the one

8 who has most information requirements to fulfil. Nevertheless, this is not compulsory and the

9 registrants submitting data jointly have the possibility to appoint a lead registrant with a lower

10 tonnage.

11 Nonetheless, a lead registrant registering themselves at a lower tonnage band than the one

12 covered by the jointly submitted data, must still submit a complete dossier for the highest

13 tonnage on behalf of the other registrants. The lead registrant, as well as any other registrant,

14 will pay the fee that corresponds only to their own tonnage band.

15 In practice this implies that there will be two different types of registration dossiers for the

16 data jointly submitted, namely:

17 1. the ‘**lead dossier**’, containing the information of the lead registrant and the data set

18 required in REACH for the highest tonnage band covered by the jointly submitted data,

19 and

20

21 2. the ‘**member dossier**’, the dossier that each of the registrants relying on the data

22 submitted jointly must submit individually.

23

24 The information requirements for each type of registration dossier are shown in **Table 1**

25 below.

26 **Table 1: Information requirements for data submitted jointly within a joint**

27 **submission**

28

| Information requirements | Lead dossier | | Member dossier |
|--|-------------------------------|------------------------------------|------------------------------------|
| | Jointly submitted information | Individually submitted information | Individually submitted information |
| (a) Technical dossier | | | |
| (i) identity of the manufacturer or importer | | X | X |
| (ii) identity of the substance | | X | X |
| (iii) boundary composition | X | | |

| | | | |
|---|----------------|----------------|----------------|
| (iv) manufacture and uses of the substance and if relevant use and exposure categories | | X | X |
| (v) classification and labelling* | X | | |
| (vi) guidance on safe use | upon agreement | upon agreement | upon agreement |
| (vii) study summaries of information derived from the application of Annexes VII to XI * | X | | |
| (viii) robust study summaries of the information derived from the application of Annexes VII to XI if required under Annex I* | X | | |
| (ix) indication regarding the review by an assessor of information submitted under (iii), (iv), (vi), (vii) and (b) | X | X | X |
| (x) proposals for testing* | X | | |
| (xi) exposure information for substances in quantities of 1 to 10 tonnes | | X | X |
| (xii) request as to which information in Article 119(2) should not be made available on the Internet | X | X | X |
| (b) Chemical safety report | upon agreement | upon agreement | upon agreement |

* Subject to opt-out (see section 4.3.3 Conditions for opting out from the jointly submitted data)

Once the lead registrant has been appointed by the other registrants, the lead registrant will create a joint submission in REACH-IT and submit the lead dossier. Only once the lead dossier with the jointly submitted data is accepted for processing, (i.e. it has passed the business rules check step, see section 11.1 Initial verification). Initial verification), the other registrants can submit their respective dossier. The joint submission page in REACH-IT will indicate to these other registrants when they may begin submitting their respective dossiers.

Legal references: Article 11, Article 19

4.3.3 Conditions for opting out from the jointly submitted data

The overall aim of the joint submission obligation is the submission of one set of information per substance, ideally also covering the intermediate use. However a registrant may submit part of the data of the registration dossier separately (opt-out) in cases where at least one of the following reasons (listed in Article 11(3) or for substances in intermediates respectively in Article 19(2)) applies:

- (a) it would be disproportionately costly for him to submit this information jointly; or
 (b) submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment; or
 (c) he disagrees with the lead registrant on the selection of the information submitted in the lead registration.

If the registrant decides to opt out, they have to submit in their IUCLID registration dossier an explanation as to why the costs would be disproportionate, why disclosure of information would be likely to lead to substantial commercial detriment or the nature of the disagreement, as the case may be.

Opting out can be partial and refer for example only to a specific study. The registrant may also decide to opt out for all the information specified in Article 10(a)(iv), (vi), (vii) and (ix) of REACH. In any case, when opting out, the registrant always needs to comply with the reasons listed in Article 11(3) or for substances in intermediates respectively in Article 19(2).

For technical instructions on how to submit the information separately and on how to substantiate the explanation, please refer to ECHA manual *How to prepare registration and PPORD dossiers* accessible at: <http://echa.europa.eu/manuals>.

In any circumstances, being part of the same joint submission is an obligation. Even if the registrant decides to opt out for part or all of the jointly submitted data they are required to submit from the same joint submission. In such cases the registrant will be able to submit their dossier only after the 'lead dossier' has been accepted for processing.

The fact that a potential registrant intends to submit separately all or part of the information to be submitted jointly, does not exempt them and existing registrants from making every effort to find an agreement on the access to the joint submission. In case the potential registrant intends to submit a full opt-out dossier under Articles 11(3) or 19(2) of REACH, but cannot find an agreement with the previous registrant on the conditions for access to the joint submission, they may contact ECHA that will provide them with a token to join the joint submission that only allows the registrant to submit a full opt-out dossier.

Registrants who decide to opt out for some or all the information, may still be required to contribute to their share of costs related to the joint submission and, if relevant, other related administrative costs.

4.3.3.1 Disproportionate costs

The REACH Regulation does not define what disproportionate costs mean. Therefore, registrants relying on this ground to opt out should provide sufficient explanations in their registration dossiers.

This situation may happen, for example, when a potential registrant already has in their possession data to fulfil an information requirement, but after negotiation with the other registrants they could not agree on the sharing of this data.

When opting out due to disproportionate costs the explanation provided in the registration dossier must include the cost of jointly submitting data (obtained from the lead registrant) and the cost of creating an opt-out member dossier as well as a justification for the difference between the two amounts being disproportionate and an explanation of the measures taken to agree on the cost of submitting the relevant information jointly.

4.3.3.2 Protection of confidential business Information (CBI)

The protection of CBI is addressed in the second opt-out criterion. The case must be based on the commercial loss which would be sustained if such CBI were disclosed by submitting data jointly.

Examples might include information allowing details of manufacturing methods to be deduced (such as technical characteristics, including impurity levels, of the product used in testing), or marketing plans (test data obviously indicating use for a particular, perhaps novel, application).

When opting out due to confidential business information the explanation provided in the registration dossier must include details of the information that is commercially sensitive, the route of disclosure and an explanation as to the substantial commercial detriment likely to be caused.

4.3.3.3 Disagreement on the selection of information to be included in the lead dossier

Disagreements over choice of information are likely to fall into one of the following categories:

- A registrant may consider that the jointly submitted data is not appropriate to their substance's specific composition. In such a case they would have to provide a qualitative explanation of their view.
- A registrant may believe that the data proposed to be submitted jointly is of an unsatisfactory quality standard. The registrant's view may also be influenced by their ownership of relevant data and/or the different purposes for which their substance is used.
- Similarly, a registrant may disagree with the number of studies submitted for the same data endpoint, especially in the absence of appropriate scientific justification or if these studies are redundant to fulfil the endpoint.

When opting out due to disagreement on the selection of the information, the explanation provided in the registration dossier must include the actions the registrant has taken to include their additional data in the lead dossier and a justification why it was not possible to include the additional data in the lead dossier.

If opting out from the jointly submitted classification and labelling information the registrant must also provide a reference to the data underlying their classification.

Consequences of opting out

An immediate consequence of opting out will be the further administrative work incurred in justifying the opt-out.

Further, the registration fees, set by Commission Regulation (EC) No 340/2008 of 16 April 2008, as amended¹⁶ consider whether the registration has been submitted by reference to the jointly submitted information or as an opt-out.

In addition, ECHA might prioritise the compliance check of opt-out registrations in line with Article 41(5)(a) of REACH.

¹⁶ The latest consolidated version of the Fee Regulation is accessible at <https://echa.europa.eu/regulations/reach/legislation>.

1

2 *Legal references: Article 11(3), Article 19(2)*

3

4 **4.4 Confidentiality and electronic public access to registration** 5 **information**

6 The REACH Regulation sets specific rules regarding the confidentiality and electronic public
7 access to certain types of information held by ECHA. Information submitted under the REACH
8 Regulation shall be either disclosed upon request (Article 118) or made publicly available, free
9 of charge on the ECHA website (Article 119).

10 The criteria for publication of the information submitted in the registration dossier are as
11 follow:

- 12 • The following information submitted in the registration dossier and held by ECHA on
13 substances whether on their own, in mixtures or in articles, must be made publicly
14 available, free of charge on the ECHA website (see list in Article 119(1)):
 - 15 ○ *the name in the IUPAC Nomenclature for substances which fulfil the criteria for*
16 *any of the hazard classes set out in Article 58 (1) of the CLP Regulation¹⁷,*
17 *without prejudice to paragraph 2(f) and (g);*
 - 18 ○ *if applicable, the name of the substance as given in EINECS;*
 - 19 ○ *the classification and labelling of the substance;*
 - 20 ○ *physicochemical data concerning the substance and on pathways and*
21 *environmental fate;*
 - 22 ○ *the result of each toxicological and ecotoxicological study;*
 - 23 ○ *any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC)*
24 *established in accordance with Annex I;*
 - 25 ○ *the guidance on safe use provided in accordance with section 4 and 5 of Annex*
26 *VI;*
 - 27 ○ *the analytical methods if requested in accordance with Annexes IX or X which*
28 *make it possible to detect a dangerous substance when discharged into the*
29 *environment as well as to determine the direct exposure of humans.*

30

- 31 • Information that is listed in Article 119(2) will be made publicly available unless the
32 registrant requests it as confidential and submits a justification, accepted as valid by
33 ECHA, as to why the disclosure of such information is potentially harmful for its

¹⁷ hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;

- hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;
- hazard class 4.1;
- hazard class 5.1;

commercial interests or those of any other party concerned (Article 10(a)(xi)). The information in question is:

- a) *If essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous;*
- b) *the total tonnage band (i.e. 1-10 tonnes, 10-100 tonnes, 100-1000 tonnes or over 1000 tonnes) within which a particular substance has been registered;*
- c) *the study summaries or robust study summaries of the information on physicochemical data concerning the substance, on pathways and environmental fate as well as on toxicological and ecotoxicological studies, but not where these data were generated by means of vertebrate animal studies;*
- d) *certain information contained in the safety data sheet as defined in Article 119(2);*
- e) *the trade name(s) of the substance;*
- f) *the name in the IUPAC Nomenclature can be claimed confidential for a substance that fulfils the criteria for any of the hazard classes set out in Article 58(1) of Regulation (EC) No 1272/2008, but only for a period of six year and if the substance is not one of the substance defined in Article 3(20) of REACH, e.g. substances listed in the European Inventory of Existing Commercial Chemical Substances ('EINECS');¹⁸*
- g) *the name in the IUPAC Nomenclature can also be claimed confidential for a substance that fulfils the criteria for any of the hazard classes set out in Article 58(1) of Regulation (EC) No 1272/2008, if the substance is only used as one or more of the following¹⁹:*
 - (i) *as an intermediate;*
 - (ii) *in scientific research and development;*
 - (iii) *in product and process orientated research and development.*

In addition, Article 118(2) lists the information whose disclosure is normally deemed to undermine the commercial interests of the concerned person, and will hence not be made available to the public, unless urgent action is essential to protect human health, safety or the environment:

- *details of the full composition of a mixture;*
- *without prejudice to Article 7(6) and Article 64(2), the precise use, function or application of a substance or mixture, including information about its precise use as an intermediate;*
- *the precise tonnage of the substance or mixture manufactured or placed on the market;*
- *the links between a manufacturer or importer and their distributors or downstream users.*

Practical instructions for requesting confidentiality in a registration are available in the ECHA manual '*Dissemination and confidentiality under the REACH Regulation*' accessible at: <http://echa.europa.eu/manuals>. The manual is also available via the help system built into IUCLID.

¹⁸ For this reason, when requesting confidentiality on the IUPAC name of a non phase-in substance, the registrant must set the 'Phase-in status' field in the IUCLID dossier header as 'non phase-in' for the claim to be considered for assessment.

¹⁹ In these cases, the 'phase-in' status does not need to be indicated in the IUCLID dossier.

1 *Legal references: Article 118, Article 119*

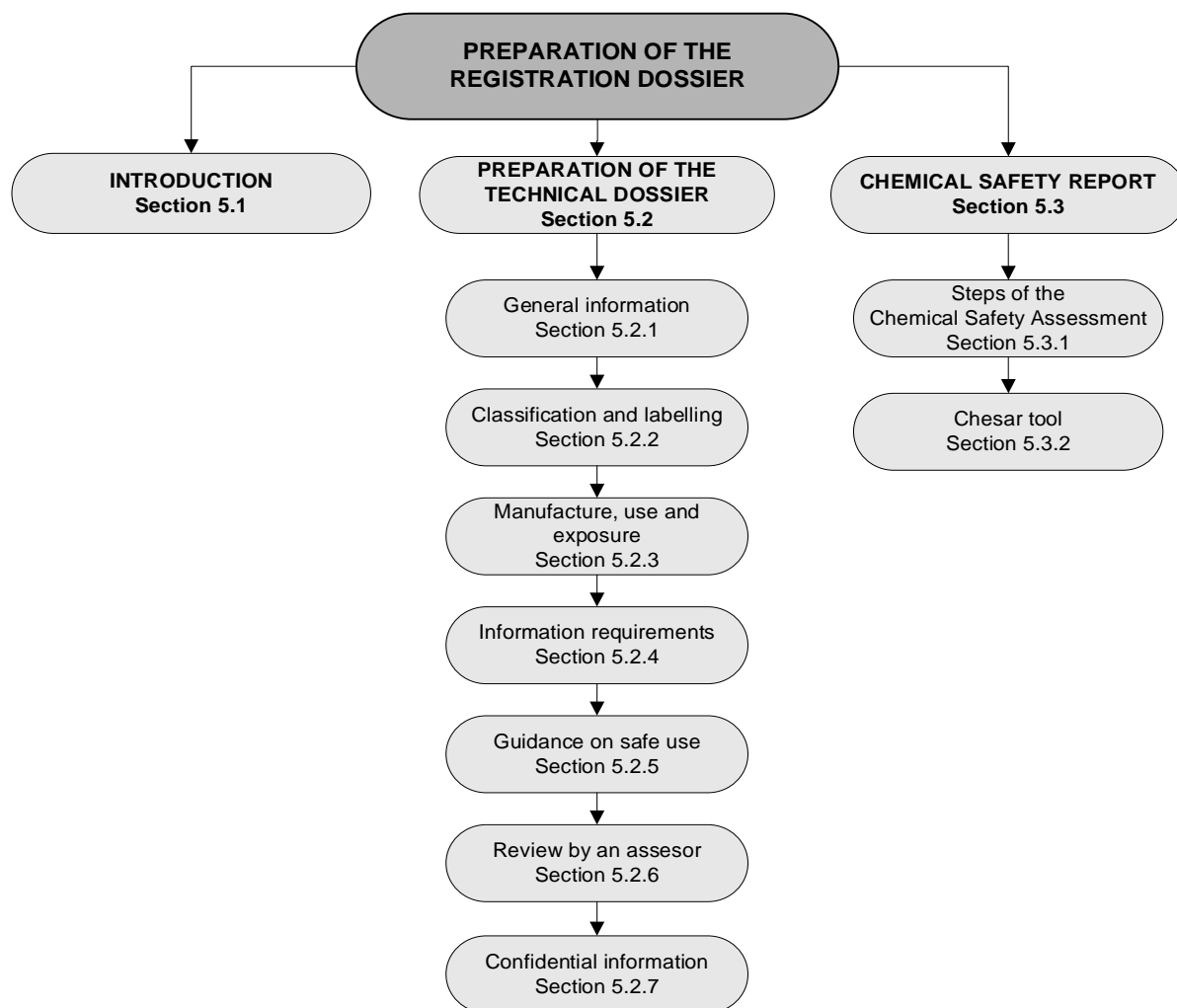
2 **4.5 Access to documents**

3 Access to documents held by ECHA may be granted on the basis of a case-by-case assessment
4 as it is foreseen in Regulation (EC) No 1049/2001 on public access to documents, (the 'ATD
5 Regulation'). The ATD Regulation provides for exceptions under which disclosure of the
6 requested documents, regardless of their medium, may be denied partly or in their entirety,
7 for instance because their disclosure would undermine the protection of commercial interests
8 of a natural or legal person, and in the absence of an overriding public interest in the
9 disclosure. Where it is not clear whether a document may or may not be disclosed, the ATD
10 Regulation requires ECHA to consult the author of the document with a view to assessing
11 whether it should or should not be disclosed, e.g. registration dossiers and Chemical Safety
12 Reports are considered documents.
13
14

5. Preparation of the registration dossier

Aim: The aim of this chapter is to describe how to prepare a registration dossier. It offers an overview on the information the registrant must submit as part of their registration dossier and explains how this information must be reported. It does not provide specific practical instructions on how to successfully submit a registration dossier to ECHA. For this consult the ECHA manual *How to prepare registration and PPORD dossiers* at: <http://echa.europa.eu/manuals>. The manual is also available via the help system built into IUCLID.

Structure: The structure of this chapter is as follows:



5.1 Introduction

Article 10(a) in combination with Annexes VI to X of REACH define the information to be documented in the technical dossier. Annex XI establishes the rules adapting the information required in Annexes VII to X. All Annexes must be considered in combination.

Similarly, Article 10(b), Article 14 and Annex I set out the general requirements for the CSA and the CSR applicable for substances subject to registration in quantities of ten tonnes or more per year.

All information of the registration dossier must be reported in IUCLID format. The relation between the information to be submitted for registration (under REACH) and the IUCLID sections where it must be reported, is detailed in **Table 2** below.

Table 2: Relation between the information requirements in Article 10 and the corresponding sections in a IUCLID file

| Information requirements | Article 10 | IUCLID |
|---|--------------------------|------------------------------|
| (a) Technical dossier | Article 10(a) | |
| (i) identity of the manufacturer or importer | Annex VI section 1 | Legal entity & Section 1 |
| (ii) identity of the substance | Annex VI section 2 | Section 1 |
| (iii) manufacture and uses of the substance and if relevant use and exposure categories | Annex VI section 3 | Section 3 |
| (iv) classification and labelling | Annex VI section 4 | Section 2 |
| (v) guidance on safe use | Annex VI section 5 | Section 11 |
| (vi) study summaries of information derived from the application of Annexes VII to XI | Annex VII to XI | Sections 4, 5, 6 and 7 |
| (vii) robust study summaries of the information derived from the application of Annexes VII to XI if required under Annex I | Annex I, Annex VII to XI | Sections 4, 5, 6 and 7 |
| (viii) indication regarding the review by an assessor of information submitted under (iii), (iv), (vi), (vii) and (b) | | Dossier header ²⁰ |
| (ix) proposals for testing | | Sections 4, 5, 6, 7 |

²⁰ The dossier header consists of information which is going to be used for administrative purposes and it is completed by the applicant when preparing their dossier from the substance data set.

| | | |
|---|--------------------------------------|---------------------------|
| (x) exposure information for substances in quantities of 1 to 10 tonnes | Annex VI section 6 | Section 3 |
| (xi) request as to which information in Article 119(2) should not be made available on the Internet | | All relevant sub sections |
| (b) Chemical safety report (CSR) | Article 10(b) Article 14, Annex 1 | Attachment in section 13 |

1

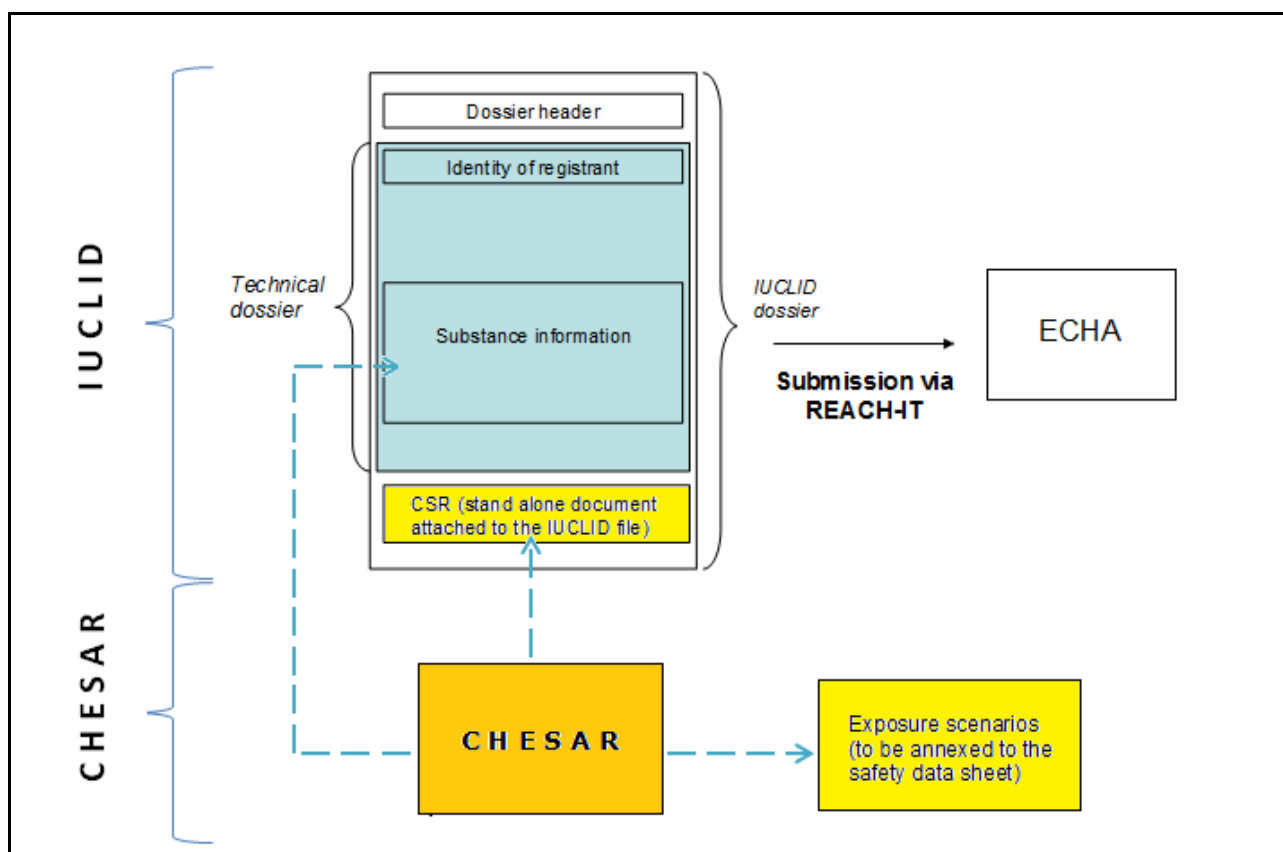
2 The creation of the registration dossier consists of the following tasks:

- 3
- 4
- 5
- Preparation of the technical dossier
 - Carry out the chemical safety assessment (when relevant), and
 - Recording the results of the chemical safety assessment in the chemical safety report

6 These tasks are described in detail in the following paragraphs.

7 The registration dossier must be submitted to ECHA via REACH-IT, as shown in. **Figure 4.**

8



9

10 **Figure 4: Structure and format of the registration dossier**

11

12

1 5.2 Preparation of the technical dossier

2 All relevant and available information on the substance, from its identification and intrinsic
3 properties to the classification and evaluation of its hazards, must be reported in the technical
4 dossier. The information requirements depend on the intended tonnage band to be
5 manufactured or imported (see section 2.2.6 Calculation of the volume to be registered).

6 "The technical dossier will also include the administrative data required for the identification of
7 the registration and for its further processing by ECHA (registrant's identity, tonnage band,
8 etc.).

9 The following sections of this guidance describe the content and level of detail needed in the
10 registration dossier.

11 Before the preparation of a registration dossier registrants are advised to consult the ECHA
12 manual 'How to prepare registration and PPORD dossiers' accessible at:
13 <http://echa.europa.eu/manuals>. The manual is also available via the help system built into
14 IUCLID.

15 16 5.2.1 General information on the registrant and on the registered substance

17 General information for the identification of the registrant and the substance to be reported in
18 the registration dossier include:

- 19 • **identity of the registrant** (as specified in section 1 of Annex VI of REACH), i.e.
20 registrant's name, address, telephone number and e-mail address, details of the
21 contact person, and as appropriate, information about the location of registrant's
22 production and own use sites.
- 23 • **role of the registrant** (manufacturer, importer or only representative). If the
24 registrant is an only representative acting on behalf of a 'non-EU manufacturer' they
25 are advised to attach a document from the 'non-EU manufacturer' appointing them as
26 only representative.
- 27 • **information required for traceability purposes**, such as the number of the pre-
28 registration or the inquiry preceding the registration.
- 29 • **identification of the substance** (as specified in section 2 of Annex VI of REACH). This
30 includes the name of the substance, its chemical identifiers (EC number, CAS name and
31 CAS number, etc.), the molecular and structural formula and its composition (degree of
32 purity, constituents, analytical data, etc.).

33 The 'one substance, one registration' principle requires registrants of the same
34 substance to register it jointly within the same joint submission. The jointly submitted
35 data must be representative for the composition(s) of the substance identified in the
36 registration dossier. The so-called *boundary composition of substance* provided in the
37 lead dossier describes the scope of the compositions covered by the jointly submitted
38 data. Several boundary compositions can be reported if different sets of hazard
39 information are representative for different compositions of the same substance.

40 It is the responsibility of each registrant to identify their substance. Information on the
41 principles of substance identification can be found in the *Guidance on identification and*
42 *naming of substances under REACH and CLP* ([http://echa.europa.eu/guidance-](http://echa.europa.eu/guidance-documents/guidance-on-reach)
43 [documents/guidance-on-reach](http://echa.europa.eu/guidance-documents/guidance-on-reach)).

44 In the case of import of a mixture, it can be difficult to obtain information on the
45 composition of the mixture from a non-EU supplier. However, also under the other
46 existing EU legislation (e.g. for classification and labelling of mixtures), importers need

to know which substances are present in the mixtures being imported to be sure they are complying with the obligations applicable to substances. It will be up to these registrants to guarantee sufficient communication through their supply chain to ensure their compliance with their REACH obligations. In case the disclosure of the composition of the mixture to the importers may have consequences, the 'non-EU manufacturer' of the substance has the possibility to appoint an only representative, as explained in section 2.1.2.5 Only representative of a 'non-EU manufacturer'.

5.2.2 Classification and labelling

Registration dossiers must include information on the classification and labelling of the substance according to the CLP criteria. The registrant must determine the classification and labelling of their substance with respect to physico-chemical properties, environment and human health.

Within a joint submission, the lead dossier may contain several classifications in case different compositions of the registered substance (having different percentage of constituents, impurities and/or differing in their form) have different hazard profiles. In such case classification records in IUCLID must be linked to the relevant compositions. If a member registrant disagrees and wants to propose another classification they will need to opt out from this information requirement in their own dossier (see section 4.3.3 Conditions for opting out from the jointly submitted data).

The rationale for the decision for a classification (as well as the rationale for non classification when this is the case) should be clearly documented. A reason for non classification can be due to:

- a lack of data,
- inconclusive data, or
- data which is conclusive but not sufficient for classification.

The classification and labelling proposed in registration dossiers are reported within the *Classification and Labelling Inventory (C&L Inventory)* established and maintained by ECHA, available at <https://echa.europa.eu/information-on-chemicals/cl-inventory-database>. The *C&L Inventory* contains the classification of all substances subject to registration as well as of all substances within the scope of the CLP Regulation which meet the criteria for classification as hazardous and are placed on the market.

It is recommended that registrants, before classifying their substance, consult Annex VI to the CLP Regulation (containing all harmonised classification and labelling of hazardous substances) as well as the *C&L Inventory* to check if their substance is already included. If the substance is included in Annex VI to the CLP Regulation (and therefore harmonised at EU level) the registrant must follow this harmonised classification. If the substance needs to be classified for additional endpoints to those covered by the harmonised classification, the registrant should report these next to the harmonised endpoints in their registration dossier. If the substance is already listed in the *C&L Inventory* but not in Annex VI to the CLP Regulation, the registrants should make every effort to agree their classification with other registrants, potential registrants having inquired and other notifiers of the classification and labelling of the same substance.

For further information on harmonised classification and labelling the reader is advised to consult the Questions and answers on Annex VI to CLP <http://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/clp/annex+vi+to+clp>. It may be also useful to view the 'Harmonised classification and labelling' section at: <http://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling>.

1 If the substance is subject to registration, but has not yet been registered, or if the substance
2 is within the scope of the CLP Regulation, meets the criteria for classification as hazardous and
3 is placed on the market either on its own or contained in a hazardous mixture above specified
4 concentration limits, the registrant must notify to ECHA the information related to its
5 classification and labelling. This must be done within one month after placing the substance on
6 the market.

7 For technical instructions on C&L notifications please consult the ECHA manual *How to prepare*
8 *a classification and labelling notification* available at: <http://echa.europa.eu/manuals>. It is also
9 advised to view the *Notification to the C&L Inventory* section accessible at:
10 <http://echa.europa.eu/regulations/clp/cl-inventory/notification-to-the-cl-inventory>.

11 Additional information is provided in the *Introductory Guidance on the CLP Regulation* and the
12 *Guidance on the application of the CLP criteria* available at: [https://echa.europa.eu/guidance-](https://echa.europa.eu/guidance-documents/guidance-on-clp)
13 [documents/guidance-on-clp](https://echa.europa.eu/guidance-documents/guidance-on-clp).

14
15

16 5.2.3 **Manufacture, use and exposure**

17 5.2.3.1 Information on manufacture and uses of the substance (section 3 of Annex VI 18 of REACH)

19 Information on the manufacture and uses of the substance is to be provided as part of a
20 registration dossier. This information plays an important role in many different REACH
21 processes including the generation of CSR when one is needed, dissemination of (non-
22 confidential) information on where substances are used as well as input to the prioritisation/
23 deprioritisation of substances for further regulatory processes.

24
25 Substances that are not used in a wide-dispersive manner (e.g. no uses by consumers of the
26 substance as such, in mixtures or in articles, no widespread uses by professional workers and
27 no industrial uses with potential for exposure) may be deprioritised from REACH/CLP
28 regulatory actions. To reflect the absence of the types of uses above, the use description
29 should:

- 30 • not include entries in sections 3.5.4 to 3.5.6 of IUCLID (as there are no registered
31 professional, consumer or service life uses),
- 32 • indicate that uses at industrial sites are limited to a few sites only
33 (for example < 5),
- 34 • claim that uses at industrial sites take place under closed (rigorously contained)
35 conditions leading to insignificant exposure to humans and insignificant release to
36 the environment on the various routes. These conditions need to be described in
37 the exposure assessment (for substances > 10 tonnes per year) or in the
38 exposure information according to Annex VI (6) (substances < 10 tonnes per
39 year).

40 Registrants may be aware that one or more uses of their substances are to be considered wide
41 dispersive (and thus qualify for being of priority concern for authorities). However, in the
42 context of the overall use pattern of the substance the extent of such uses may be minor,
43 which would be a key information for authorities in priority setting. Therefore, registrants are
44 advised to provide specific information on the tonnage for such uses.

45
46 Each registrant must report their own uses. They cannot refer to the dossier jointly submitted
47 by the lead registrant, even if the chemical safety report (CSR) has been submitted jointly. In
48 order to provide the use information, use maps developed under the CSR/ES roadmap can be
49 helpful (<https://echa.europa.eu/csr-es-roadmap/use-maps>). Use maps include the description
50 of use and its contributing activities as well as the references to the corresponding inputs to

the exposure assessment of workers, environment or consumers.

For more detailed guidance on use description, including advice on how to source and report the information please consult the *Guidance on information requirements and chemical safety assessment, Chapter R12: Use description* available at: <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

5.2.3.2 Information on exposure for substances > 10 tonnes

If, according to Article 14(4) the registrant is required to perform an exposure assessment as defined in section 5 of Annex I of REACH, then all identified uses of the registrant should be assessed (see section 5.374 Chemical Safety Report). This can be reported either in a joint or in an individual chemical safety report (CSR). The exposure assessment includes a description of the conditions of use and an estimation of the exposure resulting from these conditions. The outcome of the exposure assessment is compared with the hazard characteristics of the substance for demonstrating control of risk (risk characterisation according to section 6 of Annex I of REACH).

Registrants wishing to demonstrate that a substance is of low priority for the REACH/CLP regulatory processes may describe in their exposure assessment the condition ensuring absence/insignificance of exposure to humans and release to the environment on the various routes, e.g. how the substance is used under closed (rigorously contained) conditions. Such information may also be relevant for justifying that a certain information or test is not needed (exposure based waiving). REACH Annexes VIII to X establish in column 2 the specific rules for adaptation of standard information requirements and Annex XI establishes general rules for adaptation of those requirements (see also section 4.1.1 Fulfilling the information requirements).

5.2.3.3 Information on exposure for substances < 10 tonnes (section 6 of Annex VI)

For substances manufactured or imported between 1 and 10 tonnes per year, the registrant must provide information on exposure as specified under section 6 of Annex VI of REACH. Information regarding point 6.1.1 – *industrial use* and 6.1.2 (b) – *use resulting in inclusion into or onto matrix* will be satisfied when describing the use according to the *Guidance on information requirements and chemical safety assessment, Chapter R12: Use description* (corresponding section 3.5 of IUCLID – Life cycle description).

The extent of exposure information expected depends on what the registrant intends to demonstrate. Registrants claiming that Article 12(1)(b) does not apply for a substance due to absence of dispersive or diffuse uses (claim to be made in section 14 of IUCLID) should provide the following information in the technical dossier:

- absence of consumer uses, wide-spread uses by professional workers and service life. Registrants indicate such absence by not including the above-mentioned uses into their technical dossier (sections 3.5.4 to 3.5.6 of IUCLID empty) and advising against such uses in their safety data sheet (if a safety data sheet is required) and in section 3.6 of IUCLID;
- description of the condition ensuring absence/insignificance of exposure to humans and release to the environment on the various routes, e.g. how the substance is used under closed (rigorously contained) conditions.

The same information will also be relevant if registrants intend to demonstrate that the substance is of low priority for the REACH/CLP regulatory processes.

5.2.4 Information requirements on intrinsic properties (Annexes VII to X)

All **relevant available information** on the physicochemical, toxicological and ecotoxicological properties of the substance as specified under Annexes VII to X (and its adaptations according to Annex XI) must be provided in the technical dossier (see section 4.1 Information requirements for details).

Special considerations for 1-10 tonnes dossiers (Annex VII)

Certain substances benefit from reduced information requirements when being registered at the lowest tonnage band, as clarified in Article 2 of Implementing Regulation 2019/1692²¹. These are substances defined in Article 3(20) of REACH as phase-in substances, i.e. substances listed in the European Inventory of Existing Commercial Chemical Substances ('EINECS')²², the so-called 'no-longer polymer' (NLP)²³ and substances that were manufactured at least once in any of the current Member States of the EU, without being placed on the EU market by the manufacturer or importer after 31 May 1992²⁴.

When such a substance does not meet the Annex III criteria:

- The registrant can register the substance with reduced information requirements (i.e. only the information on physicochemical properties specified in Annex VII, section 7 of REACH) at the lowest tonnage band (1-10 tonnes per year), as clarified by the Implementing Regulation on the end of phase-in²⁵ (Article 12(1)(b));
- The registrant can register the substance with the standard information requirements at the lowest tonnage band (1-10 tonnes per year) and claim a fee waiver (Articles 12(1)(b) and 74, *recital* 34).

Not fulfilling the Annex III criteria means that:

²¹ Commission Implementing Regulation (EU) 2019/1692 of 9 October 2019 on the application of certain registration and data-sharing provisions of Regulation (EC) No 1907/2006 of the European Parliament and of the Council after the expiry of the final registration deadline for phase-in substances

²² The EINECS list contains, in principle, all substances on the Community market on 18 September 1981. The full and exhaustive list is part of the EC Inventory accessible on the ECHA website: <http://echa.europa.eu/information-on-chemicals/ec-inventory>. The list has been 'frozen' and more substances cannot be added to it or removed from it.

²³ These are substances that were placed on the market in any of the current Member States of the EU before 1 June 2007 by the manufacturer or importer and were considered as having been notified in accordance with the first indent of Article 8 (1) of Directive 67/548/EEC in the version resulting from the amendment effected by Directive 79/831/EEC (and hence did not have to be notified under that Directive), but which does not meet the REACH definition of a polymer. Also in this case, the manufacturer or importer must have documentary evidence that they placed the substance on the market, that it was a NLP and that the substance was placed on the market by any manufacturer or importer between 18 September 1981 and 31 October 1993 inclusive. Such documentary evidence can be, for example, order sheets, stock lists, labels, safety data sheets, or any other documents which can be undoubtedly traced back to a date between 18 September 1981 and 31 October 1993 inclusive. A non-exhaustive list of NLPs, that only serves for information purposes, is accessible at <http://echa.europa.eu/information-on-chemicals/ec-inventory>.

²⁴ The manufacturer or importer must have documentary evidence of this. Such documentary evidence can be, for example, order sheets, stock lists, or any other documents which can be undoubtedly traced back to a date after 31 May 1992. If the substance would have been placed on the market by the manufacturer or importer, it would normally have been notified under Directive 67/548/EEC and in that case, it will be considered as registered.

²⁵ Commission Implementing Regulation (EU) 2019/1692 of 9 October 2019 on the application of certain registration and data-sharing provisions of Regulation (EC) No 1907/2006 of the European Parliament and of the Council after the expiry of the final registration deadline for phase-in substances

- there is no indication that the substance has carcinogenic, mutagenic or toxic to reproduction (CMR, category 1A or 1B), persistent, bioaccumulative and toxic (PBT) or very persistent, very bioaccumulative (vPvB) properties, and
- there is no indication that a substance with dispersive or diffuse uses would be classified as hazardous for human health or as an environmental hazard under the CLP Regulation.

For more information, see the Annex III inventory available at:

<http://echa.europa.eu/information-on-chemicals/annex-iii-inventory>

Before registrants can claim in their technical dossier (section 14 of IUCLID) that Annex III criteria are not fulfilled, they should review and subsequently verify all available information, including:

- data from submitted REACH registrations (see ECHA's dissemination website: <http://echa.europa.eu/en/information-on-chemicals>) or C&L notifications (see ECHA's C&L Inventory: <http://echa.europa.eu/information-on-chemicals/cl-inventory-database>) or any other relevant databases, e.g. the OECD eChemPortal (<http://www.echemportal.org>);
- regulatory data (e.g. Annex VI of CLP);
- experimental data, e.g. in QSAR Toolbox (<http://www.qsartoolbox.org/>);
- ECHA's inventory of substances likely to meet the Annex III criteria (<http://echa.europa.eu/information-on-chemicals/annex-iii-inventory>);
- alternatives to test data (e.g. QSAR, read-across, *in vitro*);
- in-house marketing information and information provided by customers or downstream sector organisations for characterising the uses of the substance (see section 5.2.3 Manufacture, use and exposure).

Information on how to fill in section 14 in IUCLID, regarding the Annex III criteria is detailed in the ECHA manual *How to prepare registration and PPORD dossiers* accessible at: <http://echa.europa.eu/manuals>. The manual is also available via the help system built-in IUCLID.

Additional information on more specific information on the level of detail to be reported for each individual endpoint, can also be found in our practical guides for example *Practical guide for SME managers and REACH coordinators - How to fulfil your information requirements at tonnages 1-10 and 10-100 tonnes per year* accessible at: <http://echa.europa.eu/practical-guides>.

5.2.5 Guidance on safe use

The registrant must report the following information (as required under section 5 of Annex VI of REACH):

- First aid measures
- Fire-fighting measures
- Accidental release measures
- Handling and storage
- Transport information

Where a CSR is not required the following information is additionally required:

- Exposure controls and personal protection measures

- Stability and reactivity
- Disposal information

The information needs to be reported in the registration dossier and must be consistent with that in the safety data sheet (SDS), where an SDS is required (see section 6.1 Provide a safety data sheet (SDS) to customers).

When filling this section of the technical dossier, the registrant is advised to follow in-house current practices or the *Guidance on the compilation of safety data* sheets accessible at: <http://echa.europa.eu/guidance-documents/guidance-on-reach>.

5.2.6 Review by an assessor

The registrant is required to indicate in the technical dossier whether any of the following information was reviewed by an assessor. The assessor may be a person representing a manufacturer or importer, a formulator, a sector specific organisation, or a single company. An assessor is chosen as a voluntary option, based on their appropriate experience and expertise in:

- Information on the manufacture and use;
- Classification and labelling of the substance;
- (Robust) Study summaries on the information requirements defined in Annexes VII to X;
- Chemical Safety Report.

Such expertise allows the assessor to interpret the reported data related to the substance.

5.2.7 Confidential information

The IUCLID template allows registrants to set confidentiality request flags on information covered by REACH Article 119(2). The list of information that can be claimed confidential is included in section 4.4 Confidentiality and electronic public access to registration information.

To keep the information confidential, a confidentiality request must be submitted to ECHA and a justification needs to be provided in the corresponding IUCLID field. It is strongly recommended to use the justification template (already included in the justification field) to ensure that it contains all the necessary elements.

Confidentiality requests are subject to a fee.

For technical instruction on how to make a confidentiality request, consult the ECHA manual, *Dissemination and confidentiality under the REACH Regulation* accessible at: <https://echa.europa.eu/manuals>.

5.3 Chemical Safety Report

For substances manufactured or imported at 10 tonnes or more per year, the registrant must submit as part of their registration dossier a chemical safety report (CSR).

The CSR is a standalone document which is to be attached in section 13 of IUCLID to the registration dossier and it contains partly information that should already have been included in the technical dossier.

A summary of the CSR format (as defined in Annex I of REACH) is presented in **Table 3** below.

Table 3: Short summary of the CSR format

PART A

1. Summary of risk management measures
2. Declaration that risk management measures are implemented
3. Declaration that risk management measures are communicated

PART B

1. Identity of the substance and physical and chemical properties
2. Manufacture and uses
3. Classification and labelling
4. Environmental fate properties
5. Human health hazard assessment
6. Hazard related to physicochemical properties
7. Environmental hazard assessment
8. PBT and vPvB assessment
9. Exposure assessment²⁶
10. Risk characterisation

The CSR should document the chemical safety assessment (CSA) performed by the registrant. The purpose of the CSA is to ensure that the risks arising from the manufacture and use of a substance (on its own, in a mixture or in an article) are under control. The CSA of a manufacturer must address the manufacture and all identified uses of the substance while an importer will have to address only the identified uses. All stages of the life-cycle of the substance resulting from the manufacture (if applicable) and the identified uses must be considered in the CSA, including, where relevant, the waste stage and the service life of articles.

A CSA should include the following steps:

- Hazard assessment:
 - Human health hazard assessment
 - Physicochemical hazard assessment
 - Environmental hazard assessment
 - PBT/vPvB assessment

If the substance fulfils the criteria for any of the hazard classes or categories set out in Article 14 (4) or is assessed to be a PBT or vPvB the chemical safety assessment will have to include the following additional steps:

²⁶ It may be more user friendly to report the risk characterisation per exposure scenario together with the exposure scenario in section 9 of the CSR. Section 10 can then be used to report the risk characterisation combined from different exposure scenarios. Chesar generated CSR is taking this approach.

- Exposure assessment:
 - Generation of exposure scenario(s)
 - Exposure estimation
- Risk characterisation

To get familiarised with the concepts of the CSA, those readers without any previous knowledge on risk assessment might find it useful to refer first to Chapter 6 of the '*Practical guide for SME managers and REACH coordinators - How to fulfil your information requirements at tonnages 1-10 and 10-100 tonnes per year*' accessible at: <https://echa.europa.eu/practical-guides>.

For further information the reader should consult the *Guidance on information requirements and chemical safety assessment* accessible at: <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

5.3.1 Steps of the chemical safety assessment

5.3.1.1 Hazard assessment

The assessment starts with the assessment of the human health, physicochemical and environmental hazards. In addition, the registrant has also to assess whether the substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB).

Considerations on how to characterise a substance and its hazard are provided in chapter D2 of Part D of the *Guidance on information requirements and chemical safety assessment* (Framework for exposure assessment) accessible at <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

The hazard assessment should be performed based on all available and relevant information which should be reported in the technical dossier. The registrant should rely particularly on the key studies identified in the technical dossier for the relevant endpoints. In addition to these key studies, information available in other studies could also be used by the registrant as supporting information or as part of a weight of evidence approach.

5.3.1.1.1 Human health hazard assessment

The objective of the human health hazard assessment is to determine the classification and labelling of the substance and to define the level of exposure above which humans should not be exposed. This level of exposure is known as the derived no-effect level(s) (DNEL). The DNEL is regarded as an exposure level below which an adverse effect will not occur.

Guidance on how to derive a DNEL is available in the *Guidance on information requirements and chemical safety assessment, Chapter R.8: Characterisation of dose [concentration]-response for human health* accessible at: <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

The reader is also advised to consult the Practical Guide 14 *How to prepare toxicological summaries in IUCLID and to derive DNELs* available at: <http://echa.europa.eu/practical-guides>. A 'DNEL calculator' is available in IUCLID. More information can be found in the ECHA manual *How to prepare registration and PPORD dossiers* accessible at: <https://echa.europa.eu/manuals>.

5.3.1.1.2 Physicochemical hazard assessment

The objective of the physicochemical hazard assessment is to determine the classification and labelling of the substance and to assess, as a minimum, the potential effects to human health for explosivity, flammability and oxidising potential.

Guidance on how to assess physico-chemical properties is available in the sub-chapter *R. 7.1 'Physicochemical properties'* within '*Chapter R. 7a: Endpoint specific guidance of the Guidance on information requirements and chemical safety assessment*' available at: <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

5.3.1.1.3 Environmental hazard assessment

The objective of the environmental hazard assessment is to classify and label the substance and to determine a predicted no-effect concentration (PNEC) below which adverse environmental effects in the environmental compartments are not expected to occur.

Guidance on how to derive a PNEC is available in *Chapter R. 10: Characterisation of dose [concentration]-response for environment* within *Guidance on information requirements and chemical safety assessment* available at: <https://echa.europa.eu/guidance-documents/guidance-on-reach>. A 'PNEC calculator' is available in IUCLID.

5.3.1.1.4 PBT/vPvB assessment

The objective of the PBT/vPvB assessment is to determine if the substance fulfils the criteria given in Annex XIII and if so, to characterise the potential emissions of the substance.

Guidance on how to perform a PBT/vPvB assessment is available in *Chapter R. 11: PBT/vPvB assessment* of the *Guidance on information requirements and chemical safety assessment* available at: <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

5.3.1.2 Exposure assessment including risk characterisation

When the result of the hazard assessments indicates that the substance fulfils the criteria for any of the hazard classes or categories set out in Article 14(4) or is assessed to be a PBT or vPvB in accordance with the criteria in Annex XIII the registrant needs to perform an exposure assessment. The **exposure assessment** must address all the hazards identified in the previous steps.

For an overview on how the scope of exposure assessment can be determined, please refer to chapter D.2.3 of the *Guidance on information requirements and chemical safety assessment*, available at: <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

The exposure assessment consists of determining quantitatively or qualitatively the dose/concentrations of the substance to which humans and the environment are or may be exposed under prescribed conditions of use described in an exposure scenario. The assessment must consider all stages of the lifecycle of the substance resulting from the manufacture and identified uses.

The exposure assessment includes two steps:

- Generation of exposure scenario(s)
- Exposure estimation

An exposure scenario (ES) is a set of conditions that describe how a substance is manufactured or used during its life-cycle and how the manufacturer or importer or downstream user controls or recommends controlling exposure of humans and the

environment. It must include the appropriate risk management measures and operational conditions that, when properly implemented, ensure that the risks from the uses of the substance are controlled.

For more guidance on how to carry out an exposure assessment please consult the *Guidance on information requirements and chemical safety assessment*, Part D and the following Chapters:

- R. 14: Occupational exposure assessment
- R. 15: Consumers exposure assessment
- R. 16: Environmental exposure assessment
- R. 18: Exposure scenario building and environmental release estimation for the waste life stage.

All the guidance documents listed above are available at: <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

The **risk characterisation** is the final step in the chemical safety assessment where it should be determined whether risks arising from manufacture/import and uses of the substance are controlled. The registrant must compare the no-effect levels (DNELs) and the predicted no-effect concentrations (PNECs) with the calculated exposure concentrations to human and the environment, respectively. Where no DNEL or PNEC is available for an identified toxicological or ecotoxicological hazard, a qualitative or semi-quantitative risk characterisation is required.

The risk characterisation consists also of the assessment of the likelihood and severity of an event occurring due to physico-chemical properties of the substance and a qualitative or quantitative estimation/description on the uncertainties related to the risk assessment.

The risk characterisation must be carried out for each exposure scenario for both the human health and the environment.

5.3.2 Chesar tool

Chesar stands for **C**hemical **s**afety **a**ssessment and **r**eporting tool. The tool has been developed by ECHA to help registrants perform a CSA and generate a CSR and ESs for communication (to be annexed to the safety data sheet) in an efficient way. It provides a structured workflow for carrying out a standard safety assessment for the different uses of a substance.

Chesar supports the re-use of assessment elements across substances. The tool also helps to structure the information needed for the exposure assessment and risk characterisation which will facilitate the generation of a transparent CSR. By using Chesar registrants can more easily maintain their CSR and the consistency with their registration dossier as the uses assessed in Chesar can be exported to IUCLID together with an extract of their related assessment. The tool can be downloaded free of charge from <https://chesar.echa.europa.eu/>.

To use Chesar, a registrant needs to have sufficient information available on the properties of the substance, the uses of the substance, the related tonnages and the conditions under which the uses take place. Based on these inputs the tool calculates exposure estimates that are compared to the predicted no-effect levels. Workers' exposure estimations provided by Chesar are calculated using the 'ECETOC TRA worker' tool (available on <http://www.ecetoc.org/tra>). Environmental exposure estimates provided by Chesar are based on the EUSES 2.1 fate model (the EUSES software is available on <https://ec.europa.eu/jrc/en/scientific-tool/european->

-
- 1 [union-system-evaluation-substances](#)). Chesar also supports the assessments based on other
2 exposure estimation tools or measured data.
- 3 Chesar enables re-use of whole assessments or parts of them already carried out by the
4 registrant or prepared by industry associations via its data exchange functionality. In
5 particular, use maps developed by downstream users associations can be imported in the form
6 of a life cycle tree, with or without exposure assessment inputs. Use maps developed by
7 sectors can be downloaded in Chesar format from [https://echa.europa.eu/csr-es-](https://echa.europa.eu/csr-es-roadmap/use-maps/use-maps-library)
8 [roadmap/use-maps/use-maps-library](https://echa.europa.eu/csr-es-roadmap/use-maps/use-maps-library)). Such data exchange functionalities support efficient
9 CSA processes and cross-industry harmonisation of the description of uses and of the safe
10 conditions of use. Finally, standard phrases, in particular the ECom phrase catalogue, can be
11 imported in the Chesar library for use in the ES for communication.
- 12 Registrants are advised to consult the Chesar user manuals if in need of more detailed
13 information on the use of the tool. They are available at: <http://chesar.echa.europa.eu/>.
14

6. Duty of communication in the supply chain

To prepare their registration dossier it is important that the registrant communicates with their downstream users. In particular the registrant will need information about their uses, the operational conditions of use and the risk management measures they have already put in place. This includes the uses of the direct customers and the uses of the customers' customers that have been identified further down the supply chain.

6.1 Provide a safety data sheet (SDS) to customers

According to Article 31(1) of REACH when supplying a substance or a mixture, the **supplier** must provide an SDS formatted in accordance with Annex II to REACH to all the downstream users and distributors they supply to, whenever a substance or a mixture:

- meets the criteria for **classification as hazardous in accordance with the CLP Regulation**; or
- it is **persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB)** in accordance with Annex XIII to REACH; or
- it is included in the **candidate list of substances**²⁷ for other reasons than the above (e.g. because of endocrine disruptor properties).

In addition, Article 31(3) specifies conditions under which an SDS must be supplied on request for a mixture which does not meet the criteria for classification as hazardous in accordance with the CLP Regulation, but which contains:

- $\geq 1\%$ (by weight) for non-gaseous mixtures (or $\geq 0.2\%$ by volume for a gaseous mixture) of a substance posing human health or environmental hazards; or
- for non-gaseous mixtures, $\geq 0.1\%$ (by weight) of at least one substance that is carcinogenic category 2 or toxic to reproduction category 1A, 1B and 2, skin sensitiser category 1, respiratory sensitiser category 1, or has effects on or via lactation or is persistent, bioaccumulative and toxic (PBT) or a vPvB substance in accordance with Annex XIII or has been included in the candidate list of substances which may be subjected to authorisation; or
- a substance for which there are Community workplace limits.

It is therefore highly recommended that each supplier compiles an SDS for those mixtures, in order to have it available.

When supplying a substance on its own, the SDS must be prepared for the substance itself. When supplying a substance in a mixture, the SDS must be prepared for the mixture.

The SDS does not need to be supplied where substances or mixtures that are hazardous in accordance with the CLP Regulation, offered or sold to the general public, are provided with sufficient information (e.g. by labelling or with product inserts) to enable users to take the necessary measures as regards the protection of human health, safety and the environment, unless this is requested by a downstream user or a distributor. For further information on requirements for safety data sheets please refer to the *Guidance on the compilation of the*

²⁷ Substances may be identified as Substances of Very High Concern (SVHC) pursuant to Article 59 of the REACH Regulation based on a proposal prepared by a Member State or a proposal prepared by ECHA on request of the Commission. ECHA includes these substances in the so called 'Candidate List' of substances for possible inclusion in the authorisation list (Annex XIV of the REACH Regulation) following a unanimous agreement of ECHA's Member State Committee, or a Commission decision if a unanimous agreement is not reached. The list is available at: <https://echa.europa.eu/candidate-list-table>.

safety data sheets available at: <http://echa.europa.eu/guidance-documents/guidance-on-reach>.

Where an exposure assessment has been carried out, the final ESs developed for the identified uses as part of the CSA have to be communicated to the registrant's customers as an annex to the SDS, as this provides instructions on risk management measures that should be in place in order to ensure control of risks. This also applies, if the registrant having carried out the CSA supplies the substance in a mixture.

The registrant must ensure that the information in the CSR and in the main body of the safety data sheet is consistent with the exposure scenarios annex.

It is the responsibility of the supplier to keep the SDS updated.

Further information is available in the *Guidance on the compilation of safety data sheets*.

Legal reference: Article 31, Annex II

6.2 Provide other information to customers

When supplying a substance or a mixture for which an SDS is not required (see section above), the supplier still must provide to all downstream users and distributors they supply the following information:

- if the substance is subject to authorisation²⁸ and details of any authorisation granted or denied in this supply chain;
- the details of any restriction²⁹ imposed;
- any available and relevant information about the substance that is necessary to enable appropriate risk management;
- the registration number if available for any substances for which information is communicated as outlined above.

This information must be communicated at the latest at the time of the first delivery of the substance on its own or in a mixture after 1 June 2007.

Legal reference: Article 32

6.3 Include identified uses in the dossier

According to Article 37(2), a downstream user may intend to make their use known to the supplier. The supplier may be a distributor, a downstream user but also a registrant, i.e. manufacturer/importer who has registered the substance. In such case, the registrant prepares a new or update the existing CSR to include relevant exposure scenarios covering the communicated use, taking into account the specified timelines indicated in Article 37(3).

The registrant has to comply at least 1 month before the next supply, or within 1 month of the

²⁸ For further information on the authorisation process, please refer to the *Guidance on the preparation of an application for authorisation* (<http://echa.europa.eu/guidance-documents/guidance-on-reach>)

²⁹ For further information on the restriction process please refer to the *Guidance for the preparation of an Annex XV dossier for restriction* (<http://echa.europa.eu/guidance-documents/guidance-on-reach>). It is also recommended to view the 'Restriction' section of the ECHA website at: <https://echa.europa.eu/regulations/reach/restriction>.

1 request, whichever is later.

2 For more details about the communication between the registrant and downstream user please
3 refer to the *Guidance for downstream users* available at: [http://echa.europa.eu/guidance-
documents/guidance-on-reach](http://echa.europa.eu/guidance-
4 documents/guidance-on-reach).

5 *Legal reference: Article 37*

6

7. When and how to update a registration

Aim: The aim of this chapter is to explain when and how to update a registration. It explains all reasons why the registrant should update the registration on their own initiative and when the authorities can request the registrant to update the registration dossier. It also describes what are the updating duties for substances regarded as registered.

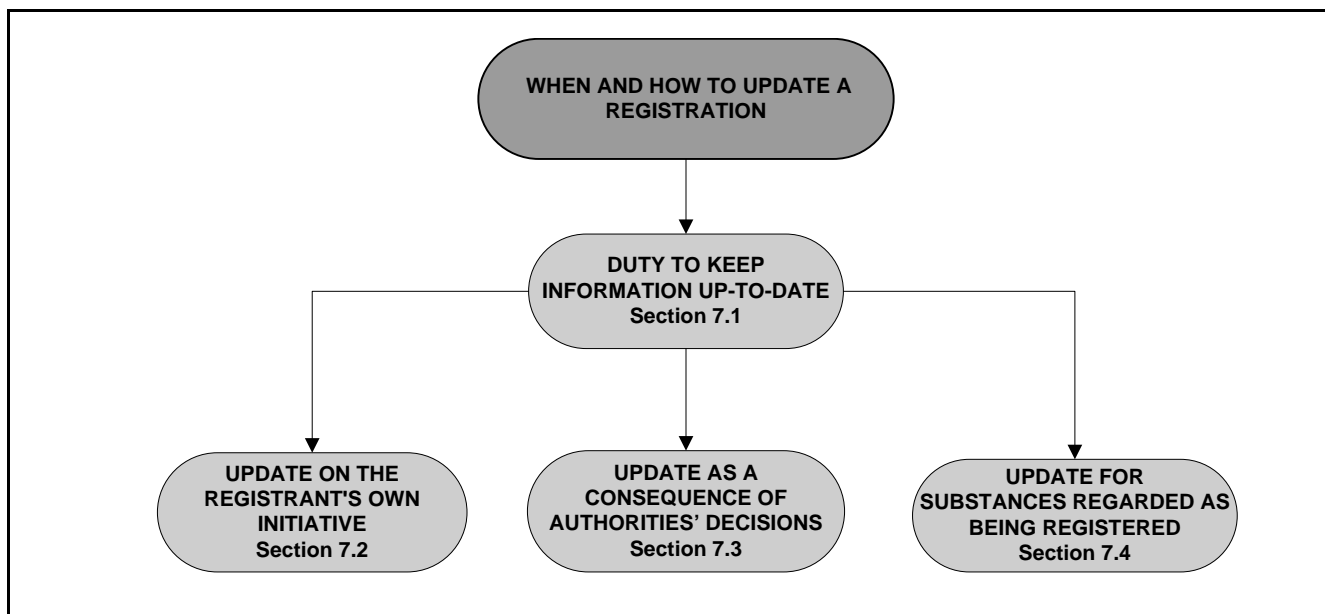
If in need of updating their registration information, the reader is advised to consult the ECHA manual *How to prepare registration and PPORD dossiers* accessible at: <http://echa.europa.eu/manuals>. The manual is also accessible from IUCLID itself.

Registrants should consider their registration dossiers as 'living documents' and update them whenever new information is available or a need to improve the quality of data is identified. Special attention should be paid to the following areas of the registration dossier: substance identity, classification and labelling, use, exposure information and justifications for adaptations to information requirements and for using alternative methods.

Better quality of information on substances helps ECHA and Member State Competent Authorities to select and prioritise the most hazardous substances for regulatory attention. This may also benefit registrants since, with better and more transparent information, their substances may be deprioritised from regulatory actions.

ECHA may perform IT screening campaigns on dossiers to highlight the aspects of registrations that can be improved. The response to such campaigns can be spontaneous updates of the registrations addressing the highlighted concerns, as well as better quality of data in further submissions. For more details on IT screening campaigns please consult the ECHA dedicated webpage available at: <http://echa.europa.eu/support/how-to-improve-your-dossier/it-screening-campaigns-on-dossiers>.

1 **Structure:** The structure of this chapter is as follows:



2
3
4

7.1 Duty to keep information up to date

5 The information submitted to ECHA must be kept up to date. It is the responsibility of the
6 registrant to update their registration information when needed. If the information to be
7 updated is part of jointly submitted information, it will normally be the lead registrant who will
8 have to update the registration on behalf of the members of the joint submission.

9 In order to update their registration information, the registrant will have to update their
10 IUCLID dossier and submit it to ECHA through REACH-IT. Where the update relates exclusively
11 to administrative data, such as the identity of the registrant, the updated information will be
12 directly reported in REACH-IT. No update of the IUCLID dossier is required in this case.

13

14 There are two types of situations where a registrant needs to update the information
15 concerning their registration:

16 1. Update on the registrant's own initiative

17 Registrants are required to report to ECHA **without undue delay** any new relevant
18 available information (e.g. new tonnage band, new uses, etc.) concerning their
19 registration. **Commission Implementing Regulation (EU) 2020/XXXX** specifies the
20 maximum deadlines by which this obligation is to be complied with, depending on the
21 situation at issue, pursuant to Article 22(1) of the REACH Regulation.

22 2. Update as a consequence of a decision made by ECHA or the Commission

23 The registrant must update their registration as a consequence of an ECHA or a
24 Commission decision under the evaluation³⁰ procedure but also, when relevant,

³⁰ For more information please consult ECHA Evaluation webpages accessible directly via the following links: <https://echa.europa.eu/regulations/reach/evaluation> and <https://echa.europa.eu/about-us/the-way-we-work/procedures-and-policies/public-procedures>.

following any decision made in accordance with the authorisation and the restriction processes. These updates must be performed **within the deadline** specified by ECHA/the Commission in the decision.

For substances regarded as registered because a notification according to Directive 67/548/EEC has been submitted, registrants need to submit updates of their dossier when any of the situations mentioned above occurs, including updates following decisions taken according to Directive 67/548/EEC and now regarded as ECHA decisions. However, the update does not have to meet the full information requirements under REACH, corresponding to the respective tonnage band, unless the quantity manufactured/imported of the notified substance by the registrant reaches the next tonnage threshold or the registrant becomes the lead registrant of a joint submission, where other registrants may rely on the jointly submitted data.

The next sections explain in further detail the different situations a registrant may encounter because of which an update of their registration dossier may be required.

An update will in certain cases be subject to the payment of a fee in accordance with the Commission Regulation (EC) No 340/2008, as amended (see section 10.2 Fee for updating a registration dossier).

Legal references: Article 16(2), Article 20(2), Article 20(6), Article 22, Article 135, Commission Implementing Regulation (EU) 2020/XXXX

7.2 Update on the registrant's own initiative

A registrant is responsible on their own initiative for updating their registration information without undue delay. The deadlines for the expected dossier updates have been clarified in the Commission Implementing Regulation (EU) 2020/XXXX (from here on out Implementing regulation on dossier updates) and they are summarised in the Table 4. They should operate as upper limits, that is, updates must be made as soon as possible, and no later than the deadline established.

Table 4 – Updates pursuant to Article 22(1) and relevant maximum deadlines

| Update reasons | REACH Article | Deadline to submit the updated dossier * |
|--|---------------|--|
| Any change in the status of the registrant, such as being a manufacturer, an importer or a producer of articles, or in their identity, such as their name or address | Art 22(1)(a) | 3 months |
| Any change in the composition of the substance | Art 22(1)(b) | 3 months |
| Changes in the annual or total quantities manufactured or imported by the registrant or in the quantities of substances present in articles produced or imported by the registrant, if these result in an increase of tonnage band or cessation of manufacture or import | Art 22(1)(c) | 3 months/6 months (in case of testing proposals) |

| | | |
|---|--------------|--|
| New identified uses and new uses advised against for which the substance is manufactured or imported | Art 22(1)(d) | 3 months |
| New knowledge of the risks of the substance to human health and or the environment of which the registrant may reasonably be expected to have become aware which leads to changes in the SDS or the CSR | Art 22(1)(e) | 6 months |
| Any change in the classification and labelling of the substance | Art 22(1)(f) | By the date from when the harmonised classification applies/ 6 months for self classification |
| Any update or amendment of the CSR or the Guidance on safe use | Art 22(1)(g) | 12 months |
| The registrant identifies the need to perform a test listed in Annex IX or Annex X, in which cases a testing proposal must be developed | Art 22(1)(h) | 6 months/12 months |
| Any change in the access granted to information in the registration | Art 22(1)(i) | 3 months |

* For detailed information on when the deadline is counted from and for clarification on cases with multiple deadlines, see the specific sections below

As indicated in Article 22(1), the registrant is responsible for updating their registration when there is:

a) Any change in their status, such as being a manufacturer, an importer or a producer of articles, or in their identity, such as their name or address³¹

The registrant must inform ECHA of any change in their role regarding the registered substance (e.g. a manufacturer becoming an importer) through an update of the registration dossier.

The roles of only representative and importer are not interchangeable. Thus, it is not possible to update a dossier in order to change from one role to another.

The role of an only representative is substantially different from that of an importer as explained in section 2.1.2.5 Only representative of a 'non-EU manufacturer'

For the same reasons, the role in the supply chain 'only representative', cannot be combined with the roles of 'manufacturer' or 'importer'.

The registrant must also inform ECHA of any change in their identity and contact details. Many of these changes can be made in REACH-IT without submitting an update of the registration dossier.

Further duties arise in cases where a change in identity involves a change in the legal personality of the registrant. This may be the case when a merger, takeover or split takes place or in case a company sells its assets related to a registration (e.g. sale of a manufacturing site, importing facilities). It also applies to the appointment of a new only

³¹ Article 1 of the Implementing regulation on dossier updates

representative by a 'non-EU manufacturer' as a replacement for a previous one.

A registration cannot be seen as a commodity, i.e. it is not an asset that can be subject to a sale on its own. It can be transferred to another company only as a result of the transfer of the activity subject to the registration obligation.

One registration cannot be shared by two different legal entities. Therefore, if an activity subject to registration is sold to several entities, only one of these entities will have its activity covered by the existing registration. The other(s) must submit a new registration to ECHA before starting the manufacture/import of the substance.

In the case of a merger or takeover where the individual legal entities have previously registered the same substance, attention must be paid to the total tonnage of the manufactured/imported substance after the merger or takeover. If the total tonnage reaches a higher tonnage band, then the registration dossier must be updated accordingly. Furthermore, if a registration is transferred from one legal entity to another who already has a registration for the same substance, the status of the newly transferred registration will be marked as 'annulled' in REACH-IT as one legal entity cannot have two registrations for the same substance.

Detailed information on how to report changes in the identity of legal entities and more scenarios can be found in the Practical Guide *How to report changes in identity of legal entities* available at: <http://echa.europa.eu/practical-guides>.

In all the above described cases, registrants have a maximum of 3 months to provide ECHA with the update, counted from the day when the specific change takes effect.

Table 5 - Examples of update reasons falling under Art 22(1)(a)

| Examples of update reasons falling under Art 22(1)(a) | IUCLID dossier update required? |
|--|---|
| Change of company name | No, changes to be reported in ECHA business account |
| Change of company address | No, changes to be reported in ECHA business account |
| Change of company size | No, changes to be reported in REACH-IT |
| Legal entity change (split/merger/change of only representative) | No, changes to be reported in REACH-IT. Following the successful legal entity change, an update of the IUCLID dossier is expected from the legal successor. |
| Change in the registrant's role within the supply chain (importer, manufacturer) | Yes |

ECHA business accounts are associated with a legal entity and can be used to access the ECHA IT tools and the ECHA website.

REACH-IT is the central IT system that supports Industry, Member State competent authorities and the European Chemicals Agency to securely submit, process and manage data and dossiers.

b) Any change in the composition of the substance ³²

If the composition of the substance changes, e.g. due to a change of process, the registrant must report the change to ECHA by updating their registration dossier. It is important to evaluate whether the change in the composition of the substance may influence the intrinsic properties of the substance registered, as that may trigger further update duties.

The registration must be updated and submitted to ECHA by no later than 3 months from the date when the manufacture or import begins with that change in the substance composition.

For further guidance on when a change in, for example the degree of purity would trigger an update see the *Guidance for identification and naming of substances under REACH and CLP*, available at: <http://echa.europa.eu/guidance-documents/guidance-on-reach>.

Example: Due to legislative changes or because of cost or process efficiency gains, there may be a change in the manufacturing process, which can lead to a different substance composition profile.

c) Changes in the annual or total quantities manufactured or imported by the registrant or in the quantities of substances present in articles produced or imported by the registrant, if these result in a change of tonnage band, including cessation of manufacture or import ³³

After the registrant has submitted their registration dossier, they must always calculate the tonnage based on the annual manufactured or imported volume (i.e. the tonnes manufactured or imported in a calendar year).

An update for the change of the tonnage band needs to be submitted in case of:

- Change of the registrant's own tonnage band;
- Change of the tonnage band covered by the jointly submitted data.

³² Article 2 of the Implementing regulation on dossier updates

³³ Article 3 of the Implementing regulation on dossier updates

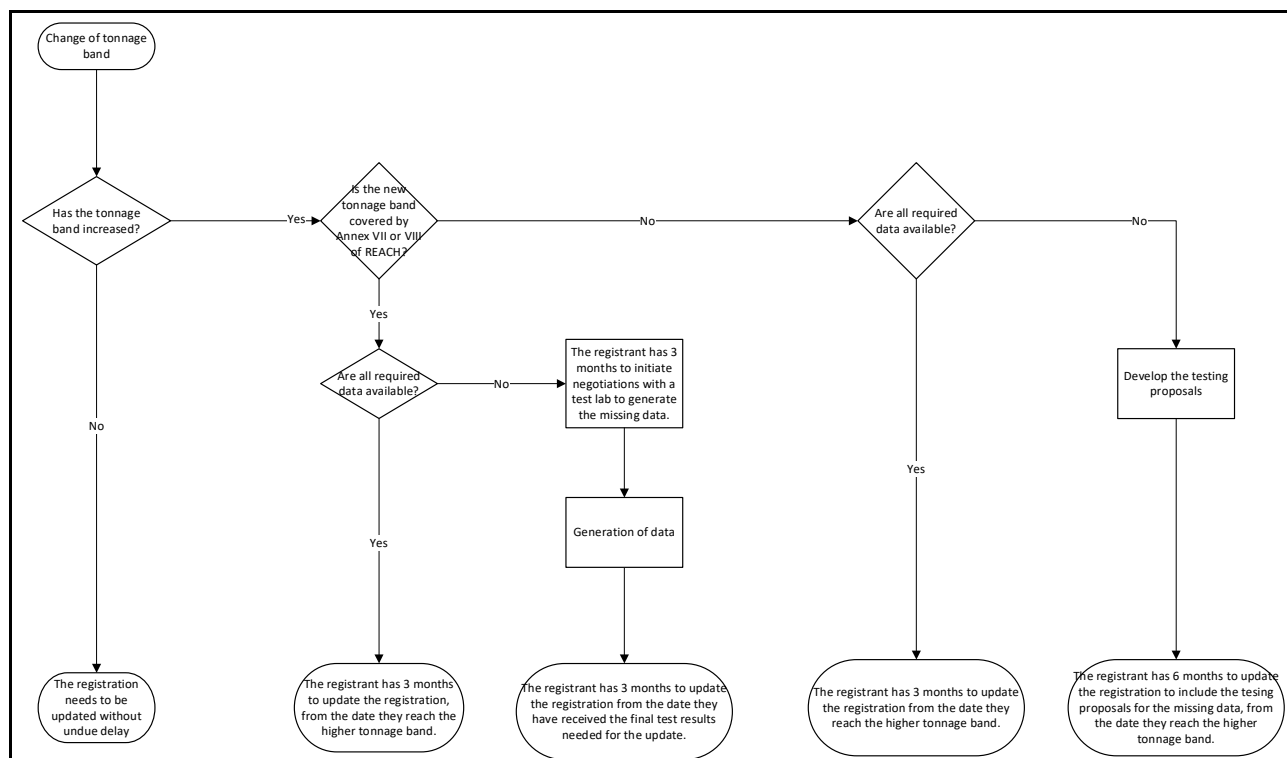


Figure 5 - Deadlines to update dossier in case of change in tonnage band

Increase in tonnage band

As soon as the volume of a registered substance reaches a higher tonnage band, the information requirements of the registration dossier change.

Before submitting an update of their registration dossier and as soon as it reaches the next tonnage threshold, the registrant must immediately inform ECHA of their need for additional information to comply with the information requirements for the new tonnage level (Article 12(2)), by submitting an inquiry to ECHA (see the *Guidance on data-sharing* at <http://echa.europa.eu/guidance-documents/guidance-on-reach>).

The registrant may continue manufacturing/importing the substance at the higher tonnage while waiting for the decision of their registration update, as long as they fulfil the deadlines indicated below.

When no new data needs to be generated, the registrant has 3 months to submit an updated dossier. This deadline is to be counted from the date when the higher tonnage band has been reached.

When new data needs to be generated to fulfil the information requirements of the higher tonnage band, for information requirements concerning Annex VII and VIII of REACH, the registrant has 3 months from the date when the higher tonnage band is reached to initiate negotiations with the testing laboratories.

For information requirements falling under Annex IX and X of REACH, the registrant has 6 months from the date when the registrant identifies the need to perform one or more of the tests listed in those Annexes. This update must include the testing proposals for the new data generation.

Regardless of whether new data needs to be generated or not, the registrant has 3 months to submit their updated dossier, counted from the date when all required data for the new

tonnage band is available.

Decrease in tonnage band

In case the manufactured or imported tonnages decrease, the registrant must submit an updated dossier without undue delay. No deadline is specified for such update in the Implementing Regulation on dossier updates, given that the change in tonnage may be of a temporary nature (Recital 6 of the Implementing Regulation on Dossier Updates).

If ECHA checks the compliance of their dossier, the requests in ECHA's dossier evaluation decisions will be based on the data submitted, the tonnage band and the use information indicated in the registration dossier at the time the draft decision is issued. Therefore for the purpose of decision-making (Articles 50 and 51 of REACH), after the registrant has received their draft decision, no dossier updates are taken into account, whether to inform on the downgrade of the registered tonnage band (except for cease manufacture under Article 50(3)) or on the removal of uses of the substance.

Cease of manufacture or import

Cease of manufacture or import refers to the situation where the registrant does not manufacture or import the substance, on its own, in mixtures or in articles, in quantities of 1 tonne or more per year anymore.

The registrant must communicate the cease of manufacture or import through REACH-IT using the functionality of 'Cease manufacture or import' available in the 'Reference number page' of the substance.

The legal consequences of the cease of manufacture differ depending on whether ECHA is notified of the cessation during the time ECHA processes an evaluation decision or outside of it.

If the cease of manufacture or import is notified to ECHA after a draft evaluation decision has been notified to the registrant, the registration is no longer valid (Article 50(3)) and its status is marked as 'invalid' in REACH-IT.

If the registrant informs ECHA of the cease of manufacture or import outside of the time an ECHA evaluation decision is being processed (Article 50(2)), the registration is de-activated and its status is marked as 'inactive' in REACH-IT.

In any case, no further information may be requested in the context of an ongoing evaluation process with respect to that substance, with the exception of situations described in Article 50(4) or unless a new registration is submitted.

The registered volumes do not count any longer towards the aggregated tonnage shown on the dissemination pages. The status of the registration is displayed for the members of the joint submission in REACH-IT and to the general public in the dissemination page. National Enforcement Authorities (NEAs) and MSCAs can also see the status of the registration through Interact Portal.

Only 'inactive' registrations can be re-activated. The restart of manufacture or import of the substance or the production or import of the article must be notified to ECHA through REACH-IT, by clicking on 'Restart manufacture or import' in the 'Reference number page'. In these cases, the registration must be reactivated, and the registration dossier updated and submitted to ECHA before manufacture or import is restarted.

In any event, the registrant must keep the relevant information on the substance for 10 years after the last manufacture or import and make it available on request (Article 36(1)). The period of at least 10 years does not start if the registrant, who ceased manufacture or import, still supplies or uses the substance.

Detailed information on the consequences that a cease of manufacture entails for ECHA Evaluation processes (Dossier and Substance Evaluation) can be found in the practical guides 'How to act in substance evaluation' and 'How to act in dossier evaluation' available at <https://echa.europa.eu/practical-guides>.

d) New identified uses and new uses advised against for which the substance is manufactured or imported³⁴

When a downstream user informs the registrant about a new use of the substance that is not identified in the registration dossier, two situations may occur:

- i. If the registrant has registered in a tonnage band at 10 tonnes or more per year and therefore is required to prepare a chemical safety report (CSR), they must assess the chemical safety for this use, and include that use in their CSR if the results of the chemical safety assessment (CSA) indicate that risks to human health and the environment from that use are controlled. For details on deadlines for updates involving multiple update reasons, please see section k), below.

The registrant will, when relevant, provide the downstream user with a revised safety data sheet (SDS), including the new use as well as the exposure scenarios describing the operational conditions for which the substance can be used safely. If on the basis of the CSA the registrant is unable to include the new identified use for reasons of human health or environmental protection, they must inform without delay ECHA and the downstream user(s) in writing with the reason for this decision. The registrant must not supply the downstream user(s) with the substance without updating the SDS by indicating the use(s) advised against.

- ii. If the registrant has registered in a tonnage band of less than 10 tonnes per year, they have no obligation to perform a CSA. However, they may decide to include or not the new use(s) in the SDS.

In both situations the registrant must update their own registration dossier to take into account the new identified use or the new use advised against.

The registrant may decide not to assess a new use (e.g. because they consider the assessment of the use as not technically possible or disproportionately costly) in which case they must stop supplying the substance for that use without updating the SDS by including the use in the uses advised against. The registrant's assessment of what is technically possible or disproportionately costly should also consider if the information provided by the downstream user is sufficient to prepare an exposure scenario. In that respect in some cases a more intense dialog between the registrant and the concerned downstream user might become necessary.

The registrant may also have to take into account a new own use or decide to identify a new use that their downstream user(s) are or may be interested in.

Following the above cases, the registration must be updated and submitted to ECHA by no later than 3 months from:

³⁴ Article 4 of the Implementing regulation on dossier updates

- in the case of a new identified use, the date when the registrant receives all the information needed to carry out the risk assessment for this new use;
- in the case of a new use advised against, the date when the information on the risks associated with that use is available to the registrant.

Example: As a result of regulatory management, the downstream user informs the manufacturer of a change in the uses, which can influence exposure to the substance. A use may be restricted and/or under authorisation. Following this, this use may be removed from the list of uses and added to the list of uses advised against.

e) New knowledge of the risks of the substance to human health and/or the environment of which the registrant may reasonably be expected to have become aware which leads to changes in the SDS or the CSR³⁵

If the registrant becomes aware of information that could lead to other or different risks for human health or the environment caused by the substance they manufacture or import, such as monitoring data in the environment or epidemiological studies, they need to take those data into account and evaluate the appropriateness of the risk management measures put in place or recommended down the supply chain.

New information triggering a revision of the CSA or the SDS could also be an international review such as International Programme on Chemical Safety (IPCS) review or an OECD dossier, or any kind of publication dealing with the release and exposure or hazard of the substance. Even if the initial registration has been completed accurately the registrant will need to update the CSA/CSR and the SDS as new or additional information on the risks of the substance becomes available that has an impact on the results of the CSA.

The registration must be updated and submitted to ECHA by no later than 6 months from the date when the registrant becomes aware or may reasonably be expected to have become aware of the new knowledge in question.

Example: A specific detergent is used in manufacturing plants. There is a new information about a substance's sensitising properties, which is used in the detergent. The risk is therefore increased, which may need to be reported in the CSR and/or in the SDS. It can also lead to removal of the substance from the product and the removal of the use from the substance. The registrant of the substance needs to update their registration with the new information on its sensitising properties within 6 months from the date when they became aware of it.

f) Any change in the classification and labelling of the substance³⁶

In cases where a harmonised classification and labelling has been adopted in accordance with Article 37 of the CLP Regulation, the registration dossier needs to be updated accordingly. Moreover, each registrant has also an obligation to update their registration dossier in the light of any other new data relevant to the classification.

The registration must be updated and submitted to ECHA:

- in the case of addition, modification or deletion of the harmonised classification and labelling, by no later than the date as of which that change is to apply;

³⁵ Article 5 of the Implementing regulation on dossier updates

³⁶ Article 6 of the Implementing regulation on dossier updates

- in the case of a new or modified self-classification by no later than 6 months from the date when the decision to change the classification and labelling of the substance has been taken.

Example: One of the impurities of the substance has obtained a harmonised classification and the impurity is present above the threshold of classification and therefore the substance also needs to be self-classified. The self-classification needs to be submitted within 6 months from the date when the harmonised classification requirement enters into force for the impurity of the substance.

- An update for the change of the classification and labelling needs to be submitted regardless of whether the information is submitted jointly or within the registrant's own dossier as an opt-out. An update is required after a change in the self- or harmonised classification.

g) Any update or amendment of the CSR or the Guidance on safe use³⁷

In addition to the reasons mentioned in the previous points, there may be a need to update the CSA/CSR due to e.g.:

- Innovation in the supply chain;
- New products and applications;
- New equipment and processes (conditions of use) at the downstream user level.

Moreover, an update of the CSA/CSR may be triggered by an increase of the production or import volumes.

The registration must be updated and submitted to ECHA by no later than 12 months from the date when the need to update or amend the CSR or the guidance on safe use was identified.

h) The registrant identifies the need to perform a test listed in Annex IX or Annex X, in which cases a testing proposal must be developed³⁸

When the registrant identifies the need to perform a test listed in Annex IX or X, even if they are at a lower tonnage band, they must submit a testing proposal via an update of their dossier in order to control the risks arising from the manufacture and use(s) of the substance. In such a case documentation showing that all non-animal methods have been considered and justification to perform an animal study must be included in the update.

The registration must be updated to include the testing proposal and submitted to ECHA by no later than 6 months from the date when the registrant identifies the need to perform one or more of the tests listed in Annex IX or X of REACH.

In the case of a testing proposal developed as part of a testing strategy addressing a group of substances, the dossier must be updated and submitted to ECHA by no later than 12 months from the date when the registrant or registrants identify the need to perform one or more of the tests listed in Annex IX or X of REACH.

Testing proposals are developed as part of a testing strategy where for example a registrant becomes aware of new hazards associated with a group of similar substances. In order to address the hazards, further testing is necessary. The registrant(s) choose the substance from the group which is the most similar to the others and develop the appropriate testing

³⁷ Article 7 of the Implementing regulation on dossier updates

³⁸ Article 8 of the Implementing regulation on dossier updates

strategy and testing proposals. If ECHA accepts the testing proposal(s) the test(s) are carried out on the selected substance and read-across strategy is used from those results for the other substances within the group.

Example: *In vivo* mutagenicity testing is triggered by a positive result in an *in vitro* test, independent from the tonnage. Before performing the *in vivo* test, the registrant needs to submit a testing proposal.

i) Any change in the access granted to information in the registration³⁹

Certain information within the registration dossier can be claimed confidential. Any change in confidentiality claims made either by the lead or a member of the joint submission will require an update of their registration dossier and a new submission to ECHA. Under specific cases, both the lead and the member registrant(s) need to include a confidentiality claim in their respective registration dossiers. More information on what information can be claimed confidential and how to include those claims in the registration dossier can be found at the 'Dissemination and Confidentiality under the REACH Regulation' manual, available at <https://echa.europa.eu/manuals>.

An update of the registration is required for:

- Introducing confidentiality claim(s) on new information in the dossier or information not previously published by ECHA;
- Removal of confidentiality claim(s).

The registration must be updated and submitted to ECHA by no later than 3 months from the date when the change occurred.

j) Cases when the update requires further testing⁴⁰

The deadlines specified in sections a), b), d), e) and f) above do not apply in case new information needs to be generated for updates covering:

- Changes in the status of the registrant;
- Changes in the composition of the substance;
- New identified uses or new uses advised against;
- New knowledge of the risks of the substance to human health and/or environment;
- Changes in the classification and labelling.

In such cases, the registrant needs to:

- Identify the need for the new data within the deadline specified for updating the registration;
- Initiate the contract negotiations with the relevant test laboratories within 3 months from the date when the need for the new data has been identified;
- Update the registration within 3 months from the date when all necessary test results have been received.

Example: A registrant has identified that a change in the composition of the substance is needed. In principle they have 3 months to update their dossier. However, during the preparation of the updated dossier, they have come to the conclusion, that further testing is necessary. In case of a change in the composition, the need for the further testing must be identified within the original 3 months deadline. Within 3 months from the date the new need was identified, the registrant must initiate negotiations with a relevant laboratory for ordering the new test(s). Once all the necessary test results have been received, the registrant has a

³⁹ Article 9 of the Implementing regulation on dossier updates

⁴⁰ Article 10 of the Implementing regulation on dossier updates

further 3 months to update their dossier to include both the new composition and the results of the newly generated data.

k) Other combined updates⁴¹

For any update where the registrant, as a result of that update, needs to modify the CSR or the Guidance on Safe Use, a combined deadline of 12 months for submitting both updates in the new dossier to ECHA applies. The deadline is to be counted from the date when the final test reports needed for the update have been received.

If the registrant has multiple reasons to update their registrations falling under the scenarios described in Table 4, the longest of the deadlines is applicable for the update. The deadline is to be counted from the date when the first need to update the registration has been identified.

Example 1: The substance has a new composition following a change in manufacturing process. The registrant needs to update their registration within 3 months. Furthermore, they wish to keep this new information confidential from their competitors and decide to submit also a confidentiality claim on the newly identified impurity. The deadline to submit this combined update is altogether 3 months, counted from the date when the need to update the dossier was first identified.

Example 2: A member of a joint submission who until now had a registration for 1-10 tonnes per annum has reached the next tonnage threshold and now need a registration for 10-100 tonnes per annum. The joint submission already covers this tonnage band, therefore no need for any data generation and the member registrant does not need to wait for the lead to update their dossier either. This means that they have 3 months to submit the update. However, as they are now above 10 tonnes per year, they are also required to provide a CSR, which is in this example not submitted jointly by the lead registrant. The member registrant needs to prepare their own CSR, for which they have 12 months. Therefore, the registrant has altogether 12 months to prepare and submit an update that contains both the update to the higher tonnage band and the CSR.

Example 3: A registrant has identified the need to update the composition of their registration. This update needs to be submitted within 3 months. However, the change in composition has also triggered a change in classification and labelling. Therefore, the registrant has altogether 6 months to update the dossier, counted from the date when the change in the composition has been identified.

l) Updates within a joint submission⁴²

If based on sections a) – k) above, a member registrant needs to update their registration, the lead dossier may need to be updated before the member can rely on that information.

Following the acceptance by ECHA of the jointly submitted information, the member registrant must update their own dossier, according to the following deadlines:

- 3 months in case of:
 - o Changes in the status of the registrant;
 - o Changes in the composition of the substance;
 - o Changes in the tonnage band;
 - o New identified uses or new uses advised against;
 - o New knowledge of the risks of the substance to human health and/or environment;
 - o Changes in the classification and labelling;
 - o Changes in the access granted to the information.

⁴¹ Article 11 of the Implementing regulation on dossier updates

⁴² Article 12 of the Implementing regulation on dossier updates

- 9 months in case:

- any of the updates mentioned above trigger the need to also update the CSR and/or the Guidance on Safe Use;
- of an update of the Chemical Safety Report or the Guidance on Safe Use;

These deadlines are to be counted from the date when ECHA informs the lead registrant and the other members of the joint submission that the registration dossier updated by the lead registrant is complete.

For cases where the member registrant's update does not depend on the lead registrant updating their dossier first, the regular deadlines, specified in Table 4 for each of the update reasons, apply.

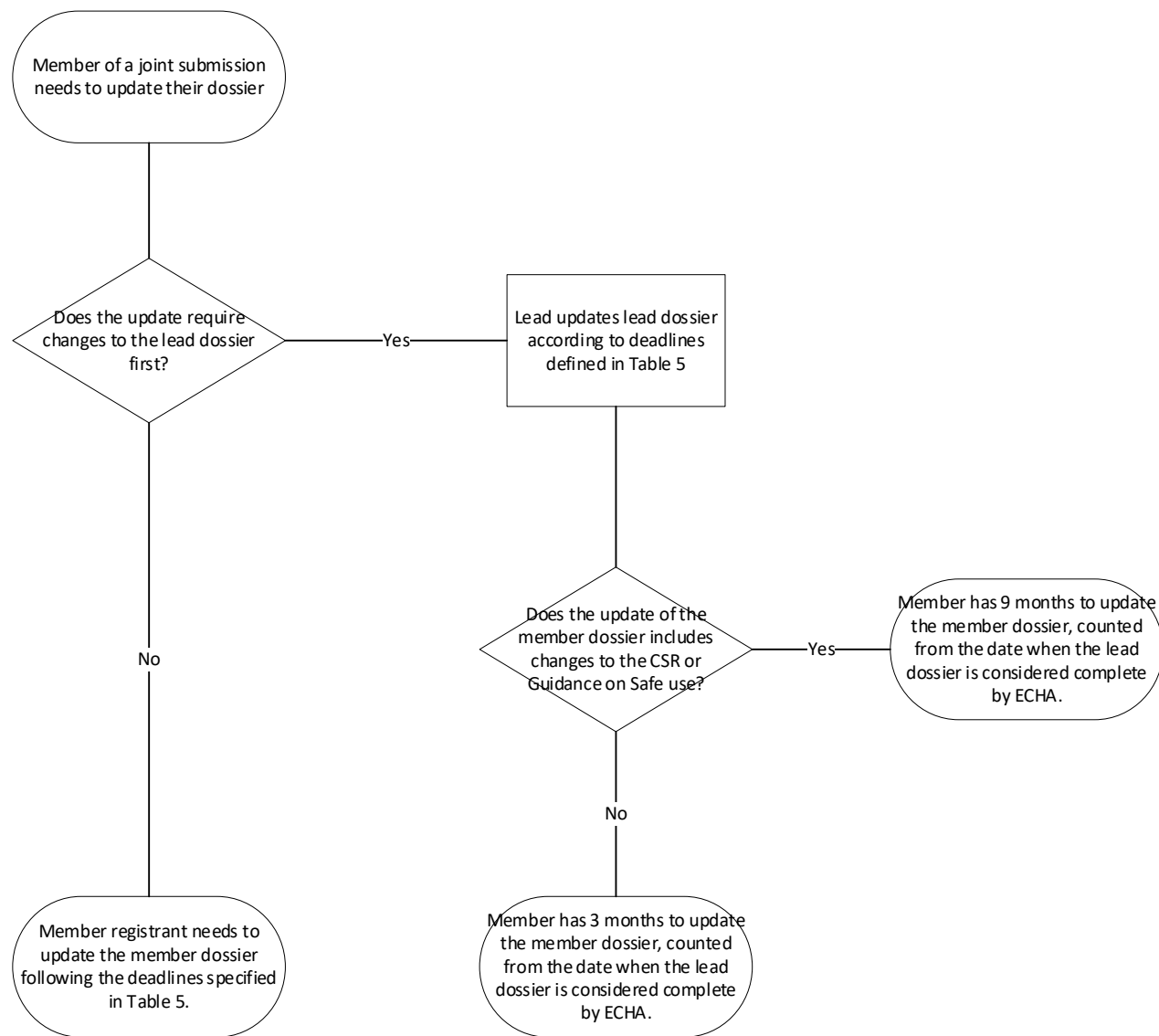


Figure 6 - Deadlines for updating member dossiers

Example: A member registrant is currently registered at the tonnage band of 1-10 tonnes per annum (Annex VII data requirements). Due to an increase in the demand of the substance, they wish to update their registration to the next tonnage threshold, 10-100 tpa (Annex VIII data requirements). Currently the joint submission only covers registrations up to 1-10 tpa, therefore, before the member registrant can submit their update, the lead registrant needs to update the jointly submitted data, in order to cover the data requirements of the higher

tonnage band. If the data is not available, the deadlines specified for tonnage band upgrade are applicable for the lead. Once the joint submission data coverage has been increased to the new level, the member registrant has 3 months to submit their updated dossier.

m) Updates as a consequence of an update of the Annexes of REACH⁴³

In case of an update to the Annexes of REACH which changes the data requirements of the registration, the registrant must submit an update at the latest by the date from which that amendment is to apply. Should this update requirement trigger additional needs for an update for any scenario listed in Table 4, the deadline applicable is the one provided in the amendment of REACH, unless otherwise specified therein.

7.3 Update as a consequence of an ECHA or a Commission decision

The registrant may have to update their registration as a consequence of an ECHA or a Commission decision under the evaluation procedure or they may have to take into account decisions made under the authorisation or restriction processes. The update must be submitted within the deadline specified by ECHA/the Commission in their decision.

a) Evaluation procedures

There are two types of evaluation procedures: dossier evaluation and substance evaluation. The former is further subdivided into an examination of any testing proposal and a compliance check of the registration dossier. The different decisions taken under the evaluation process that can have an impact on the updating obligations of registrants are briefly explained below.

Examination of testing proposals

All proposals for tests specified in Annexes IX and X submitted as part of registrations will be examined by ECHA within certain timelines. The examination of a testing proposal could trigger the need for the registrant to update their registration dossier when a decision requesting one or several tests to be carried out is taken by ECHA or the Commission.

All tests carried out based on a decision of ECHA on a testing proposal must be submitted in the form of a study summary, or a robust study summary (if required by Annex I), in an updated registration dossier. Moreover, depending on the outcome of the new test conducted, the registrant may have to update the hazard profile of the substance and/or the CSR including the ESs.

The testing proposal decision is addressed to all concerned registrants.

Compliance check

ECHA may examine any registration dossier to check whether the registrant has met their obligations and the registration dossier complies with the provisions of REACH.

As the outcome of the compliance check, ECHA or the Commission can require the registrant to submit, within a given deadline, any information needed to bring the registration into compliance with the relevant information requirements. In response, the registrant should update their registration dossier, including the CSR, with the additional information requested.

Compliance check addresses concerned registrants for which the requested further information

⁴³ Article 13 of the Implementing regulation on dossier updates

1 is relevant.

2 Substance evaluation

3 Substance evaluation aims to clarify the concern that a substance might constitute a risk to
4 human health or the environment. It provides a mechanism for authorities to require industry
5 to obtain and submit additional information in case of suspicion of a risk to human health or
6 the environment. When the Member State Competent Authority considers that additional
7 information is necessary for clarifying the suspicion, they will prepare a draft decision stating
8 the reasons for this request.

9 When a decision is taken by ECHA or the Commission under the substance evaluation process,
10 the registrant must provide the requested information and submit an update of their
11 registration dossier to ECHA by the deadline set.

12 Substance evaluation addresses all registrants of a substance. This means that the update of
13 any registration dossier may be required depending on the scope of the information requested
14 in the decision.

15 Further information on the evaluation procedures is available at the ECHA Evaluation webpages
16 accessible at <https://echa.europa.eu/regulations/reach/evaluation> and
17 [https://echa.europa.eu/about-us/the-way-we-work/procedures-and-policies/public-](https://echa.europa.eu/about-us/the-way-we-work/procedures-and-policies/public-procedures)
18 [procedures](https://echa.europa.eu/about-us/the-way-we-work/procedures-and-policies/public-procedures).

19 **b) Authorisation and restrictions**

20 If the use of a substance is authorised through a Commission decision, the conditions for the
21 authorisation should be reflected in the registration dossier. Consequently, the registration
22 dossier will have to be updated if it does not consider these conditions already.

23 For a substance subjected to restriction, the registration dossier should reflect the relevant
24 uses that are exempted from restriction or the relevant conditions for use that are included in
25 the restriction.

26

27 **7.4 Update of registration dossier for substances regarded as being** 28 **registered under REACH**

29 **a) Substances notified in accordance with Directive 67/548/EEC**

30 A distinction must be made between updates of notification dossiers made due to a change of
31 tonnage, updates to become part of a joint submission and updates of notification dossiers for
32 other reasons.

33 Increase of tonnage band

34 Under the REACH Regulation, substances notified in accordance with Directive 67/548/EEC
35 (NONS) are regarded as registered by the manufacturer or importer who submitted the
36 notification⁴⁴. Nevertheless, the REACH registration dossier for those substances which are
37 regarded as registered should be updated without undue delay when the manufactured or
38 imported quantity of the substance reaches the next tonnage threshold i.e. 10, 100 or 1000
39 tonnes per year. Also, an update is required for notified substances notified in the tonnage
40 range below one tonne under Directive 67/548/EEC, when reaching the one tonne threshold

⁴⁴ See Article 24(1) of REACH

1 under REACH.

2 When making a tonnage update, registrants of notified substances will also have to comply
3 with all other REACH requirements and provisions. The update should contain the information
4 required by REACH which corresponds to the higher tonnage threshold and any information
5 which corresponds to lower tonnage thresholds but which was not yet submitted⁴⁵. For
6 example, when submitting their update, they will have to prepare a CSR and to prepare an ES
7 to attach to their SDS when relevant.

8 However, in order to avoid unnecessary testing on vertebrate animals, the registrant first has
9 to inform ECHA of the additional information that they would require to comply with the
10 information requirements for the new tonnage threshold by submitting an inquiry dossier as
11 soon as the next tonnage threshold is reached (Article 12(2)). After submitting an inquiry
12 dossier, the registrant receives a communication from ECHA which includes the link to the
13 relevant Co-Registrants page in REACH-IT. In this way ECHA informs the registrant of the
14 names and addresses of those who intend to register (potential registrants) or have already
15 registered the same substance.

16 For more information, see the Guidance on data-sharing at: [https://echa.europa.eu/guidance-](https://echa.europa.eu/guidance-documents/guidance-on-reach)
17 [documents/guidance-on-reach](https://echa.europa.eu/guidance-documents/guidance-on-reach)

18 Update to become part of a joint submission

19 Given that the joint submission obligation did not exist prior to REACH, notifications under
20 Directive 67/548/EEC are regarded as registrations under REACH that are outside of a joint
21 submission, and therefore they are not linked to any existing joint submission. According to
22 Articles 11 and 19 of REACH, a joint submission that includes the previous notifier(s) must be
23 established when another entity intends to register the same substance. In this case the
24 potential registrant will also need to contact the previous registrant and they will need to agree
25 together on who will be the lead registrant.

26 In such cases, the previous notifier might decide to become the lead registrant of the joint
27 submission. This means that they will submit the joint information with the agreement of the
28 other registrants. In this situation, like the case of tonnage band update, the dossier must fulfil
29 all the REACH data requirements and must be submitted in IUCLID format.

30 Alternatively, the previous notifier might decide to join the joint submission as a member
31 registrant. As for any other registrant, the possibility of opting out for some or all of the
32 information applies, provided that vertebrate data are shared.

33 More details on the information required for updating substances notified in accordance with
34 Directive 67/548/EEC are available at the ECHA manual *How to prepare registration and*
35 *PPORD dossiers* accessible at: <http://echa.europa.eu/manuals>.

36 Other updates

37 All the updates described under sections Update on the registrant's own initiative and Update
38 as a consequence of an ECHA or a Commission decision above must also be submitted if and
39 when relevant.

40 For such updates, it is strongly encouraged to provide all information according to REACH.
41 However, derogation statements may be used stating that for such an update additional
42 REACH data is not necessary.

⁴⁵ See Article 24(2) of REACH

1 In these cases the notifier does not normally need to submit a CSR, or to provide an ES and an
2 SDS for uses and information covered in the original notification, as the risks have been
3 assessed and the necessary measures taken based on the risk assessment of the relevant
4 Member State Competent Authority.

5 The registrant is only required to submit a CSR in the following cases:

- 6 • a CSR must be submitted only for the new identified uses, though submitting a CSR for
7 **all** identified uses is encouraged;
- 8 • a CSR must be submitted when new knowledge arises with regard to the risks of the
9 substance to human health and/or the environment which would lead to changes in the
10 SDS;
- 11 • a CSR must be submitted because of the change in the classification and labelling of the
12 substance if this leads to changes in the SDS resulting in a stricter classification.

13

14 The notifier is strongly encouraged to submit a CSR as defined under REACH in order i) to
15 confirm that the ESs developed by the regulatory authority are still appropriate and ii) to
16 describe risk management measures (and subsequent advice to downstream users) at the
17 earliest opportunity.

18 The notifier must, where this is required under REACH, submit robust study summaries for any
19 new study such as the studies requested following decisions made according to Directive
20 67/548/EEC. For data which was originally submitted as part of the notification and which have
21 already been evaluated by the Member State Competent Authority, the robust study
22 summaries do not need to be prepared, unless required due to the generation of the CSR.

23 **b) Substances in Biocidal products and in Plant Protection Products**

24 For uses of substances regarded as registered under the Biocidal Product Regulation or Plant
25 Protection Products Regulation the updating requirements do not apply (Article 16(2)), see
26 sections 2.2.4.1 Substances for use in biocidal products and 2.2.4.2 Substances for use in
27 plant protection products.

28

8. When is a registration no longer valid?

When is a registration no longer valid?

A registration can eventually be no longer valid when it is revoked after ECHA discovers that the registration was granted on erroneous or incomplete information, or when the registrant notifies a cease of manufacture after the reception of a draft evaluation decision (Article 50(3) of REACH).

The consequence for both cases is that the registration cannot be used to cover the manufacture and import of the substance. Without a valid registration number, registrants cannot legally manufacture or import the substance above 1 tonne per year.

In addition, when, upon information by relevant Member State Competent Authorities, it becomes known to ECHA that a company does not exist, ECHA will revoke their registration.

a) ECHA discovers that the registration was granted on erroneous information which is not corrected

A registration decision can be revoked when ECHA discovers, *ex-post*, that it was granted based on erroneous information. ECHA grants the opportunity to the registrant to correct the erroneous information. If the registration dossier still does not satisfy the requirements for registration, ECHA will revoke the registration decision.

Currently, there are two different reasons for revoking a registration:

Ex-post technical completeness check

The Board of Appeal decision A-022-2013 clarified that after a registration has been granted, ECHA can request information to be completed via an *ex-post* completeness check.

If a registration dossier is found retrospectively to be technically incomplete, the registration decision was issued based on erroneous information. Therefore, the registrant will be given a reasonable amount of time to update their registration with the missing information. If they provide the requested information within the deadline, the dossier is then considered complete. If the requested information is not provided within the deadline, ECHA will revoke the registration.

Failure to pay the balance to the correct registration fee

A registrant is entitled to claim SME status and benefit from a discounted registration fee if they fulfil the criteria described in the Commission Recommendation 2003/361/EC.

ECHA regularly performs a verification of the SME status claimed by registrants. If it is proved that the registrant did not fulfil the criteria to benefit from the discounted registration fee, ECHA issues a top up invoice for the difference between the paid fee and the correct fee. Additionally, an invoice with an administrative charge for the verification carried out is issued.

If a registrant does not pay the top up invoice issued by ECHA, their registration is considered incomplete due to lack of full payment of the registration fee, and ECHA will revoke the registration.

b) Notification of a cease of manufacture after the reception of a draft evaluation

1 **decision**

2 According to Article 50(3), if after the notification of a draft evaluation decision (for either dossier
3 evaluation or substance evaluation), the registrant ceases manufacture or import of a substance
4 or article, their registration is no longer valid and they cannot manufacture or import the
5 substance in quantities of 1 tonne or more per year.

6 If the registrant intends to restart the manufacture or import of the substance in quantities
7 above 1 tonne per year, they will need to submit a new registration.

9. Appeal procedures

Where a registrant or potential registrant disagrees with certain decisions issued by ECHA, they can appeal against the decision to ECHA's Board of Appeal.

An appeal may be brought against ECHA's decisions in the following cases:

i. PPORD exemptions

a. decision of ECHA to impose additional conditions on the exemption to ensure that the substance is handled and disposed of in a controlled way and is not made available to the public (Article 9(4));

b. decision of ECHA on the extension of the exemption period (Article 9(7)).

Additional information can be found in the Guidance on Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD) available at: <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

ii. Completeness check - decision of ECHA to reject a registration if the registrant failed to complete their registration within the deadline set by ECHA (Article 20(2)) (see section 11.4 Rejection of the registration dossier).

iii. Data sharing - decision of ECHA on a data sharing dispute submitted by a potential registrant in order to be granted permission to refer to the information already submitted by a previous registrant (Article 27(6)). Additional information can be found in the Guidance on data-sharing available at: <https://echa.europa.eu/guidance-documents/guidance-on-reach>;

iv. Evaluation - decision of ECHA requesting the submission of additional information under the evaluation procedures (Articles 51 (3), 51(6) and 52(2)).

An appeal has a suspensive effect. All appeals must contain a statement of the grounds on which the appeal is based. Any natural or legal person may appeal against a decision addressed to that person, or against a decision which although addressed to another person is of direct and individual concern to the person making the appeal.

The appeal must be filed in writing to ECHA within three months of the notification of the decision to the person concerned, or in the absence of notification, within three months of the day on which the decision became known to them. The appeal is subject to the fees established in the Commission Regulation (EC) No 340/2008 of 16 April 2008, as amended on the fees and charges payable to the European Chemicals Agency.

If, after consultation with the Chair of the Board of Appeal, the Executive Director of ECHA considers the appeal to be admissible and well-founded, he or she may rectify the decision within 30 days of the appeal being filed. Otherwise the Chair of the Board of Appeal examines if the appeal is admissible within 30 days of the appeal being filed. If the appeal is admissible, she or he remits the appeal to the Board of Appeal for examination of the grounds. The Board of Appeal may exercise any power which lies within the competence of ECHA or remit the case to the competent body of ECHA for further action.

If the party concerned still disagrees with the result, an action may be brought before the General Court or the Court of Justice contesting the decision taken by the Board of Appeal.

Similarly, where no right of appeal lies before the Board, action against an ECHA decision may be brought before the General Court or the Court of Justice.

Legal references: Article 90, Article 91, Article 92, Article 93 and Article 94

10. Fees

Title IX of the REACH Regulation describes the general principles regarding the payment of fees and charges in relation to REACH. More specifically, the Fee Regulation (Commission Regulation (EC) No 340/2008 of 16 April 2008, as amended) stipulates the payment terms for ECHA's invoices. The fee level depends on the type of submission. Fee reductions further apply to SMEs.

The SME (medium, small and micro enterprises) status is determined by application of Commission Recommendation 2003/361/EC. The reader is advised to consult the ECHA website for more specific information on the SME definition:

<https://echa.europa.eu/support/small-and-medium-sized-enterprises-smes>.

Legal reference: Article 74

10.1 Calculation of applicable fees

A registrant must pay a fee for their registration as a contribution to covering the costs incurred by ECHA and the Member States Competent Authorities. In order for ECHA to be able to issue an invoice, the registrant is asked to fill-in the billing information in REACH-IT before the first submission and update it, if necessary, before each subsequent submission.

Once the registrant has submitted a registration dossier and it has been accepted for processing (see section 11.1 Initial verification Initial verification), REACH-IT automatically calculates the applicable fee for the dossier submitted.

Upon receipt of the invoice, the registrant needs to carry out the payment as indicated in the invoice.

When calculating the fee, the following parameters are taken into consideration:

- i. type of registration, i.e. standard, intermediate;
- ii. a reduction for submitting the dossier jointly, if applicable;
- iii. initial or update submission;
- iv. the registered tonnage band;
- v. the items flagged as confidential (see section 4.4 Confidentiality and electronic public access to registration information on access to information and confidential data);
- vi. claim for fee waiver, if applicable⁴⁶.
- vii. claim for SME fee reduction, if applicable.

When declaring SME (micro, small and medium enterprise) size and claiming for the SME fee reductions, a registrant has to upload a complete set of supporting documentary evidence to their REACH-IT account, under the Menu section 'Company size'. Only representative has to upload supporting documents of the non-EU enterprise which they represent.

Where a registration is submitted by an only representative, the company size of the 'non-EU manufacturer' is decisive for the fee and must be entered into the relevant field in REACH-IT, not the company size of the only representative. That is, the assessment of whether the reduction for SMEs applies shall be determined on the applicable ownership structure,

⁴⁶ For more information on the fee waiver and the Annex III criteria, see section 5.2.4 Information requirements on intrinsic properties (Annex VII to X)

1 headcount, turnover and balance sheet data related to the 'non-EU manufacturer', in
2 accordance with Recommendation 2003/361/EC.

3 ECHA may check at any time whether companies which claimed SME status, and thus paid
4 reduced fees for their registrations, meet the requirements defined by Commission
5 Recommendation 2003/361/EC. Where such a verification results in finding that the registrant
6 did not meet the definition, and hence not entitled to the fee reduction, the registrant is liable
7 to complete their registration by paying the difference between the reduced fee and the full
8 registration fee, and to pay an administrative charge, if applicable.

9

10 **10.2 Fee for updating a registration dossier**

11 An update must be accompanied by the relevant fee. As it happens when submitting an initial
12 dossier, the registrant must submit the updated dossier through REACH-IT and the system will
13 automatically calculate the applicable fee for the update and send the relevant invoice to the
14 registrant.

15 In practice an update will trigger a fee in case there is a change in the fee determining
16 parameters compared to the last successful submission, e.g. a higher tonnage band, or an
17 increase in the number of items flagged as confidential, etc.

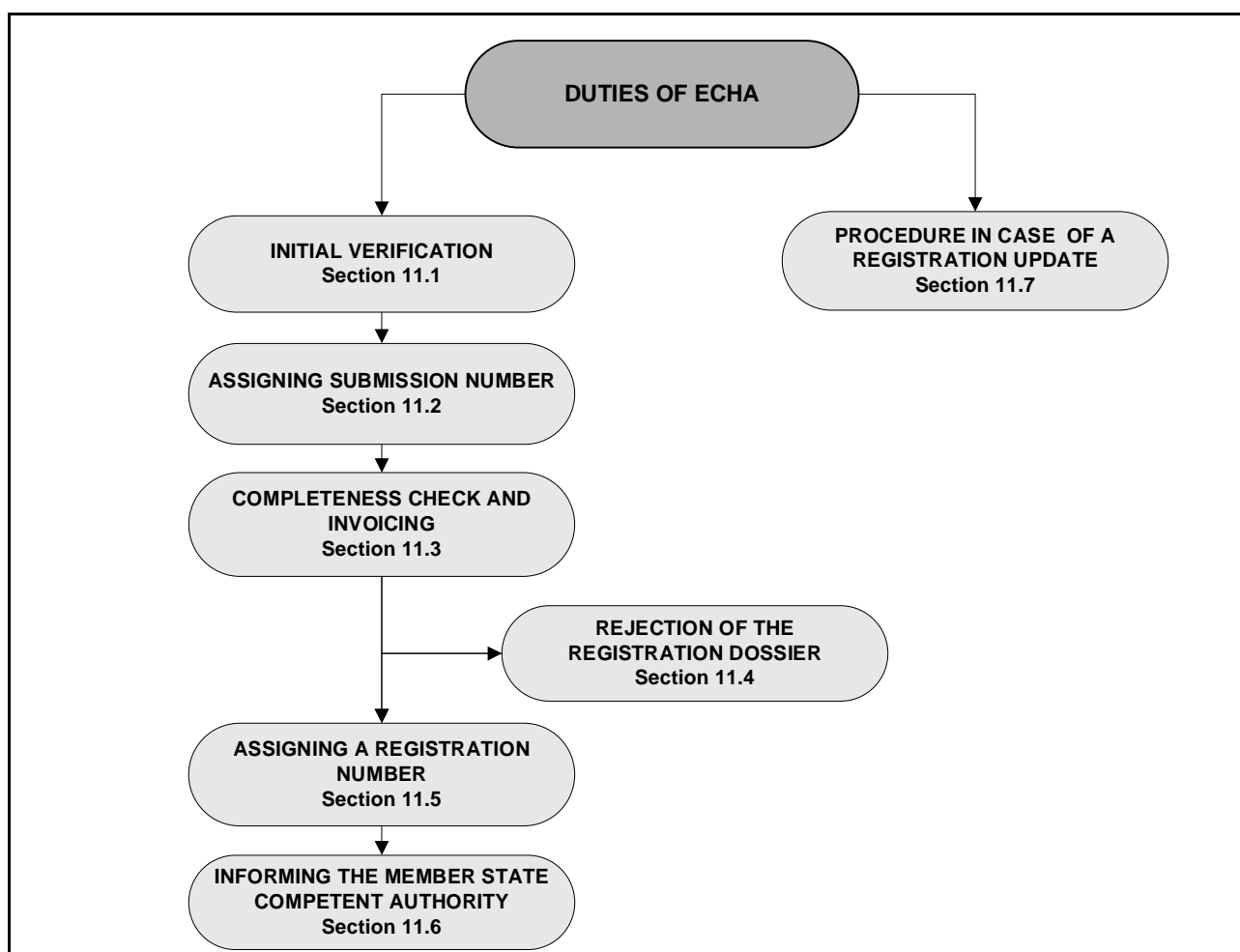
18 Registrants are encouraged to use the IUCLID fee calculator to simulate the applicable fee
19 before submitting their dossiers to ECHA.

20

11. Duties of ECHA

Aim: The aim of this chapter is to explain, what the duties of ECHA are after the submission of the registration dossier. It explains what kind of initial verifications are required, how the submission number and date are assigned, what the completeness check is, what the registration number is and how and when the relevant Member State Competent Authorities are informed about registrations.

Structure: The structure of this chapter is as follows:



11.1 Initial verification

All dossiers submitted to ECHA undergo a number of initial technical and administrative checks in order to ensure that they can be handled properly and that the required regulatory processes can be successfully carried out. The different initial checks are described below in the chronological order in which they take place.

Virus scan

The submitted dossier is scanned for known viruses. Only virus-free dossier files will proceed to the next step.

1 File format validation

2 The file format validation checks that the submitted dossier file is of the appropriate format (.i6z
3 file format) and is compliant with the XML schema used by IUCLID.

4 Internal structure validation

5 This verification ensures that the submitted dossier file does not contain attachments for which
6 the format is not supported or recognised by REACH-IT.

7 Business rule validation

8 The business rules are a set of pre-requisites that must be fulfilled before ECHA can establish
9 that the dossier can be accepted for processing and are checked by REACH-IT.

10 A dossier can be accepted for processing only if all the relevant business rules are satisfied.
11 After that, the submission can proceed to the next steps (technical completeness check and
12 financial completeness check). If the dossier submission fails at the business rule level, the
13 dossier cannot be accepted for processing and **a new submission is required** before any
14 regulatory processes can be initiated.

15

16 **11.2 Assigning submission number**

17 REACH-IT automatically assigns **a submission number and a submission date** to any
18 submission which is accepted for processing after successful business rule validation. REACH-
19 IT without delay communicates this submission number and date to the concerned registrant.

20 For registrations (including registration of on-site isolated intermediates and transported
21 isolated intermediates), the submission number is to be used for all correspondence until the
22 registration dossier is deemed to be complete (Article 20(1)). It will then be replaced by the
23 registration number.

24

25 **11.3 Completeness check and invoicing procedures**

26 The completeness check (Article 20(2)) comprises two distinct sub-processes:

- 27 • Technical completeness check
- 28 • Financial completeness check

29 The technical completeness check is performed on all registrations. The financial completeness
30 check is performed on those dossier types for which a fee is required.

31 **11.3.1 Technical completeness check (TCC)**

32 ECHA performs the TCC on each incoming registration. The aim of TCC is to ensure that all the
33 required information is provided as per REACH Regulation. TCC does not assess the quality of
34 the information.

35 TCC consists of two types of checks:

- 36 • Automated checks are included in the IUCLID Validation assistant. This tool offers
37 registrants the possibility to check the completeness of the dossier before submitting it
38 to ECHA. However, even if the Validation assistant does not report any
39 incompletenesses, it does not mean that the registration dossier is complete.

- Manual checks are done by ECHA staff and are not included in the Validation assistant. These checks cannot be replicated by the Validation assistant and the related incompletenesses are not displayed in the Validation assistant report.

Regularly updated information on each of the manual verification areas can be found in the document *Information on manual verification at completeness check* which is located under the section *How to prepare registration and PPORD dossiers* accessible at: <https://echa.europa.eu/manuals>. It is recommended to consult the manual whenever preparing a registration dossier.

The outcome of the completeness check is communicated to the registrant via REACH-IT within three weeks of the submission date.

If the registration dossier is considered complete, the registrant is notified accordingly via a REACH-IT message.

If the registration dossier is considered incomplete, the registrant receives a letter which provides details on the identified incompleteness(es), the deadline by when the complete registration must be submitted and instructions on how to submit the updated dossier. The deadline generally applicable in the context of technical completeness check is four months during which the registrant has one opportunity to complete the registration dossier with the missing information.

If the registrant submits a new dossier by the given deadline, ECHA will perform a second completeness check, considering the information submitted in that update.

If this updated dossier is still incomplete, or if the registrant fails to submit the complete dossier by the given deadline, the submission will be rejected (see section 11.4 Rejection of the registration dossier).

11.3.2 "Financial completeness check"

As soon as the dossier has received a submission number, ECHA will issue an invoice to the registrant if a fee applies (see section 10 Fees). The invoice is communicated to the registrant through REACH-IT. The payment terms are included in the invoice.

ECHA will monitor the payment of the fee as specified in the invoice. If a registrant fails to pay the full amount by the deadline indicated on the invoice, ECHA will set a second payment deadline. If the registrant fails to meet the second deadline, the registration dossier will be rejected. There could be circumstances, such as internal procedures or periods of limited service within a company, under which timely payment could be problematic. In that case it is recommended to prepare the payment of the fee due before submitting the dossier so that ECHA will receive the proof of payment in time before finalising the completeness check after the submission of the dossier.

11.4 Rejection of the registration dossier

If the registrant does not submit a complete dossier within the deadline set in the context of completeness check, or if the fee payment is not considered as paid by the second deadline, then ECHA will reject the registration. This decision can be challenged before ECHA's Board of Appeal.

Where a registration is rejected, the registration fee will not be reimbursed (Article 20(2)).

Rejection of a new registration means that a registration number is not assigned to the substance and any fees paid for this registration will not be refunded or otherwise credited.

The registrant may only start to manufacture or import the substance or to produce or import an article once they have a complete registration and ECHA has issued a registration number. In order to receive the registration number, the registrant needs to make a new initial submission. This submission will be subject to a new completeness check and registration fee.

11.5 Assigning a registration number

Once the registration is complete (both technically and financially), a registration number is assigned to the substance and registrant concerned. The registration date will be the same as the submission date. ECHA sends to the registrant a decision including the registration number and date of the registration via REACH-IT. The registration number will be used in all subsequent correspondence regarding this registration procedures (Articles 20(3)). The import or manufacture can start from that moment.

For a given substance, distinct dossier types may apply. For example, a substance initially notified as a PPORD may require the submission of a registration dossier at the end of the exemption period if the PPORD leads to a commercial use of the substance. Also, a substance for which initially a notification of the classification and labelling was submitted may have to later be registered if the tonnage increases above 1 tonne per year. In those cases, the substance will hold an identification number of each kind: a PPORD notification number and a registration number in the first example above, and a classification and labelling notification number and a registration number in the second example.

11.6 Informing the relevant Member State Competent Authority

Within 30 days of the submission date, ECHA has to notify the competent authority of the Member State within which the manufacture takes place or the importer is established that the registration has been submitted and that the information is available in the ECHA database (Article 20(4)).

If the manufacturer has production sites in more than one Member State, all relevant Member States will be notified.

ECHA will also notify about any request for further information including deadlines set and when any further information submitted by the registrant is available on ECHA database.

11.7 ECHA procedure in case of a registration update

A registrant may update its registration dossier either on its own initiative or in response to a request by the authorities (see sections 7.2 Update on the registrant's own initiative and 7.3 Update as a consequence of an ECHA or a Commission decision).

The registration update dossier will undergo the same processes as the initial submission: initial verification (see section 11.1 Initial verification), assignment of a submission number (see section 11.2 Assigning submission number) and the completeness check (see section 11.3

- 1 Completeness check and invoicing procedures)⁴⁷.
- 2 Rejection of a registration update means that the registrant maintains their existing
3 registration number but any new information included in that update will not be included in
4 ECHA's database. Any fees paid in relation to this registration update will not be refunded or
5 otherwise credited. The rejection decision can be challenged before ECHA's Board of Appeal.
- 6 When the registration update is considered complete, it is confirmed in a decision sent through
7 REACH-IT. ECHA will inform the relevant Member State Competent Authority accordingly
8 (Articles 22(1), 22(2)).
- 9

⁴⁷ See Article 22(3) of REACH.

| | | |
|----|--|--|
| 1 | Appendix 1. Glossary/List of acronyms | |
| 2 | C&L | Classification and labelling |
| 3 | | |
| 4 | CBI | Confidential Business Information |
| 5 | | |
| 6 | Cefic | <i>'Conseil Européen des Fédérations de l'Industrie</i> |
| 7 | | <i>Chimique'</i> - European Chemical Industry Council |
| 8 | | |
| 9 | Chesar | Chemical Safety Assessment and Reporting tool |
| 10 | | |
| 11 | CMR | A substance or mixture that is carcinogenic, mutagenic |
| 12 | | or toxic to reproduction. |
| 13 | | |
| 14 | CSA | Chemical safety assessment |
| 15 | | Process aimed at determining the risk posed by a |
| 16 | | substance and, as part of the exposure assessment, |
| 17 | | develop exposure scenarios including risk management |
| 18 | | measures to control the risks. |
| 19 | | |
| 20 | CSR | Chemical safety report |
| 21 | | Report that documents the chemical safety assessment |
| 22 | | for a substance on its own, in a preparation or in an |
| 23 | | article or a group of substances. It details the process |
| 24 | | and the results of a CSA. |
| 25 | | |
| 26 | CWG | Commission Working Group |
| 27 | | |
| 28 | DNEL | Derived No-Effect Level |
| 29 | | Level of exposure to the substance, below which no |
| 30 | | adverse effects are expected to occur. It is therefore the |
| 31 | | level of exposure to the substance above which humans |
| 32 | | should not be exposed. |
| 33 | | |
| 34 | DSD | Dangerous Substances Directive (67/548/EEC) |
| 35 | | |
| 36 | DPD | Dangerous Preparations Directive (1999/45/EC) |
| 37 | | |
| 38 | DU | Downstream user |
| 39 | | Any natural or legal person established within the |
| 40 | | Community, other than the manufacturer or the |
| 41 | | importer, who uses a substance, either on its own or in |
| 42 | | a preparation, during their industrial or professional |
| 43 | | activities. |

| | | |
|----|---------------|---|
| 1 | | |
| 2 | ECHA | European Chemicals Agency |
| 3 | | Agency established by Regulation (EC) No 1907/2006 of |
| 4 | | the European Parliament and of the Council of 18 |
| 5 | | December 2006 to manage all REACH and CLP tasks by |
| 6 | | carrying out or co-coordinating the necessary activities, |
| 7 | | to ensure a consistent implementation at Community |
| 8 | | level, and to provide Member States and the European |
| 9 | | institutions with the best possible scientific advice on |
| 10 | | questions related to the safety and the socio-economic |
| 11 | | aspects of the use of chemicals. |
| 12 | | |
| 13 | EEA | European Economic Area |
| 14 | | The European Economic Area (EEA) unites the 27 EU |
| 15 | | Member States and the three EEA EFTA States (Iceland, |
| 16 | | Liechtenstein, and Norway) into an Internal Market |
| 17 | | governed by the same basic rules. |
| 18 | | |
| 19 | EFTA | European Free Trade Association |
| 20 | | Intergovernmental organisation set up for the |
| 21 | | promotion of free trade and economic integration to the |
| 22 | | benefit of its four Member States: Iceland, |
| 23 | | Liechtenstein, Norway and Switzerland. |
| 24 | | |
| 25 | EINECS | European Inventory of Existing Commercial Chemical |
| 26 | | Substances |
| 27 | | Inventory that lists and defines those chemical |
| 28 | | substances, which were deemed to be on the European |
| 29 | | Community market between 1 January 1971 and 18 |
| 30 | | September 1981. |
| 31 | | |
| 32 | ELINCS | European List of Notified Chemical Substances |
| 33 | | Inventory that lists those substances which were |
| 34 | | notified under Directive 67/548/EEC, the Dangerous |
| 35 | | Substances Directive Notification of New Substances |
| 36 | | (NONS) that became commercially available after 18 |
| 37 | | September 1981. |
| 38 | | |
| 39 | ES | Exposure scenario |
| 40 | | Set of conditions, including operational conditions and |
| 41 | | risk management measures, that describe how the |
| 42 | | substance is manufactured or used during its life-cycle |
| 43 | | and how the manufacturer or importer controls, or |
| 44 | | recommends downstream users to control exposure of |
| 45 | | humans and the environment. These exposure scenarios |
| 46 | | may cover one specific process or use, or several |
| 47 | | processes or uses as appropriate. |
| 48 | | |

| | | |
|----|---------------|---|
| 1 | EU | European Union |
| 2 | | |
| 3 | GHS | Globally Harmonised System for Classification and |
| 4 | | Labelling |
| 5 | | Classification and labelling of hazardous chemicals |
| 6 | | agreed by the UN whose purpose is to ensure a high |
| 7 | | level of protection of health and the environment, as |
| 8 | | well as the free movement of substances, mixtures and |
| 9 | | articles. |
| 10 | | |
| 11 | GLP | Good Laboratory Practice |
| 12 | | Quality system concerning the organisational process |
| 13 | | and the conditions under which non-clinical health and |
| 14 | | environmental safety studies are planned, performed, |
| 15 | | monitored, recorded, archived and reported. |
| 16 | | |
| 17 | IPCS | International Programme on Chemical Safety |
| 18 | | |
| 19 | IUCLID | International Uniform Chemical Information Database |
| 20 | | Database co-developed by ECHA and the OECD for |
| 21 | | managing chemical data to record, store and exchange |
| 22 | | data on the intrinsic and hazardous properties of |
| 23 | | chemical substances. |
| 24 | | |
| 25 | IUPAC | International Union of Pure and Applied Chemistry |
| 26 | | |
| 27 | NGO | Non-Governmental Organisation |
| 28 | | A non-profit group or association organized outside of |
| 29 | | institutionalized political structures to realize particular |
| 30 | | social objectives or serve particular constituencies. |
| 31 | | |
| 32 | NLP | No-Longer Polymer |
| 33 | | A substance which was considered as notified under |
| 34 | | Article 8(1) of the 6 th amendment of Directive |
| 35 | | 67/54/EEC (and hence did not have to be notified under |
| 36 | | that Directive), but which does not meet the REACH |
| 37 | | definition of a polymer (which is the same as the |
| 38 | | polymer definition introduced by the 7 th amendment of |
| 39 | | Directive 67/548/EEC). |
| 40 | | |
| 41 | OC | Operational conditions |
| 42 | | Any action, use of tool or parameter state that prevails |
| 43 | | during manufacture or use of a substance (either in a |
| 44 | | pure state or in a preparation) that as a side effect may |
| 45 | | have an impact on exposure of humans and/or the |
| 46 | | environment. |

| | | |
|----|-----------------|--|
| 1 | | |
| 2 | OECD HPV | Organisation for Economic Co-operation and |
| 3 | | Development, High Production Volume (chemicals) |
| 4 | | |
| 5 | PBT | Persistent, Bioaccumulative, Toxic substances |
| 6 | | |
| 7 | PNECs | Predicted No-Effect Concentrations |
| 8 | | Concentration of the substance below which adverse |
| 9 | | effects in the environmental sphere of concern are not |
| 10 | | expected to occur. |
| 11 | | |
| 12 | PPORD | Product and Process Orientated Research and |
| 13 | | Development |
| 14 | | Any scientific development related to product |
| 15 | | development or the further development of a substance, |
| 16 | | on its own, in mixtures or in articles in the course of |
| 17 | | which pilot plant or production trials are used to develop |
| 18 | | the production process and/or to test the fields of |
| 19 | | application of the substance. |
| 20 | | |
| 21 | QSARs | Quantitative structure-activity relationships |
| 22 | | The relationship between the physical and/or chemical |
| 23 | | properties of a substance and their ability to cause a |
| 24 | | particular effect. The goal of QSAR studies in toxicology |
| 25 | | is to develop whereby the toxicity of a substance can be |
| 26 | | predicted from its chemical structure by analogy with |
| 27 | | the properties of other toxic substances of known |
| 28 | | structure and toxic properties. In practice, QSARs are |
| 29 | | mathematical models used to predict the properties of |
| 30 | | substances from their molecular structure. |
| 31 | | |
| 32 | REACH | Registration, Evaluation, Authorisation and Restriction of |
| 33 | | Chemicals (EC 1907/2006) |
| 34 | | |
| 35 | REACH-IT | Portal that supports Industry, Member State competent |
| 36 | | authorities and the European Chemicals Agency to |
| 37 | | securely submit, process and manage data and dossiers |
| 38 | | under the REACH and the CLP Regulations. |
| 39 | | |
| 40 | RIPs | REACH Implementation Projects |
| 41 | | Projects intended for the production of technical guides |
| 42 | | and IT tools for the use of ECHA, the competent |
| 43 | | authorities and the industry. |
| 44 | RMM | Risk Management Measures |
| 45 | | It includes any action, use of tool, change of parameter |
| 46 | | state that is introduced during the manufacture or use |

| | | |
|----|-----------------------------|---|
| 1 | | of a substance (either in a pure state or in a |
| 2 | | preparation) in order to prevent, control, or reduce |
| 3 | | exposure of humans and/or the environment. |
| 4 | | |
| 5 | Robust study summary | A detailed summary of the objectives, methods, results |
| 6 | | and conclusions of a full study report providing sufficient |
| 7 | | information to make an independent assessment of the |
| 8 | | study minimising the need to consult the full study |
| 9 | | report. |
| 10 | | |
| 11 | SCED | Specific Consumer Exposure Determinants |
| 12 | | Set of realistic exposure values that can be used in |
| 13 | | consumer exposure models to assess chemical safety. |
| 14 | | |
| 15 | SDS | Safety data sheet |
| 16 | | Tool used in industry for communicating information on |
| 17 | | the hazard of dangerous substances and preparations |
| 18 | | through the supply chain. Annex II of REACH explains |
| 19 | | what information should be included under each of the |
| 20 | | sixteen safety data sheet headings. |
| 21 | | |
| 22 | SIEF | Substance Information Exchange Forum |
| 23 | | A forum formed after the pre-registration phase, to |
| 24 | | share data on a given phase-in substance. |
| 25 | | |
| 26 | SME | Small and Medium Sized Enterprise |
| 27 | | The category of micro, small and medium-sized |
| 28 | | enterprises, made up of enterprises which employ fewer |
| 29 | | than 250 persons and which have an annual turnover |
| 30 | | not exceeding EUR 50 million, and/or an annual balance |
| 31 | | sheet total not exceeding EUR 43 million. |
| 32 | | |
| 33 | SPERC | Specific Environmental Release Category |
| 34 | | Set of realistic exposure values that can be used in |
| 35 | | environmental exposure models to assess chemical |
| 36 | | safety. |
| 37 | | |
| 38 | Study summary | A summary of the objectives, methods, results and |
| 39 | | conclusions of a full study report providing sufficient |
| 40 | | information to make an assessment of the relevance of |
| 41 | | the study. |
| 42 | | |
| 43 | SWED | Specific Workers Exposure assessment Description |
| 44 | | Set of realistic exposure values that can be used in |
| 45 | | worker exposure models to assess chemical safety. |

| | | |
|---|-----------------------|---|
| 1 | | |
| 2 | SVHC | Substances of Very High Concern |
| 3 | | |
| 4 | UVCB substance | Substances of Unknown or Variable Composition, |
| 5 | | Complex reaction products or Biological materials |
| 6 | | |
| 7 | vPvB | Very Persistent and very Bioaccumulative substances |
| 8 | | |

1 **Appendix 2. Roles and duties of the main actors of REACH**

2 This appendix provides an overview of the main responsibilities defined by REACH or derived
3 from REACH in the context of the registration, evaluation, authorisation and restriction
4 processes. It is not an exhaustive list and should only be used for reference purposes. The
5 reader is advised to consult the related guidance document if in need of detailed information
6 on a specific process.

7 **I. Industry**

8 **(1) Manufacturers and importers of substances in quantities of less than 1 tonne per** 9 **year need to:**

- 10 • Prepare and supply safety data sheets (SDS) for substances and mixtures (as required
11 by Article 31 and Annex II) to downstream users and distributors;
- 12 • Prepare and supply information on substances that do not require an SDS (as defined
13 by Article 32) to direct customers;
- 14 • Comply with any restrictions on manufacture, placing on the market and use of
15 substances and mixtures as set out in Annex XVII;
- 16 • Apply for authorisation for use(s) of substances listed in Annex XIV;

17 **(2) Manufacturers of substances in quantities of 1 tonne or more per year need to:**

- 18 • Submit an inquiry to ECHA as to whether a registration has already been submitted for
19 the same substance;
- 20 • Collect and share existing, and generate and propose to generate new, information on
21 properties and use conditions of substances. The vertebrate animal data should be
22 shared and should not be duplicated;
- 23 • Prepare a technical dossier (special provisions apply for intermediates);
- 24 • Prepare CSA and CSR (for each substance ≥ 10 tonnes per year per manufacturer);
- 25 • Prepare CSA and CSR including exposure scenarios and risk characterisation (for each
26 substance ≥ 10 tonnes per year per manufacturer, which fulfils the criteria for any of
27 the hazard classes or categories set out in Article 14(4) or is assessed to be a PBT or
28 vPvB);
- 29 • Implement appropriate Risk Management Measures (RMM) for own manufacture and
30 use;
- 31 • Submit registration for substances (≥ 1 tonne per year per manufacturer) unless an
32 exemption applies;
- 33 • Keep the information submitted in the registration up to date and submit updates to
34 ECHA;
- 35 • Prepare and supply safety data sheets (SDSs) for substances and mixtures (as required
36 by Article 31 and Annex II) to downstream users and distributors;
- 37 • Recommend appropriate RMMs in the SDS;
- 38 • Communicate ESs developed in CSA as annex(es) to the SDS (≥ 10 tonnes per year per
39 manufacturer);
- 40 • Prepare and supply information on substances that do not require an SDS within the
41 scope of Article 32 to downstream users and distributors;
- 42 • Respond to any decision requiring further information as a result of the evaluation
43 process;

- Comply with any restrictions on manufacture, placing on the market and use of substances and mixtures as set out in Annex XVII;
- Apply for authorisation for use(s) of substances listed in Annex XIV.

(3) Importers of substances and mixtures in quantities of 1 tonne or more per year:

- Submit an inquiry to ECHA as to whether a registration has already been submitted for the same substance;
- Collect and share existing, and generate and propose to generate new, information on properties and use conditions of substances. The vertebrate animal data should be shared and should not be duplicated;
- Prepare a technical dossier (special provisions apply for intermediates);
- Prepare CSA and CSR including exposure scenarios and risk characterisation (for each substance ≥ 10 tonnes per year per manufacturer, which fulfils the criteria for any of the hazard classes or categories set out in Article 14(4) or is assessed to be a PBT or vPvB);
- Implement appropriate RMMs for own use;
- Submit registration for substances, on their own or in mixtures (≥ 1 tonne per year per importer) unless an exemption applies;
- Keep the information submitted in the registration up-to-date and submit updates to ECHA;
- Prepare and supply safety data sheets (SDS) for substances and mixtures (as required by Article 31 and Annex II) to downstream users and distributors;
- Recommend appropriate RMMs in the SDS;
- Communicate ESs developed in CSA as annex(es) to SDS (≥ 10 tonnes per year per importer);
- Prepare and supply information on substances that do not require an SDS within the scope of Article 32 to downstream users and distributors;
- Respond to any decision requiring further information as a result of the evaluation process;
- Comply with any restrictions on manufacture, placing on the market and use of substances and mixtures as set out in Annex XVII;
- Apply for authorisation for use(s) of substances listed in Annex XIV.

(4) Only representative of 'non-EU manufactures' of substances and mixtures in quantities of 1 tonne or more per year:

- Submit an inquiry to ECHA as to whether a registration has already been submitted for the same substance;
- Collect and share existing, and generate and propose to generate new, information on properties and use conditions of substances. The vertebrate animal data should be shared and should not be duplicated;
- Prepare a technical dossier (special provisions apply for intermediates);
- Prepare CSA and CSR including exposure scenarios and risk characterisation (for each substance ≥ 10 tonnes per year per manufacturer, which fulfils the criteria for any of the hazard classes or categories set out in Article 14(4) or is assessed to be a PBT or vPvB);

- Submit registration for substances, on their own or in mixtures (≥ 1 tonne per year per importer) unless an exemption applies;
- Keep the information submitted in the registration up-to-date and submit updates to ECHA;
- Respond to any decision requiring further information as a result of the evaluation process;
- Apply for authorisation for use(s) of substances listed in Annex XIV.

(5) Producers of articles:

- If the conditions of Article 7(1) are met, register substances in articles (tonnage trigger > 1 tonne per year per producer). Comply with the inquiry obligation if relevant;
- Keep the information submitted in the registration up-to-date;
- If the conditions of Article 7(2) are met, notify substances in articles (tonnage trigger > 1 tonne per year per producer);
- If the article contains a substance included in the candidate list in a concentration above 0.1 % w/w (weight by weight), provide the recipient of the article (and consumers on request) with sufficient information to allow safe use of the article;
- When receiving SDS with ESs annexed for hazardous substances and mixtures to be incorporated into the articles:
 - if the use is covered by the ESs, implement RMMs as set out in the ESs, or
 - if the use is not covered by the ESs, inform the supplier of the use (i.e. make use known with the aim to make it an identified use) and await new SDS with updated ESs or conduct own chemical safety assessment and (if ≥ 1 tonne per year) notify ECHA.
- Implement those RMMs as set out in SDSs for hazardous substances and mixtures which are applicable when incorporated into the articles;
- Respond to any decision requiring further information as a result of the evaluation process (only relevant for registered substances);
- Comply with any restrictions on manufacture, placing on the market and use of substances and mixtures as set out in Annex XVII;
- Use substances authorised for incorporation into the articles as set out in the authorisation or apply for authorisation for use(s) of substances listed in Annex XIV.

(6) Importers of articles:

- If the conditions of Article 7(1) are met, register substances in articles (tonnage trigger > 1 tonne per year per producer). Comply with the inquiry obligation if relevant;
- Keep the information submitted in the registration up to date;
- If the conditions of Article 7(2) are met, notify substances in articles (tonnage trigger > 1 tonne per year per importer);
- Respond to any decision requiring further information as a result of the evaluation process (only relevant for registered substances);
- Comply with any restrictions on manufacture, placing on the market and use of substances and mixtures as set out in Annex XVII.

(7) Downstream Users (DU):

- Implement RMMs as set out in the SDS;

- When receiving SDSs with ESs annexed:
 - if DU use is covered by the ESs, implement RMMs as set out in ESs annexes to SDS; or
 - if DU use is not covered by the ESs, inform the supplier of the use (i.e. make use known with the aim to make it an identified use) and await new SDS with updated ESs or conduct own chemical safety assessment and (if ≥ 1 tonne per year) notify ECHA.
- Prepare and supply SDSs and recommend appropriate RMMs in them and annex ESs for further downstream use;
- Prepare and supply information on substances that do not require a SDS within the scope of Article 32 to further downstream users and distributors;
- Pass on new information directly to their suppliers on the hazard of the substance and information that might call into question the RMM identified in the SDS for identified uses;
- Respond to any decision requiring further information as a result of the evaluation of testing proposals in downstream user reports;
- Comply with any restrictions on manufacture, placing on the market and use of substances and mixtures as set out in Annex XVII;
- Use authorised substances as set out in the authorisation (this information should be found in the suppliers' SDS) or apply for authorisation for use(s) of substances listed in Annex XIV;
- Notify use of an authorised substance to ECHA.

II. Member States:

- Provide advice to manufacturers, importers, only representatives, downstream users and other interested parties on their respective responsibilities and obligations under REACH (competent authorities' help desks);
- Conduct substance evaluation of prioritised substances listed in the Community Rolling Action Plan. Prepare draft decisions;
- Identify substances of very high concern for authorisation;
- Suggest restrictions;
- Nominate candidates to membership of ECHA's Committee for Risk Assessment and Committee for Socio-Economic Analysis;
- Appoint member for ECHA's Member State Committee (MSC). Amongst other tasks, the MSC is responsible for resolving divergences of opinions among Member States on decisions following evaluation;
- Provide adequate scientific and technical resources to the members of the Committees that they have nominated;
- Appoint member to the Forum and meet to discuss enforcement matters;
- Enforce REACH.

III. ECHA:

- Provide technical and scientific guidance and tools for the operation of REACH in particular to assist the development of CSR by industry and especially by SMEs;
- Provide technical and scientific guidance on the operation of REACH for Member State competent authorities and provide support to the competent authorities' helpdesks;

- Receive and check requests for PPORD exemptions;
- Operate the rules on data-sharing;
- Registration: check completeness, require completion of registration and reject incomplete registrations;
- Evaluation:
 - ensure a harmonised approach,
 - set priorities and take decisions,
 - conduct dossier evaluation of registrations including testing proposals and other selected registrations,
 - prevent any unnecessary animal testing by verifying if the testing proposals are likely to produce reliable and adequate data,
 - substance evaluation: Propose draft Community rolling action plans, coordinate the substance evaluation process,
 - take decisions on testing proposals.
- Substances in articles: take decisions on notifications;
- Authorisation/restrictions: manage the process and provide opinions. Suggest priorities;
- Act as secretariat for the Forum and Committees;
- Publish certain specified data on a publicly accessible database;
- Promote the use of non-animal methods of hazard assessment;
- Deal with complaints and appeals.

IV. Commission:

- Take decisions on further information needs under the evaluation process where there is no unanimous agreement by the Member State Committee;
- Include substances into the authorisation system;
- Take decisions on granting or rejecting authorisations;
- Take decisions on restrictions.

V. All stakeholders including trade or industry associations, NGOs, and the public:

The following are possibilities/options for stakeholders:

- Access to non-confidential information via the ECHA website;
- Request access to information;
- Evaluation: submit scientifically valid, relevant information and studies addressed by the testing proposal published on the ECHA website.
- Authorisation:
 - provide comments on substances which ECHA has proposed to be prioritised and on uses which are to be exempted from the authorisation requirement,
 - provide information on possible alternatives.
- Restrictions:
 - provide comments on restriction proposals,
 - provide socio-economic analysis for suggested restrictions, or information to contribute to one,

- 1
 - 2
 - 3
 - 4
- provide comments on draft opinions from ECHA's Committee for Risk Assessment and Committee for Socio-Economic Analysis.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52

53
54
55
56
57
58