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Version 2.0	Revision of the document covering the following: - Restructuring of the content of the guidance: - 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. The changes are listed in Appendix 3 of the guidance.	May 2012
Version 3.0	[tbd]	xx 2016

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LEGAL NOTICE

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

Guidance on registration

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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 and/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 website[1].

This document relates to the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006[2].

[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

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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?
- When to pre-register and when to submit an inquiry?
- What is the registration dossier?
- When does a registration dossier have to be submitted to ECHA?
- What is a joint submission?
- What are registrants' obligations regarding data-sharing?
- 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 document 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 document helping him to identify his 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. This document 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 http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/identify-your-obligations/navigator.

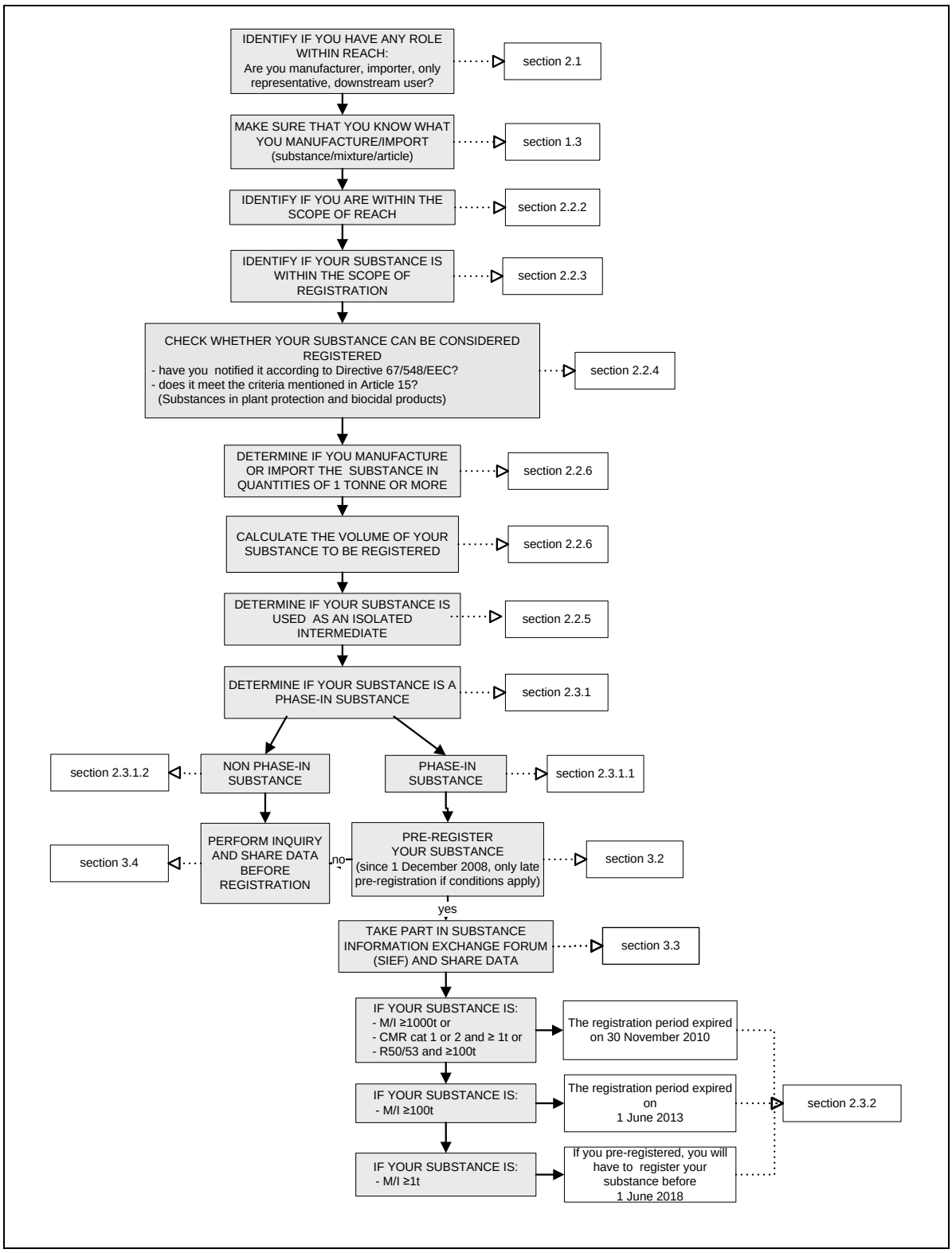


Figure 1: Steps within the registration process and link to the structure of this document

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 activities.

The registration provisions require manufacturers and importers to collect or generate data on the substances they manufacture or import, to use these data to assess the risks related to these substances and to develop and recommend appropriate risk management measures to control these risks. To ensure that they actually meet these obligations, as well as for transparency reasons, manufacturers and importers are required to prepare a registration dossier in IUCLID format (by using IUCLID software application) and submit it to ECHA via REACH-IT (see section 5 of this guidance).

When a substance is intended to be or is being manufactured or imported by more than one manufacturer or importer, certain data must be shared (see section 3) and submitted jointly (see section 4.3) with the purpose of increasing the efficiency of the registration system, saving costs and reducing testing on vertebrate animals. While still being a part of the joint submission, a registrant may opt-out from some information requirements and submit the information separately to ECHA in certain specified cases (see section 4.3.2).

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). Normally, 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.

However, for most substances that are already being manufactured or imported (so called 'phase-in substances') a special transition regime applies provided the substances have been pre-registered.

The last phase-in deadline ends on 31 May 2018. For substances that need to be registered by this date, the late pre-registrations can be submitted until 31 May 2017. This allows to continue the manufacture or import without registration until the corresponding deadline (31 May 2018) is met (for more information see sections 2.3 and 3.2 of this guidance).

If a manufacturer or importer does not register by this deadline, the substance may not be manufactured in the EU or placed on the EU market until after it has been registered.

Registered substances can in principle circulate freely on the internal market.

1.3 Substances, mixtures and articles

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

Substance means a chemical element and its compounds. The term substance includes both substances obtained by a manufacturing process (for example formaldehyde or methanol) and substances in their natural state. The term substance also includes its additives and impurities where these are part of its manufacturing process, but excludes any solvent which can be separated without affecting the stability of the substance or changing its composition. Detailed guidance on substances and substance identity can be found in the *Guidance on identification 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 and 2.2.6.4). 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 he is 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) have to 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 need not 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

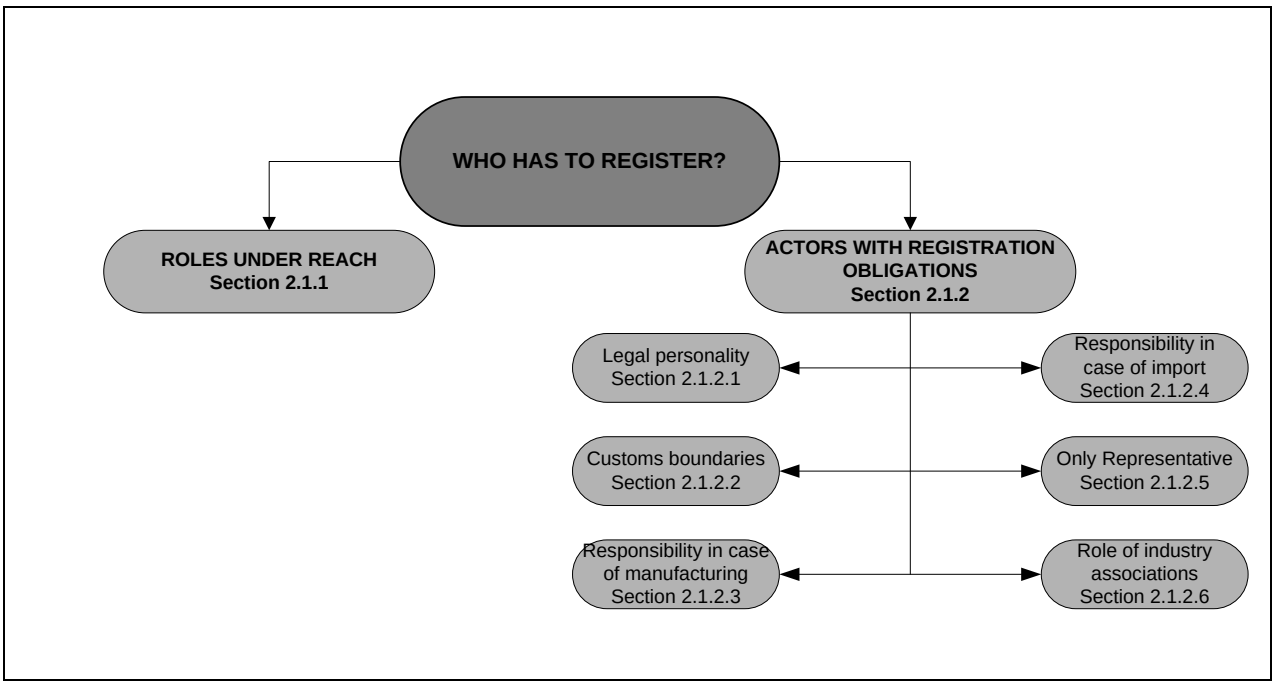
The registration obligations apply therefore to the individual substances themselves, independently of whether they are on their own, in a mixture or in an article. In other words, only substances have to be registered under REACH, mixtures or articles do not.

2 Registration obligations

2.1 Who has to register?

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

Structure: The structure of this chapter is as follows:



2.1.1 Roles under REACH

The obligation to register a substance applies only to certain actors established in the EU. Before explaining the obligations of registrants, it is important to have a clear understanding on the different roles a company may have under the REACH Regulation.

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

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))*.

***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, formulator[3] 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.*

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 to be 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.

[3] A formulator is a producer of mixtures in the context of the REACH Regulation

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.
- **'Only representatives'** established in the EU and appointed by a manufacturer, formulator or article producer established outside the EU to fulfil the registration obligations of importers (see section 2.1.2.5).

Examples of when registration is needed

- A manufacturer of a substance who uses the manufactured substance himself 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 his own use(s) and any identified uses of his customers in his registration.
- An importer of a mixture has to register those substances which are present in the imported mixture in quantities of 1 tonne or more per year, unless exemptions apply. He will have to include information in his registration on the identified use(s) of the substance(s) 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 <u>not</u> needed

- Any user of substances not manufactured or imported by himself, 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 and therefore does not need to register. The non-EU company needs to inform the importer of the appointment. In addition, the only representative should 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.

2.1.2.1 Legal personality

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

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

- A 'natural person' is a concept applied in many legal systems to refer to human beings who are capable and have the right to engage into contracts or commercial

transactions. These are usually people who have reached the age of legal maturity and are in full possession of their rights (meaning that these rights have not been taken away from them, for example due to a criminal conviction).

- A 'legal person' is a similar concept, applied in many legal systems to refer to companies who have been endowed with legal personality by the legal system applicable to them (the law of the Member State where they are established) and therefore are capable of carrying rights and obligations, independently of the people or other companies behind them (in the case of a 'société anonyme' or 'limited company', their shareholders). In other words, the company usually has its own existence and its 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 has to 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 daughters 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. In the case of a company group which 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 28 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, he 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 his substances in Germany or Iceland will be considered as a

downstream user.

A formulator purchasing his 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), the registration should be made by the legal entity who undertakes the process of manufacturing. It is important to bear always in mind that 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.

Who is the registrant in case of toll manufacturing?

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

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

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

For more details on the obligations of toll manufacturers under REACH please consult ECHA fact sheet: 'Toll manufacturer under the REACH Regulation' available at: http://echa.europa.eu/web/guest/publications/fact-sheets.

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

In case of import (see definition in section 2.1.1), the registration should be made by the legal entity established in the EU who is responsible for the import. The responsibility for import depends on many factors such as who orders, who pays, who is dealing with the customs formalities or the 'INCOTERMS'[4] chosen, but this might not be conclusive on its own.

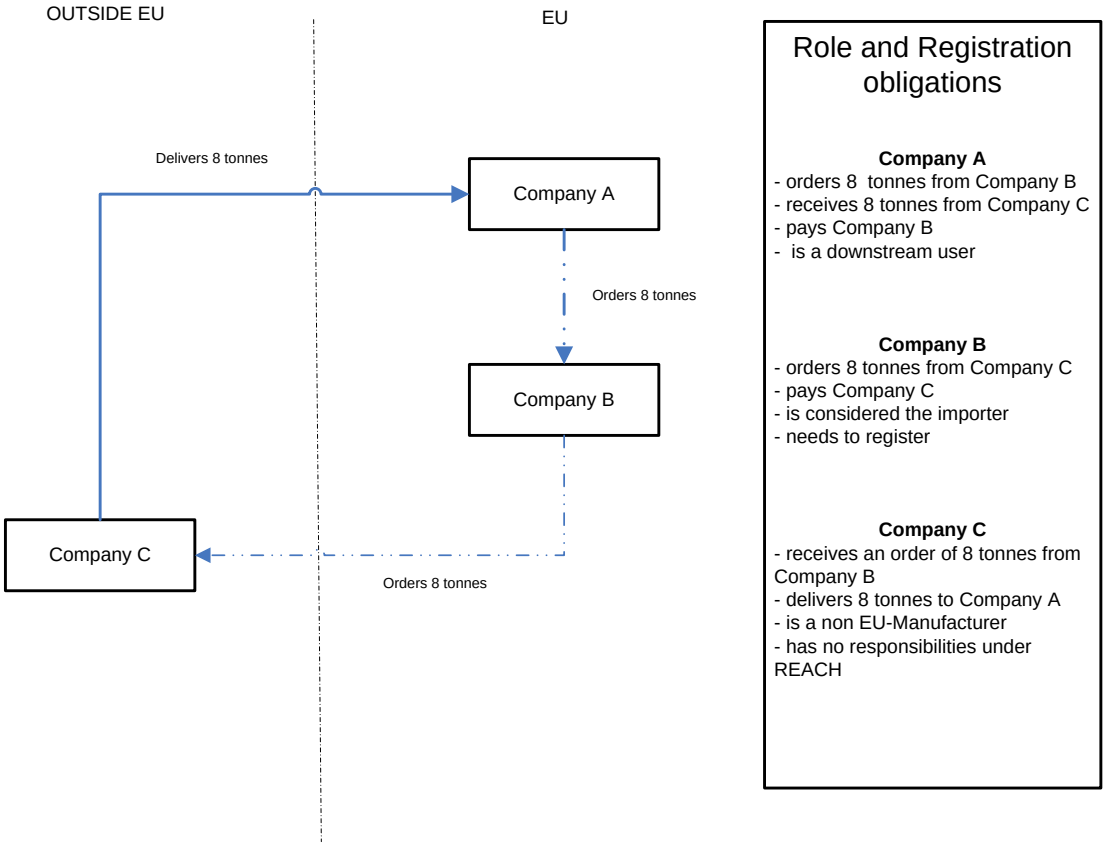
For example, in the case of a 'sales agency' established in the EU and acting as an intermediary, i.e. transmitting an order from a buyer to a non-EU supplier (and being paid for that service) but taking no responsibility whatsoever on the goods or the payment for the goods and not having their ownership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

In many instances it will be the ultimate receiver of the goods (the consignee) who is the legal entity that is responsible for the import. However this is not always the case. If for example company A (established in an EU country) orders goods from company B (established in another EU country) who acts as a distributor, company A probably does not know from where the goods originate. Company B may choose to order the goods from either an EU manufacturer or from a non-EU manufacturer. In case company B chooses to order from a non-EU manufacturer (company C) the goods may be delivered directly from company C to company A in order to save on transportation costs. Because of this company A will be stated as the consignee on the documents used by the customs authorities and customs handling will

[4] International Commercial Terms - a set of international rules for the interpretation of trade terms.

take place in company A's country. Payment for the goods is, however, settled between companies A and B. Also note that in the present example company B is not a 'sales agency' as described above as the 'sales agency' does not choose the manufacturer from which to order the goods. Because the decision whether to order goods from an EU or non-EU manufacturer lies with company B, this company (and not company A) should be considered the legal entity responsible for the physical introduction of the goods into the customs territory of the EU, while company A is a downstream user. The registration obligation consequently would lie with company B. Company A on the other hand will have to be able to prove through documentation to the enforcement authorities that it is a downstream user, for example by showing that the order was placed to company B.

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



It is important to note that the 'non-EU manufacturer' or supplier who is exporting a substance or mixture into the EU has no responsibilities under REACH. The shipping company that is transporting the substance or mixture normally has no obligations under REACH either. Exceptions may occur under specific contractual arrangements if the shipping company is established in the EU and if it is responsible for the introduction of the substance into the EU.

In addition, it should be noted that when interpreting the term 'importer' according to the REACH Regulation, it is not possible to fall back upon the Regulation (EU) No 952/2013 laying down the Union Customs Code (UCC).

In case an 'only representative' has been appointed the only representative is responsible for the registration (see next section).

2.1.2.5 Only representative of a 'non-EU manufacturer'

Substances imported into the EU on their own, in mixtures or, under certain conditions, in articles need to be registered by their EU importers. This implies that each individual importer needs to register the substance(s) he imports. However, under REACH, **a natural or legal person established outside the EU, who manufactures a substance, formulates a mixture or produces an article can appoint an only representative** to carry out the required 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 within the same supply chain from their registration obligations, as they will be regarded as downstream users.

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'[5] are not mentioned in *Article 8(1)* and can therefore not appoint an only representative. An only representative must be able to document who he is representing and is advised to attach a document from the 'non-EU manufacturer' appointing him as only representative in his registration dossier. Although it is not mandatory to include this information in the registration dossier, it needs to be presented to the enforcement authorities upon request.

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.

It should be noted that 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 downstream user to allow this potential registrant or data holder to remain anonymous vis-à-vis other stakeholders in the data-sharing process. It is neither necessary nor advisable for an only representative to appoint a third party representative because an only representative is not obliged to disclose to the other participants in the data-sharing process the identity of the 'non-EU manufacturer' he is representing (for more guidance on this see the *Guidance on data sharing* at http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach).

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

When appointing an only representative, it is recommended that the 'non-EU manufacturer' provides his only representative with up to date information on the list of EU importers which should be covered by the registration of the only representative 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 'non-EU manufacturer' and the only representative.

The 'non-EU manufacturer' needs to inform all the EU importers in the same supply chain that he has appointed an only representative to conduct the registration thus relieving the importers from their registration obligations. A 'non-EU manufacturer' can only appoint one

[5] Please note that a 'non-EU distributor' is **not** a distributor for the purposes of REACH as he is not a natural or legal person **established in the EU** (as defined in *Article 3(14)*)**.** An EU-based distributor cannot, of course, in any case appoint an only representative.

only representative per substance. The only representative's registration should clearly specify which quantity of the imported substance it covers – be it the entire import into the EU from a given 'non-EU manufacturer', or only specified quantities within that total. In cases where an importer is also importing quantities of the same substance from other non-EU sources, then both the only representative and the importer must be able to clearly document to enforcement authorities which imports are covered by the registration of the only representative; and which are covered by the importer; otherwise, the importer remains responsible for all his imports. In other words, an importer has to submit a registration for the quantity of a substance he imports, but does not have to cover the volume of the substance that is covered by the registration of the only representative.

What are the consequences for the EU importers?

When an importer receives information from a 'non-EU manufacturer' in his supply chain that an only representative has been appointed to cover the registration obligations, this importer will be regarded as a downstream user of the only representative for the tonnage covered by the registration of the only representative. This change of status from importer to downstream user only pertains to the same supply chain, i.e. to the tonnage imported from the 'non-EU manufacturer' having appointed the only representative. If this importer also imports the substance from other non-EU suppliers, he still has to register the tonnage imported from this or these non-EU suppliers unless the latter has/have appointed an only representative(s) to cover the respective imports.

Although the importer will receive confirmation from his 'non-EU manufacturer' on the appointment of the only representative, he should preferably also obtain confirmation in writing from the only representative that his imported tonnage and use is indeed covered by the registration submitted by the only representative. This would not only provide the importer with the contact point to whom he, acting as a downstream user, can make his use known, but would also give the importer a clear documentation that the imports are indeed covered by the registration of the only representative, as otherwise he remains responsible for the imports.

The importer may decide, as can any downstream user, to perform his own chemical safety assessment (for further information see the *Guidance on downstream users* at http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach). This requires considerable effort so it is advisable for the importer to consider carefully to what extent it may be necessary.

Obligations of the only representative regarding the registration of substances

An only representative is fully responsible and liable for fulfilling all obligations of importers for the substances he is responsible for. These do not only pertain to registration but also to all other obligations of importers under REACH.

The following paragraphs describe the role of the only representatives in regard to their registration obligations. The reader is reminded that other only representative obligations, such as pre-registration, data-sharing, etc. are described in the corresponding sections of this guidance under the obligations of importers. Where the only representative obligations differ from those of the importers, they are specifically mentioned.

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

REACH does not distinguish between direct and indirect imports into the EU and therefore such terms are not used in this guidance. It is essential that there is a clear identification of:

- who in the supply chain of a substance outside the EU is the manufacturer, formulator or producer of an article;

- who has appointed the only representative;
- which imports the only representative has responsibility for.

As long as the above conditions are met, **it does not matter what the steps or supply chain are outside the EU between the manufacturer, formulator or producer of an article and the importer into the EU**.

It should, however, be pointed out that the appointment of an only representative by the 'non-EU manufacturer' creates the need for importers to keep exact documentation on which imported quantities of the substance are covered by the only representative registration and which imported quantities are not In case of import of mixtures the importers will also need to know what quantity of the substance in a mixture is covered by an only representative registration, as he would otherwise be subject to a registration requirement himself. This documentation will need to be presented to the enforcement authorities upon request.

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

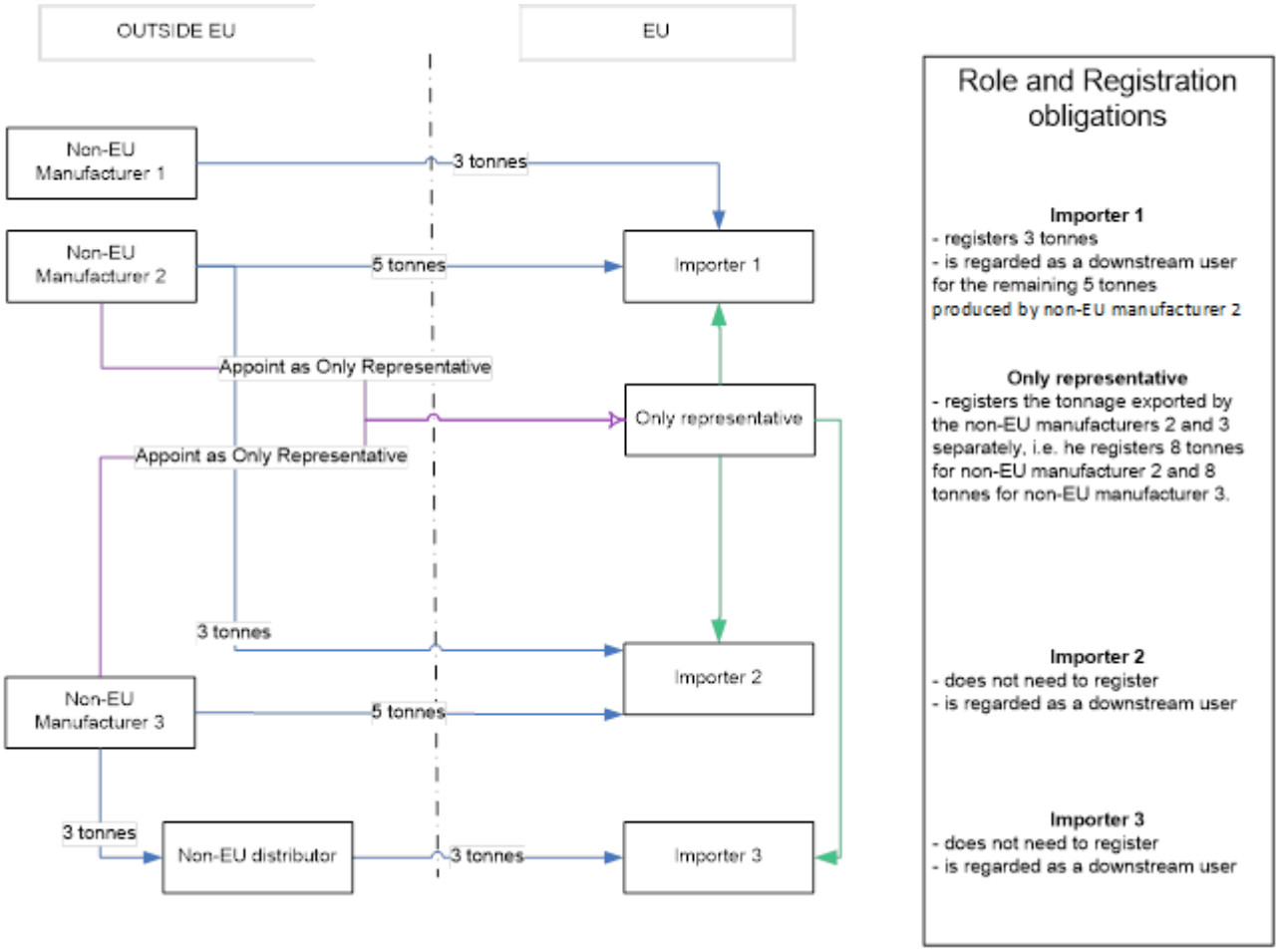
Although the only representative is legally responsible for the registration, it can be anticipated that in many cases, it will be the 'non-EU manufacturer' that will provide him with all necessary data for his registration dossier. If a 'non-EU manufacturer' decides to change his only representative, the successor will have to update the information related to the legal entity provided to ECHA. It is recommended that the new only representative submit evidence of his appointment and of the agreement of the earlier only representative to this change. A change of only representative constitutes a change of legal personality and the same obligations as described in section 7.2 of this guidance apply. In order to prevent disputes, it is recommended to include clauses on the eventuality of a later change of the only representative in the contracts between the 'non-EU manufacturer' and the only representative.

The only representative can represent one or several 'non-EU manufacturers'. If he acts on behalf of several 'non-EU manufacturers', he must submit a separate registration for each of these manufacturers. The tonnage of the substance to be registered in each registration is the total of the tonnages of the substance covered by the contractual agreements with the only representative and the specific non-EU manufacturer represented by him. The information requirement for the registration dossier must be determined according to this tonnage. By making separate submissions, the confidential business information (CBI) of the 'non-EU manufacturer' can be preserved and equal treatment with EU manufacturers can be ensured (EU manufacturers must submit separate registration dossiers for each legal entity). It is noted that only representatives are required to submit separate registrations not only for each 'non-EU manufacturer' they represent but also for quantities of the same substance which they manufacture themselves or import from other 'non-EU manufacturers'.

The only representative needs to declare the size of the non-EU company that he represents and **not** the size of the company that is an only representative.

In case several companies established outside the EU are part of the same group, and those companies export the same substances into the EU, each company constitutes a 'non-EU manufacturer' under REACH and may appoint an only representative. Even if the same only representative is appointed by several of the companies or by all of them, the only representative will have to submit separate registrations for each of the companies he is representing. From a technical perspective, this means that the only representative needs to create as many OR accounts in REACH-IT as non-EU manufacturers he represents (not only one OR account in REACH-IT for several non-EU manufacturers).

Figure 3: Roles and registration obligations of different actors when an only representative is appointed



Import of mixtures when an only representative is appointed

An importer of mixtures is obliged to register the individual substances in the mixtures he imports and needs to know therefore the chemical identity and the concentration of the substances in the mixtures. If the 'non-EU manufacturer' of the mixture or of the individual substances in the mixture appoints an only representative, it will be the only representative who will carry out the registration of the individual substances instead of the importers. The 'non-EU manufacturer' will inform the importers that an only representative has been appointed. If the 'non-EU manufacturer' appoints separate only representatives for the different substances in the mixture or only appoints only representatives for some of the substances in the mixture, this information needs to be communicated clearly to the importers, so that they are aware of which obligations they are relieved of and which obligations they still have to fulfil pertaining the registration of the substances. In any case, the importers of the mixtures and the corresponding only representative(s) must be able to document which quantities of the substances imported in the mixture(s) are covered by the registration dossier of the only representative(s) and which quantities are covered by the registration dossier of the importers themselves.

2.1.2.6 Role of industry associations and other types of service providers

The actual registration of a substance can only be done by the manufacturer, importer or

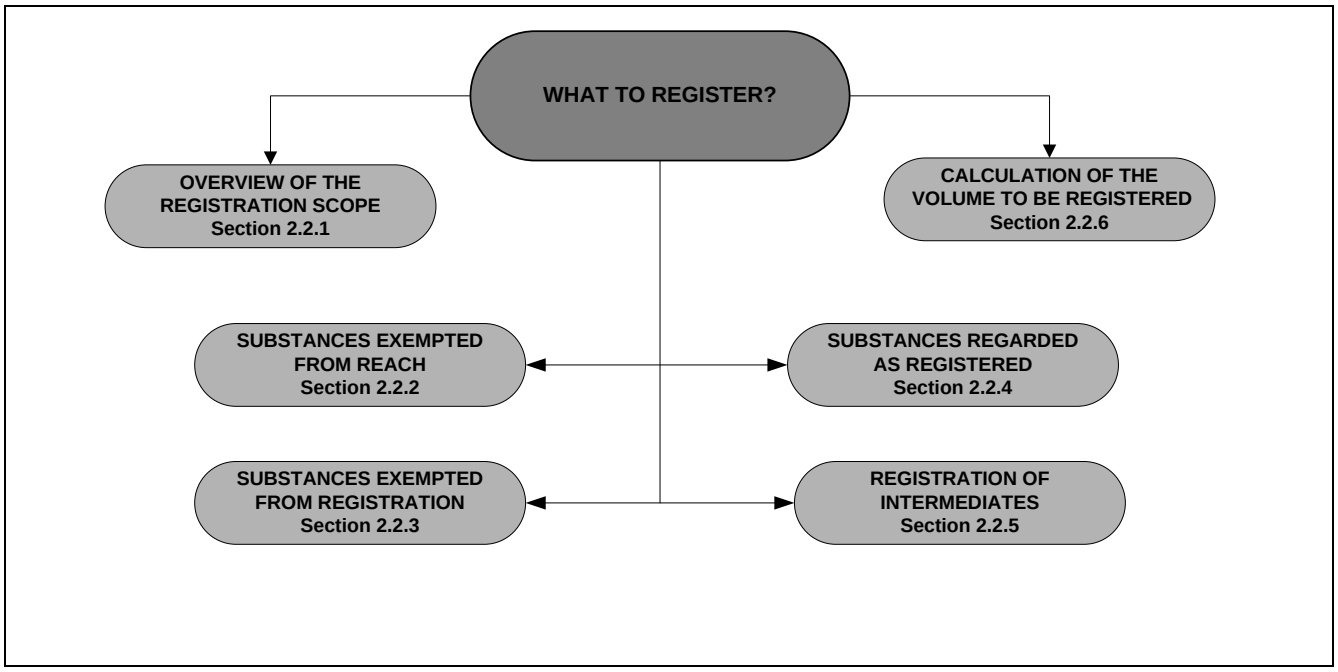
producer of an article or only representative and cannot be done by any third party including industry associations, unless they act as the only representative for one or more non-EU companies.

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

2.2 What to register?

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

Structure: The structure of this chapter is as follows:



2.2.1 Overview of the registration scope

Registration is required for all substances manufactured or imported in quantities of one tonne or more per year per manufacturer or importer unless they are exempted from the scope of registration. The registration requirement applies to all substances irrespective of whether they are hazardous or not. This includes substances on their own, in mixtures or substances in articles when they are intended to be released under normal or reasonably foreseeable conditions of use.

For all registrations, a registration dossier has to be prepared and submitted electronically to ECHA. The information that the registrant has to provide in the registration dossier will depend

on the volume (tonnes manufactured or imported per year) of the substance to be registered.

The definition of a substance under REACH (see section 1.3) is very broad and includes not only chemicals whether hazardous or not, but every type of substance manufactured in or imported into the EU. 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 following sections below). Other substances within the scope of specific pieces of legislation, e.g. food-packaging and cosmetics, although subject to registration, have reduced risk assessment requirements under REACH (see section 4.2.1).

When the manufacturer or importer intends to register more than one composition or form of a substance (e.g. nanomaterial (NM)[6]) 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 further information and specific advice on preparation of the registration dossiers for nanomaterials, please consult *Appendix 4: Recommendations for nanomaterials applicable to the Guidance on Registration* available at: http://echa.europa.eu/guidance-documents/guidance-on-reach.

This guidance document 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* (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 legislation[7] 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 the REACH Regulation.

Importers of substances who wish to rely on the exemption from REACH are therefore advised

[6] Commission Recommendation on definition of nanomaterial (2011/696/EU) available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1464877817743&uri=CELEX:32011H0696

[7] Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (OJ L 159, 29.9.1996, p.1)

to ensure that these substances meet all the following conditions:

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

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

Legal reference: Article 2 (1) (b)

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

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

It should be noted that this exemption will only apply once a Member State has taken a formal measure, in accordance with its national legal system, to exempt in specific cases certain substances from REACH. The exemption will, naturally, only apply within the territory of the Member State having fixed the exemption.

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

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

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

Legal reference: Article 2 (3)

2.2.2.4 Waste

Waste is defined in the Waste Framework Directive 2008/98/EC[8] 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 or bottles) or from professional businesses or from industry (e.g. tyres, slag, window frames that are discarded).

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

The requirements of the REACH Regulation for substances, mixtures and articles do not apply to waste; and waste operations are not downstream uses under REACH. This however 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 of this guidance) 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* (http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach).

It is important to remark that once waste is recovered 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 guidance on recovery is available in section 2.2.3.5 of this guidance.

Legal reference: Article 2 (2)

2.2.2.5 Non-isolated intermediates

Intermediates are a class 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 of this document.

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.

Note however that 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 requirements under REACH must be fulfilled.

Additional information on intermediates can be found in the *Guidance on intermediates* (http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach).

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

2.2.2.6 Transported substances

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

exemption).

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

Legal reference: Article 2 (1) (d)

2.2.3 Substances exempted from registration

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

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

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

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

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

2.2.3.1 Food or feedingstuffs

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

- as a food additive in foodstuffs within the scope of Council Directive 89/107/ECC, as amended by Directive 94/34/EC;
- as a flavouring in foodstuffs within the scope of Council Directive 88/388/ECC and Commission Decision 1999/217/EC;
- 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, feedingstuffs 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 of substances which may be

put to food or feedingstuffs related uses to be aware if their own legal entity or their clients actually use the substance in food or feedingstuffs in accordance with the Food Safety Regulation, since in that case they will not have to register this use at least for the quantities of the substance which are used in this way.

Substances manufactured in the EU and exported to a third country that satisfy the requirements of the Food Safety Regulation are also exempted from registration under REACH to the extent that the substances are used in food or feedingstuffs. Imports of substances for that use from a third country are also covered by the same exception and do not have to be registered under REACH.

Note that 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)

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 important for manufacturers and importers of substances which may be put to pharmaceutical related uses to be aware if their own legal entity or their clients actually use the substance in medicinal products covered by the pharmaceuticals legislation referred to above, since 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 any substance 'used in medicinal products'. Excipients used in medicinal products are therefore also exempted from registration.

Note that quantities of the same substance used for other uses than pharmaceuticals are not

exempted. Only the quantities of the substance used in medicinal products are exempted from the 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.

Legal reference: Article 2 (5) (a)

2.2.3.3 Substances included in Annex IV of the REACH Regulation

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

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

Legal reference: Article 2 (7) (a)

2.2.3.4 Substances covered by Annex V of the REACH Regulation

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

The full Annex V list is shown below. The reader is advised to consult the *Guidance for Annex V* (http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach) if in need of more detailed information on any category of substances. The guidance provides explanations and background information for applying the different exemptions and clarifies when an exemption can be applied and when not.

> ***ANNEX V***
>
> ***EXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(7)(b)***
>
> 1. *Substances which result from a chemical reaction that occurs incidental to exposure of another substance or article to environmental factors such as air, moisture, microbial organisms or sunlight.*
> 2. *Substances which result from a chemical reaction that occurs incidental to storage of another substance, mixture or article.*
> 3. *Substances which result from a chemical reaction occurring upon end use of other substances, mixtures or articles and which are not themselves manufactured, imported or placed on the market.*

4. Substances which are not themselves manufactured, imported or placed on the market and which result from a chemical reaction that occurs when:

(a) a stabiliser, colorant, flavouring agent, antioxidant, filler, solvent, carrier, surfactant, plasticiser, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, desiccant, binder, emulsifier, de-emulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutraliser, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended; or

(b) a substance solely intended to provide a specific physicochemical characteristic functions as intended.

5. By-products, unless they are imported or placed on the market themselves.

6. Hydrates of a substance or hydrated ions, formed by association of a substance with water, provided that the substance has been registered by the manufacturer or importer using this exemption.

7. The following substances which occur in nature, if they are not chemically modified:

Minerals, ores, ore concentrates, raw and processed natural gas, crude oil, coal.

8. Substances which occur in nature other than those listed under paragraph 7, if they are not chemically modified unless they meet the criteria for classification as dangerous according to Regulation (EC) No 1272/2008 or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or unless they were identified in accordance with Article 59(1) at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 57(f).

9. The following substances obtained from natural sources, if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC with the exception of those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36] or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or unless they were identified in accordance with Article 59(1) at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 57(f):

Vegetable fats, vegetable oils, vegetable waxes; animal fats, animal oils, animal waxes; fatty acids from C_6 to C_{24} and their potassium, sodium, calcium and magnesium salts; glycerol.

10. The following substances if they are not chemically modified:

Liquefied petroleum gas, natural gas condensate, process gases and components thereof, coke, cement clinker, magnesia.

11. The following substances unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC and provided that they do not contain constituents meeting the criteria as dangerous in accordance with Directive 67/548/EEC present in concentrations above the lowest of the applicable concentration limits set out in Directive 1999/45/EC or concentration limits set out in Annex I to Directive 67/548/EEC, unless conclusive scientific experimental data show that these constituents are not available throughout the lifecycle of the substance and those data have been ascertained to be adequate and reliable:

Glass, ceramic frits.

12. Compost and biogas.

13. Hydrogen and oxygen.

Legal reference: Article 2 (7) (b)

2.2.3.5 Recovered substance already registered

The REACH Regulation exempts from registration substances which are recovered in the EU, provided a number of conditions are met. Recycling is a form of recovery and therefore 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 it is produced).

Criteria for defining when waste is no longer considered to be waste (so-called end of waste criteria) after recycling are currently under development in relation to the Waste Framework Directive. Such a decision must be taken within the legislative framework of the Waste Framework Directive. A recovered substance will only fall within the scope of the REACH Regulation when a decision has been taken, in accordance with the provisions of the Waste Framework Directive, that the waste it is originated from meets the end of waste criteria and as such is no longer waste.

The REACH Regulation sets the following conditions which have to be respected in order 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 manufacturing or import stage, the recovered substance has to 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: http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach). For example, if the substance itself was modified in the recovery and the modified substance has not been registered, then the recovered substance has to be registered.

(3) The legal entity that did the recovery must have available:

- the information that is contained in a safety data sheet (see section 6.1.1); 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 6.1.2).

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, have also to comply with their duties regarding the provision of information on the substance down the supply chain, as specified in sections 6.1.1 and 6.1.2.

More detailed information can be found in the *Guidance on waste and recovered substances*. 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 he intends to register or claim an exemption from registration for a recovered substance.

It is worth noting that 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 a registration has been submitted for the substance by any registrant.

ECHA recommends a recycler, who starts recycling a phase-in substance, to late pre-register that substance where possible in order to benefit from the transitional provisions for registration (see section 2.3.2). He can still be exempted from the registration requirements if another pre-registrant registers the 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 has to 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: http://echa.europa.eu/web/guest/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 has to be registered.

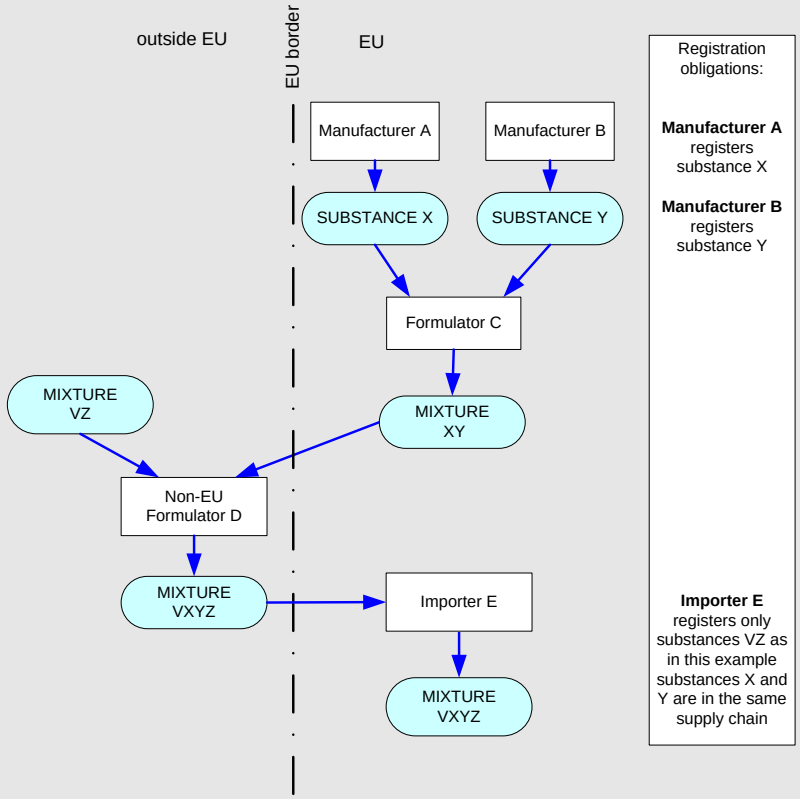
Again, the reason is clear; if the substance is not the same, it has not yet been registered (the registration information will be different), and therefore there will not be duplication of registrations.

(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.

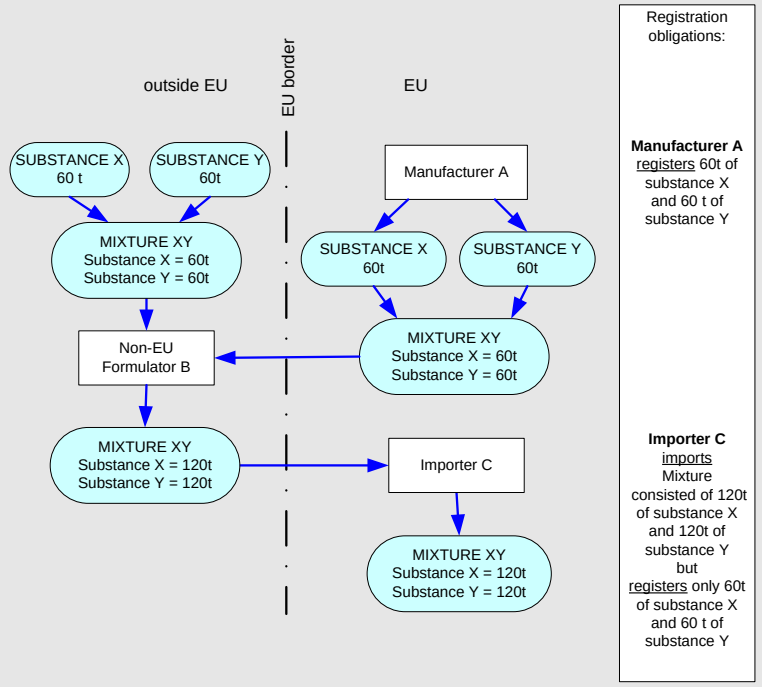
(4) The re-importer must have been provided with information on the exported substance, and that information must comply with the requirements established under REACH for the provision of information down the supply chain. The required information is described in detail in section 6.1.1 and 6.1.2 of this guidance.

Legal reference: Article 2 (7) (c)

Example (1)



Example (2)



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) 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;

b) 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 substance(s) or other substance(s) used for the manufacture of the polymers if all the following conditions are met:

a) the monomer substance(s) or other substance(s) 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 substance(s) or other substance(s) in the form of monomer units and chemically bound substance(s);

c) the total quantity of such monomer substance(s) or other substance(s) 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: http://echa.europa.eu/web/guest/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 monomer(s) or other substance(s) fulfilling both the conditions (b) and (c) stated above, the monomer(s) or other substance(s) 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 monomer(s);
- 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;
- 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 substance(s) or any other substance(s) in the form of monomeric units and chemically bound substance(s) 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 for the purpose of research and development

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).

Scientific research and development

Scientific research and development means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume below 1 tonne per year (Article 3 (23)). A substance being used solely for scientific research and development does not need to be registered since the registration obligation applies to volumes of one tonne or more per year.

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 articles[9] 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. Substances used for PPORD in quantities below one tonne per year do not need to be notified since they fall below the registration threshold of one tonne per year.

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, himself or in cooperation with listed customers referred to in Article 9(4*)*. The notifier must identify these customers in his 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 the research and development programme 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 also 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 has to comply with any conditions imposed by ECHA according to Article 9(4). 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.

Legal references: Article 3 (22), Article 3(23), Article 9

2.2.4 Substances regarded as registered

Certain substances or uses of substances are regarded as being registered, and so no registration will be required for these substances for these uses. This applies to:

- substances in biocidal products as described below; and
- substances in plant protection products as described below.

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

Similarly, a notification under Directive 67/548/EEC[10] (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*[11] *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.

Please consult the list of approved active substances 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, please consult Annex II, part I to Commission Delegated Regulation (EU) No 1062/2014. For more information about the review programme, please consult the following page on the ECHA website:
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 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).

Note that **only active substances can be regarded as registered** and that other

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

[11] The reader is reminded that 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.

substances used for producing the biocidal product are subject to registration.

It is important to remark that 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.

If a manufacturer or importer manufactures or imports the substance for biocidal and non-biocidal uses, it will have to submit a registration for the quantities of the substance used in non-biocidal products.

Once a decision is adopted that an active substance is not approved, the manufacture and import of the substance is subject to the same registration requirements as any other 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 has to be registered; the former use is in biocidal products and is regarded as registered.

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

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-organisms[13] 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.

[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] Note that 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.

Active substances manufactured or imported for use in plant protection products in accordance with Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market, are regarded as registered under REACH (for that use) if the active substance:

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

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

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

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

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

Adjuvants are not substances used in plant protection products but they may be placed on the market to be mixed by the user with a plant protection product. Therefore, they cannot satisfy 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 has to be registered; the former use is in plant protection products and is regarded as registered.

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

Legal references: Article 15 (1), Article 16

2.2.4.3 Notified substances according to Directive 67/548/EEC

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

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

ECHA has assigned registration numbers to all notifications and distributes them electronically upon request of the notification's owner through REACH-IT. Please note that the registration is assigned for the tonnage band referred to in the notification of the substance. As soon as the

actual volume differs from this initial tonnage band the registrant will have to update his registration dossier as described in section 7.4 of this guidance.

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 merely manufactured in the EU, but not placed on the market, a notification would not have been made. These substances will have to 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) where the specific steps to claim a registration number for a notified polymer are explained in detail.

It is important to remark that a notification under Directive 67/548/EEC is nominal so that only the notifier benefits from being considered registered; any other parties manufacturing or importing the substance but who have not notified it, must register, 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 2.2.5. While non-isolated intermediates are not covered by REACH, isolated intermediates have reduced requirements depending on the conditions of manufacture and use.

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

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

A manufacturer or importer of an isolated intermediate in quantities of one tonne or more per year is required to register his substance under REACH. However he may benefit from reduced registration requirements provided the manufacture and use of the substance takes place under strictly controlled conditions. In case the registrant cannot demonstrate that the strictly controlled conditions are met, he will have to comply with the standard registration requirements defined by REACH. Note that the requirements for registration vary depending on whether the isolated intermediate is an on-site or a transported intermediate. It is important to remark that isolated intermediates can benefit from an exemption for registration under

REACH as far as the conditions for the exemption apply.

For the sake of simplification, isolated intermediates will be referred to simply as intermediates in the context of this document. The reader is advised to consult the *Guidance on intermediates* available at http://echa.europa.eu/guidance-documents/guidance-on-reach if in need of more detailed information. The guidance is designed to support potential registrants of intermediates in assessing whether the conditions of manufacture and use fulfil the requirements to be considered as strictly controlled conditions. A detailed description of the registration requirements is also included.

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

2.2.6 Calculation of the volume to be registered

The following sections describe how to calculate the volume (tonnes per year) to be used in order to decide whether a registration must be submitted for a substance, what are the information requirements that have to be fulfilled and in the case of pre-registered phase-in substances, to identify when the registration of the substance is due.

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

The volume of the substance will also determine the information to be submitted in the registration dossier. REACH defines four tonnage bands (1 to <10 tonnes, 10 to <100 tonnes, 100 to <1000 tonnes, 1000 tonnes or more per year) and the standard information requirements for each of them. If the volume of the substance reaches the lower limit of a tonnage band, the standard information requirements for that tonnage band apply. The standard information to be submitted depending on the tonnage band is discussed in detail in section 4.1.

The volume of the substance also plays a role in determining when the registration dossier for a substance is due (see section 3.2 of this guidance where the pre-registration process of phase-in substances is outlined). Although in principle substances should not be manufactured in the EU or placed on the market unless they have been previously registered, REACH defines a transition regime for the registration of certain substances that are already on the market provided that they have been pre-registered (the so called phase-in substances). These transitional arrangements introduce different deadlines for the registration of phase-in substances based on the hazards of a substance and on the yearly tonnage manufactured or imported (see section 2.3.2).

2.2.6.1 Calculation of the volume in case of exemptions

In principle a potential registrant needs to calculate the total volume (tonnes per year) of the substance he manufactures or imports and based on that decide 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 his calculation to determine the volume he has to register.

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

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, this company or its customers may at the same time make other uses of the same substance. To determine its registration obligation under REACH, it must determine the quantities for the other uses. 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.

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.

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 he intends to register is used as an intermediate and is manufactured and used under strictly controlled conditions (see previous section 2.2.5). If this is the case, he 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 he intends 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 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 the dossier.

2.2.6.3 Calculation of the total volume

In any case, it will be necessary to calculate the total volume (tonnes per year) of the substance that is intended to be manufactured and imported by the given registrant and that is not exempted from registration. As stated before, this total volume will determine the information to be submitted in the registration dossier and in the case of a pre-registered phase-in substance it also defines the registration deadline (see section 2.3.2 and 3.2 on phase-in substances). Note, however, that for combined registrations of substances used as intermediates under strictly controlled conditions and for other uses, as in the example above, the volume to be used as an intermediate will not be taken into account for the definition of the information requirements. The total volume, covering the use as intermediate and the other uses, determine in any case the deadline for the registration of the substance.

In the case that the same registrant manufactures and/or imports the same substance at different sites which belong to the same legal entity, then the volume of the substance to be registered is the total volume of the substance manufactured and/or imported at the different sites, because the sites are not separate legal entities.

If a substance is imported in several mixtures, the volume of the substance in each mixture (calculated as defined in section 2.2.6.4) will have to be aggregated.

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

> **Example:** If a 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 article B and C: 120 tonnes, i.e. in the 100-1000 tonnes 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, he is required to register the volume of the substance he manufactures or imports. He need not submit a separate registration for the volume of the substance in the article. Nevertheless, the registration of the substance manufactured or imported needs to 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 of this guidance). 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 and/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*.

2.2.6.5 Calculation of the volume for phase-in and non-phase-in substances

For a registration, the registrant must report in tonnes the volume he manufactures or imports per year. REACH defines different methods to determine the *tonnes per year* (*Article 3 (30)*) depending on whether a substance is a phase-in substance or a non-phase-in substance. For the definition of phase-in substances and non-phase-in substances please refer to sections 2.3.1.1 and 2.3.1.2 respectively.

Calculation of tonnes per year for the registration of **non-phase-in substances**

The tonnes per year of a non-phase-in substance to be reported in a registration dossier is the estimated quantity in tonnes that is expected to be manufactured and/or imported in the calendar year (1 January - 31 December) of registration. If manufacturing starts only later in a particular calendar year, the registration dossiers can cover the expected tonnes for a full calendar year rather than the remaining months of the first calendar year, in order to avoid the need for a very quick update of the registration dossier for the second year.

Calculation of the tonnes per year for the registration of **phase in-substances**

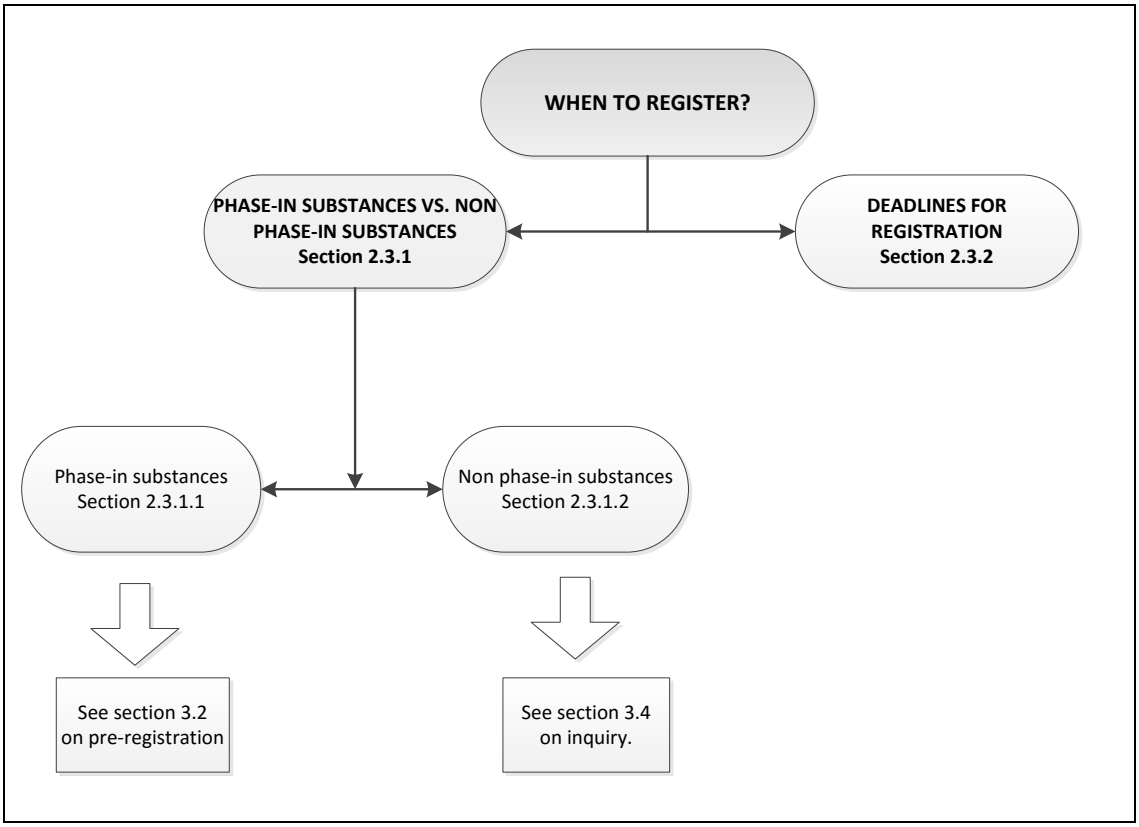
In the case of a phase-in substance that has been imported or manufactured for at least three consecutive years, the tonnes per year must be calculated for registration purposes on the basis of the average tonnes manufactured or imported in the three preceding calendar years. If the substance has not been manufactured or imported for three consecutive years then the tonnes manufactured or imported in a calendar year should be used. This provision has been put in place to avoid situations where a sudden increase in demand would lead to the impossibility to comply with the registration obligations. Note that in the case of pre-registered phase-in substances manufactured or imported for three consecutive years the tonnes per year (calculated as a three-year average) determine the deadline for registration (please refer to section 2.3 and 3.2 of this guidance which describes the pre-registration process of phase-in substances). Detailed examples on how to determine the tonnes per year and the registration deadline for phase-in substances are provided in section 2.3.2.

Legal Reference: Article 3 (30), Article 22(1)(c)

2.3 When to register?

Aim: The aim of this chapter is to inform potential registrants when they should submit their registrations to ECHA. It explains in detail what are phase-in and not phase-in substances and what the deadlines for registration are.

Structure: The structure of this chapter is as follows:



2.3.1 Phase-in substances vs. non-phase-in substances

2.3.1.1 Phase-in substances

The REACH Regulation creates a special transition regime for substances which, under certain conditions, were already being manufactured or placed on the market before the entry into force of the REACH Regulation on 1st June 2007 and were not notified according to Directive 67/548/EEC. For these substances, the registration can be submitted within deadlines foreseen by the REACH Regulation and described in section 2.3.2.

Such substances are called **phase-in substances** because they are being subjected to the registration system in different phases over time, rather than immediately in one go.

A precondition to benefit from the transitional regime for registration is that the phase-in substance has been pre-registered between the 1st June 2008 and the 1st December 2008. Phase-in substances which are manufactured or imported for the first time after 1st December 2008 can benefit from a later pre-registration under special conditions.

Further information on pre-registration of phase-in substances is included in section 3.2.

Phase-in substances are substances which fall under at least one of the following criteria:

- *The substance is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) (Article 3 (20)(a)).* The EINECS list contains, in principle, all substances on the Community market on 18 September 1981. These are the so-called 'existing substances'. 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. Note that the list has been 'frozen' and no more substances can be added to it or removed from it.

- The substance was 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 1992 (15 years before entering into force of REACH), provided that the manufacturer or importer has 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.

- The substance was placed on the market in any of the current Member States of the EU before 1 June 2007 by the manufacturer or importer, and is a so-called 'no-longer polymer' (NLP). A NLP is a substance which was 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 he placed the substance on the market and 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 is accessible at http://echa.europa.eu/information-on-chemicals/ec-inventory. Note that it only serves information purposes.

Please note that the transitional regime for phase-in substances also applies to on-site and transported isolated intermediates as well as to substances in articles which need to be registered.

Legal references: Article 3 (20)

2.3.1.2 Non-phase-in substance

All substances that do not fulfil any of the criteria for phase-in substances as presented in the previous section are considered to be **non-phase-in substances**. Non-phase-in substances do not benefit from the transitional regime provided for phase-in substances and need to be registered before they can be manufactured, imported or placed on the market in the EU, unless they have already been notified under Directive 67/548/EEC (see section 2.2.4.3).

It is important to stress that registration of non-phase-in substances will first require the submission of an **inquiry dossier** to determine whether a registration or another inquiry has already been submitted for the same substance so that data-sharing mechanisms can apply. For more information on inquiry and data-sharing processes see section 3.4.

2.3.2 Deadlines for registration

Substances falling under the scope of the REACH Regulation and not exempted from the registration obligation must be registered before they can be manufactured, imported or placed on the market. Phase-in substances and non-phase-in substances have **different timelines** for registration.

Non-phase-in substances and phase-in substances which have not been pre-registered, must be registered before manufacture or import.

For phase-in substances, which are manufactured or imported in a quantity of one tonne or more per year and which have been pre-registered between 1 June 2008 and 1 December 2008 (inclusive), the registration provisions are applied in a stepwise way to facilitate the transition to REACH.

The transitional arrangements introduce different deadlines for registration, without the need to interrupt the manufacture or import of these substances.

The deadlines set for the registration of phase-in substances have been based on the tonnage manufactured or imported per manufacturer or importer or producer of articles. This follows from the assumption that chemicals manufactured in high volumes will in many cases be more likely to present a greater risk to humans and the environment. A greater priority has also been given to substances of higher concern, such as carcinogenic, mutagenic and reprotoxic substances (CMR) and substances which are very toxic to aquatic organisms and may cause long-terms effects in the aquatic environment (classified as R50/53).

The **'phase-in' deadlines** after entry into force of the Regulation are presented in **Table 1** on the next page (applicable only if the substance has been pre-registered).

Table 1: Deadlines for the registration of phase-in substances

Deadline to submit registration dossier to ECHA	Criteria for substances
30 November 2010 at 23:59:59 (GMT) (at the latest)	Phase-in substances manufactured in the EU or imported in quantities of 1000 tonnes or more per year per manufacturer or per importer, at least once after 1 June 2007;
30 November 2010 at 23:59:59 (GMT) (at the latest)	Phase-in substances classified[14] as carcinogenic, mutagenic or toxic to reproduction, category 1 or 2, in accordance with Directive 67/548/EEC and manufactured in the Community or imported in quantities reaching 1 tonne or more per year per manufacturer or per importer, at least once after 1 June 2007;
30 November 2010 at 23:59:59 (GMT) (at the latest)	Phase-in substances classified as very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment (R50/53) in accordance with Directive 67/548/EEC and manufactured in the Community or imported in quantities reaching 100 tonne or more per year per manufacturer or per importer at least once after 1 June 2007;
31 May 2013 at 23:59:59 (GMT) (at the latest)	Phase-in substances manufactured or imported in quantities of 100 tonnes or more per year per manufacturer in the Community or per importer at least once after 1 June 2007;
31 May 2018 at 23:59:59 (GMT) (at the latest)	Phase-in substances manufactured in the Community or imported in quantities of 1 tonne or more per year per manufacturer or per importer at least once after 1 June 2007.

Figure 4 on the next page presents the registration deadlines graphically.

[14] 'Classified in accordance with Directive 67/548/EEC' refers to substances listed in Annex VI of the CLP Regulation with a harmonised classification and labelling and substances self-classified by the registrant.

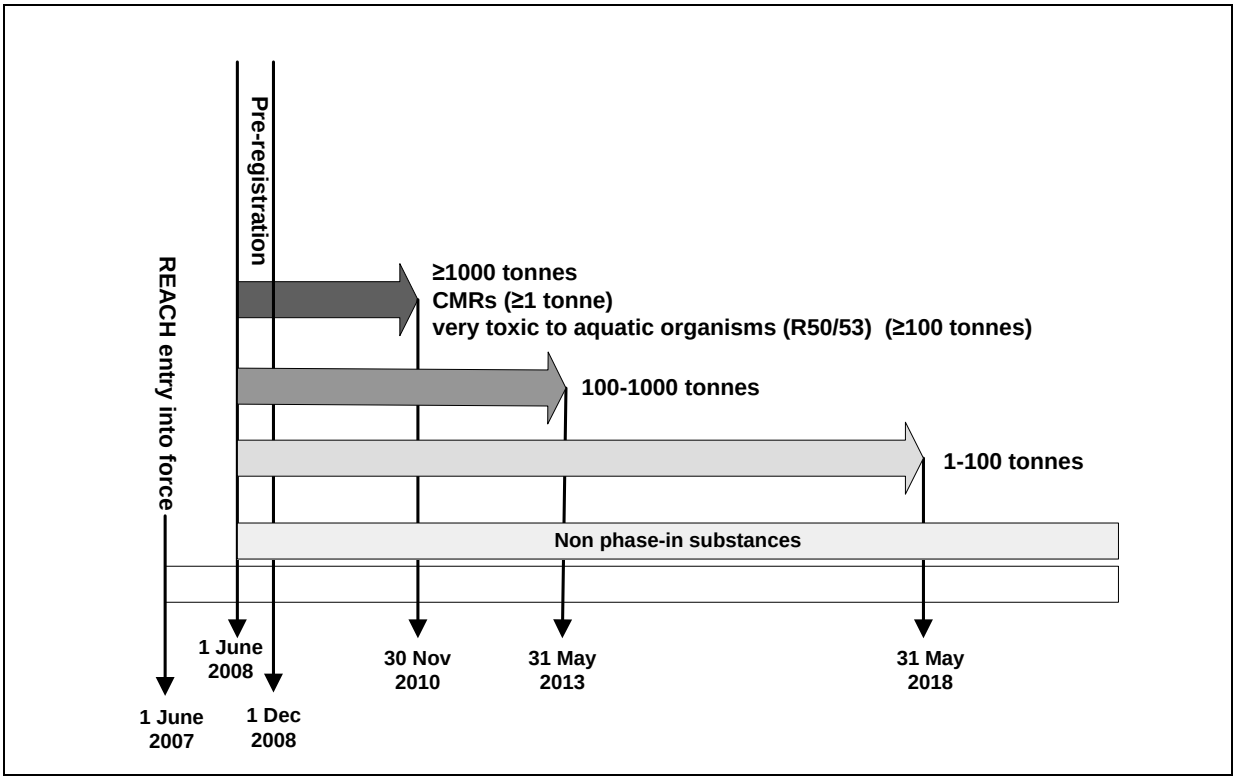


Figure 4: Registration deadlines

Therefore, if you are a manufacturer or importer of a phase-in substance, your registration deadline will depend on the criteria above.

As explained in section 2.2.6.5, the 'tonnes per year' for phase-in substances that have been imported or manufactured for at least three consecutive years is calculated on the basis of the average volume for the three preceding calendar years. If the substance has not been manufactured or imported for three consecutive years then the calendar year tonnage should be used as for non-phase-in substances.

Note that the highest tonnage per year (calculated as the average of the three preceding years or per calendar year, as applicable) manufactured or imported after 1 June 2007 will determine the deadline for registration. However, the information requirements will be based on the three-year average tonnage calculated in the year of the registration (please refer to the examples on the next pages).

The following examples show how to calculate the registration deadline for pre-registered phase-in substances based on the yearly tonnage (i.e. based on the average over the three preceding years).

Example 1:

Company X needed to determine its registration deadline. For this purpose, Company X needed each year to calculate its yearly tonnage as the average over the three preceding years (e.g. in 2007 it was the average over 2004-2006). The deadline for registration is based on the highest tonnage calculated starting in 2007.

Based on the abovementioned manufacture projections, Company X determined that it needed to register a phase-in substance by 31st May 2013 (as its manufacture volume was expected to be in the 100-1000 tonnes range). The tonnage for 2013 (calculated as the average over 2010-2012) had to be reported in the registration dossier and provided the basis for the information requirements. If the calculated tonnage had reached 1000 tonnes, the registration would have been due by 1st December 2010. If this had happened in 2011 or 2012, the registration would have been due without delay.

Once the substance has been registered, Company X needs to determine the volume every calendar year. If for example in 2017 alone the volume reaches 1000 tonnes, Company X will need to submit an update and comply with the additional information requirements in accordance with Annex X to REACH.

Example 2:

If the volume manufactured by Company Y was 120 tonnes (calculated as three-year average) in 2009 and decreased to less than 100 tonnes after that, Company Y still had to register by 31 May 2013, as the substance has been manufactured at least once at 100 tonnes or more after 1st June 2007. The tonnage to be reported in the registration dossier was the 2013 tonnage calculated as the average over 2010-2012. This tonnage determined the registration information requirements.

Example 3:

The volume manufactured by Company Z was 60 tonnes in 2010, 90 tonnes in 2011, 140 tonnes in 2012 and 200 tonnes in 2013. The three-year average in 2013 was 97 tonnes per year, but the three-year average in 2014 was 144 tonnes per year. In this case company Z had to register the substance as soon as possible, as the registration deadline for the substances at 100 tonnes or more per year had passed on 1 June 2013. The registration requirements were based on the 2014 tonnage calculated as the average over 2011-2013, i.e. 144 tonnes.

Example 4:

Company W manufactures 9 tonnes in 2015, 14 tonnes in 2016 and 20 tonnes in 2017.

The three-year average tonnage in 2018 is 14.3 tonnes per year.

In this case, the registration deadline of 31 May 2018 applies (substances below 100 tonnes and not classified as CMR). The registration requirements should be based on the 2018 tonnage calculated as the average over 2015-2017, i.e. 14.3 tonnes.

Example 5:

Company U imports 9 tonnes of a substance in 2015, 0 tonnes in 2016 and 10 tonnes in 2017 and continues the import in 2018 estimating that the total quantity for the full year will stay below 10 tonnes.

The company already exceeded the 1 tonne tonnage threshold once after 1 June 2007 and remained under the threshold of 100 tonnes. Therefore, registration of this substance is due by 31 May 2018 at the latest.

Since the substance has not been imported during the three consecutive years, to determine the information requirements for the registration, the estimated tonnage during the calendar year of registration should be used. Therefore, the information requirements for the registration will be based on the estimated quantity in the year of registration, i.e. 2018 tonnage (below 10 tonnes).

Example 6a:

Company V imports 15 tonnes in 2015, 20 tonnes in 2016, 15 tonnes in 2017 and 0.5 tonnes in 2018 up to the month of April. The company then ceases all imports of the substance (and does not manufacture it) from May 2018.

As company V has lost the status of importer (and is not a manufacturer either) it has no registration obligations on 31 May 2018 or thereafter, unless it re-starts imports.

Example 6b:

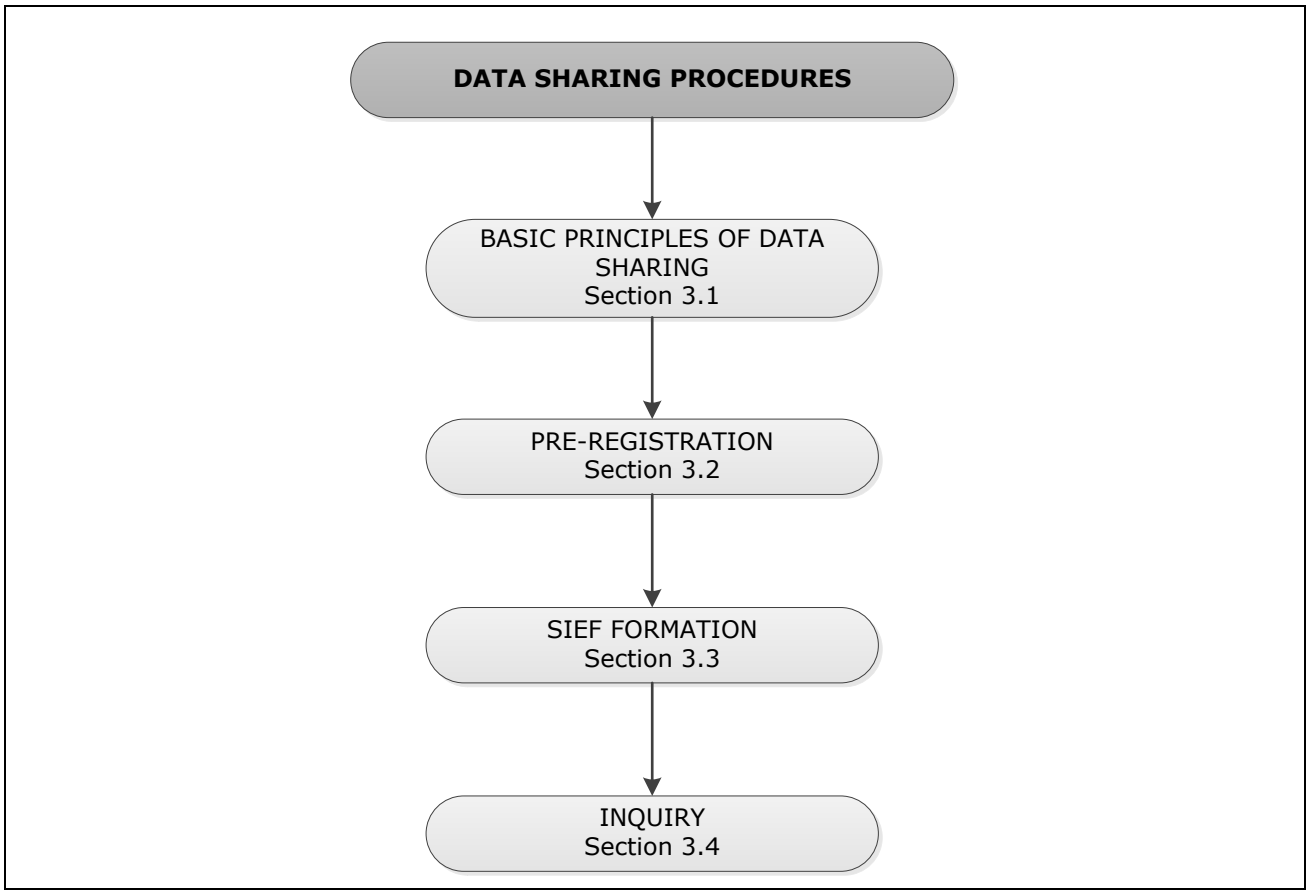
Company W imports 15 tonnes in 2015, 20 tonnes in 2016, 15 tonnes in 2017 and 0.15 tonnes in 2018 up to the month of May and intends to import a further 0.35 tonnes before the end of 2018 (total 2018 tonnage 0.5 tonnes). In this case a registration is due on 31 May 2018; in the registration the estimated annual volume for 2018 should be stated as 0.5 tonnes, but the data requirements will be based on the average volume for the preceding 3 years (16.7 tonnes).

Legal references: Article 23

3 Data-sharing procedures

Aim: This chapter provides an overview on the data-sharing provisions set out in REACH to facilitate the sharing of data between registrants. It describes the main principles of data-sharing as well as the pre-registration and inquiry process. If in need of further information, the reader is advised to refer to the *Guidance on data sharing* at http://echa.europa.eu/guidance-documents/guidance-on-reach where the data-sharing procedures are described in detail.

Structure: The structure of this chapter is as follows:



3.1 Basic principles of data-sharing procedures

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. Duplicate animal testing has to be avoided and tests on vertebrate animals must only be undertaken as a last resort (*Article 25*).

To facilitate data-sharing, the REACH Regulation requires that, **prior to registration, all substances must either be pre-registered or an inquiry must be submitted according to Article 26**. In general, pre-registration is relevant for phase-in substances and inquiry for non-phase-in substances, as well as for phase-in substances that have not been pre-registered (see section 2.3.1 for the definition of phase-in and non-phase-in substances).

The communication mechanism for phase-in substances is the Substance Information Exchange Forum (SIEF) established following pre-registration. For non-phase-in substances and for phase-in substances that have not been pre-registered the mechanism is the inquiry

process.

With respect to data-sharing, 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 either in the SIEF or 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 he needs within the SIEF or from the previous registrant, as applicable.

The existing 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.

The obligation to make every effort applies to any information requested, whether this concerns data involving testing on vertebrates, other data not involving testing on vertebrate animals, or conditions of access to joint submission. Article 25 stipulates that animal testing must be conducted only as a last resort.

The data-sharing mechanisms aim to ensure that sharing of studies which are already available and of their related costs is agreed amongst potential registrants in a fair, transparent and non-discriminatory way. Importantly, in the case of lacking data, the aim of the sharing mechanism is for potential registrants of the same substance to agree who will undertake the necessary data collection to ensure that the test (if agreed that it is needed and cannot be covered by alternatives to testing) is carried out only once. The Implementing Regulation (EU) 2016/09 on joint submission and data-sharing[15] (which entered into force on 26 January 2016) established rules to ensure an efficient implementation of the already existing data-sharing and joint submission obligations.

In accordance with the REACH Regulation, ECHA has set up procedures to assist in the resolution of data-sharing disputes. When potential registrants submit a data-sharing dispute, they must provide documentary evidence showing the efforts made by the negotiating parties to reach an agreement. To ensure equal treatment and the right to be heard, ECHA will also request the other party to provide documentary evidence. ECHA will assess the parties' efforts to reach an agreement on the sharing of the data and its costs. This assessment is solely based on the negotiations, meaning all documented communication between the parties.

After the assessment, ECHA issues a decision either allowing the potential registrant to refer to the requested data or requesting both parties to continue their negotiations. All data-sharing dispute decisions are appealable at the Board of Appeal within three months. Note that data-sharing dispute procedures must be initiated **as a last resort**, i.e. only after all the possible efforts and arguments have been exhausted.

More details on the ECHA dispute mechanism can be found on the webpage "Data sharing disputes in practice": http://echa.europa.eu/regulations/reach/registration/data-sharing/data-sharing-disputes/data-sharing-disputes-in-practice.

[15] Commission Regulation (EU) 2016/9 on joint submission and data-sharing in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 3, 6.1.2016, p.41.

To view ECHA decisions on data-sharing disputes under REACH, please consult the following webpage: http://echa.europa.eu/regulations/reach/registration/data-sharing/data-sharing-disputes/echa-decisions-on-data-sharing-disputes-under-reach.

For practical advice on data-sharing negotiations, please consult the ECHA webpage: http://echa.europa.eu/regulations/reach/registration/data-sharing/practical-advice-for-data-sharing-negotiations.

Third party representative for data-sharing proceedings

Any manufacturer, importer, or where relevant, downstream user, may, whilst retaining full responsibility for complying with his obligations under REACH appoint a third party representative for all data-sharing proceedings involving discussions with other manufacturers, importers, only representatives and where relevant downstream users. In these cases, the identity of a manufacturer or importer or downstream user who has appointed a third party representative must not be disclosed by ECHA to other manufacturers, importers, or, where relevant, downstream users. It is important to note that it is up to the manufacturer or importer of the substance to submit the registration, as a third party cannot register a substance for the company he represents in the data-sharing discussions.

3.2 Pre-registration of phase-in substances

Each potential registrant of a phase-in substance in quantities of one tonne or more per year must take part in the pre-registration process in order to benefit from the later registration deadlines outlined in section 2.3.2. The pre-registration mechanism allows potential registrants to get in contact for the purpose of data-sharing through the formation of a SIEF (see section 3.3).

Manufacturers or importers not submitting a pre-registration dossier will have to register their substance before being allowed to restart manufacture, or import. According to Article 26 they will have to submit an inquiry dossier to ECHA (see section 3.4 of this guidance) and then restart manufacture or import of their substance once a registration is completed.

Although the main pre-registration period ended on 1 December 2008, potential registrants who **for the first time** manufacture or import a phase-in substance in a quantity of one tonne per year or more after 1 December 2008 can still benefit from the transitional regime and the phase-in deadlines for registration. In order to achieve this, the potential registrant would have to submit to ECHA a pre-registration dossier within six months of first manufacturing or importing the substance and no later than 12 months before the relevant registration deadline, for his tonnage band (see section 2.3.2 of this guidance). This means that the **late pre-registrations can be submitted until 31 May 2017 for substances that need to be registered by 31 May 2018. For substances which cannot be pre-registered anymore, potential registrants need to submit an inquiry to ECHA before registering.**

Producers or importers of articles containing a phase-in substance that would require registration and not having submitted a pre-registration dossier before 1 December 2008 will similarly have to register their substance before being allowed to restart the production or import of the articles containing the substance. They can also benefit from the late pre-registration of the substance in case that they produce or import the articles containing the substance in a quantity over one tonne per year for the first time after 1 December 2008. To benefit from this, the producer or importer will have to submit a pre-registration dossier within six months of first using the substance for the production of the articles or first importing the article containing the substance and no later than 12 months before the registration deadline for their tonnage band.

Note that in the case of a non-EU manufacturer appointing an only representative, it will be

the only representative who will have to pre-register the substance in order to benefit from the extended registration deadlines. An only representative appointed after 1 December 2008 can pre-register the substance until 12 months before the relevant registration deadline, provided that the substance originating from the non-EU manufacturer was not placed on the market previously in a quantity at or above one tonne per year after 1 June 2008 (when the registration obligations entered into force). If a non-EU manufacturer decides to change his only representative and the previous only representative had pre-registered the substance originating from the non-EU manufacturer, then the successor should communicate the change of only representative to ECHA in order to continue to benefit from the phase-in deadlines for registration of that substance.

Legal reference: Article 28

3.3 SIEF formation

All potential registrants and data holders for the same pre-registered phase-in substance are participants in a 'Substance Information Exchange Forum' (SIEF). Registrants who registered the same phase-in substance earlier, or whose substance is considered as registered (see section 2.2.4) are also participants of the SIEF. The aims of the SIEF are to:

- facilitate data-sharing for the purposes of registration, thereby avoiding the duplication of studies, and
- agree on the classification and labelling of the substance concerned where there is a difference in the classification and labelling of the substance between the potential registrants.

Participants are free to organise themselves as they see fit to carry out their duties and obligations under REACH. The organisation used for the SIEF co-operation may also be used to jointly submit the relevant Annex VII-XI information.

Note that the responsibility for defining the 'sameness' or scope of the registered substances lies with the SIEF participants. The *Guidance on data sharing* (http://echa.europa.eu/guidance-documents/guidance-on-reach) provides extensive information on the rights and duties of SIEF participants. The reader is advised to consult this guidance if in need of further information on the subject.

For practical information regarding the organisation of the SIEF and related data gathering and data-sharing processes, please consult the following ECHA website: http://echa.europa.eu/support/registration/working-together.

Legal reference: Article 29

3.4 Inquiry for substances that are non-phase-in or have not been pre-registered

Inquiry is the process by which a potential registrant must inquire from ECHA whether a valid registration has already been submitted for the same substance. This is to ensure that data are shared by the relevant parties. The duty to submit an inquiry applies to non-phase-in substances and to phase-in substances that have not been pre-registered.

Therefore, for non-phase-in substances and for phase-in substances that have not been pre-registered an inquiry must always be submitted before proceeding with the registration of the substance. If the potential registrant wishes to access the market he must submit an inquiry.

3.4.1 The inquiry dossier

When submitting an inquiry, potential registrants are required to submit a dossier with the following information:

Identity of the inquirer

This will include contact details and the location of the inquirer's production site.

Substance identity

The information must be sufficient to enable the substance to be identified. The information required for substance identity is identical to that required in the technical dossier for standard registration (section 2 of Annex VI) and is outlined in the *Guidance on identification and naming of substances under REACH and CLP* available at http://echa.europa.eu/guidance-documents/guidance-on-reach. Please refer also to section 5.2.1 of this guidance.

It is important to remark that for substances used as intermediates, the information to be provided in the inquiry dossier for the identification of the substance will have to comply with the same requirements as for non intermediates and will not benefit from reduced requirements even if manufactured and used under strictly controlled conditions (see section 2.2.5).

Providing thorough and accurate information on substance identity is essential to enable ECHA to provide the contact details of existing and potential registrants to the inquirer and so to facilitate all parties in their data-sharing obligations. Potential registrants are strongly recommended to consult the *Guidance on identification and naming of substances under REACH and CLP* to ensure that the information on substance identity they provide in the inquiry dossier follows the current guidelines.

List of information requirements and of new studies which may be required

The information requirements for a specific substance will depend on the intended **tonnage band** to be manufactured or imported. The potential registrant needs to identify the list of information requirements for their particular substance in order to facilitate the subsequent data-sharing stage (see section 4.1.1 on fulfilling the information requirements). The potential registrant must identify in the inquiry dossier the list of information requirements for which he would require to fulfil his registration obligations.

Practical instructions for the preparation of an inquiry are available in the ECHA manual 'How to prepare an inquiry dossier' accessible at: http://echa.europa.eu/manuals. This document is also available via the help system built into IUCLID.

3.4.2 The inquiry process

Upon receipt of the inquiry dossier ECHA will perform a substance identity check to identify existing registrants and/or other successful inquirers of the same substance. This assessment can lead to the following, possible outcomes:

1. **The same substance has not been registered and no party has submitted a successful inquiry to date**

   In this situation, the potential registrant receives a communication from ECHA which includes the inquiry number and the link to the relevant Co-Registrants page in REACH-IT. On the Co-Registrants page, this potential registrant will see himself listed under the "Potential registrants" tab and the list under the "Registrants" tab will be left

empty.

The potential registrant will also be able to access the pre-SIEF and see if there are companies which pre-registered the same substance. In this case, the potential registrant will need to contact the SIEF and determine how to fulfil the obligations to share data and submit a joint registration.

2. The same substance has been previously registered

In this situation, ECHA will provide the potential registrant with a link to the Co-Registrants page in REACH-IT which will contain the contact details of the existing registrants and other successful inquirers of the same substance. Once the lead registrant has registered the joint dossier for that substance, his contact details will also be visible.

In parallel, ECHA will inform the existing and potential registrants of the submitted inquiry (name and contact details of potential registrant and his registration requirements).

Based on the information submitted in the inquiry, ECHA will also provide the potential registrant with the list of relevant **study summaries** or **robust study summaries** already submitted and available.

- **For studies submitted at least 12 years previously**[16], ECHA will provide with the inquiry communication in the "Annotation" in REACH-IT, a copy of the relevant study summaries which can only be used for the purpose of registration by the potential registrant. ECHA will also identify the registrant(s) who have submitted the data.
- **For studies submitted less than 12 years previously**[17], as part of a notification under the previous legislation (Directive 67/548/EEC), or as part of a registration under REACH, ECHA will identify the registrant(s) who have submitted the data.

The data-sharing process can be initiated, and the potential registrant will need to form part of a joint submission with the previous registrants. The rules to ensure an efficient implementation of the data-sharing and joint submission obligations are established by the Implementing Regulation (EU) 2016/09 on joint submission and data-sharing. For further information, please refer to the *Guidance on data sharing* at http://echa.europa.eu/guidance-documents/guidance-on-reach.

Please note also that the potential registrant:

- must, in the case of information involving tests on vertebrate animals, and
- may in the case of information not involving tests on vertebrate animals,

[16] Any study summaries or robust study summaries submitted in the framework of a registration under REACH at least 12 years previously can be used for the purposes of registration by another manufacturer or importer. In the case of an update of the registration because a higher tonnage band is reached and information on additional studies for this higher tonnage band is submitted, a period of 12 years starts for the new information when it is submitted (*Article 25(3)*). In addition, for data that has already been submitted within a notification dossier under Directive 67/548/EEC, these data will be available for the purpose of registration, starting 12 years after their submission date.

[17] Data submitted at least 12 years previously may be requested as part of the inquiry process to ECHA.

request the (robust) study summaries required for registration, directly from the previous registrants.

Registrants are encouraged to request and to share **all** available data, irrespective of whether these were derived using animal studies or not.

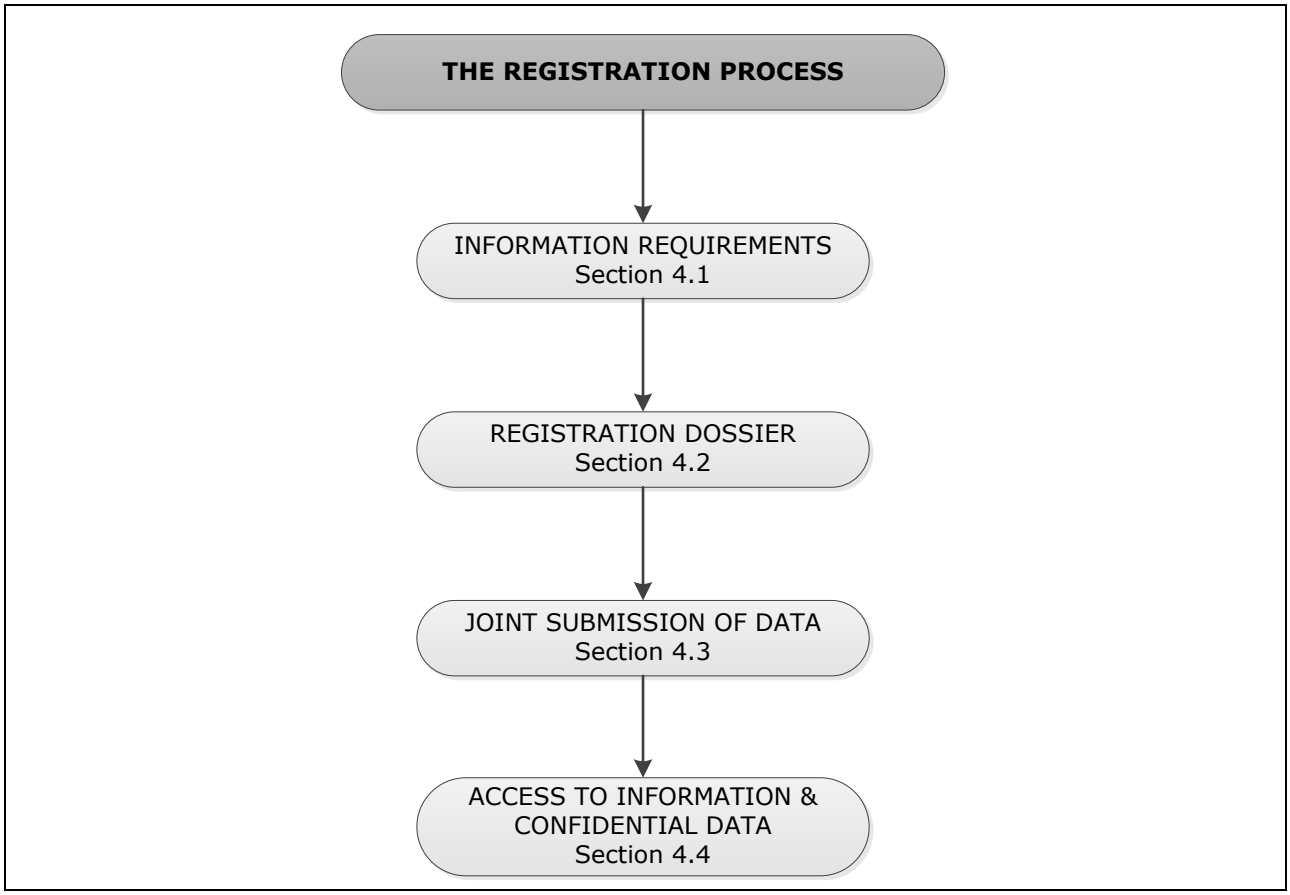
It is recommended that the potential registrant contacts first the lead registrants displayed on the Co-Registrants page. This communication will enable the potential registrant to request sharing of existing data from the previous registrant(s), while engaging in negotiations to join/create the joint registration dossier.

Legal references: Article 26 and 27

4 The registration process

Aim: The aim of this chapter is to present the information that the registrant has to submit as part of his registration. It also describes what a joint submission of registration data is.

Structure: The structure of this chapter is as follows:



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. This document is also available via the help system built into IUCLID.

4.1 Information requirements

Manufacturers and importers will need to obtain information on the substances they manufacture or import and use this information to assess the risks arising from the manufacture and uses of the substances and to ensure that the risks that the substances may present are controlled.

The information gathered and the assessment performed has to be documented in the registration dossier and submitted to ECHA for the registration of the substance.

4.1.1 Fulfilling the information requirements

Manufacturers and importers have to collect **all available existing information** on the properties of the substance for registration purposes, regardless of the tonnage manufactured or imported. This information has in turn to be compared with the standard information requirements set up by the REACH Regulation.

The information to be gathered includes:

- test data (*in vivo* and *in vitro*);
- non test data from alternative methods such as (Q)SARs ((Quantitative) Structure Activity Relationships), grouping of substances and read across;
- information on manufacture, uses, risk management measures and resulting exposures.

Table 2 below presents an overview of the standard information requirements defined in REACH (Annex VII to X). For each tonnage band, REACH defines the minimum information that the registrant has to provide on the intrinsic properties of the substance. For the lowest tonnage level, the standard information requirements are defined in Annex VII, and when a new tonnage level is reached, the requirements of the corresponding Annex have to be added. These standard requirements may, however, be adapted (waived or increased) when appropriately justified according to the criteria set out in Annexes VII to XI. Therefore**, for each substance the precise information requirements may differ depending on the available information on intrinsic properties as well as on tonnage, use and exposure.**

Where available data are not adequate to meet the requirements of REACH, additional testing may need to be generated. It should be noted that any study required to fulfil the information requirements defined in Annex IX and X (see Table 2) should not be conducted by the registrant at the stage of registration. Instead the registrant will have to develop a **testing proposal** and include it in his registration dossier.

Before proposing a new test involving vertebrate animals the registrant needs to consider all the relevant and available data sources as well as available testing methods other than *in vivo* tests to avoid unnecessary animal testing. 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) grouping or read-across, provided that the use of such methods is justified. All sources of information can also be used in a weight of evidence approach. If the outcome of this analysis justifies a proposal for animal testing, registrants need to make their justifications for animal testing clear in the registration dossier, including a documented analysis of alternative methods they have considered.

Article 25 states that animal testing should only be performed as a last resort. Therefore, where possible the **registrant is obliged to share or generate data with other registrants** of the same substance, instead of generating data by himself, **if this would involve animal experiments** (see section 3.1 on data-sharing).

Where tests on substances are required to generate information on intrinsic properties of substances, they must be conducted in accordance with the test methods laid down in Commission Regulation (EC) No 440/2008 and its amendments or in accordance with other international test methods recognised by the Commission or ECHA. Ecotoxicological and toxicological tests and analyses must be carried out in compliance with the principles of good laboratory practice (GLP) or other international standards recognised as being equivalent[18] by

[18] Note that no other international standards have so far been recognised as being equivalent.

ECHA or the Commission and with the provisions of Directive 2010/63 EU on the protection of animals used for scientific purposes.

For further information about the process for information gathering and data generation please refer to *Guidance on information requirements and chemical safety assessment* (http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment). The following chapters 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

Practical information on alternative methods for the generation of information on intrinsic properties of substances can also be found in the following documents:

- Practical Guide: 'How to use alternatives to animal testing to fulfil your information requirements'
- Practical Guide 5: 'How to use and report (Q)SARs'

The above-mentioned practical guides are available at http://echa.europa.eu/practical-guides.

Table 2: Overview of the standard information requirements as defined in REACH

ANNEX VII (1 tonne or more)	
7	**INFORMATION ON THE PHYSICOCHEMICAL PROPERTIES OF THE SUBSTANCE**
7.1	State of the substance (at 20 °C and 101,3 kPa)
7.2	Melting/freezing point
7.3	Boiling point
7.4	Relative density
7.5	Vapour pressure
7.6	Surface tension
7.7	Water solubility
7.8	Partition coefficient n-octanol/water
7.9	Flash point
7.10	Flammability
7.11	Explosive properties
7.12	Self-ignition temperature
7.13	Oxidising properties
7.14	Granulometry
8	**TOXICOLOGICAL INFORMATION**

8.1		Skin irritation or skin corrosion
8.1.1		Skin irritation (*in vitro*)
8.1.2		Skin corrosion (*in vitro*)
8.2		Serious eye damage or eye irritation
8.2.1		Serious eye damage or eye irritation (*in vitro*)
8.3		Skin sensitisation
8.3.1		Skin sensitisation (*in vitro*/*in chemico*)
		The test(s) do not need to be conducted if an *in vivo* study under point 8.3.2 of Annex VII is available, or the available in *vitro/in chemico* test methods are not applicable for the substance or are not adequate for classification and risk assessment under point 8.3.
8.3.2		Skin sensitisation (*in vivo*)
		An *in vivo* study must be conducted only if in *vitro/in chemico* test methods described under point 8.3.1 of Annex VII are not applicable, or the results obtained from those studies are not adequate for classification and risk assessment according to point 8.3.
8.4.1		Mutagenicity (*in vitro* gene mutation in bacteria)
8.5.1		Acute toxicity (by oral route)
9		**ECOTOXICOLOGICAL INFORMATION**
9.1.1		Short term aquatic toxicity on invertebrates (preferred species *Daphnia*)
9.1.2		Growth inhibition aquatic plants (algae preferred)
9.2.1.1		Ready biodegradability
ANNEX VIII (10 tonnes or more)		
8		**TOXICOLOGICAL INFORMATION**
8.1		Skin corrosion or skin irritation
		(An *in vivo* study must be considered only if the *in vitro* studies under points 8.1.1 and 8.1.2 of Annex VII are not applicable, or the results of these studies are not adequate for classification and risk assessment)
8.2		Serious eye damage or eye irritation
		(An *in vivo* study for eye corrosion/irritation must be considered only if the *in vitro* study(ies) under point 8.2.1 of Annex VII are not applicable, or the results obtained from these study(ies) are not adequate for classification and risk assessment).
8.4.2		Cytogenicity in mammalian cells (*in vitro*)
8.4.3		Gene mutation in mammalian cells (*in vitro*)
8.5.2		Acute toxicity (by inhalation)
8.5.3		Acute toxicity (by dermal route)
8.6.1		Short-term repeated dose toxicity test (28 days)
8.7.1		Screening for reproductive/developmental toxicity
8.8.1		Toxicokinetics
9		**ECOTOXICOLOGICAL INFORMATION**

9.1.3	Short-term aquatic toxicity to fish
9.1.4	Activated sludge respiration inhibition test
9.2.2.1	Hydrolysis as a function of pH
9.3.1	Adsorption/desorption screening
	ANNEX IX (100 tonnes or more)
7	**INFORMATION ON THE PHYSICOCHEMICAL PROPERTIES OF THE SUBSTANCE**
7.15	Stability in organic solvents and identity of relevant degradation products
7.16	Dissociation constant
7.17	Viscosity
8	**TOXICOLOGICAL INFORMATION**
8.6.1	Short-term repeated dose toxicity test (28 days)
8.6.2	Sub-chronic toxicity (90 days)
8.7.2	Pre-natal developmental toxicity
8.7.3	Extended One-Generation Reproductive Toxicity Study
9	**ECOTOXICOLOGICAL INFORMATION**
9.1.5	Long-term aquatic toxicity on invertebrates (preferred species *Daphnia*)
9.1.6	Long-term aquatic toxicity on fish
9.2.1.2	Simulation testing on ultimate degradation in surface water
9.2.1.3	Soil simulation testing
9.2.1.4	Sediment simulation testing
9.2.3	Identification of degradation products
9.3.2	Bioaccumulation in aquatic species (preferably fish)
9.3.3	Further information on adsorption/desorption
9.4.1	Short-term terrestrial toxicity to invertebrates
9.4.2	Effects on soil micro-organisms
9.4.3	Short-term terrestrial toxicity to plants
	ANNEX X (1000 tonnes or more)
8	**TOXICOLOGICAL INFORMATION**
8.6.3	Long-term repeated dose toxicity (≥ 12 months)
8.7.2	Developmental toxicity
8.7.3	Extended One-Generation Reproductive Toxicity Study
8.9.1	Carcinogenicity
9	**ECOTOXICOLOGICAL INFORMATION**
9.2	Further biotic degradation testing
9.3.4	Further information on the environmental fate and behaviour of the substance and/or degradation products
9.4.4	Long-term terrestrial toxicity to invertebrates
9.4.6	Long-term terrestrial toxicity to plants

9.5.1 Long-term toxicity to sediment organisms

9.6.1 Long-term or reproductive toxicity to birds

4.1.2 Use of information from other assessments

As stated 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). Registrants may rely on existing assessments in meeting the information requirements given in the Annexes VIII - X as long as they are in legitimate possession or have permission to refer to the full study reports that have been summarised in the registration dossier. Therefore, registrants need to take into account and to use these already available assessments to prepare their registration dossier. This includes in particular assessments carried out under other EU programmes such as the Existing Substances Risk Assessment Programme, assessments of active substances under the Biocidal Products Regulation or the Plant Protection Products Regulation when such substances are covered by REACH.

Another important source of information is the OECD HPV (Organisation for Economic Co-operation and Development High Production Volume) Chemicals Programme where a lot of similarities exist with REACH. Those similarities should be taken into account when preparing a registration dossier where a dossier for the OECD HPV Chemicals Programme is available. To reduce duplicative 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;

(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). 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 need not 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 need not 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 5.

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 a large number of 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 is downloadable from the IUCLID website at https://iuclid6.echa.europa.eu/ free of charge by all parties, if used for non-commercial purposes.

Each manufacturer or importer or only representative is **individually obliged to submit a registration dossier** for each of his substances to ECHA in order to register them. The registration dossier must be submitted electronically through the REACH-IT portal accessible at: https://reach-it.echa.europa.eu. Practical instructions for the preparation of a registration dossier are available in ECHA manual 'How to prepare registration and PPORD dossiers' accessible at: http://echa.europa.eu/manuals. This document 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 same substance is manufactured or imported or intended to be manufactured or imported by more than one company, all the registrants must submit part of data within one, joint submission. In other words: multiple registrants of the same substance are obliged to be part of the same, joint submission for that substance.

Registrants are required to jointly submit the following information:

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

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 4.3.2 of this guidance document where opt-out possibilities are described). However, the registration must be part of the same joint submission even in this case. Separate registrations are not allowed.

Registrants may decide to submit jointly or separately:

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

The intention of a joint submission is that registrants will minimise costs by co-operating within the SIEF on the preparation of the dossier, participate in the data and cost sharing process to finally submit to ECHA jointly one set of information for the substance. The joint submission also ensures reducing the need for testing, in particular on vertebrate animals. In addition, registrants submitting data jointly can benefit from a reduced registration fee. For more information on how to gather and share existing information see also section 3 of this guidance.

It is important to stress that in case an only representative has been appointed by a non-EU manufacturer to carry out the registration of the substance, he must be part of a joint submission with the other manufacturers, importers and only representatives for the same substance. Only representative must join the joint submission for each non-EU manufacturer he represents separately.

The joint submission of data applies both for the registration of phase-in substances and that of non-phase-in substances. It also applies if a given substance is a phase-in substance to some of the registrants and a non-phase-in substance to others. The requirement to make a joint submission also applies regardless of whether the substance has been pre-registered by all, some or none of the registrants.

Due to the reduced information requirements applicable to intermediates (used under strictly controlled conditions), registrants of intermediates may choose for practical reasons to either

form a joint submission together with the 'normal' registrants or to form one parallel joint submission for intermediate use only. However, in case of the separate joint submission for intermediate use only it is recommended to bring all existing, available information together (especially the information necessary for the classification of the substance). For more information about the registration of intermediates, please consult section 6.2 of the *Guidance on data sharing*.

Note that the joint submission of data does not eliminate the obligation for each registrant (manufacturer, importer or only representative) to also submit an individual dossier as part of the joint submission.

Registrants must submit individually:

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

For details on which information must be submitted jointly as part of the lead dossier, and which must be submitted individually in each member dossier, please refer to **Table 3** on the next page.

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

Legal reference: Article 11

4.3.1 Mechanisms of joint submission

The information that needs to be submitted jointly is submitted by one lead registrant on behalf of the other registrants (the so-called 'member registrants'). Other information needs to be submitted by all registrants individually.

The lead registrant of a joint submission could, for example, be the largest producer as he in any case will have to register the entire data set by the earlier deadline. However, this is not obligatory: the joint submission registrants have the possibility to appoint a lead registrant with a lower tonnage (for instance, if they have to prepare joint submissions for more substances and decide to share the workload of managing the joint submissions). If they arrange their joint submission in this way, a lead registrant in a lower tonnage band has to provide a complete dossier (i.e. with studies for the highest tonnage band to be registered for that substance).

It is important to stress that the lead registrant will always pay the fee corresponding only to his own tonnage band, as well as any other member of the joint submission. In practice this implies that there will be two different types of registration dossiers, namely:

1. the '**lead dossier**' (containing the information of the lead registrant and the data set required in REACH for the highest tonnage band to be registered for that substance)

and

2. the '**member dossier**' (with the individual information to be submitted by each member of the joint submission).

The information requirements for each type of registration dossier are shown in **Table 3**.

Table 3: Information requirements for the lead dossier and the member dossiers in joint submissions

Information requirements	Lead dossier		Member dossier
	Joint information	Individual information	Individual information
(a) Technical dossier			
(i) identity of the manufacturer or importer		X	X
(ii) identity of the substance		X	X
(iii) manufacture and uses of the substance and if relevant use and exposure categories		X	X
(iv) classification and labelling *	X		
(v) guidance on safe use	upon agreement	upon agreement	upon agreement
(vi) study summaries of information derived from the application of Annexes VII to XI *	X		
(vii) robust study summaries of the information derived from the application of Annexes VII to XI if required under Annex I *	X		
(viii) indication regarding the review by an assessor of information submitted under (iii), (iv), (vi), (vii) and (b)	X	X	X
(ix) proposals for testing *	X		
(x) exposure information for substances in quantities of 1 to 10 tonnes		X	X
(xi) 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 4.3.2)

Once the lead registrant has been appointed by the other registrants (Article 11) he needs to create a joint submission in REACH-IT and will submit the lead dossier for the joint submission

first. Only once the lead dossier for the joint submission is accepted for processing, (i.e. it has passed the business rules check step, see section 10.1), the members can submit their dossiers. The joint submission page in REACH-IT will indicate to members when the lead dossier has passed the business rules check and that they may now begin submitting their respective member dossiers.

When a potential registrant prepares to register a non-phase-in substance and the inquiry process (see section 3.4) results in finding that one or several registrations have previously been submitted for the same substance, the potential registrant will not only need to share data with the previous registrants, but he will also need to be part of the joint submission.

Where the same substance has previously been registered by only one other company, the potential registrant will need to make contact with this previous registrant. They must agree on who will be the lead registrant. In most cases, it would be most sensible if the previous registrant takes over the role of the lead registrant, as he has already submitted a full dataset. However, the previous registrant and the potential registrant are also free to agree that the potential registrant will be the lead registrant and make the joint submission. In that case, the potential registrant must create and submit a joint submission with the full dataset required for the highest tonnage range of the two registrants, and the previous registrant will subsequently need to join this submission.

The joint submission obligation also applies to previous notifiers under Directive 67/548/EEC. Given that the joint submission obligation did not exist prior to REACH and in order to ease the previous notifications into the registration system, they are regarded as registrations under REACH that are outside a joint submission. Therefore, such notifications are not linked to any existing joint submission. According to Articles 11 or 19 of REACH, a joint submission that includes the previous notifier(s) must be established when another entity intends to register the same substance.

In case the lead registrant ceases manufacture the other registrants will have to consider the need to appoint a new lead registrant. For further information about designation or transferring the lead registrant role please consult *Guidance on data sharing* at http://echa.europa.eu/guidance-documents/guidance-on-reach.

The registration fees, set by Commission Regulation (EC) No 340/2008 of 16 April 2008, as amended[19] take into account whether the submission is joint or separate.

Legal references: Article 11, Article 19

4.3.2 Opt-out possibilities

A manufacturer or importer 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

[19] The latest consolidated version of the Fee Regulation is accessible at http://echa.europa.eu/web/guest/regulations/reach/legislation.

the lead registration.

In this case the registrant has to submit in his 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. For technical instructions please refer to ECHA manual 'How to prepare registration and PPORD dossiers' accessible at: http://echa.europa.eu/manuals.

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.

Please note that the joint submission is required even if the registrant decides to opt-out for part or all of the data. In such case the registrant still remains part of the same joint submission and will be able to submit his dossier only after the lead dossier has been accepted for processing. Hence, a registrant can opt-out from certain information requirements but not from the joint submission as such.

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

More information on the opting out possibilities and mechanisms can be found in the *Guidance on data sharing* available at: http://echa.europa.eu/guidance-documents/guidance-on-reach.

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

4.4 Access to information and confidential data

Although the REACH Regulation requires information to be provided to ECHA and potentially exchanged with the other manufacturers and importers, some provisions (*Articles 118* and *119)* to protect commercially sensitive information are foreseen.

The general provisions on access to information are as follow:

- Information that is listed in *Article 119 (1)* and submitted in the registration dossier will be made publicly available on the ECHA website.
- A registrant may identify certain information listed in *Article 119 (2)* as confidential in his registration dossier for reasons of commercial interests (*Article 10(a)(xi)*). If the justification is accepted as valid by ECHA, such information will not be made publicly available. The information listed in *Article 119 (2)* will be published on the ECHA website if no valid confidentiality claim is submitted by the registrant and is accepted as valid by ECHA.
- Access to such pieces of information and other pieces of information may be granted by ECHA on request on a case-by-case basis whenever this is foreseen in Regulation (EC) No 1049/2001. This Regulation also defines cases in which public access to documents, whatever its medium, has to be denied, for instance for reasons related to commercial interests. Where it is not clear whether a document may or may not be disclosed, the regulation requires ECHA to consult the owner of the document with a view to assessing whether it should or should not be disclosed.

According to *Article 119(2)* the following pieces of information can be claimed confidential for reasons relating to commercial interests of the registrant or any other party, if justified:

- *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;*
- *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;*
- 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;
- certain information contained in the safety data sheet as defined in *Article 119(2)*;
- *the trade name(s) of the substance;*
- *the name in the IUPAC Nomenclature for non-phase-in substances which fulfil the criteria for any of the hazard classes set out in Article 58 (1) of Reg (EC) No 1272/2008 for a period of six years;*
- *the name in the IUPAC Nomenclature for substances which fulfil the criteria for any of the hazard classes set out in Article 58 (1) of the CLP Regulation that are only used as one or more of the following:*

  (i) as an intermediate;

  (ii) in scientific research and development;

  (iii) in product and process orientated research and development.

Disclosure of the following information must normally be deemed to undermine the protection of the commercial interests of the concerned person, and therefore according to *Article 118* this information must not be published on the ECHA website or disclosed otherwise, with an exception when 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 his distributors or downstream users.*

In contrast, the following information submitted in the registration dossier and held by ECHA on substances whether on their own, in mixtures or in articles, must be made publicly available, free of charge on the ECHA website:

- *the name in the IUPAC Nomenclature, for substances which fulfil the criteria for any of the hazard classes set out in Article 58 (1) of the CLP Regulation[20], without prejudice to paragraph 2(f) and (g);*

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– 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;

- *if applicable, the name of the substance as given in EINECS;*
- *the classification and labelling of the substance;*
- *physicochemical data concerning the substance and on pathways and environmental fate;*
- *the result of each toxicological and ecotoxicological study;*
- *any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC) established in accordance with Annex I;*
- *the guidance on safe use provided in accordance with section 4 and 5 of Annex VI;*
- *the analytical methods if requested in accordance with Annexes IX or X which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.*

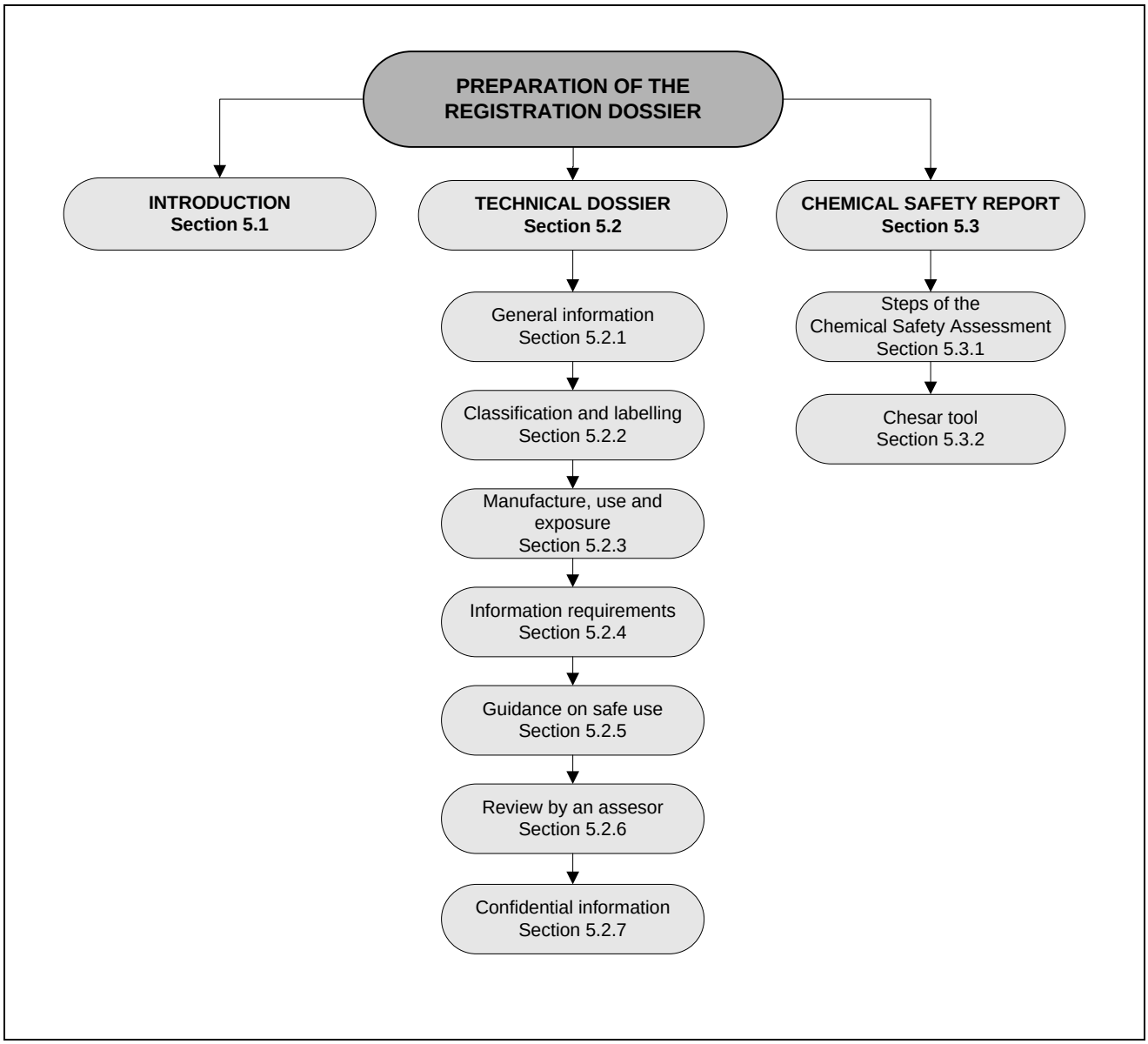
Legal references: Article 118, Article 119

- 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;

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 has to submit as part of his registration dossier and explains how this information has to be reported. It does not, however, provide specific practical instructions on how to successfully submit a registration dossier to ECHA. For this latter information, the reader is advised to consult the ECHA manual 'How to prepare registration and PPORD dossiers' accessible at: http://echa.europa.eu/manuals. This document is also available via the help system built into IUCLID.

Structure: The structure of this chapter is as follows:



5.1 Introduction

All relevant and available information has to be documented in both the technical dossier and (for substances manufactured or imported in quantities of 10 tonnes or more per year per registrant) in the chemical safety report (CSR). The information needs to be reported in IUCLID format, and submitted to ECHA via REACH-IT, as shown in **Figure 5**. Members of the joint submission have also the possibility to create their registration dossiers online in REACH-IT, instead of installing and using IUCLID[21]. This is however not possible for the lead registrant. For further technical details, see ECHA manual 'How to prepare registration and PPORD dossiers' (http://echa.europa.eu/manuals).

Article 10 (a), in combination with Annexes VI to X defines the information to be documented in the technical dossier. Annex XI establishes the rules for the adaptation of the information defined in Annexes VI to X and has to be considered in combination with these annexes. 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. The relation between the information to be submitted for registration, as defined in REACH, and the IUCLID sections where it has to be reported is shown in **Table 4** below.

Table 4: Relation between the information requirements in *Article10* 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[22]
(ix) proposals for testing		Sections 4, 5, 6, 7
(x) exposure information for substances in quantities of 1 to 10 tonnes	*Annex VI section 6*	Section 3

[21] Please note that only those dossiers created online in REACH-IT can be updated via REACH-IT.

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

(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	*Article 10 (b)* *Article 14, Annex 1*	Attachment in section 13

In order to generate his registration dossier, the registrant will have to undertake the following tasks**:**

- Document the technical dossier with all relevant and available information
- Carry out the chemical safety assessment (CSA) for substances manufactured or imported in quantities of 10 tonnes or more per year per registrant
- Record the results of the CSA in the CSR.

These tasks are described in detail in the following sections for an individual registration. Note that in case of a joint submission the information to be provided by the lead registrant and the members of the joint submission will not be the same as explained previously in section 4.3.

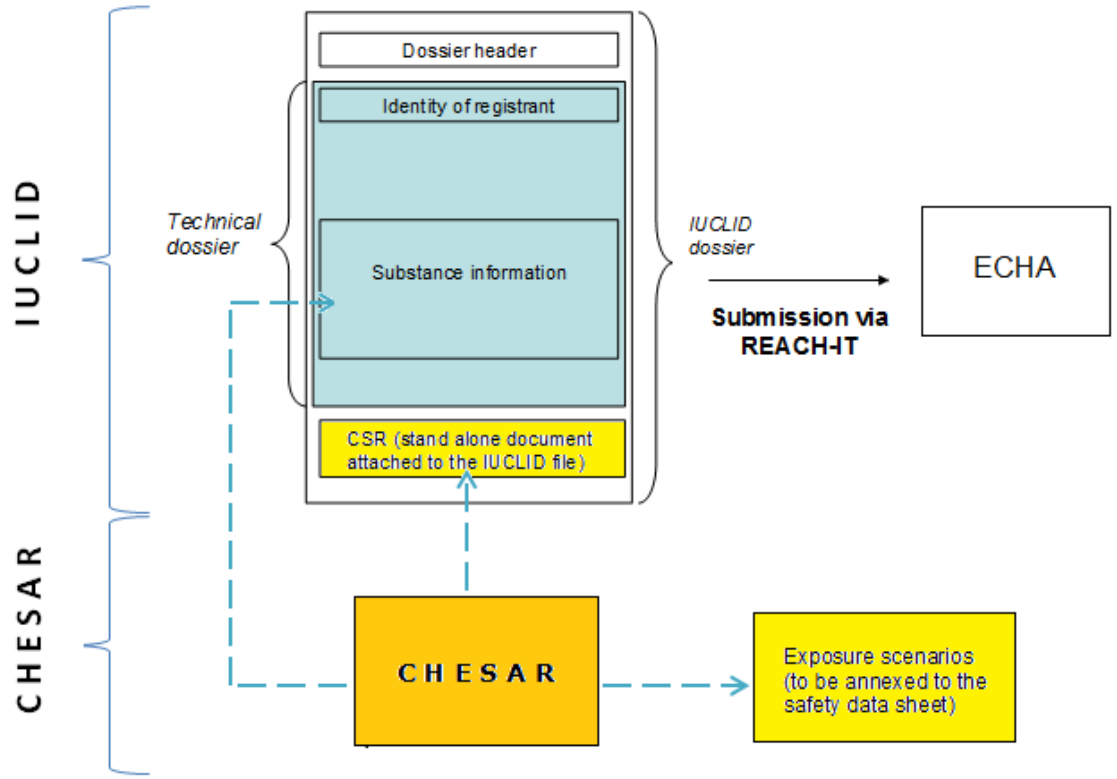


Figure 5: Structure and format of the registration dossier

5.2 Generation of the technical dossier

All relevant and available information on the substance, from its identification and intrinsic properties to the classification and evaluation of its hazards needs to be reported in the technical dossier. The information requirements depend on the three-year average tonnage calculated in the year of the registration for substances manufactured/imported during the three consecutive years. For substances which has not been manufactured/imported during the three consecutive years the information requirements depend on the tonnage estimated during the calendar year of registration.

The data will be reported in IUCLID which is the reporting format for the technical dossier.

In some cases more than one hazard profile would be relevant for a substance (for example if various compositions of the registered substance exist with different hazard profiles or if a substance transforms during the use and both parent and transformation products play a role in a safety assessment). To ensure a transparent organisation of the dataset for such substances, so-called "assessment entities" can be defined in IUCLID. For more information about this concept please refer to chapter D.2 of the *Guidance on information requirements and chemical safety assessment*, *Part D: Framework for exposure assessment* available at: http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.

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

The following sections of this guidance describe in a general way the content and level of detail needed in the registration dossier.

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

5.2.1 General information on the registrant and on the registered substance

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

- **registrant identification** (as specified in section 1 of Annex VI), i.e. registrant's name, address, telephone number, fax number and e-mail address, details about the contact person and when appropriate information about location of registrant's production and own use sites.
- **role of the registrant** (manufacturer, importer or only representative). If the registrant is an only representative acting on behalf of a non-EU manufacturer he is advised to attach a document from the non-EU manufacturer appointing him as only representative.
- **information required for traceability purposes**, such as the number of the pre-registration or the inquiry preceding the registration.
- **identification of the substance** (as specified in section 2 of Annex VI). This includes the name of the substance, its chemical identifiers (EC number, CAS name and number, etc.), the molecular and structural formula and its composition (degree of purity, constituents, analytical data, etc.).

The 'one substance, one registration' principle requires multiple registrants of the same substance to be part of the same, joint submission for that substance. This means that registrants of the same substance agree to submit a joint registration covering the substances manufactured/imported by them individually. Such an agreement on the data submitted must be relevant for the scope of the substance as jointly registered by the registrants. In this respect, the joint registration is expected to include specification of the boundaries of the substance covered by the registration, in terms of its chemical composition. The specifications of the boundary of the substance covered by the registration are commonly known as the **substance identity profile (SIP)**. The SIP concept has been developed by Cefic to aid preparation of SIEFs document sameness criteria for the joint submission[23].

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

In the case of import of a mixture, it can be difficult to obtain information on the composition of the mixture from a non-EU supplier. However, also under 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 law. It will be up to companies to improve the communication through their supply chain to ensure their compliance with REACH. In case disclosure of the composition of the mixture may have consequences, the non-EU manufacturer has the possibility to appoint an only representative, as explained in section 2.1.2.6 of this guidance.

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 has to determine the classification and labelling of his substance with respect to physico-chemical properties, environment and human health. Within a joint submission, the lead dossier can report several classifications in case several 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 have to be clearly linked to the relevant compositions.

If a member registrant disagrees and wants to propose another classification, then he needs to 'opt-out' from this information requirement (see section 4.3.2 of this guidance). Different classifications for the same substance may be reported and justified jointly in the lead dossier. However, in case of disagreement a member registrant will need to opt-out from this information requirement in his own dossier.

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,

[23] Cefic guidance documents, for example Guidance for Lead Registrants (http://www.cefic.org/Industry-support/Implementing-reach/Guidances-and-Tools1/) outline the advantages of having a documented SIP available for transparency on cost sharing for joint submission.

- inconclusive data, or
- data which is conclusive for non 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, see http://echa.europa.eu/web/guest/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 his 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 pre-registered and other notifiers of the classification and labelling of the same substance.

For further information on harmonised classification and labelling please consult 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 'Harmonised classification and labelling' section on the ECHA website http://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling.

5.2.3 Manufacture, use and exposure

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

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

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

- not include entries in sections 3.5.4 to 3.5.6 of IUCLID (as there are no registered professional, consumer or service life uses),
- indicate that uses at industrial sites are limited to a few sites only (for example $\leq$ 5),
- claim that uses at industrial sites take place under closed (rigorously contained) conditions leading to insignificant exposure to humans and insignificant release to the environment on the various routes. Note: These conditions need to be described in the exposure assessment (for substances > 10 t/a) or in the

exposure information according to Annex VI (6) (substances < 10 ta).

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

Members of a joint submission also have to report their own uses and cannot simply refer to the dossier of the lead registrant, even if the chemical safety report (CSR) has been submitted jointly. In order to provide the use information, use maps developed under the CSR/ES roadmap can be helpful (http://www.echa.europa.eu/en/web/guest/csr-es-roadmap/use-maps). Use maps include the description 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 http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.

5.2.3.2 Information on exposure for substances > 10 t

If according to Article 14 (4) the registrant is required to perform an exposure assessment as defined in section 5 of Annex I, then all identified uses of the registrant should be assessed (see section 5.3 of this guidance). This can be reported either in a joint or 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).

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 of this guidance).

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. 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 *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) have to be provided in the technical dossier. For substances manufactured/imported below 10 tonnes per year, Annex III sets the criteria triggering information requirements set out in Annex VII.

Special considerations for 1-10 tonnes dossiers

For the lowest tonnage level (1-10 tonnes per year) the standard information requirements are defined in Annex VII and divided into two types:

1. Information on physicochemical properties required for all substances in this tonnage band (Annex VII, section 7);

2. Information on toxicological and ecotoxicological properties required for substances predicted to be hazardous (Annex VII, sections 8-9).

According to Article 12(1)(a), the information in section 8-9 of Annex VII is only required when existing information suggests that a substance meets the criteria of Annex III. Registrants can claim in their technical dossier (section 14 of IUCLID) that Annex III criteria are not fulfilled (and thus information according to section 8 and 9 of Annex VII is not required). For this purpose registrants should review and subsequently verify available information, including:

- data from submitted REACH registrations (i.e. ECHA's dissemination website: http://echa.europa.eu/en/information-on-chemicals) or C&L notifications (i.e. ECHA's C&L Inventory: http://echa.europa.eu/information-on-chemicals/cl-inventory-database) or any other relevant databases, for example 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 also chapter 5.2.3 of this guidance).

Information on how to fill in section 14 – Annex III criteria in IUCLID is given in the ECHA manual 'How to prepare registration and PPORD dossiers' accessible at:

http://echa.europa.eu/manuals. This document is also available via the help system built-in IUCLID.

The reader is also advised to consult Practical guide 3: 'How to report robust study summaries' if in need of more specific information on the level of detail to be reported for each individual endpoint. The document is available at http://echa.europa.eu/practical-guides.

For more information please visit the Annex III inventory the ECHA website (http://echa.europa.eu/information-on-chemicals/annex-iii-inventory).

5.2.5 Guidance on safe use

The registrant will have to report the following information (as required under section 5 of Annex VI):

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

Where a CSR is not required the following additional information is also 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 6.1.1 of this guidance).

The registrant is advised to follow in-house current practices or *Guidance on the compilation of safety data* sheets (http://echa.europa.eu/guidance-documents/guidance-on-reach) when filling this section of the technical dossier.

5.2.6 Review by an assessor

The registrant is required to indicate in the technical dossier which of the following information has been reviewed by an assessor. Assessor is a person chosen by the registrant with appropriate experience in:

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

Such special experience allows the assessor to make judgements and interpret the measured data related to the substance. Assessor may be a person representing a manufacturer or importer, a formulator, a sector specific organisation, or a single company. Please note that choosing an assessor is a voluntary option.

5.2.7 Confidential information

The registrant has the possibility in IUCLID to flag as confidential those sections, endpoint study records or any other information that can be claimed as confidential according to REACH

(Article 119). The list of information that can be claimed confidential is included in section 4.4 of this guidance.

In order for ECHA to assess the confidentiality claim the registrant needs to provide a justification in the corresponding field. It is strongly recommended to use the justification template (already included in the justification field) to ensure that the justification contains all the necessary information. Please note that confidentiality claims are subject to fee payment.

For technical instruction on how to make a confidentiality claim, please consult ECHA manual 'Dissemination and confidentiality requests under REACH Regulation' accessible at http://echa.europa.eu/manuals.

5.3 Chemical Safety Report

For substances manufactured or imported at 10 tonnes or more per year, the registrant needs to submit as part of his registration dossier a chemical safety report (CSR), as described in section 3.2.1.

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 reported in the technical dossier.

A summary of the CSR format (as defined in Annex I of REACH) is presented in **Table 5** below.

Table 5: 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.	Human health hazard assessment of physicochemical properties
7.	Environmental hazard assessment
8.	PBT and vPvB assessment
9.	Exposure assessment
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[24] 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:

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

The different steps of the CSA are explained below although the assessment should have been done earlier in the process, while preparing the technical dossier.

The reader should also consult the *Guidance on information requirements and chemical safety assessment* (http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment) if in need of further help and advice. Please refer specifically to Part D (Building the Chemical Safety Report Report).

Those readers without any previous knowledge on risk assessment might find it useful to refer first to the Guidance in a nutshell on chemical safety assessment (http://echa.europa.eu/guidance-documents/guidance-on-reach) to get familiarised with the concepts of the CSA.

Note that ECHA has developed an IT tool called Chesar to help registrants perform a CSA and generate a CSR. This is explained in further detail in section 5.3.2.

5.3.1 Steps of the chemical safety assessment

5.3.1.1 Hazard assessment

The assessment starts with the assessment of the physicochemical, human health 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).

As mentioned previously the hazard assessment should be performed on the basis of 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

[24] PBT: persistent, bioaccumulative and toxic; vPvB: very persistent and very bioaccumulative.

could also be used by the registrant as supporting information or as part of a weight of evidence approach as described previously in section 5.2.4 of this guidance.

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. It is derived from toxicity test results using appropriate assessment factors. While toxicity test results are reported in the technical dossier in the different endpoint study records, the DNEL values and the assessment factors used in their calculation should be reported in the endpoint summary records, as previously explained in section 5.2.4 of this guidance.

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

The reader is also advised to consult Practical Guide 14: 'How to prepare toxicological summaries in IUCLID and to derive DNELs' available at http://echa.europa.eu/practical-guides.

The classification and labelling of the substance should be performed on the basis of information available in the endpoint study records as detailed in section 5.2.2 of this guidance.

In conclusion, the main task of the registrant is to first document the human health assessment of the relevant endpoints in the endpoint summaries in IUCLID and then to use this information in section 5 of the CSR.

Please, note that for substances used in food contact materials within the scope of Regulation (EC) No 1935/2004 or in cosmetic products within the scope of Regulation (EC) 1223/2009, the human health risk assessment does not need to consider these uses, as they are already taken into account in the aforementioned regulations.

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 sub-chapter R.7.1 "Physicochemical properties" within "*Chapter R.7a: Endpoint specific guidance* of the *Guidance on information requirements and chemical safety assessment* (http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment).

The classification and labelling of the substance should be performed on the basis of information available in the endpoint study records as detailed in section 5.2.2 of this guidance.

A summary of the different effects and at least the explosivity, flammability and oxidising potential must be reported in section 6 of the CSR on the basis of the information available in the endpoint study records.

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,* (http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment).

The classification and labelling of the substance should be performed on the basis of information available in the endpoint study records as detailed in section 5.2.2 of this guidance.

A summary of the different effects on the environmental targeted compartments (aquatic, terrestrial, atmospheric and micro-organisms of the sewage treatments systems) must be reported in section 7 of the CSR on the basis of the information available in the technical dossier under the relevant IUCLID endpoint study record. The result of the assessment, once finalised, should also be reported under the relevant endpoint summaries in IUCLID as well as the calculated PNECs values. In addition to information on potential effects on the environment, the registrant has also to document the environmental fate (e.g. degradation, bioaccumulation) of the substance under section 4 of the CSR.

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* (http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment).

Relevant information regarding the persistent, bioaccumulative and toxic (PBT) properties of the substance should be already available in the CSR under respectively sections 4 for Persistence and Bioaccumulation and 5 and 7 for Toxicity. The registrant should then be consistent with what is written under these sections when performing the PBT/vPvB assessment. In addition further information, like monitoring data might also be useful. The conclusion of the PBT, vPvB assessment should be reported in section 8 of the CSR. If at the end of the assessment the substance is assessed to be PBT/vPvB, an emission characterisation must be performed and reported as well under section 8 of the CSR[25].

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.

[25] IUCLID has been adapted (from version 5.4 onwards) to include a section to report the outcome of the PBT assessment.

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

The exposure assessment consists of determining quantitatively or qualitatively the dose/concentrations of the substance to which humans and the environmental are or may be exposed. 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:

1) Generation of exposure scenario(s)
2) 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.

These exposure scenarios are the output of the iterative CSA. The exposure assessment has to be reported in section 9 of the CSR.

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

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 and the results and discussion reported in section 9 and 10 of the CSR. As the purpose is to prove that the risks are controlled it is expected that the results of the risk characterisation should not indicate a risk.

5.3.2 Chesar tool

Chesar stands for **Che**mical **s**afety **a**ssessment and **r**eporting tool. The tool has been developed by ECHA to help registrants perform a CSA, 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. It 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-union-system-evaluation-substances). Chesar also supports the assessments based on other exposure estimation tools or measured data.

Chesar enables re-use of whole assessments or parts of them already carried out by the registrant or prepared by industry associations via its data exchange functionality. In particular, use maps developed by downstream users associations can be imported in the form of a life cycle tree, with or without exposure assessment inputs (see Box 6 below). Such data exchange functionalities support efficient CSA processes and cross-industry harmonisation of the description of uses and of the safe conditions of use.

Please note that Chesar is not a mandatory tool to carry out the CSA and generate the CSR. More information on different tools used for exposure estimation can be found in *Guidance on information requirements and chemical safety assessment*, Part D, Chapters R.14, R.15 and R.16 (http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment).

5.3.2.1 Assessment workflow supported by Chesar

Chesar is divided in six major groups of functionalities listed below and called Boxes. All Boxes are connected and contribute to the generation of the CSR and/or the ES for attachment as an annex to the safety data sheet (SDS).

Box 1 – Substance management

When starting the assessment process for a certain substance with Chesar, the assessor will usually assume that the hazard assessment (see section 5.3.1.1 of this guidance) has been largely finalised. Thus, all the information related to the substance intrinsic properties should be available in the endpoint summaries in IUCLID. This information is imported from IUCLID into Chesar with the Box 1 functionalities. Based on this information the required scope of exposure assessment and the type of risk characterisations (qualitative or quantitative) is determined by the tool.

Box 2 - Report uses

Chesar provides a life cycle tree structure in which the assessor can report the relevant information with regard to the uses of the substance. This includes information relevant from both the human health and the environmental perspective, including a tonnage break-down into the different uses. Life cycles can be made available by sectors in the form of use maps for direct use by registrants. Also a registrant may re-use an existing life cycle for several substances. When the assessment has been finalised, the uses reported in Box 2 can be exported to IUCLID (see section 5.2.3).

Box 3 – Exposure assessment

In Box 3, the assessor carries out the exposure assessment and derives the corresponding risk characterisation. Depending on the substance properties and the uses, it may be sufficient to only apply the plugged in exposure estimation tools to demonstrate control of risk. However, the assessor may also face the situation that he needs to switch to another method (e.g. using other exposure estimation tools or measured data), or to even combine different methods in the exposure assessment. For situations where a qualitative risk characterisation is required the assessor needs to include in the contributing scenarios[26] appropriate conditions of use and make a qualitative statement on control of risk, justifying that those conditions of use (operational conditions and measures) lead to a sufficiently low level and/or likelihood of exposure. Functionalities exist to carry out qualitative risk characterisation for several uses or contributing activities in one go.

Box 4 – Generation of CSR

The generation of the full CSR is launched from Box 4, including those chapters of the CSR (chapter 1 to 8) that are directly populated with information from IUCLID.

Box 5 – Generation of exposure scenarios for communication

Box 5 supports the building of exposure scenarios for communication along the supply chain (i.e. to be annexed to the SDS). The exposure scenarios for communication are based on the exposure scenarios built in the CSR but normally expressed using standard phrases. Principles defined in the CSR/ES roadmap[27] are implemented (e.g. the generation of a table of content for the annex to the SDS composed of structured short titles for all the ESs).

Box 6 – Library management

Box 6 includes all functionalities with regard to the Chesar library of elements used for the chemical safety assessment and its reporting. The library enables creation, storage, import and export of objects that the assessor may need for his assessment. These are for example description of conditions of use or exposure assessment inputs that may be used for several CSAs. Exposure assessment inputs are usually defined by sector associations and describe the standard practice in the sector. They are called Specific Environmental Release Category (SPERCs) for the environment[28], Specific Consumer Exposure Determinants (SCEDs) for

[26] A contributing scenario (CS) is a set of OC/RMM reflecting safe conditions of use for the environment and for a given use for workers/consumers. An exposure scenario contains as default structure one contributing scenario for the environment and one contributing scenario for each contributing activity (for workers/consumers). For more information about the concept and use of CSs please refer to the *Guidance on information requirements and chemical safety assessment, Chapter R.12: Use description* (http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment).

[27] http://echa.europa.eu/regulations/reach/registration/information-requirements/chemical-safety-report/csr-es-roadmap

[28] See *Guidance on information requirements and Chemical Safety Assessment, Chapter R.16: Environmental exposure assessment*

consumers[29] and Specific Workers Exposure assessment Description (SWEDs) for workers[30].

Use maps developed by sectors will also be available in the library in a future version of Chesar. Finally, standard phrases (in particular ESCom phrase catalogue) can be imported in the Chesar library for use in the ES for communication.

Registrants are advised to consult the Chesar user manuals if in need of more detailed information on the use of the tool. They are available at http://chesar.echa.europa.eu/.

[29] See *Guidance on information requirements and Chemical Safety Assessment, Chapter R.15: Consumer exposure estimation*

[30] See *Guidance on information requirements and Chemical Safety Assessment, Chapter R.14: Occupational exposure estimation*

6 OTHER DUTIES OF REGISTRANTS

6.1 Registrants duty of communication

In order to prepare his registration dossier it is important that the registrant communicates with his downstream users. In particular he 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. Tentative Exposure Scenarios (ES) could be used for the communication with the downstream users in order to refine the ES.

6.1.1 Provide a safety data sheet (SDS) to customers

According to Article 31(1) when supplying a substance or a mixture, the **supplier** must provide an SDS formatted according to Annex II of REACH to all the downstream users and distributors he supplies to as of 1st June 2007, 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 of the REACH Regulation; or
- it is included in the **candidate list of substances**[31] which may be subjected to authorisation.

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:

- ≥1% (by weight) for non-gaseous mixtures (or ≥0.2% by volume for a gaseous mixture) of a substance posing human health or environmental hazards; or
- for non-gaseous mixtures, ≥0.1% (by weight) of a 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 has to be prepared for the substance itself. When supplying a substance in a mixture, the SDS has to be prepared for the mixture.

The SDS need not 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 safety data sheets*

[31] 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: http://echa.europa.eu/web/guest/candidate-list-table.

(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.

Please, note that **from 1 June 2015 both substances and mixtures must be classified, labelled and packaged according to CLP only[32]**. This classification must be provided in the SDS for substances and mixtures. There is no longer a requirement to provide either DSD[33] classifications of substances themselves or of component substances in mixtures or the DPD[34] classifications for mixtures in the SDS. Only the corresponding information according to CLP need be provided.

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

Legal reference: Article 31, Annex II

6.1.2 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 has to provide to all downstream users and distributors he supplies the following information:

- if the substance is subject to authorisation[35] and details of any authorisation granted or denied in this supply chain;
- the details of any restriction[36] imposed;

[32] In the situation where a mixture was already classified, labelled and packaged according the DPD rules and placed on the market before 1 June 2015, the manufacturer, importer, downstream user or distributor may postpone its re-labelling and re-packaging to comply with the CLP rules until 1 June 2017. This means that the mixture can be sold further in the supply chain with the DPD label until 1 June 2017 (see Article 61 (4) of CLP). The mixtures prepared before 1 June 2015 and stored in a formulator's warehouse after 1 June 2015 can also benefit from this arrangement provided they are already labelled and packaged according to the DPD rules.

[33] Dangerous Substances Directive (67/548/EEC)

[34] Dangerous Preparations Directive (1999/45/EC)

[35] 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)

[36] 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: http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/restriction

- 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

6.1.3 Include identified uses in the dossier

According to Article 37(2), a downstream user may intend to make his 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 needs to prepare a new or update the existing CSR to include relevant ES covering the communicated use. In this respect, the registrant has to comply within specified timelines, as indicated in Article 37(3).

For registered substances the registrant has to comply at least 1 month before the next supply, or within 1 month of the request, whichever is later.

For phase-in substance for which the last registration deadline still applies, the registrant has to comply, provided the request was made a minimum of 12 months before this deadline (i.e. before 1 June 2017).

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

Legal reference: Article 37

6.2 Classification and labelling notification

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

For registered substances the classification and labelling is reported in the registration dossier and no separate notification is required.

The obligation to classify and label a **substance** according to the CLP Regulation applies from 1 December 2010[37]. This means that in cases where a registration was submitted earlier than 1 December 2010, the registration dossier might still contain only the classification and labelling information according to DSD. In this case the registrant needs to update his

[37] For more information on CLP transitional provisions for classification, labelling and packaging please consult *Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008* (http://echa.europa.eu/web/guest/guidance-documents/guidance-on-clp).

registration dossier without undue delay. Further information on how to update a registration dossier is provided in section 7 of this guidance.

The classification and labelling notification can be prepared using any of the following tools:

- IUCLID: a classification and notification dossier can be created in IUCLID, in a similar way to a registration dossier. This is the only option if confidentiality of the IUPAC name of the substance is to be claimed.
- Online: the information can be entered manually in REACH-IT. This can be the preferred option if the notifier is not currently using IUCLID.

Submission of the classification and labelling notification must be done electronically via the REACH-IT portal on the ECHA website (https://reach-it.echa.europa.eu/).

ECHA has compiled all the information submitted on classification and labelling and established a C&L Inventory as required by the CLP Regulation. The Inventory is publicly accessible through the ECHA website (http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database) and allows free access to most of the information provided, in particular to the classification and labelling of the substance.

Access to part of the information is however restricted to notifiers and registrants who have submitted information on the same substance. If the classifications submitted for the same substance by different registrants or notifiers differ, the registrants and notifiers are required to make every effort to come to an agreed classification, and update their registrations/notifications as appropriate.

Additional information is provided in the *Introductory Guidance on the CLP Regulation* and the *Guidance on the application of the CLP criteria* (both available at: http://echa.europa.eu/web/guest/guidance-documents/guidance-on-clp).

For technical instruction please consult ECHA manual 'How to prepare a classification and labelling notification' available at http://echa.europa.eu/manuals. It is also advised to view the 'Notification to the C&L Inventory' section on the ECHA website (http://echa.europa.eu/regulations/clp/cl-inventory/notification-to-the-cl-inventory).

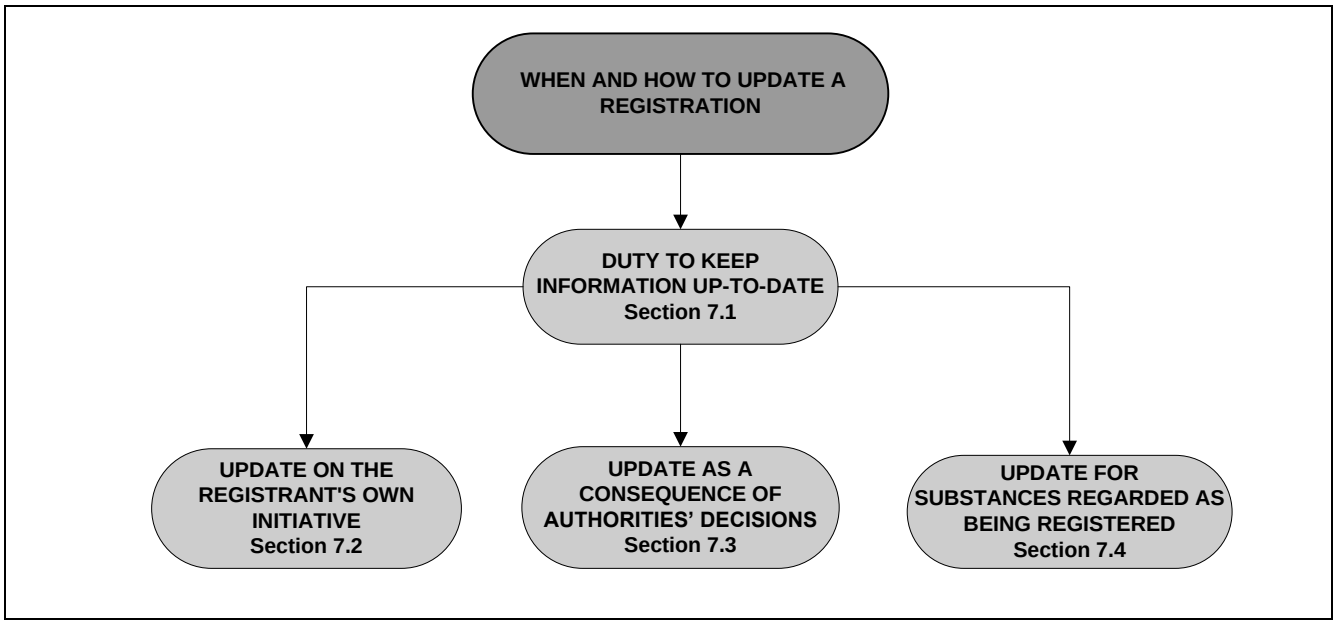
Legal reference: Article 40 and 41 of the CLP Regulation

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 his own initiative and when the authorities can request the registrant to update the registration dossier. It also describes what the updating duties for substances regarded as registered are.

If in need of updating his 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. This document is also available via the help system built into IUCLID.

Structure: The structure of this chapter is as follows:



7.1 Duty to keep information up to date

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

In order to update his registration information, the registrant will have to update his IUCLID dossier and submit it to ECHA through REACH-IT. Where the update relates exclusively to administrative data such as the identity of the registrant or the composition of the group of registrants in a joint submission, however, the updated information will be directly reported in REACH-IT. No update of the IUCLID dossier is required in this case.

There are basically two types of situations where a registrant needs to update the information concerning his registration:

1. *Update on the registrant's own initiative*

   Registrants are required to report to ECHA **without undue delay** any new relevant available information (e.g. new tonnage band, new uses) concerning their registration (*Article 22 (1)*).

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

   The registrant has to update his registration as a consequence of an ECHA or a Commission decision under the evaluation[38] procedure but also, when relevant, following any decision made in accordance with the authorisation and the restriction processes. These updates have to be performed **within the deadline** specified by ECHA/the Commission in the decision *(Article 22(2)).*

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 (*Article 135*). 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.

There is no requirement to update a registration dossier for substances in plant protection and biocidal products (*Article 16(2)*).

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

Note that 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 9.2).

Legal references: Article 22, Article 20 (2), Article 20 (6), Article 16 (2), Article 135

7.2 Required update on the registrant's own initiative

A registrant is responsible on his own initiative for updating his registration information without undue delay. The following cases are identified (*Article 22(1*)):

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

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

Further duties may arise in cases where a change in identity involves a change in the

[38] For more information please consult ECHA Evaluation webpages accessible directly via the following links: http://echa.europa.eu/web/guest/regulations/reach/evaluation and http://echa.europa.eu/web/guest/about-us/the-way-we-work/procedures-and-policies/public-procedures

legal personality of the company. This might be the case when a merger, takeover or split takes place or in case a company sells its assets related to a registration. It also applies to the appointment of a new only representative by a non-EU manufacturer as a replacement for a previous one.

As a general rule, a registration may be transferred from one legal entity to another legal entity following a change of legal personality. It is important to note that one registration cannot be owned by more than one legal entity.

In the case of a merger or takeover where the individual legal entities have previously registered the same substance, attention has to 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 has to be updated accordingly.

Detailed information on how to report changes in the identity of legal entities can be found in Practical guide 8: 'How to report changes in identity of legal entities' (http://echa.europa.eu/practical-guides). Additionally, any change in the role of the registrant regarding the registered substance (e.g. a manufacturer becoming an importer) will have to be reported to ECHA through an update of the registration dossier.

b) Any change in the composition of the substance

If the composition of the substance changes, e.g. due to a change of process, this should be reported to ECHA by resubmitting the updated registration dossier. It is important that the registrant evaluates whether the change in the composition of its substance has some influence on its intrinsic properties. Further guidance on when a change in, for example, the degree of purity would trigger an update is available in the *Guidance for identification and naming of substances under REACH and CLP* (http://echa.europa.eu/guidance-documents/guidance-on-reach).

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

After a registration dossier has been submitted, the tonnage should be always calculated based on the **annual** manufacture or import (i.e. the tonnes manufactured and/or imported in a calendar year). This rule applies to all substances.

As soon as the volume of a registered substance reaches a higher tonnage band, the information requirements of the registration dossier change, i.e. at 10, at 100 and at 1000 tonnes per year.

Before submitting an update of the registration dossier the registrant has to inform ECHA of the additional information that he would require to comply with the information requirements for the new tonnage level *(Article 12(2)).* This is achieved by submitting an inquiry dossier to ECHA (see section 4.4 of this guidance).

If a registrant has ceased the manufacture or import of the substance, or the production or import of an article, he needs to inform ECHA of this fact with the consequence that the registered volume in his registration, if appropriate, must be put to zero *(Article 50(2)).* He must keep the relevant information for 10 years after last manufacture or import and make it available on request *(Article 36(1))*. In the case where he restarts the manufacture or import of the substance or he restarts the production or import of the article he has to notify ECHA accordingly.

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

If a downstream user informs the registrant about a new use of the substance, not identified in the registration dossier, there might be two situations:

1. If the registrant has registered in a tonnage band starting at 10 tonnes per year and therefore is required to prepare a chemical safety report (CSR), he must assess the chemical safety for this use, and include that use in his CSR if the results of the chemical safety assessment (CSA) indicate that risks to human health and the environment from that use are controlled. He will then, where relevant, provide the downstream user with a revised safety data sheet (SDS), including the new use as well as the exposure scenarios (ES) describing the operational conditions for which the substance can be used safely. If on the basis of the CSA he is unable to include that new identified use for reasons of human health or environmental protection, he 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.
2. If the registrant has registered in a tonnage band of less than 10 tonnes per year, he has no obligation to perform a CSA. However he may decide to include or not the new use(s) in the SDS.

In both situations the registrant needs to update his registration to take into account the new identified use or the new use advised against.

Note that the registrant may decide not to assess a new use (e.g. because he considers the assessment of the use as not technically possible or disproportionately costly) in which case he 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 disproportionally costly should also take into account if the information provided by the DU is sufficient to prepare an exposure scenario. In that respect in some cases a more intense dialog between the registrant and concerned DU might become necessary.

It can also be the case that the registrant has to take into account a new own use or that he himself decides to identify a new use that his downstream user(s) are or may be interested in.

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 CSR

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 he manufactures or imports, such as monitoring data in the environment or epidemiological studies, he needs 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 chemical safety assessment or the safety data sheet 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 there will be an on-going 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.

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

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 also has an obligation to update his registration dossier in the light of any other new data relevant to the classification.

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

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

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

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

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 developed

In some cases, even if higher level studies are not required by REACH i.e. due to lower tonnage band, they still might be considered as necessary in the opinion of the registrant in order to control the risks arising from the manufacture and use(s) of the substance. In such a case when the registrant identifies the need to perform a higher-level study listed in *Annexes IX* or *X*, he will have to submit to ECHA an update of the registration dossier including the testing proposal for this test, documentation showing that all non-animal methods have been considered and justification for proceeding to an animal study.

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

Any change in confidentiality claims made either by the lead or the members of the joint submission will require an update of the registration dossier and a new submission to ECHA.

Please note:

The registrants should consider their registration dossiers as "living documents" and regularly 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, use, exposure information and justifications for adaptations to information requirements and for using alternative methods.

Better quality of information on substances helps ECHA and MSCAs 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 regularly performs 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: http://echa.europa.eu/support/how-to-improve-your-dossier/it-screening-campaigns-on-dossiers

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

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

a) Evaluation procedures

There are two types of evaluation procedures, a substance evaluation and a dossier evaluation. The latter 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 will be analysed separately below.

In the examination of testing proposals, all proposals for tests specified in *Annexes IX and X* submitted as part of registrations **have to** be examined by ECHA within certain timelines. The examination of a testing proposal by ECHA could trigger the need for the registrant to update his 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 have to 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 ES.

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

For details on compliance check please consult the ECHA Evaluation webpages accessible directly via the following links: http://echa.europa.eu/web/guest/regulations/reach/evaluation and http://echa.europa.eu/web/guest/about-us/the-way-we-work/procedures-and-policies/public-procedures).

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

Substance evaluation aims to clarify a concern that a given substance constitutes a risk to human health or the environment.

Substance evaluation provides a mechanism for authorities to require industry to obtain and submit additional information in case of suspicion of a risk to human health or the environment. When the Member State Competent Authority considers that additional information is necessary for clarifying the suspicion, it will prepare a draft decision stating the reasons for this request.

When a decision is taken by ECHA or the Commission under the substance evaluation process, the registrant has to provide the requested information by way of submitting an update of his registration dossier to ECHA by the deadline set. Please note that substance evaluation addresses all registrations of a substance (the lead registrant's dossier and the dossiers of the members). This means that that the updates of both the lead and/or member registration dossiers may be required depending on the scope of the information requested in the decision.

b) Authorisation/Restrictions

If the use of a substance is authorised through a Commission decision, the conditions for the authorisation should be reflected in the registration dossier. As a consequence, the registration dossier will have to be updated if it does not take into account these conditions already.

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

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

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

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

Tonnage update

Under the REACH Regulation, substances notified in accordance with Directive 67/548/EEC (NONS) are regarded as registered by the manufacturer or importer who submitted the notification. Nevertheless, the REACH registration dossier for those substances which are regarded as registered should be updated without undue delay when the manufactured/imported quantity reaches the next tonnage threshold i.e. 10, 100 or 1000 tonnes per year. Moreover, an update is required for notified substances notified in the tonnage range below one tonne under Directive 67/548/EEC, when reaching the one tonne threshold under REACH. The update should not only contain the information required by REACH which corresponds to that higher tonnage threshold, but also any information which corresponds to lower tonnage thresholds but which was not yet submitted.

However, in order to avoid unnecessary testing on vertebrate animals, the registrant first has to inform ECHA of the additional information that he would require to comply with the information requirements for the new tonnage level by submitting an inquiry dossier as soon as possible (see section 3.4) *(Article 12(2))*. After submitting an inquiry dossier, the registrant receives a communication from ECHA which includes the link to the relevant Co-Registrants page in REACH-IT. In this way ECHA informs the registrant of the names and addresses of the previous registrants. For substances registered less than 12 years previously ECHA will inform of the relevant summaries or robust study summaries already submitted by the registrants. For substances registered at least 12 years previously ECHA will attach to the communication any relevant study summaries already submitted by them in order to share existing data and to ensure that studies on vertebrate animals are not unnecessarily repeated. When making a tonnage update, registrants of notified substances will also have to comply with all other REACH requirements and provisions. For example, when submitting their update they will have to prepare a CSR and to prepare an ES to attach to their SDS when relevant.

Update to become part of a joint submission

Given that the joint submission obligation did not exist prior to REACH, notifications under Directive 67/548/EEC are regarded as registrations under REACH that are outside a joint submission, and therefore they are not linked to any existing joint submission. However, when the same substance needs to be registered by another actor, a joint submission needs to be established with the NONS notifier according to Article 11 or 19 of REACH, which apply to notified substances too.

In such cases, the previous notifier might decide to become the lead registrant of the joint

submission. This means that he will submit the joint information with the agreement of the other registrants. In this situation, similar to the case of tonnage band update, the dossier has to be fully in line with REACH requirements in the IUCLID format specified by ECHA.

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

Other updates

All the updates described under sections 7.2 and 7.3 above must also be submitted if and when relevant. This includes updates following a decision made according to Directive 67/548/EEC, which is now regarded as an ECHA decision under REACH *(Article 135*).

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

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

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

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

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

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

b) Substances in Biocidal products and in Plant Protection Products

For uses of substances regarded as registered under the Biocidal Product Regulation or Plant Protection Products Regulation (see sections 2.2.4.1 and 2.2.4.2) the updating requirements do not apply (*Article 16(2)*).

8 Appeal procedures

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

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

1) 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))*.
2) Completeness check - decision of ECHA to reject a registration if the registrant failed to complete his registration within the deadline set by ECHA (*Article 20(2)*) (see section 10.4 of this guidance).
3) Data-sharing
   a. decision of ECHA to give permission to a potential registrant of a non-phase-in substance to refer to the information submitted by a previous registrant in his registration dossier (*Article 27(6)*);
   b. decision of ECHA on data-sharing for phase-in substances (*Article 30 (3)*).
4) 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 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 him. For fees on the appeal, please consult 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 Chairman of the Board of Appeal, the Executive Director of ECHA considers the appeal to be admissible and well-founded he may rectify the decision within 30 days of the appeal being filed. Otherwise the Chairman of the Board of Appeal examines if the appeal is admissible within 30 days of the appeal being filed. If yes, 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

9 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 amount and deadlines for payment depend on the type of submission under consideration.

Legal reference: Article 74

9.1 Applicable fees and calculation of fees

A registrant is obliged to pay a fee for his registration as a contribution to covering the costs imposed on ECHA and the Member States Competent Authorities. In order for ECHA to be able to establish an invoice, the registrant is asked to submit his billing information on-line either before the first registration is made or during the first registration process.

The system to be applied for the computation of the applicable fee must be the following:

Once the registrant has submitted a registration dossier and it has been accepted for processing (see section 10.1), the REACH-IT system automatically computes the applicable fee for the dossier submitted.

When calculating the fee, the following points will be taken into consideration:

- the scale of fees fixed for the different tonnage bands;
- an SME (small and medium-sized enterprise) reduction if applicable, for this purpose the registrant will be asked to make a declaration of his status in REACH-IT;
- a reduction for joint submission, if applicable;
- the items flagged as confidential (see section 4.4 of this guidance on access to information and confidential data).

Where a registration is submitted by an only representative, the size of the 'non-EU manufacturer' is decisive for the fee and must be entered into the relevant field in REACH-IT, not the size of the only representative.

As soon as possible after the registration dossier has been accepted for processing, normally in the course of the next working day, ECHA will issue an invoice for the registration dossier(s) submitted. Upon receipt of the invoice, the registrant needs to carry out the payment as indicated in the invoice.

ECHA checks whether companies that claimed to be SMEs and thus paid reduced fees for their registrations are indeed SMEs. Where such a verification results in a finding that the registrant was not a SME and hence not entitled to the fee reduction, he will be liable to pay the difference between the reduced fee and the full registration fee as well as an administrative charge.

The criteria to be applied for the definition of an SME are established in Commission Recommendation 2003/361/EC. The reader is advised to consult the ECHA website (http://echa.europa.eu/web/guest/support/small-and-medium-sized-enterprises-smes) if in need of more specific information on the SME status.

9.2 Fee for updating of a registration dossier

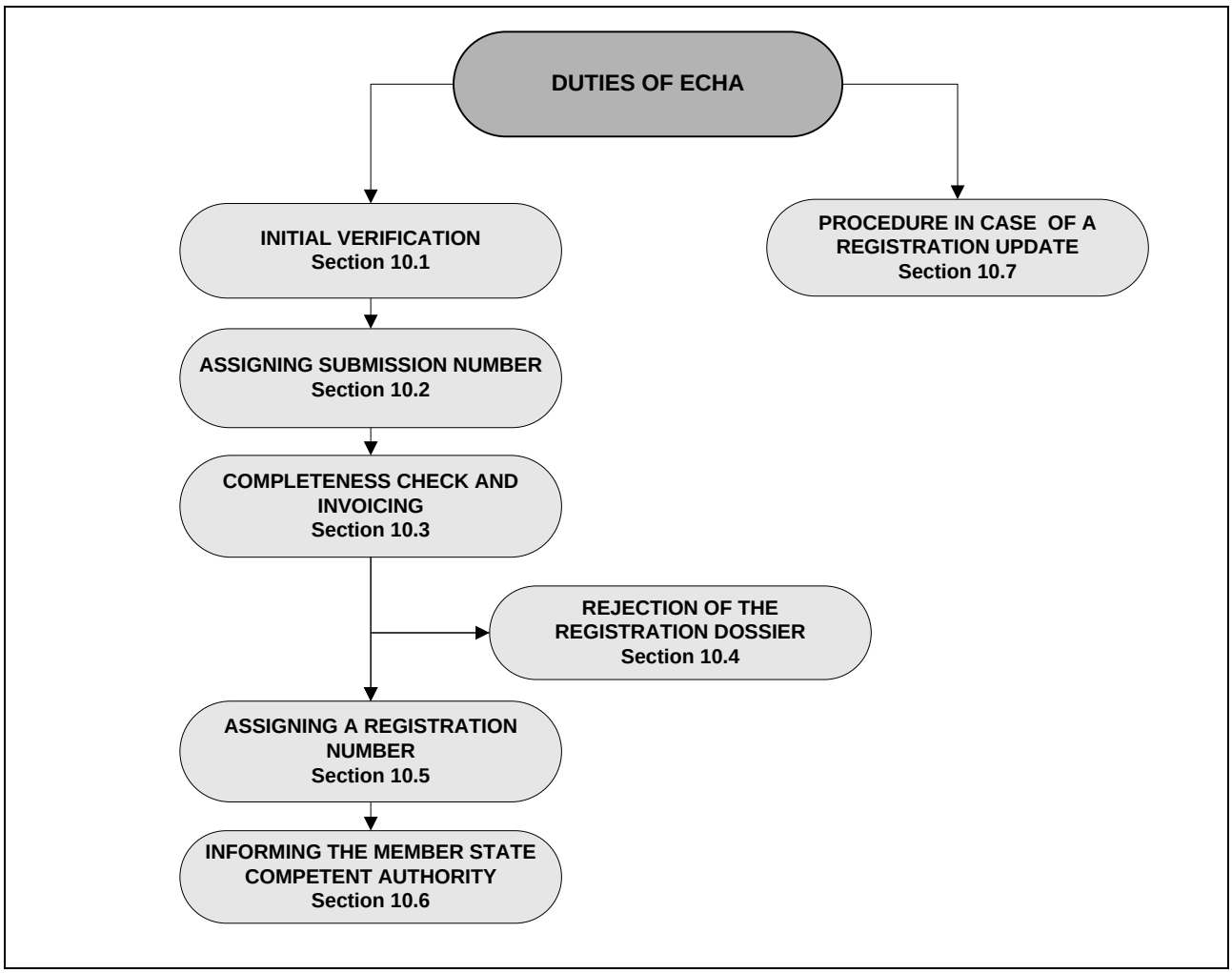
An update must be accompanied by the relevant part of the fee. As with a first time registration, the registrant has to submit the updated dossier through REACH-IT and the system will automatically compute the applicable fee for the update and send the relevant invoice to the registrant.

Note that in practice an update will only trigger a fee in case there is a change to a higher tonnage band or an increase in the number of items flagged as confidential.

10 Duties of ECHA

Aim: The aim of this chapter is to explain, for reasons of transparency, 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:



10.1 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.

10.1.1 Virus Scan

The submitted dossier is scanned for known viruses. Only virus-free dossier files will proceed to the next step.

10.1.2 File format validation

The file format validation checks that the submitted dossier file is of the appropriate format (.i6z file format) and is compliant with the XML schema used by IUCLID.

10.1.3 Internal structure validation

This verification ensures that the submitted dossier file does not contain attachments for which the format is not supported or recognised by REACH-IT.

10.1.4 Business rule validation

The business rules are a set of pre-requisites that must be fulfilled before ECHA can establish that the dossier can be accepted for processing. They are checked using the REACH-IT software.

A dossier can be accepted for processing only if all of the relevant business rules are satisfied. After that, the submission can proceed to the next steps (technical completeness check and invoicing). If the dossier submission fails at the business rule level, the dossier cannot be accepted for processing and **a new submission is required** before any regulatory processes can be initiated.

10.2 Assigning submission number

The REACH-IT system automatically assigns **a submission number and submission date** to any submission which is accepted for processing after successful business rule validation. The REACH-IT system without delay communicates this submission number and date to the concerned registrant. The submission number is to be used for all correspondence regarding the relevant dossier type (e.g. pre-registration, registration or PPORD notification). In the case of registration (including registration of on-site isolated intermediates and transported isolated intermediates) and PPORD notification the submission number is to be used until the registration/notification is deemed to be complete (Article 20 (1)). It will then be replaced by the registration/notification number.

10.3 Completeness check and invoicing procedures

The completeness check process comprises two distinct sub-processes:

- Technical completeness check
- Financial completeness check

The technical completeness check is performed for the following dossier types: registration (including intermediates), updated registration and PPORD notification. The financial completeness check is performed for those dossier types for which a fee is required.

10.3.1 Technical completeness check

This process is aimed at checking the technical completeness of the dossier. The main purpose of this check is to make sure that all information as required in REACH has been provided.

After being accepted for processing, each received dossier is screened for technical completeness using a specially created algorithm that is specific for each dossier type depending on the legal requirements. The system checks if all required fields are filled and all testing proposals, derogation statements, waving statements etc. are included. In the case of a negative result, ECHA will verify the outcome of the completeness check to make sure that the decision is fully correct.

Registrants are strongly encouraged to verify the technical completeness of their dossiers before submission with the help of the IUCLID application called "Validation Assistant plugin". This tool offers registrants the possibility to check the completeness of the dossier before submitting it to ECHA. It is recommended to run the plugin first on the substance dataset and then on the final dossier. Using the plugin in both steps is vital to avoid any unnecessary failures and potential rejection if the submission is for a requested update.

The latest version of the plugin can be downloaded from the IUCLID website

In addition to the algorithms included in the "Validation Assistant", ECHA will also stop and manually verify registration dossiers where manifestly irrelevant data is provided instead of the required information.

It is recommended to consult the ECHA manual 'How to prepare registration and PPORD dossiers' accessible at: http://echa.europa.eu/manuals. This document is also available via the help system built into IUCLID.

10.3.2 Financial completeness check

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 reasonable 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 submission of the dossier.

10.3.3 Completeness check procedures

ECHA will undertake the completeness check of a registration dossier within three weeks of the submission date, or within three months of the relevant deadline (see section 2.3.2) as regards registrations of pre-registered phase-in substances submitted in the course of the two-month period immediately preceding that deadline (Article 20(2)). The completeness check verifies whether all the required information elements have been submitted and the payment of the fee has been received.

If the registration dossier is incomplete and/or the fee payment is missing, ECHA will inform the registrant, before expiry of the given period, as to what further information is required in order for the registration to be complete. ECHA will set a reasonable deadline for providing the necessary information and /or payment (Article 20(2)).

If the registration dossier is incomplete, the registrant must complete his registration accordingly and submit it once more to ECHA, this time identified as an update, within the deadline set. ECHA will confirm the submission date of the further information to the registrant and will perform a second completeness check, considering all information submitted in the update. Registrants are strongly encouraged to verify the technical completeness of their dossiers before submission by using the Validation Assistant plugin.

A registrant may start or, in the case of a phase-in substance, continue without interruption the manufacture or import of a substance or production or import of an article, if there is no indication to the contrary from ECHA within three weeks of the submission date or, in the case of registrations of phase-in substances submitted within the two-month period before the relevant deadline, if there is no indication to the contrary from ECHA within the three months of that deadline (Article 21(1)).

10.4 Rejection of the registration dossier

In case the registrant fails to complete his registration within the deadline set, ECHA will reject his registration. This decision can be challenged through the appeal procedure. Where a registration is rejected, the registration fee will not be reimbursed (Article 20(2)).

If a manufacturer or importer submits a registration dossier for a pre-registered phase-in substance, which is rejected before the expiry of the appropriate registration deadline, it may submit a new registration dossier and pay a new fee using the same pre-registration number.

If a registration dossier for a pre-registered phase-in substance is submitted within the two-month period before the expiry of the relevant registration deadline, manufacturing or importing can continue beyond this deadline if there is no indication to the contrary from ECHA within three months of the deadline.

If the registration of a pre-registered phase-in substance is rejected after the expiry of the relevant registration deadline, or if no registration dossier is submitted by the relevant registration deadline, the manufacturer or importer will not be allowed to manufacture or import this substance in the EU. In order to be allowed to manufacture or import the substance again, the manufacturer or importer will need to submit a new registration dossier and pay the fee required. Then he may start importing or manufacturing once ECHA has confirmed the completeness of the registration, or three weeks after the submission date, if there is no indication to the contrary from ECHA.

Similarly, if the registration dossier for a non-phase-in substance or for a phase-in substance which is not pre-registered is rejected, the company will need to submit a new registration dossier and pay the required fee in order to be allowed to manufacture or import the substance. The import or manufacture can be commenced once ECHA has confirmed that the registration is complete, or three weeks after the submission of the dossier, if there is no indication to the contrary from ECHA.

10.5 Assigning a registration number

Once the registration is complete the REACH-IT system at ECHA automatically assigns a registration number to the registrant for the substance concerned and a registration date that will be the same as the submission date. ECHA without delay communicates the registration number and date to the concerned registrant. From that moment on the registrant must use the registration number for the subsequent correspondence regarding registration procedures (Articles 20 (3)).

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 later lead to the submission of a registration dossier. In those cases, the substance will hold an identification number of each kind, a PPORD number and a registration number in the first above example, and a classification and labelling number and a registration number in the second above example. All those numbers are called ‘reference numbers’. The reference number is unique for every dossier type, substance and company and is issued only once at the end of the initial and successful submission process.

10.6 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.

10.7 ECHA procedure in case of a registration update

New relevant information prepared either on the registrant's own initiative or in response to a request by the authorities has to be communicated to ECHA without undue delay. If the changes trigger an update of the registration dossier, the updated dossier will undergo upon submission a similar process to the initial dossier:

- initial verification,
- assignment of a submission number and
- completeness check.

Manufacture or import may continue if there is no indication to the contrary from ECHA within three weeks after the updated registration dossier has been accepted for processing (Article 21(1)).

ECHA will inform the relevant Member State Competent Authority accordingly (Articles 22(1), 22(2)).

Appendix 1. Glossary/List of acronyms

C&L	Classification and labelling
CBI	Confidential Business Information
Cefic	*'Conseil Européen des Fédérations de l'Industrie Chimique'* - European Chemical Industry Council
Chesar	Chemical Safety Assessment and Reporting tool
CMR	a substance or mixture that is carcinogenic, mutagenic or toxic to reproduction
CSA	Chemical safety assessment
CSR	Chemical safety report
CWG	Commission Working Group
DNEL	Derived No-Effect Level
DSD	Dangerous Substances Directive (67/548/EEC)
DPD	Dangerous Preparations Directive (1999/45/EC)
DU	Downstream user
ECHA	European Chemicals Agency
EEA	European Economic Area
EFTA	European Free Trade Association
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances

ES	Exposure scenario
EU	European Union
GHS	Globally Harmonised System for Classification and Labelling
GLP	Good Laboratory Practice
IPCS	International Programme on Chemical Safety
IUCLID	International Uniform Chemical Information Database
IUPAC	International Union of Pure and Applied Chemistry
NGO	Non-Governmental Organisation
NLP	No-Longer Polymer
OC	Operational conditions
OECD HPV	Organisation for Economic Co-operation and Development, High Production Volume (chemicals)
PBT	Persistent, Bioaccumulative, Toxic substances
PNECs	Predicted No-Effect Concentrations
PPORD	Product and Process Orientated Research and Development
QSARs	Quantitative structure-activity relationships
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RIPs	REACH Implementation Projects
RMM	Risk Management Measures

Robust study summary	a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report
SCED	Specific Consumer Exposure Determinants
SDS	safety data sheet
SIEF	Substance Information Exchange Forum
SIP	Substance identity profile
SME	Small and Medium Sized Enterprise
SPERC	Specific Environmental Release Category
Study summary	a summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study
SWED	Specific Workers Exposure assessment Description
SVHC	Substances of Very High Concern
UVCB substance	substances of Unknown or Variable Composition, Complex reaction products or Biological materials
vPvB	vPvB - very Persistent and very Bioaccumulative substances

Appendix 2. Roles and duties of the main actors of REACH

This appendix provides an overview of the main responsibilities defined by REACH or derived from REACH in the context of the registration, evaluation, authorisation and restriction processes. Please note that it is not an exhaustive list and should only be used for reference purposes. The reader is advised to consult the related guidance document if in need of detailed information on a specific process.

I. Industry

(1) Manufacturers and importers of substances in quantities of less than 1 tonne per year need to:

- Prepare and supply safety data sheets (SDS) for substances and mixtures (as required by Article 31 and Annex II) to downstream users and distributors;
- Prepare and supply information on substances that do not require an SDS (as defined by Article 32) to direct customers;
- 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;
- In the case of having relevant data, decide whether to act as data holder in Substance Information Exchange Fora (SIEF).

(2) Manufacturers of substances in quantities of 1 tonne or more per year need to:

- Pre-register their substances with ECHA if they wish to secure their substances' phase-in status;
- In case their substance is a non-phase-in substance, 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 (note that special provisions apply for intermediates);
- Prepare CSA and CSR (for each substance ≥ 10 tonnes per year per manufacturer);
- 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 Risk Management Measures (RMM) for own manufacture and use;
- Submit registration for substances (≥ 1 tonne per year per manufacturer) 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 (SDSs) 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 the SDS (≥ 10 tonnes per year per manufacturer);

- 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.

(3) Importers of substances and mixtures in quantities of 1 tonne or more per year:

- Pre-register their substances with ECHA if they wish to secure their substances' phase-in status;
- In case their substance is a non-phase-in substance, send 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 (note that 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) 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 pre-registration and inquiry obligations 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 ES, implement RMMs as set out in ES, or
  - if the use is not covered by the ES, inform supplier of the use (i.e. make use known with the aim to make it an identified use) and await new SDS with updated ES(s) 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.

(5) 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 pre-registration and inquiry obligations 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.

(6) Downstream Users (DU):

- Check if the substance is placed on the list of pre-registered substances published by ECHA. If not, and considered relevant, ask ECHA to add the substance to the list;
- In the case of having relevant data, decide whether to act as data holder in Substance Information Exchange Fora (SIEF);
- Implement RMMs as set out in the SDS;
- When receiving SDSs with ESs annexed:
  - if DU use is covered by the ES, implement RMMs as set out in ES annexes to SDS; or
  - if DU use is not covered by the ES, inform supplier of the use (i.e. make use known with the aim to make it an identified use) and await new SDS with updated ES(s) or conduct own chemical safety assessment and (if ≥ 1 tonne per year) notify ECHA.

- Prepare and supply SDS(s) and recommend appropriate RMMs in them and annex ES(s) 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, 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;
- Pre-registration:
  - receive information and grant access to all manufacturers and importers who have submitted information on one substance. When foreseen decide about conflicting issues,

  - publish a list of pre-registered substance on ECHA website. Update the list on the request of downstream users.
- Operate the rules on data-sharing for non-phase-in substances;
- 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;
- Secretariat for the Forum and Committees;
- Take decisions on access to submitted data;
- Publish certain specified data on a publicly accessible database;
- Help to share the available data on animal testing, if the registrants cannot agree;
- 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,
  - provide comments on draft opinions from ECHA's Committee for Risk Assessment and Committee for Socio-Economic Analysis.

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