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This document contains guidance on REACH explaining the REACH obligations and how to fulfil them. However, users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

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# Preface

This document describes when and how to register a substance under REACH. It consists of two parts: one on registration tasks and obligations and the other on the preparation and submission of a dossier. 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. These guidance documents can be obtained via the website of the European Chemicals Agency (ECHA) (http://echa.europa.eu/). Further guidance documents will be published on this website when they are finalised or updated.

This document relates to the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006[1] and its amendments as of 31 August 2011.

1 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).

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# Part I: Registration under REACH

# 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?
- How to prepare the registration dossier and submit it to ECHA?
- 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 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. All references to the relevant *Articles* or *Annexes* or legal text quotations from the REACH Regulation are always indicated in italics (e.g. *Article 23*).

Whenever the EU is referred to in the text of this guidance, Iceland, Liechtenstein and Norway are also covered.

The first part of 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.

The second part of the document provides an overview on how to prepare, update and submit a registration dossier.

Figure 11 guides the reader through this document helping him to identify his registration obligations.

A tool, called the Navigator is also available 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.

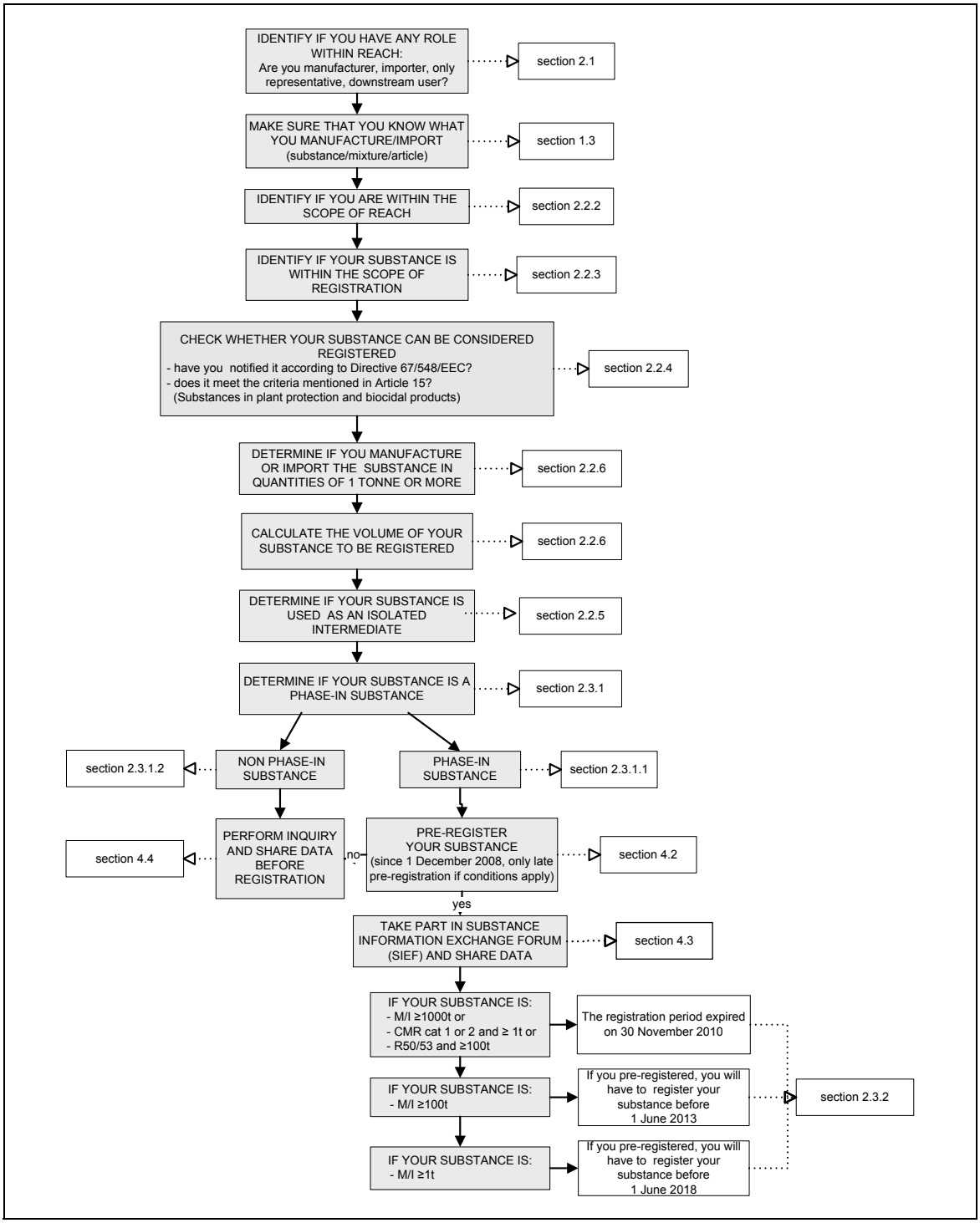



Figure 1 Steps within the registration process and link to the structure of this document

## 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) and submit it to ECHA via REACH IT (see section 5).

When a substance is intended to be or is actually being manufactured or imported by more than one manufacturer or importer, certain data must be shared (see section 4) and submitted jointly (see section 3.3.1) with the purpose of increasing the efficiency of the registration system, saving costs and reducing testing on vertebrate animals. A registrant may opt-out from some information requirements and submit the information separately to ECHA in certain specified cases (see section 3.3.2).

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. This allows their manufacture or import to continue without registration until the corresponding deadlines are met (see section 2.3). If a manufacturer or importer does not register by the appropriate 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 substance identification.

**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 for articles.

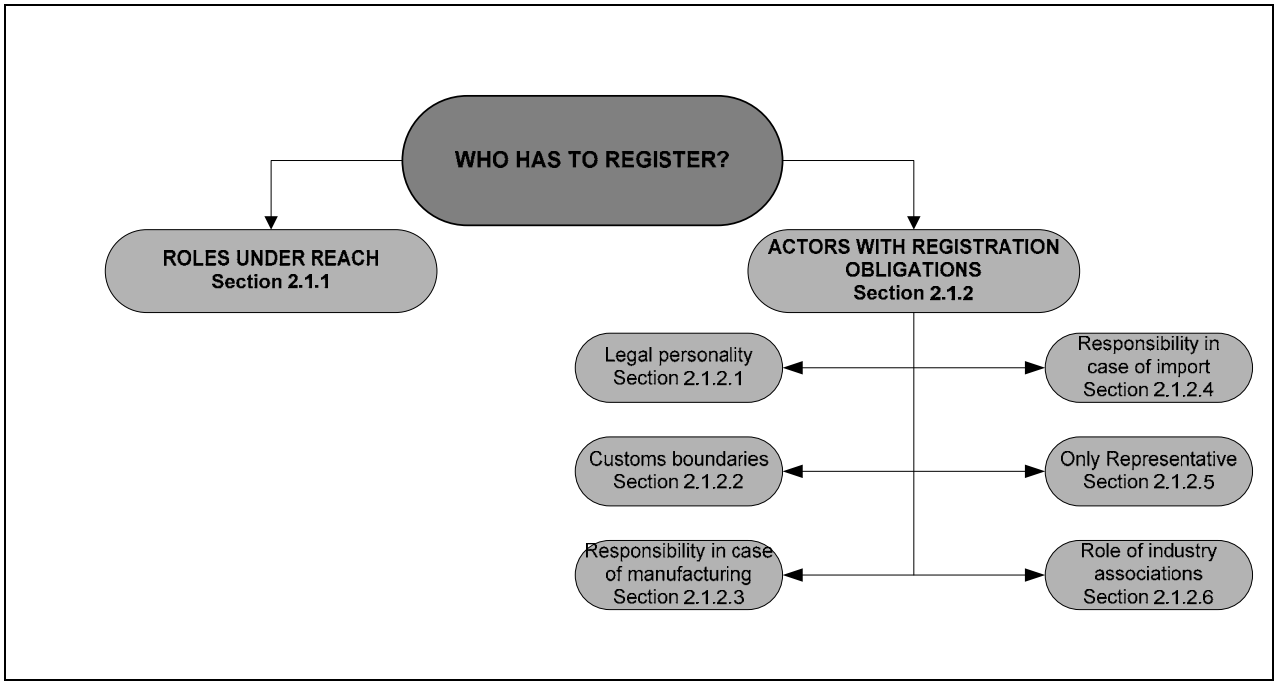
**The registration obligations apply therefore to the individual substances themselves, independently of whether they are on their own, in a mixture or in an article. In other words, only substances have to be registered under REACH, mixtures or articles do not.**

# 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[2] 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 preparation, for third parties (Article 3(14))*.

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.

### 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.

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

- 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.
- 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 daughters in the EU acting as importers, often spread over several Member States. Each of those daughters, if it has legal personality, is a legal person within the meaning of REACH. Depending on the distribution of work within the group, each of them can be an 'importer' responsible for import. It is for the group or the individual companies to assign the tasks and the responsibilities to companies in the group.

#### 2.1.2.2 Customs boundaries for manufacturing and import

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

Therefore, an importer of a substance from Iceland, Liechtenstein or Norway is not required to register the substance under REACH and is simply regarded as a distributor or downstream user. However if the manufacturer of the substance is established in Iceland, Liechtenstein or Norway, 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.

Please note that whenever the term EU is used in this guidance document, Iceland, Liechtenstein and Norway are also included.

#### 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.

<u>Who is the registrant in case of toll manufacturing?</u>

A toll manufacturer (or subcontractor) is normally understood to be a company that

manufactures a substance (on its own, in a preparation or in an article) 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 construction is used for an intermediate step in the production process for which sophisticated equipment is needed (distillitation, centrifugation, etc.).

In this regard, the legal entity that manufactures the substance 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 running the manufacturing process is different from the legal entity owning the production facility, one of these entities must register the substance.

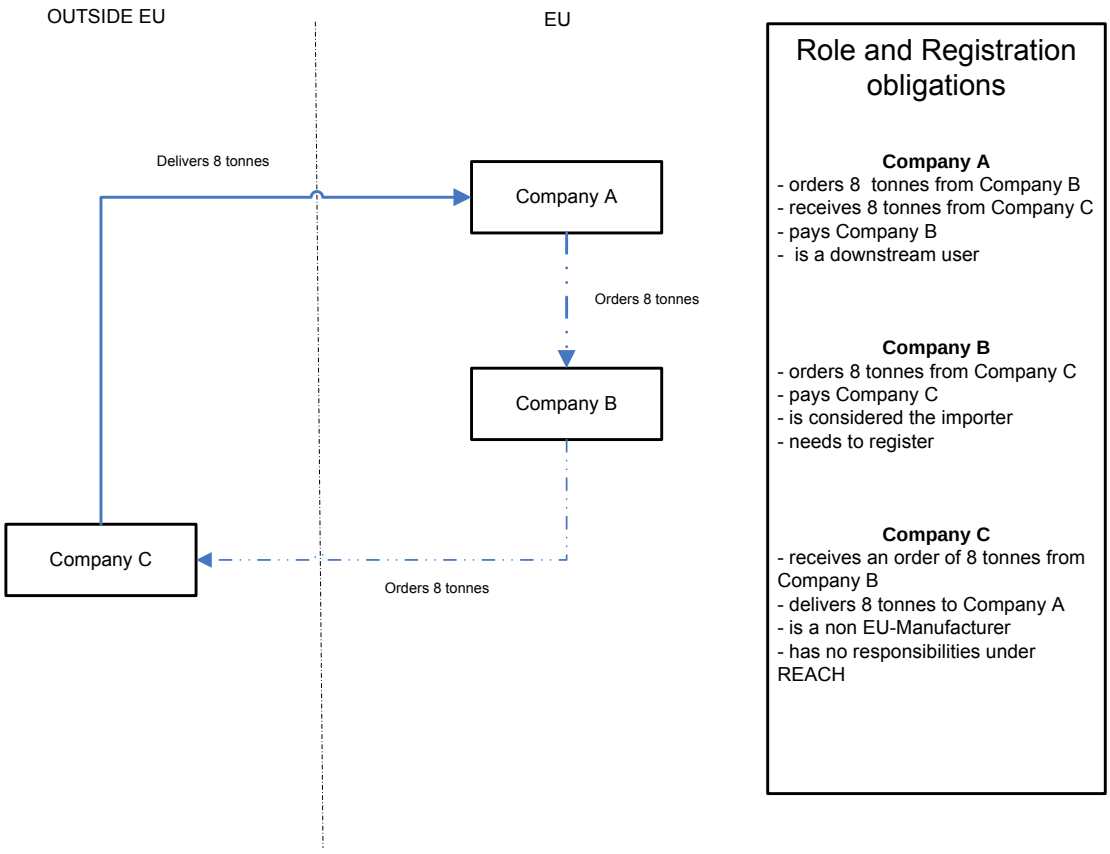
#### 2.1.2.4 Who is responsible for the registration in case of import?

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, 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 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 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.

**Example: 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 Community Customs Code (Regulation (EEC) No 2913/92) or the 'INCOTERMS'.

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'[3] 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).

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 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

[3] 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.

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 (see the Guidance on downstream users for further information). 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.

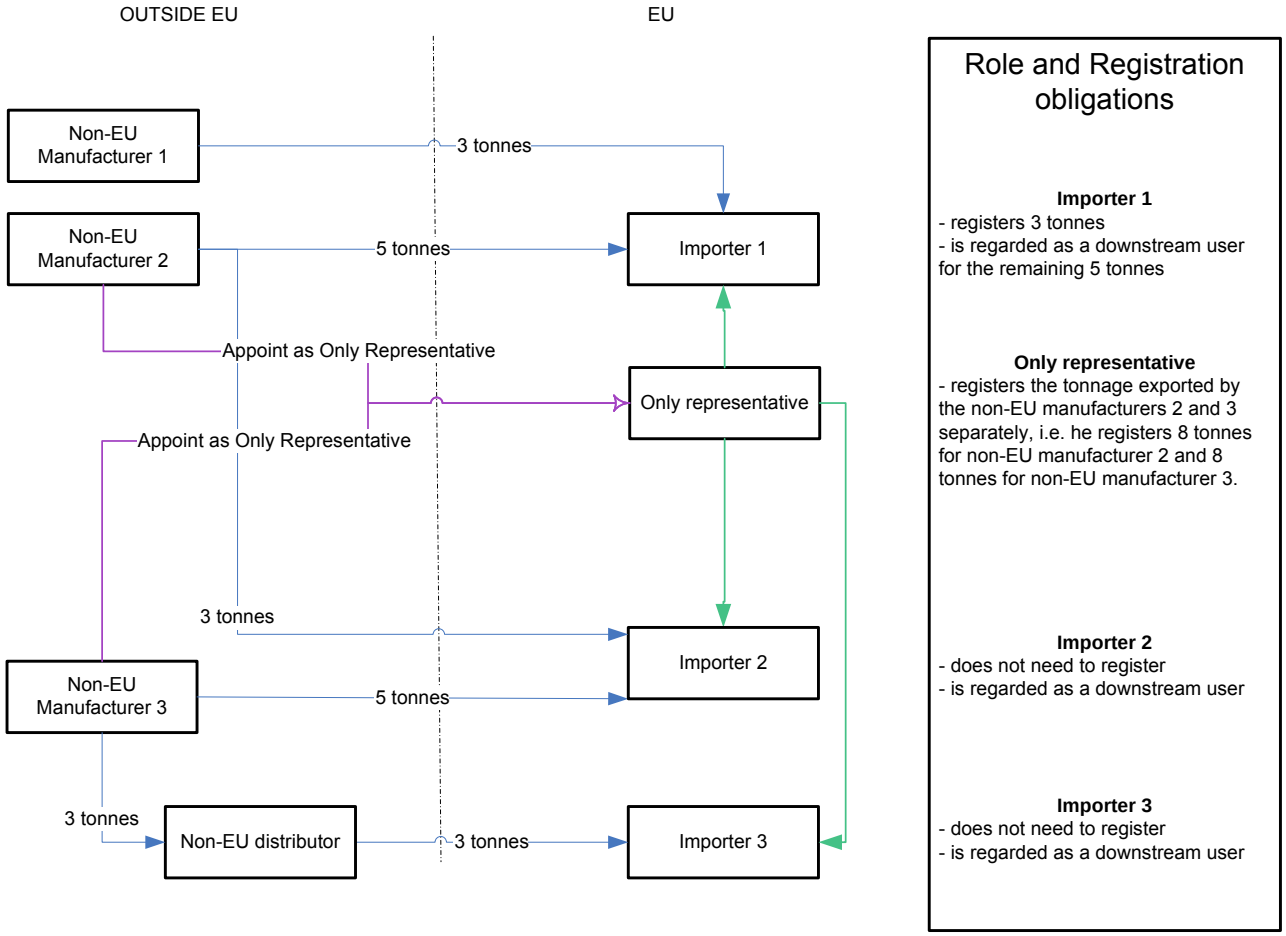
The registration dossier of the only representative should comprise all uses of the importers (now downstream users) covered by the registration. The only representative shall keep an up-to-date list of EU customers (importers) within the same supply chain of the 'non-EU manufacturer' and the tonnage 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.a of the present 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 shall be determined according to this tonnage. By making separate submissions, the confidential business information 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'.

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.

**Example: Role 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 susbtances. 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

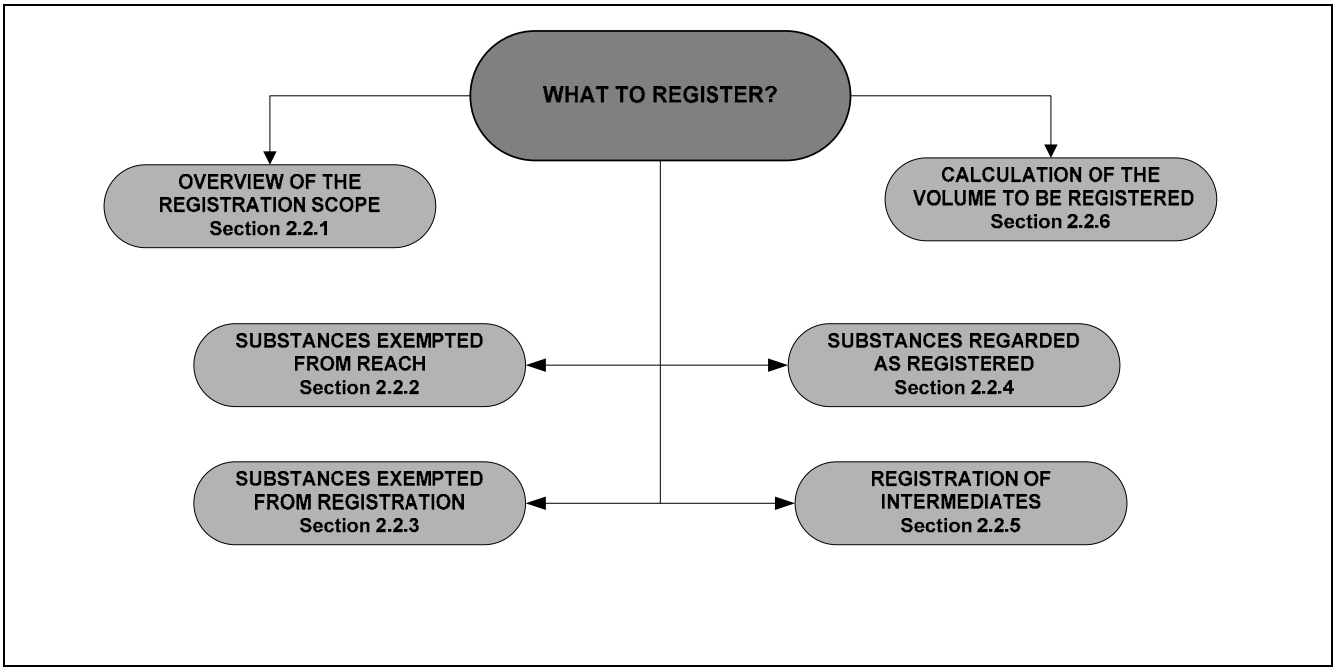
The actual registration of a substance can only be done by the manufacturer, importer or producer of an article or only representative and cannot be done by any third party including industry associations, unless they act as the only representative for one or more non-EU companies.

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 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 3.2.1).

When the registrant manufactures or imports the substance in the nanoform as well as in the bulk form, the registration dossier should include the information of the substance in both the

bulk form and the nanoform.

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 for articles 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[4] 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 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 (EEC) No 2913/92 on the Community Customs Code 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

[4] 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)

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. 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[5] 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 professionals or from industry (e.g. tyres, slag, window frames that are discarded).

The requirements of the REACH Regulation for substances, mixtures and articles do not apply to waste; 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 3.2.1) 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.

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 0.

*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*

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

*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.

*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) 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 inappropiate or unnecessary (such as substances occuring 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 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 Council Directive 82/471/EEC.

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 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 Directive 67/548/EEC 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 C6 to C24 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 shall 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 on substance identification). 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 on substance identification). 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.

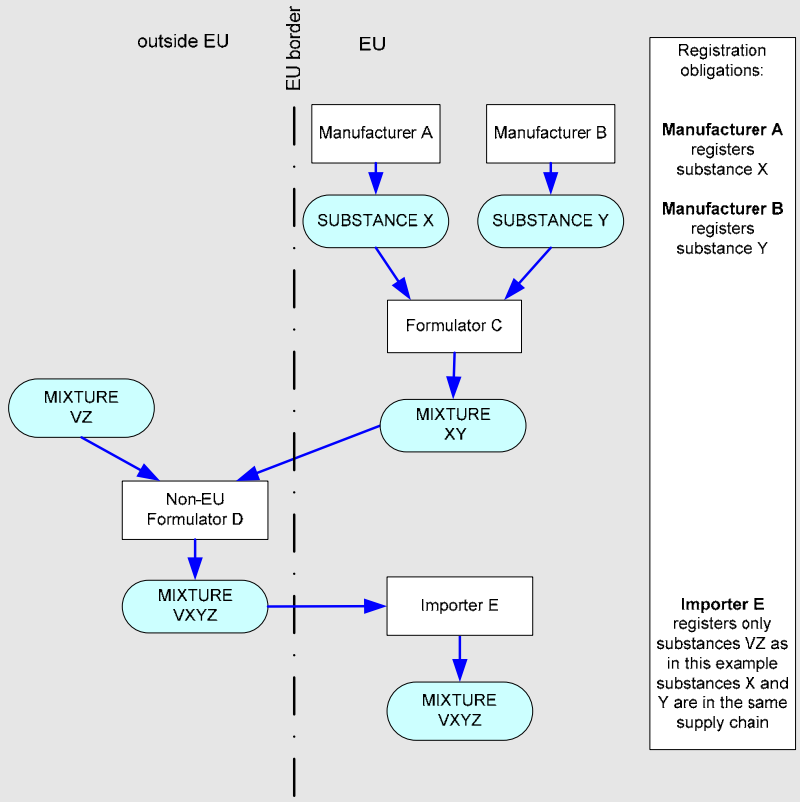
Again, the reason is clear; if the substance is not the same, it has not yet been registered (the registration information will be different), and therefore there will not be duplication of registrations.

(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.

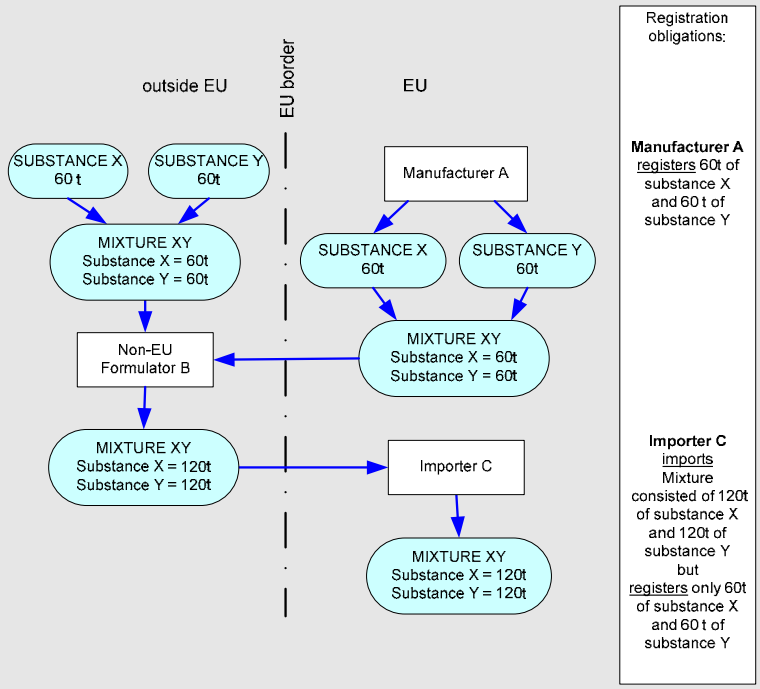
(4) The re-importer must have been provided with information on the exported substance, and that information must comply with the requirements established under REACH for the provision of information down the supply chain. The required information is described in detail in section 6.1.1 and 6.1.2 of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

*Legal reference: Article 2 (7) (c)*

**Example (1)**


outside EU
EU border
EU
Manufacturer A
Manufacturer B
SUBSTANCE X
SUBSTANCE Y
Formulator C
MIXTURE VZ
MIXTURE XY
Non-EU Formulator D
MIXTURE VXYZ
Importer E
MIXTURE VXYZ
Registration obligations:
Manufacturer A registers substance X
Manufacturer B registers substance Y
Importer E registers only substances VZ as in this example substances X and Y are in the same supply chain

**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:

- the monomer substance(s) or other substance(s) have not been already registered by their supplier or another actor up their supply chain;
- 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);
- 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 polymers).

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.

More detailed information can be found in the Guidance for 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

Since one of the main objectives of REACH is to enhance innovation, the REACH Regulation promotes research and development, *inter alia*, through a number of exemptions from the registration obligations.

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 used for PPORD in quantities of one tonne or more per year will receive an exemption from registration for five years if they are notified to ECHA. The notifier must pay a fee to ECHA when submitting his 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 being used for PPORD by a manufacturer, importer or producer of articles, himself or in cooperation with a limited number of customers. The notifier must identify these customers in his notification dossier including their names and addresses. These identified customers are referred under REACH as listed customers.

ECHA may extend the exemption period for up to a further five years (or ten years in the case of medicinal products or substances not placed on the market) upon request, as long as this

can be justified by the programme of research and development presented by the notifier.

ECHA will check the completeness of the information supplied by the notifier in the PPORD notification dossier.

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 any detailed or specific issues on research and development see the Guidance on PPORD.

*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.

Similarly, a notification in accordance with Directive 67/548/EEC (NONS) is regarded as a registration.

#### 2.2.4.1 Substances for use in biocidal products

Active substances manufactured or imported for use in biocidal products are regarded as registered if the following conditions are fulfilled:

(1) The substance is an active substance for use in a biocidal product.

An active substance in the context of biocides is a substance or micro-organism[6] including a virus or a fungus having general or specific 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.

(2) The substance is included in one of the following:

- Annex I to Directive 98/8/EC – this is the list of active substances which may be used in biocidal products; it is regularly updated and manufacturers and importers are advised to check the latest version.
- Annex IA to Directive 98/8/EC – this is the list of active substances which may be used in low-risk biocidal products; it is regularly updated and manufacturers and importers are advised to check the latest version.
- Annex IB to Directive 98/8/EC – this is the list of basic substances which may be used as or in biocidal products; it is regularly updated and manufacturers and importers are advised to check the latest version. Basic substances are substances which only have a minor use as a biocide and which are not directly marketed for that biocidal use.

[6] 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.

- Regulation (EC) No 2032/2003 – this regulation lists active substances which were already on the market on 14 May 2000 and for which information was submitted with a view to including them in the Commission's review programme of active substances for use in biocidal products. However, once a decision is taken for an active substance on a list of Regulation (EC) No 2032/2003 not to include it into Annex I, IA or IB, the active substance loses the exemption and must be registered. Decisions not to include active substances, which are on the lists of Regulation (EC) 2032/2003, into Annex I, IA or IB of Directive 98/8/EC will be published in the Official Journal of the European Union and may take the form of a Commission Decision or a Commission Regulation.

If a substance complies with conditions (1) and (2) above and is used in biocidal products it is regarded as being registered under REACH. Note that **only active substances can be regarded as registered** and that other substances used for producing the biocidal product are subject to registration.

It is important to remark that if the substance is used in non-biocidals products it will have to be registered even if it complies with conditions (1) and (2) 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.

If a substance does not comply with conditions (1) and (2) above, it will have to be registered under REACH even if used in a biocidal product. Once a decision not to include the substance in Annex I, IA or IB of the Biocidal Product Directive (Directive 98/8/EC) as an active substance has been issued, 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: Article 15 (2), Article 16*

### 2.2.4.2 Substances for use in plant protection products

Active substances and co-formulants manufactured or imported for use in plant protection products (pesticides) are regarded as registered if the following conditions are fulfilled:

(1) The substance is either an active substance or a co-formulant for use in a plant protection product.

An active substance in the context of plant protection products is a substance or micro-organism[7], including a virus, having general or specific action against harmful organisms or on plants, parts of plants or plant products. A plant protection product may be composed of only one active substance, with or without co-formulants, or it may contain several active substances.

[7] 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.

A co-formulant in the context of plant protection products is a non-active substance in a plant protection product which is a mixture.

(2) The substance is included in one of the following:

- Annex I to Directive 91/414 – this is the list of active substances which may be used in plant protection products; it is regularly updated and manufacturers and importers are advised to check the latest version.
- Regulation (EEC) No 3600/92 – this regulation lists 90 active substances which were already on the market on 26 July 1993 and which were the first ones to be identified for assessment with a view to being authorised and included into Annex I to Directive 91/414/EEC.
- Regulation (EC) No 703/2001 – this regulation lists a further 63 active substances which were already on the market on 26 July 1993 and for which their producers wished to secure inclusion into Annex I of Directive 91/414/EEC and which were thus identified for assessment.
- Regulation (EC) No 1490/2002 - this regulation lists a further 161 active substances which were already on the market on 26 July 1993 and for which their producers wished to secure inclusion into Annex I of Directive 91/414/EEC and which were thus identified for assessment.
- Decision 2003/565/EC – this decision lists further active substances already on the market on 26 July 1993 for which the assessment period was extended.
- a Commission decision on the completeness of the dossier submitted pursuant to Article 6 (3) of Directive 91/414/EEC – such decisions are taken in respect of active substances which were not yet on the market on 26 July 1993 but for which an application for inclusion into Annex I of Directive 91/414/EEC was submitted and deemed admissible. They concern the admissibility of applications filed by individual legal entities and are therefore not published in the Official Journal, but notified to the legal entities concerned. Accordingly, relevant operators will be aware of decisions of interest to them.

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 included in one of the above-mentioned categories.

It is important to remark that since condition (2) above can only be met by active substances, in practice **only active substances can be regarded as registered**. Other substances (including co-formulants) used for producing the plant protection product need to be registered.

Registration is not necessary even after a decision not to include the active substance in Annex I to Directive 91/414.

**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 included in one of the acts mentioned under (2) above, 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.

*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. Detailed instructions on how to request a registration number for a notified substance is available on the ECHA website at http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/nons. 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 document.

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 polymers 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 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 3.1.

The volume of the substance also plays a critical role in determining when the registration dossier for a substance is due. 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 will also define the registration deadline (see section 2.3.2 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, will 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 agregated.

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). Additional information on the requirements for the registration of substances in articles is available in the Guidance for articles.

### 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 for articles.

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

For the registration, the registrant must report the volume in tonnes 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 the 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. In case manufacturing starts only later in a particular calendar year, registration dossiers could 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 pe 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 shall be calculated 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.

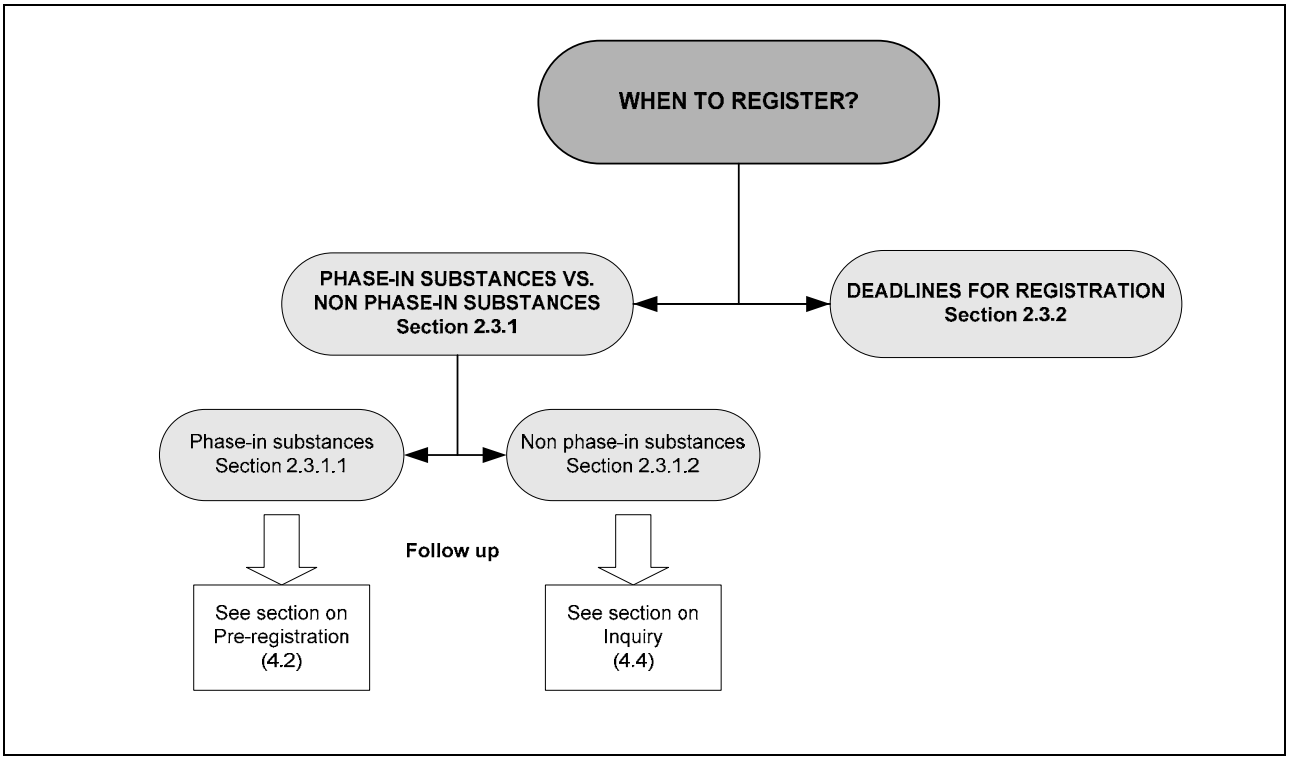
Note that in the case of pre-registered phase-in substances the tonnes per year determine the deadline for registration. Detailed examples on how to determine the tonnes per year and the registration deadline for phase-in substances are provided in section 2.3.2.

*Legal Reference: Article 3 (30)*

## 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 substance 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 4.2.

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 accessible at http://esis.jrc.ec.europa.eu/. 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://esis.jrc.ec.europa.eu/. 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 4.4.

### 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 starting 12 months after entry into force of the legislation, i.e. by 1 June 2008.

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 the following Table (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[8] 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. |

[8] '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 2 presents the registration deadlines graphically.

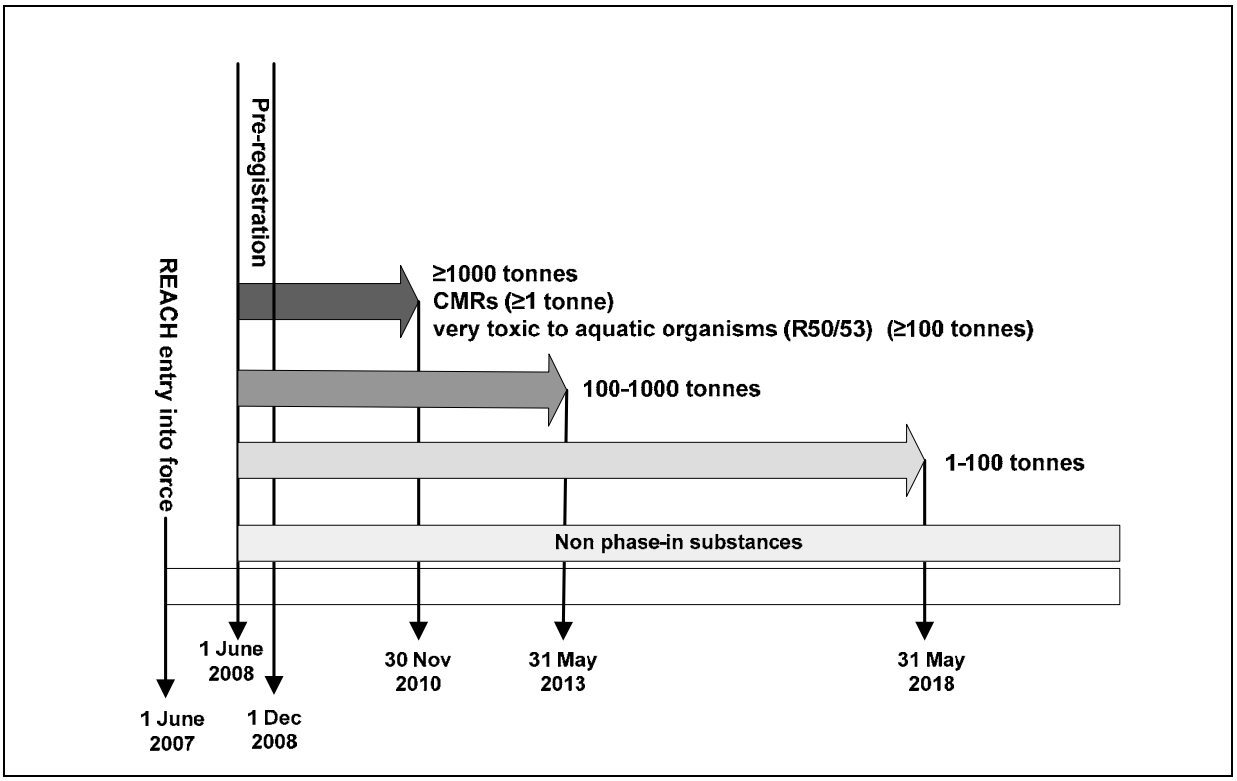



Figure 2: Registration deadlines

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

Note that, as explained in section 2.2.6.5, the 'tonnes per year' for phase-in substance 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 like for non-phase in substances.

**Note also 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.**

The following examples show how to calculate the registration deadline for pre-registered phase-in substances based on the yearly tonnage.

**Example 1**

A company, based on its manufacture projections, has determined that it should register a phase-in substance by the 31st May 2013 (as its manufacture volume is expected to be in the 100-1000 tonnes range).

Each year the company needs to calculate its yearly tonnage as the average over the three preceding years, e.g. in 2007 it is the average over 2004-2006.

The deadline for registration is based on the highest tonnage calculated starting in 2007.

In case this tonnage reaches 1000 tonnes, the registration is then due before the 1st December 2010. If this happens in 2011 or 2012 the registration is due without delay. As the yearly tonnage is based on a three year average it should be easier for companies to anticipate any increase of yearly tonnage.

If the tonnage stays in the 100-1000 tonnage band, then the registration should be submitted by the 31st May 2013. The tonnage for 2013 (calculated as the average over 2010-2012) has to be reported in the registration dossier and provides the basis for the information requirements.

**Example 2**

If the volume manufactured by Company Z is 120 tonnes (calculated as 3 years average) in 2009 and decreases to less than 100 tonnes after that, Company Z will still have to register ultimately 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 will be the 2013 tonnage calculated as the average over 2010-2012. This tonnage will determine the registration information requirements.

**Example 3**

The volume manufactured by Company V is 600 tonnes in 2007, 900 tonnes in 2008, 1400 tonnes in 2009 and 2000 tonnes in 2010. The 3 year-average tonnage in 2010 is 966 tonnes per year, but the 3 year-average tonnage in 2011 is 1433 tonnes per year. In this case company V will have to register the substance as soon as possible in 2011 as the registration deadline for the substances on 1000 tonnes or more per year has passed on 30 November 2010. The registration requirements should be based on the 2011 tonnage calculated as the average over 2008-2010, i.e. 1433 tonnes.

**Example 4**

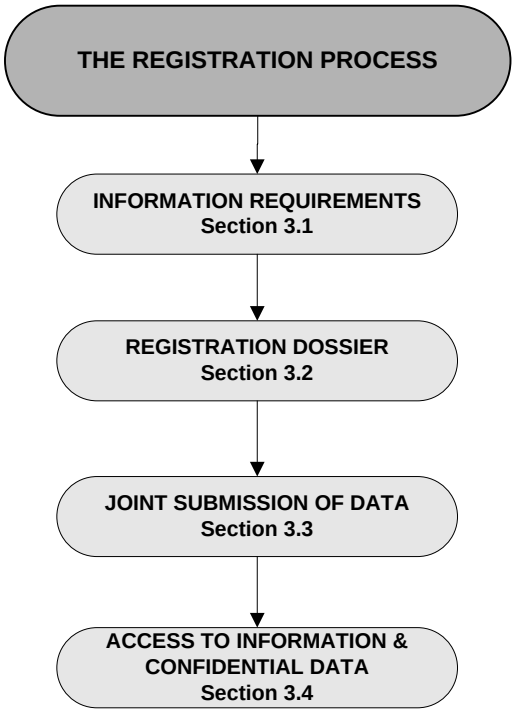
The volume manufactured by Company V is 900 tonnes in 2007, 0 tonnes in 2008, 1000 tonnes in 2009. As the substance has not been manufactured during three consecutive years then the calendar year tonnage should be used. In this case the 1000 tonnes threshold has been reached in 2010, meaning that a registration is due on 30 November 2010 at the Latest. The information requirements for the registration will be based on the 2010 tonnage, i.e. 1000 tonnes.

*Legal references: Article 23*

# 3 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 and to explain how to submit it to ECHA. It also describes what a joint submission of registration data is and how to submit jointly the registration information to ECHA.

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




## 3.1 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.

### 3.1.1 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.

It has to be stressed that 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 4.1 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 or other international standards recognised as being equivalent by ECHA or the Commission and with the provisions of Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes.

Information on intrinsic properties of substances may be generated by using sources of information other than *in vivo* testing, The registrant may use a variety of alternative methods such as *in vitro* tests, (Q)SARs ((Quantitative) Structure Activity Relationships), grouping or read-across, provided that the use of alternative methods is justified. All these different sources of information can also be used in a weight of evidence approach.

*Available guidance*

The Guidance on information requirements and chemical safety assessment explains in detail the process for information gathering and data generation. The following chapters may be particularly useful for the reader:

- Part B: Hazard Assessment
- Chapter R.2: Framework for Generation of Information
- 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 Guidance on alternative methods for the generation of information on intrinsic properties of substances can also be found in the following documents:

- Practical Guide 1: How to report *in vitro* data

- Practical Guide 2: How to report weight of evidence
- Practical Guide 4: How to report data waiving
- Practical Guide 5: How to report (Q)SARs
- Practical Guide 6: How to report read-across and categories
- Practical Guide 10: How to avoid unnecessary testing on animals.

**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 (in vitro) |
| 8.2 | Eye irritation (in vitro) |
| 8.3 | Skin sensitisation (in vivo) |
| 8.4.1 | Mutagenecity (gene mutation in bacteria) |
| 8.5.1 | Acute toxicity (by oral route) |
| **9** | **Ecotoxicological information** |
| 9.1.1 | Short term aquatic toxicity on invertebrates(Daphnia) |
| 9.1.2 | Growth inhibition aquatic plants (algae) |
| 9.2.1.1 | Ready biodegradability |
| **ANNEX VIII (10 tonnes or more)** | |
| **8** | **Toxicological information** |
| 8.1.1 | Skin irritation (in vivo) |
| 8.2.1 | Eye irritation (in vivo) |
| 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 | Two-generation reproductive toxicity |
| **9** | **Ecotoxicological information** |
| 9.1.5 | Long-term aquatic toxicity on invertebrates (*Daphnia*) |
| 9.1.6 | Long-term aquatic toxicity on fish |
| 9.2.1.2 | 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 (fish) |
| 9.3.3 | Further information on adsorption/desorption |
| 9.4.1 | Short-term terrestrial toxicity on 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 | Two-generation reproductive toxicity |
| 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 |

### 3.1.2 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).* 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 Directive or the Plant Protection Products Directive 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.

## 3.2 Registration dossier

### 3.2.1 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*

### 3.2.2 Format 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. The last version of this software is IUCLID 5[9] which will be used as the reference in this document and for which a specific guidance is available (Guidance on IUCLID).

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 5 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 5 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 5 software is downloadable from the IUCLID website at http://iuclid.eu for free by all parties, if used for non-commercial purposes.

*Legal reference: Article 111*

### 3.2.2 Submission of the registration dossier

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 of the ECHA website.

The submission of the registration dossier requires a number of practical steps with which the registrant should be familiar before attempting it. Part II of this guidance offers a detail

[9] Although IUCLID 5.3 is the last version of IUCLID 5 available at the time of publishing this guidance, all the descriptions contained in this document related to IUCLID 5 are also applicable to IUCLID 5.4.

explanation of the process to be followed and the tasks to be performed as well as the reference documents to be consulted.

## 3.3 Joint submission of data

Although each registrant is obliged to submit his own registration dossier for each of his substances, in cases where a substance is manufactured or imported or intended to be manufactured or imported by more than one company, they are required to submit certain information together. The joint submission of data applies both for the registration of phase-in substances and that of non phase-in substances.

**Registrants are required to jointly submit information on the intrinsic properties of the substance (studies and testing proposals, if any) and its classification and labelling and can, if they agree to do so, also jointly submit the guidance on safe use and the chemical safety report (CSR)** (*Article 11*). The intention is that registrants will save money by co-operating on the preparation of the dossier and also to reduce the need for testing, in particular on vertebrate animals. In addition, registrants submitting a joint submission benefit from a reduced registration fee. For additional information on how to gather and share existing information see also section 4.

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 shall be part of a joint submission with the other manufacturers, importers and only representatives for the same substance.

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

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.

### 3.3.1 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) meeting the earliest deadline applying to any of the registrants. 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: 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 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 below.

**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 use(s) 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 3.3.2 below)

In terms of chronology, the lead registrant will submit the lead dossier for the joint submission first. Only once the lead dossier for the joint submission is accepted for processing, in other words has passed the business rules check step (see section 10.1), may members submit their member 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 4.4) 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 there were several previous registrants and a joint submission exists, the potential registrant will need to contact the lead registrant to join 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.

In case the lead registrant ceases manufacture the other registrants will have to consider the need to appoint a new lead registrant.

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

*Legal references: Article 11, Article 19*

### 3.3.2 Opt-out possibilities

A manufacturer or importer may submit certain information of the registration dossier separately (opt-out) in cases where at least one of the following reasons (listed in *Article 11(3)* or for substances in intermediates respectively in *Article 19(2))* applies:

(a) *it would be disproportionately costly for him to submit this information jointly; or*

(b) *submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment; or*

*(c) he disagrees with the lead registrant on the selection of the information submitted in the lead registration.*

In this case the registrant has to submit along with his dossier an explanation as to why the costs would be disproportionate, why disclosure of information would be likely to lead to substantial commercial detriment or the nature of the disagreement, as the case may be. Opting out can be partial and refer for example only to a specific study. More detailed guidance on the opting out possibilities and mechanisms can be found in the Guidance on data sharing.

**Note that even when the registrant decides to exercise his opt-out option, he remains a member of the 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.

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

## 3.4 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;
- 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 shall 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, shall be made publicly available, free of charge on the ECHA website:

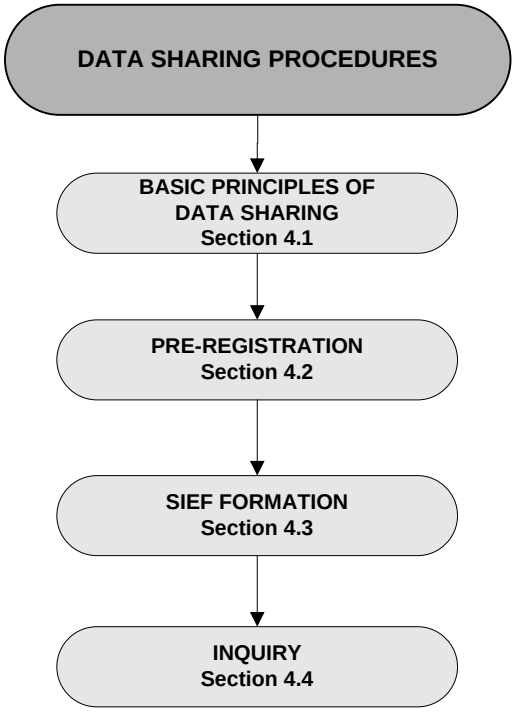
- *the name in the IUPAC Nomenclature, for substances which fulfil the criteria for any of the hazard classes set out in Article 58 (1) of the CLP Regulation[11], without prejudice to paragraph 2(f) and (g);*
- *if applicable, the name of the substance as given in EINECS;*
- *the classification and labelling 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*

# 4 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 where the data sharing procedures are described in detail.

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




## 4.1 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*).

In order 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**. In general, pre-registration is relevant for phase-in substances and inquiry for non phase-in and 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 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 identification of a substance and the determination of whether a substance is or is not the same are critical steps in the data sharing proceedings. It is highly recommended to refer to the Guidance on substance identification in order to assess the identity of the substance before getting involved in any data sharing mechanisms.

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 is carried out only once.

In accordance with the REACH Regulation, ECHA has set up procedures to assist in the resolution of data sharing disputes. Data sharing dispute procedures must be initiated **as a last resort**, i.e. only after all the possible efforts and arguments have been exhausted.

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 shall not normally 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.

## 4.2 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 4.3).

Manufacturers or importers not submitting a pre-registration dossier will have to register their substance before being allowed to restart manufacture, or import. They will have to submit an inquiry dossier to ECHA (as described in section 4.4) 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, i.e. the deadline given in section 2.3.2 for his tonnage band.

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 for 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*

## 4.3 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 information.

Note that the responsibility for defining the 'sameness' of the substances lies with the SIEF participants.

The Guidance on data sharing 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.

*Legal reference: Article 29*

## 4.4 Inquiry for non phase-in and non pre-registered phase-in substances

Inquiry is the process by which every potential registrant must inquire from ECHA whether a registration has already been submitted for the same substance. This is to ensure that data are shared by the relevant parties. The duty to inquire 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.** In cases where the potential registrant wishes to access the market rapidly it will be in his interest to submit an inquiry as early as possible.

### 4.4.1 The inquiry dossier

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

Identity of the inquirer

This will include contact details and the location of the inquirer's production site, where relevant for the purposes of data sharing.

Substance identity

For each substance, the information shall 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 registration *(Annex VI (2))* and is outlined in the Guidance on substance identification and in 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 identify previous and potential registrants and so to minimise the burden on the registrant to generate new data. Potential registrants are strongly recommended to consult the Guidance on substance identification 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 3.1.1 on fulfilling the information requirements).

The potential registrant shall identify in the inquiry dossier the list of information requirements which would require new studies.

The inquiry dossier can be prepared on line using the REACH-IT web application or in IUCLID 5 format and subsequently submitted via REACH-IT to ECHA, (see Part II of this guidance for practical instructions and recommendations on how to prepare and submit an inquiry dossier).

### 4.4.2 The inquiry process

Upon receipt of the inquiry dossier:

- ECHA will perform a substance identification check in order to identify previous registrants or potential registrants.
- After performing the substance identification check, if ECHA concludes that the same substance has previously not been registered or if the information required is not available (for instance, if the previous registration referred to a lower tonnage band), ECHA will inform the potential registrant accordingly and he may proceed with his registration.
- If the same substance has been previously registered less than 12 years earlier, ECHA will inform the potential registrant of the names and addresses of the previous

registrant(s), and of the availability of the relevant **study summaries** or **robust study summaries** already submitted by them. ECHA must simultaneously inform the previous registrant(s) of the name and address of the potential registrant and his registration requirements. The data sharing process can be initiated, and the registrant of the non-phase in substance who has submitted an inquiry will need to form part of a joint submission with the previous registrants.

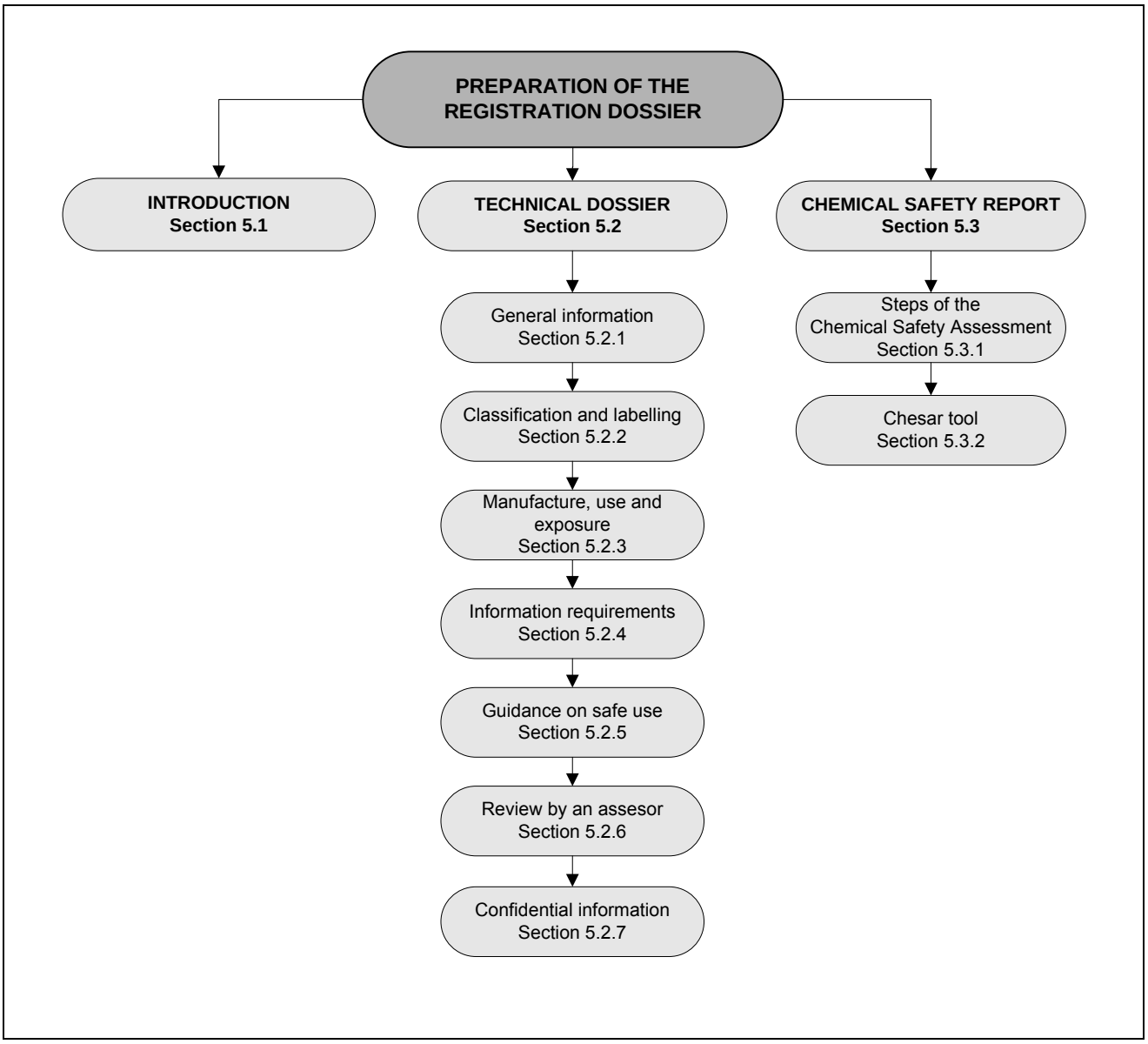
- Any study summaries or robust study summaries submitted in the framework of a registration under REACH at least 12 years previously can be used for the purposes of registration by another manufacturer or importer. In the case of an update of the registration because a higher tonnage band is reached 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. Data submitted at least 12 years previously may be requested as part of the inquiry process to ECHA.
- If several potential registrants have made an inquiry with respect to the same substance, ECHA will inform all potential registrants without delay of the names and addresses of the other potential registrants. If more than one registrant subsequently decides to proceed with their registration then they will need to make a joint submission (see section 3.3 on joint submission).
- If ECHA concludes that the substance is in fact a phase-in substance for which the pre-registration deadline has passed, the inquirer should verify whether the conditions for late pre-registration are met. If they are, they can submit the relevant information to ECHA, participate in the data sharing mechanisms facilitated by the Substance Information Exchange Forum (SIEF) and register in accordance with the relevant extended registration deadline. However, if the conditions for late pre-registration are not met, registration must take place before the substance is manufactured in, imported into or marketed within the EU.

*Legal references: Article 26 and 27*

# 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 Part II of this guidance where the different steps to generate and submit a dossier are described in detail.

**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 3.

*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 5 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 5 file**

| Information requirements | *Article 10* | IUCLID 5 |
|---|---|---|
| (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 use(s) 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 [10] |
| (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 |
| (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)*<br>*Article 14, Annex 1* | Attachment in section 13 |

[10] 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.

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 3.3.

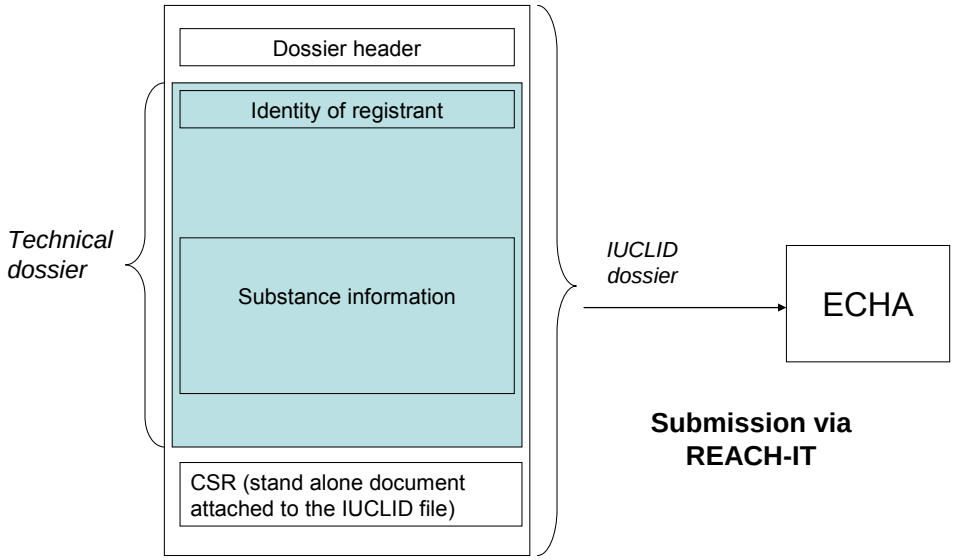



Figure 3: Structure and format of the registration dossier prepared using IUCLID

## 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 technical dossier will also include the administrative data required for the identification of the registration and its further processing at ECHA (registrant's identity, tonnage band, etc.). The data will be reported in IUCLID 5 which is the reporting format for the technical dossier.

The way to fill the different fields in IUCLID 5 as well as the level of detail needed is described in the following sections. In order to facilitate the work of the registrant these sections have been developed following the structure of IUCLID 5 but with clear links to the information requirements defined in REACH.

In addition to the information provided in this section, ECHA has developed a number of documents i.e. Data Submission Manuals and Practical Guides that provide detailed and practical information on how to generate a registration dossier. Registrants are advised to consult these documents, together with the present guidance, before the preparation of a registration dossier. All the documents are available on the ECHA website at

http://echa.europa.eu/.

### 5.2.1 General information on the registrant and on the registered substance

General information for the identification of the registrant and the substance to be registered must be reported in section 1 of IUCLID 5. This includes:

- Information regarding the registrant identification (as specified in *section 1 of Annex VI*) such as: 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 site(s). If the registrant has appointed a third party representative, the identity and the contact details of this representative should also be included under this section of the technical dossier.
- Information regarding the role(s) of the registrant, whether he is a 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 (see section 4.1 on data sharing).
- Information regarding the joint submission if applicable. In case of a joint submission the lead registrant can identify the members of the joint submission in this section. The same applies to the other registrants who can identify the lead registrant that submits the technical information on their behalf. However, this information has only an administrative value in IUCLID 5 and it is not required since the identification of a joint submission and its members has to be carried out in REACH-IT.
- Information required for the 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 identification step is an essential part for REACH registration and the registrant should consult the Guidance on substance identification in order to clearly identify and name their substance appropriately. The step of gathering information on the identity of the substance should be done early in the registration process at the level of the pre-registration or inquiry steps (see section 4.1 on data sharing). Therefore the registrant should have all the information required in the technical dossier and should be able to fill all the required fields in IUCLID 5.

It is recognised that 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.

### 5.2.2 Classification and labelling

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 propose several classifications depending on the form of the substance, impurities, etc. If a registrant disagrees and wants to propose another classification, then he needs to 'opt-out' from this information requirement as discussed in section 3.3.2.

The classification and labelling should be documented within section 2 of IUCLID 5 as well as

the rationale for non classification when this is the case. The rationale for the decision for a classification can be clearly documented in each of the relevant sections of IUCLID. For example the classification for human health should be justified under the relevant section (e.g. acute toxicity, eye irritation, etc.).

Registration dossiers submitted from 1 December 2010 onwards must include information on the classification and labelling of the substance according to the CLP criteria. Before 1 December 2010, the classification and labelling information required in the registration dossier had to be developed in accordance with the criteria in Directive 67/548/EEC.[11]

All registration dossiers submitted to ECHA before 1 December 2010 will have to be updated without undue delay regarding the information on the classification and labelling, unless this information was already provided according to the CLP Regulation criteria.

To ensure that the classification and labelling of hazardous substances are available to all stakeholders and the general public, ECHA will record the classification and labelling proposed in the registration dossier within the classification and labelling inventory established and maintained by ECHA. The classification and labelling inventory will contain 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 of the CLP Regulation (where all harmonised classification and labelling of hazardous substances have been listed) as well as the classification and labelling inventory in order to check if their substance is already listed. If already listed in the CLP Regulation (and therefore harmonised at EU level) they should follow this harmonised classification. If already listed in the inventory but not in Annex VI of the CLP Regulation, they should make every effort to harmonise their classification with other registrants, potential registrants having pre-registered and other notifiers of the classification and labelling of the same substance.

### 5.2.3 Manufacture, use and exposure

Information on the manufacture and use(s) of the substance, as specified under *section 3 of Annex VI*, must be documented in section 3 of IUCLID 5. Although it is up to the registrant to decide on the level of detail to be reported, at least the following data must be provided:

- Tonnage manufactured, imported or used for article production in tonnes per year, including the tonnage used for own purposes and for intermediates uses (see section 5.2.3.1 below).
- Brief description of the technological process used in the manufacture of the substance or in the production of articles (not applicable for importers).
- Information on the form (substance, mixture or article) and the physical state under which the substance is made available in the supply chain. This includes the concentration or concentration range of the substance in mixtures and the quantities of the substance in articles if applicable.
- Information on waste quantities and composition of waste.
- Brief description of the identified uses of the substance.
- Information on the uses advised against and why.

[11] The reader is reminded that during the transition period from 1 December 2010 until 1 June 2015 Safety Data Sheets for substances must however include information on the classification of the substance according to both Directive 67/548/EEC and the CLP Regulation (see section 6.1.1).

In addition, for substances manufactured or imported between 1 and 10 tonnes per year for which no CSR is required, the registrant will have to provide information on exposure as specified under *section 6* of *Annex VI.* This information will include at least the types of use for the substance (industrial, professional or consumer), the significant routes for human and environmental exposure and the pattern of exposure and will be also reported in section 3 of IUCLID 5.

Please, note that although exposure scenario(s) (see section 5.3.1.2) will be attached to the IUCLID 5 file as an integral part of the CSR where the CSR is required, IUCLID 5 includes relevant fields to be filled in under section 3[12].

#### 5.2.3.1 How to report the tonnage

The following fields will have to be completed:

- *Year*: calendar year for which the tonnage is reported.
- *Tonnage*: total tonnes per year (see section 2.2.6) manufactured or imported in the form of substance on its own or in mixtures, including 'intermediate' uses reported (see below). It should NOT include the tonnes of the substance imported in articles per year.

  The registrant is requested to report the tonnage for the year of submission of the dossier.
- *Own use*: tonnes per year used by the registrant. This should include both uses as an intermediate and as a non- intermediate.
- *Intermediate (on-site)*: tonnes per year of the substance manufactured for use as on-site intermediate under strictly controlled conditions.
- *Intermediate (transported*): tonnes per year of the substance manufactured or imported and used as intermediate under strictly controlled conditions.

If part of the tonnage is used for the purpose of PPORD and covered by a PPORD notification it should not be included here. If it is not covered by a PPORD notification it should be reported here and included in the tonnage used for the determination of the information requirements.

### 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 sections 4 to 7 in IUCLID 5 in the form of study summaries or robust study summaries.

According to REACH, robust study summaries need to be provided only when a chemical safety report is required, i.e. for substances above 10 tonnes per year, and only for key studies (see text box above). However, it is recommended to provide robust study summaries for all key studies including for substances manufactured or imported at less than 10 tonnes per year. This would facilitate the evaluation work to be done by ECHA and eventually Member States in the frame of substance evaluation and may potentially avoid the need for them to request further information.

In addition there might be cases where it could be useful to provide robust study summaries for non key studies. For example, in case the key study is not the one giving rise to the highest concern it might be useful to prepare a robust study summary for this study as well as for all the studies demonstrating a higher concern, or at least to report sufficient information to justify the disregard of these results so that the choice of the key study is better justified.

[12] Fields available from IUCLID version 5.4 onwards.

**Robust study summary**

A robust study summary is a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independet assessment of the study minmising the need to consult the full study report.

**Study summary**

A study summary is 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.

**Key study**

A key study is the study that has been identified as the most suitable to describe an information requirement from the perspective of quality, completeness and representativity of data. When several results are available for a given information requirement there can be several key studies.

For substances with more than one study available, the study or studies giving rise to the highest concern should normally be used as the key study or studies for the assessment of the substance. In case another study is used as key study this should be fully justified in the technical dossier for the study being used as well as for all studies demonstrating a higher concern.

For all other available studies, used as supporting information in the assessment of the substance, only a **study summary** needs to be provided in the dossier as for these studies less details are necessary. It is nevertheless very important that the reasons why the study has not been selected as a key study are reported, especially in case of those demonstrating a higher concern.

Study summaries or robust study sumaries are reported in the corresponding **endpoint study records** in IUCLID 5. When there are several sources of information on a given endpoint several endpoint study records can be reported. In addition it is recommended to also provide information in the **endpoint summary** on the different information gathered on a particular endpoint (e.g. acute toxicity to fish) or a more general assessment (e.g. ecotoxicological information). Definitions of endpoint study record and endpoint summary record in the context of IUCLID are detailed in the box below.

The endpoint study records and summary records provide a structured way to fill in the information for each endpoint. The **level of detail** required, however, will vary substantially depending on each situation. For key studies it is important that as many details as necessary to describe the test protocol and justify the validity of the result are reported. For information that has been judged as of insufficient quality by the registrant, a justification should be given, in particular, for all studies potentially demonstrating a higher concern than in the retained information. For data that are judged of insufficient quality and which would demonstrate a lower concern, only a minimum level of detail can be reported such as the reference of method and the result.

The reader is advised to consult Practical guide 3: 'How to report study summaries' if in need of more specific information on the level of detail to be reported for each individual endpoint. Additional information on how to technically fill in the information is given in the IUCLID 5 End User Manual.

**Endpoint**

An endpoint is an information requirement or data point with regard to the physicochemical, ecotoxicological and toxicological properties defined under *Annexes VII* to *X* of the REACH Regulation.

**Endpoint study record**

An endpoint study record provides a standard format for reporting the results of a test on a chemical, with predefined fields and free text prompts which helps the user to summarise a study. The information is entered and stored in the fields provided on the data entry window of IUCLID.

**Endpoint summary record**

The purpose of endpoint summaries is to describe and summarise the results of the evaluation made on all available information for a specific endpoint and conclude on the assessment for that endpoint.

Endpoint summaries are also available at section level, i.e. for section 6 (ecotoxicological information) and section 7 (toxicological information), where the key conclusions from the hazard assessment are recorded. This information is then to be included in the CSR (see section 5.3 on chemical safety assessment).

### 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 section 11 of the IUCLID 5 file and must be consistent with that in the safety data sheet (SDS), where an SDS is required (see section 6.1.1). The registrant is advised to follow in-house current practices or guidance on compilation of SDSs 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 chosen by him with appropriate experience in the field:

- 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

The information on the review must be recorded in the dossier header in IUCLID 5.

### 5.2.7 Confidential information

The registrant has the possibility in IUCLID 5 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 3.4 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 and attach the justification template provided by ECHA (at http://echa.europa.eu/) to ensure that the justification contains all the necessary information.

Please note that confidentiality claims are subject to fee payment.

## 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 stand alone document which will be attached in section 13 of IUCLID to the registration dossier and will contain 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[13] 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 if in need of further help and advice. Those readers without any previous knowledge on risk assessment might find useful to refer first to the Guidance in a nutshell on chemical safety assessment 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 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.

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

#### 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. Guidance on how to derive a DNEL is available in Chapter R.8 of the 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.

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 5 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 Directive 76/768/ECC, 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 Chapter R.7 of the 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.

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.9 of the 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.

A summary of the different effects on the environmental targeted compartments (aquatic, terrestrial, atmospheric and micro-organisms of the sewage treatments systems) shall be reported in section 7 of the CSR on the basis of the information available in the technical dossier under the relevant IUCLID 5 endpoint study record. The result of the assessment, once finalised, should also be reported under the relevant endpoint summaries in IUCLID 5 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 of the 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 shall be performed and reported as well under section 8 of the CSR[14].

### 5.3.1.2 Exposure assessment

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 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 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. For more guidance how to develop exposure scenarios and perform exposure estimation please consult the Guidance on information requirements and chemical safety assessment, Section D and Chapters R.14 - R.18.

The exposure assessment has to be reported in section 9 of the CSR.

### 5.3.1.3 Risk characterisation

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

[14] IUCLID 5 has been adapted (from version 5.4 onwards) to include a section to report the outcome on the PBT assessment.

controlled. The registrant shall 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 shall be carried out for each exposure scenario for both the human health and the environment and the results and discussion reported in section 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.

Guidance on how to characterise risk is available in Section E of the Guidance on information requirements and chemical safety assessment.

### 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 and generate a CSR. It provides a structured workflow for carrying out a standard safety assessment for the different uses of a substance. 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. The tool can be downloaded free of charge from http://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 (http://ihcp.jrc.ec.europa.eu/). 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. This functionality therefore supports efficient CSA processes and cross-industry harmonisation of the description of uses and of the safe conditions of use.

Registrants may decide to use other assessment tools instead of Chesar as long as they are adequate to comply with the REACH requirements.

#### 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 exposure scenario for attachment as an annex to the Safety Data Sheet (SDS).

Manage substance (Box 1)

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) has been finalised. Thus all the information related to the substance intrinsic properties should be available in the endpoint summaries in IUCLID. The assessor manages the import of all this information from IUCLID into Chesar with the Box 1 functionalities. Based on this information and a few additional judgements by the assessor, the required scope of exposure assessment and the type of risk characterisations (qualitative or quantitative) can be determined.

Report uses (Box 2)

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. When the assessment has been finalised, the uses reported in Box 2 can be exported to IUCLID section 3 (see section 5.2.3).

Manage assessment (Box 3)

In Box 3, the assessor carries out the exposure assessment and derives the corresponding risk characterisation. Based on the information imported in Box 1, Chesar will already have made suggestions on the required scope of exposure assessment and type of 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 exposure assessment based on measured data), or to even combine different methods in the exposure assessment. For situations where a qualitative risk characterisation is required, Chesar provides support for a modified assessment-workflow. The assessor needs to make a qualitative statement on control of risk, justifying that the operational conditions and measures described lead to a sufficiently low level and/or likelihood of exposure.

Build exposure scenario for the CSR (Box 4)

Box 4 supports the building of exposure scenarios based on the uses reported in Box 2 and the assessments carried out in Box 3. The generation of the full CSR is also launched from Box 4, including those chapters of the CSR (chapter 1 to 7) that are directly populated with information from IUCLID.

Build exposure scenarios for the SDS (Box 5)

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.

Administration tool (Box 6)

Box 6 includes all functionalities with regard to the Chesar library. The library enables creation, storage, import and export of objects that the assessor may need for his work process. The library also provides functionalities for data exchange with other users of Chesar, or sharing of assessments (full or parts of them) across industry. 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/.

# 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 and the risk management measures they have already put in place. 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

When supplying a substance or a mixture, the **supplier** has to provide an SDS according to *Annex II* of REACH to all the downstream users and distributors he supplies to as of 1st June 2007, as soon as the substance (on its own or in a mixture) falls within one of the following categories:

- it meets the criteria for **classification as hazardous in accordance with the CLP Regulation or the mixture containing the substance is classified as dangerous under Directive 1999/45/EC**;
- it is **persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB)** in accordance with *Annex XIII* of the REACH Regulation;
- it is included in the **candidate list of substances**[15] which may be subjected to authorisation.

In addition, a supplier of a substance **could be requested at any time by his customer** to provide him with a SDS for any mixture which does not meet the criteria for classification as dangerous 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 prepares a SDS for those mixtures.

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 that are hazardous in accordance with the CLP Regulation or mixtures that are dangerous in accordance with Directive 1999/45/EC, offered or sold to the general public, are provided with sufficient information 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.

*Annex II* of the REACH Regulation defines the requirements for SDSs. The SDS will identify the hazards the substance or mixture presents to man and the environment and the classification of the substance or mixture which arises from application of the classification rules in Directive

[15] 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.

67/548/EEC and Regulation (EC) 1272/2008 or in Directive 1999/45/EC. The relevant exposure limit values will be also identified in the SDS.

The final ES developed for identified uses as part of the CSA has to be communicated to the registrant's customers as an annex to the SDS, as this provides instructions of risk management measures that should be in place in order to ensure control of risks.

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

Please, note that with the entry into force of the CLP Regulation on 20 January 2009, the following **transition period applies regarding the classification of substances to be included in the SDS:**

- From 1 December 2010 until 1 June 2015, the SDS for substances shall contain the classification according to both Directive 67/548/EEC and the CLP Regulation.

On 1 June 2015 the transition period ends and from then onwards the SDS must include only the classification according to the CLP Regulation and need no longer make reference to the classification according to 67/548/EEC.

The **following transition period applies to the classification of mixtures in the SDS**:

- From the entry into force of the CLP Regulation on 20 January 2009 until 1 June 2015, the classification of a mixture in accordance to the CLP Regulation may be added on a voluntary basis together with the classification in accordance to Directive 1999/45/EC in the SDS. However, where a mixture is both classified and labelled according to the CLP Regulation, that classification shall be provided in the SDS together with the classification for the mixture and its constituents in accordance to Directive 1999/45/EC and Directive 67/548/EEC respectively.

From 1 June 2015 onwards, the transition period ends and mixtures and their constituents will be classified exclusively according to the CLP Regulation.

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[16] and the details of the granted authorisation or appropriate information if authorisation has been denied;
- the details of any restriction[17] imposed;
- any available and relevant information about the substance that is necessary to enable appropriate risk management;
- the registration number if available for any substances for which information is communicated under the points above.

This information shall be communicated at the latest at the time of the first delivery of the

[16] For further information on the authorisation process, refer to the Guidance on authorisation application
[17] For further information on the restriction process, refer to the Guidance on Annex XV on restrictions

substance on its own or in a mixture after 1 June 2007.

*Legal reference: Article 32*

## 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 or within one month after 1 December 2010 for substances already on the market at that date.

For substances registered before 1 December 2010 the classification and labelling will be reported in the registration dossier and no separate notification is required. Note that the obligation to classify and label a substance according to the CLP Regulation applies from 1 December 2010. This means that in cases where a registration was submitted earlier than 1 December 2010 the registration dossier may contain only the classification and labelling information according to Directive 67/548/EEC. In this case the registrant needs to update his registration dossier without undue delay by including the new classification and labelling according to the CLP Regulation. Further information on how to update a registration dossier is provided in section 7.

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

- IUCLID 5: 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.
- Bulk: this option allows the notifier to submit notifications for several substances defined by their EC or CAS number in a single file.
- Online: the information can be entered manually in REACH-IT. This can be the preferred option if only a few substances are to be notified and the notifier is not currently using IUCLID 5.

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 classification and labelling 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.

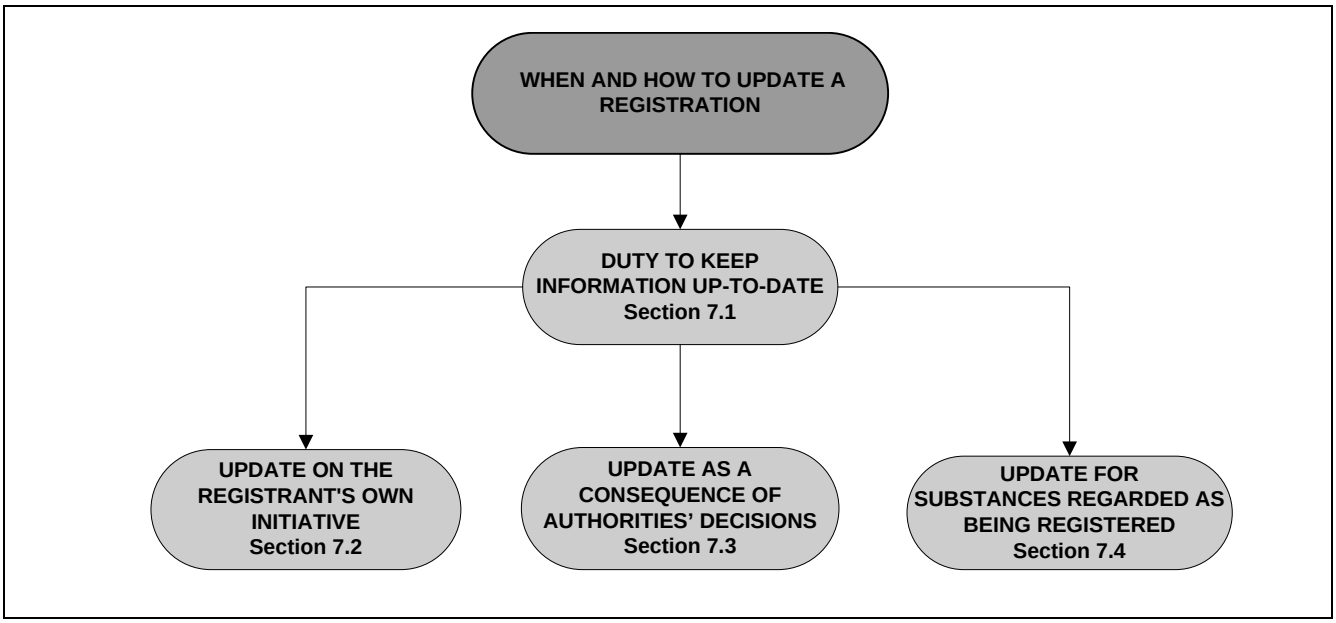
Additional information is provided in the Introductory Guidance on the CLP Regulation, the Guidance on the application of the CLP criteria and the Practical Guide 7: How to notify substances in the Classification and Labelling Inventory.

*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 also consult Part II of this guidance where detailed practical instructions are provided.

**Structure:** The structure of this chapter is as follows (to be corrected):




## 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 5 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 5 dossier is required in this case.

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

- *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) concerning their registration (*Article 22 (1)*).

- *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[18] 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 Agency 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 (Fee Regulation) (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 or 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 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 . Additionally, any change

[18] For further information on the evaluation procedures, refer to the Guidance on dossier and substance evaluation

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 on substance identification.

*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*

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). ECHA will then inform the registrant of the names and addresses of the previous registrants (and any potential registrants) and of any relevant study summaries already submitted by them in order to share existing data and ensure that studies on vertebrate animals are not unnecessarily repeated.

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, shall 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:

- 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.
- 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 feasible or not economical) in which case he must stop supplying the substance for that use unless he includes the use in the uses advised against.

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 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 shall 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.

*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.

## 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 a Commission decision under the evaluation procedure or he may have to take into account decisions made under the auhorisation 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 main 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 (for more details see the Guidance on evaluation).

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 in order to check whether the registrant has met his obligations and the registration dossier complies with the provisions of REACH (for details on compliance check see the Guidance on evaluation).

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.

The 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 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.

*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 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. 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 4.4) *(Article 12(2))*. Upon receipt of this information, ECHA should inform the registrant of the names and addresses of the previous registrants and of 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.

*Updates other than tonnage update*

Apart from the update required when reaching the next tonnage threshold, 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, not all information according to REACH must be provided, as REACH only requires such complete information to be submitted when the next tonnage threshold is reached. Therefore, when submitting a NONS update **not involving a tonnage band increase**, 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 shall be submitted only for the new identified uses, though submitting a CSR for **all** identified uses is encouraged;

- a CSR shall 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 shall 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 should, 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 Biocides Directive or Plant Protection Products Directive (see section 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).
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 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) 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 shall 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 3.4 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 shall be accompanied by the relevant part of the fee. As with a first time

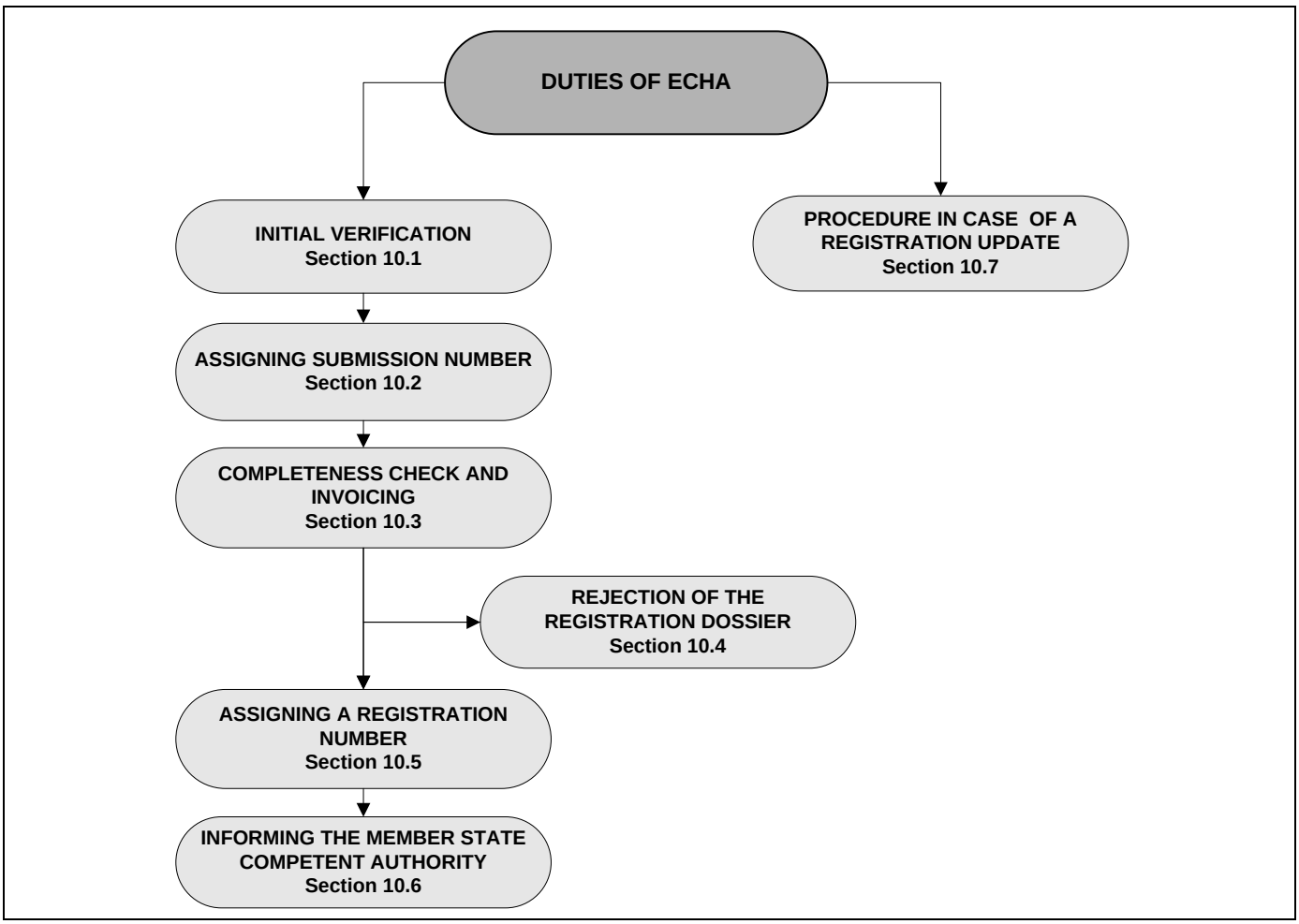
registration, the registrant has to submit the updated dossier through REACH-IT and the system will automatically compute the applicable fee for the update and send the relevant invoice to the registrant.

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 (.i5z file format) and is compliant with the XML schema used by IUCLID 5.

### 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 by applying the IUCLID Technical Completeness Check (TCC) plug-in.The

TCC plug-in also includes several of the business rules checked at ECHA. Please note that as some of the business rules depend on information stored within REACH-IT, the plug-in cannot simulate all the business rules included in the Business rules validation step.

### 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)*).

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. Please note that, although the new submission of the dossier is identified for technical reasons as an update, it is not considered an update within the meaning of the requirement to keep infomation up to date as described in section 7 of this guidance.

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 shall 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 Agency Procedure in the 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)*).

# PART II: Practical instructions on how to prepare and submit a dossier

# 11 Registration dossier

## 11.1 Practical information / recommendations

Potential registrants of the same substance have to share data and submit information jointly to ECHA. This obligation applies both to phase-in and non-phase-in substances. In order to fulfil this obligation, potential registrants of a pre-registered phase-in substance are put in contact with each other after pre-registration. In the case of non phase-in substances or phase-in substances which have not been pre-registered, potential registrants need to submit an inquiry to ECHA and they will receive in return information about any other registrant of the same substance.

In this chapter you will find practical information and recommendations for use when preparing your registration dossier as (a) lead of a joint submission, (b) member of a joint submission, or (c) as an individual registrant in the case of a unique registrant for a substance.

**a) Lead Registrant of a joint submission**

Existing Lead Registrants:

Lead Registrants that have already registered still have obligations to future registrants wishing to register the same substance. Depending on the arrangements between the Lead Registrants and the other registrants within the SIEFs, the following actions may need to be taken:

- Inform (pre-)SIEF members of your existence as soon as possible
- Ensure that data sharing conditions are fair, transparent and non discriminatory
- Ensure that newcomers are only required to share costs of data needed for their tonnage band
- Distribute the tokens to new registrants to allow them to submit their registrations via REACH-IT

New Lead Registrants:

- Nominate yourself to ECHA https://comments.echa.europa.eu/comments_cms/LeadRegistrantNotification.aspx
- Inform the supply chain that your SIEF is functioning and your substance will be registered

**b) Member of a joint submission**

New registrants:

- Is your substance already registered?
  - Check the ECHA website:
    - http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances
  - Verify within the SIEF or industry associations
  - Contact the Lead Registrant
  - Verify whether you have the same substance
  - Initiate data sharing negotiations
  - Ask for your token to join the joint submission in REACH-IT once you are ready to register

- If your substance is not registered yet
  - Some SIEFs already exist, the Lead Registrant may have been nominated already
    - Verify on the ECHA website or with industry associations
  - If not, start the process of SIEF formation
    - Verify whether a SIEF Formation Facilitator (SFF) exists for your substance in REACH-IT
    - If not, contact the pre-SIEF members to identify those registering before the relevant deadline

For information on pre-SIEFs and SIEFs please refer to "Industry User Manual - Part 5: PreSIEF" and to the dedicated section on SIEFS of the ECHA website.

For information on data and cost sharing please refer to the Guidance on data sharing and to the dedicated section on Data Sharing of the ECHA website.

**c) Individual registration**

As described above, potential registrants of the same substance have to share data and submit information jointly. This obligation applies both to phase-in and non phase-in substances.

However, there might be cases where only one company intends to register a particular substance and therefore an individual registration would be justified. For details on how to prepare individual registrations please see section 11.3.below.

## 11.2 Before preparing a dossier

Signing-up in REACH-IT is the starting point for any data submission to ECHA. You can refer to the Industry User Manual - Part 1: Getting started with REACH-IT, for a general overview of the system.

Each legal entity must create an account online in REACH-IT, and provide the required identification details (i.e. legal entity name, contact details and billing information). These details will then be included in the Legal Entity Object (LEO), which also includes a unique identifier (UUID – Universal Unique Identifier) for each company.

There are only two accepted methods for creating an official Legal Entity Object (LEO):

- via the official IUCLID 5 website (but not from your IUCLID 5 stand-alone application)
- directly in REACH-IT

The second step is downloading and installing IUCLID 5. You will need to sign-up in the IUCLID 5 website before being able to download the software. During the installation you will be prompted to create a user account and to assign a Legal entity. In the IUCLID 5 website (http://iuclid.echa.europa.eu) you can find all supporting documents including the "Getting started" and "End-user" manuals.

It is important to maintain consistency, between IUCLID 5 and REACH-IT regarding the Legal Entity Object (LEO). For more detailed information, please refer to the Industry User Manual - Part 2: Sign-up and account management.

After signing-up in REACH-IT, the Industry User Manual - Part 3: Login and Message Box will help you to familiarise with the system.

Only representatives have to sign-up in REACH-IT for each non-EU manufacturer they represent and submit (late pre-) registrations using the appropriate accounts. It is not possible to use the same LEO (having the same company UUID) for multiple accounts, but it is possible to use the same company identification information (name, VAT, etc.). Only representatives must indicate, in the "company size" field, the size of the non-EU manufacturer they are representing.

## 11.3 How to prepare a dossier

**a) Lead Registrant of a joint submission**

(http://www.echa.europa.eu/web/guest/joint-submission-lead)

*Please note that during the process you need to prepare the Joint Submission in REACH-IT and manage the security tokens. Industry User Manual – Part 7: Joint Submission, helps you by providing step-by-step instructions.*

- Collect all data needed according to the highest tonnage band within the joint submission (REACH *Annexes VI-X)*
- Agree with the rest of registrants whether the following information will be submitted jointly or separately: (i) the chemical safety report, (ii) the guidance on safe use and (iii) an indication that information included in the dossier has been reviewed by an assessor
- It is important to carefully read the relevant Data Submission Manuals during the creation of your substance dataset and your final dossier. Special attention should be given to:
  - Data Submission Manual 4: How to Pass Business Rule Verification ("Enforce Rules");
  - Data Submission Manual 5: How to complete a Technical Dossier for Registrations and PPORD Notifications;
  - Data Submission Manual 18: How to report the substance identity in IUCLID 5 for registration under REACH.
- As the lead registrant you may need to prepare a joint chemical safety report (CSR) and/or an individual CSR (if relevant). For detailed instructions please refer to Data Submission Manual 19: How to submit a Chemical Safety Report as part of a joint submission . Other relevant links:
  - Chesar tool – Software to support the chemical safety assessment and generate the chemical safety report.
  - CSR Template – Document structured according to the format specified in Annex I of REACH.
  - CSR plug-in – Plug-in for IUCLID that generates the chemical safety report.
- When your substance dataset is complete (i.e. the relevant IUCLID 5 fields have been filled in with the necessary information), create the final dossier following the instructions as prompted by the IUCLID 5 'Dossier Creation wizard'. When the dossier has been created it is then ready to be exported to your computer
- Before submitting your dossier to ECHA, you are advised to run the following IUCLID 5 plug-ins on your substance dataset and on the final dossier (plug-ins are available at the IUCLID 5 website – "Download" section):
  - IUCLID 5 TCC plug-in: checks the technical completeness of the substance dataset and dossier
  - IUCLID 5 Fee Calculation plug-in: calculates the fee payable on the successful submission of your dossier
  - IUCLID 5 Dissemination plug-in: simulates which information from your dossier ECHA will make available over the internet

**b) Member of a joint submission**

(http://echa.europa.eu/web/guest/joint-submission-member)

*Please note that during the process you need to confirm membership in the Joint Submission created by the Lead in REACH-IT. Industry User Manual - Part 7: Joint Submission, helps you by providing step-by-step instructions.*

- Collect all data needed according to your tonnage band in consultation with your Lead Registrant (REACH *Annexes VI-X*).
- Some of the information may be submitted by the Lead on your behalf after agreement (i.e. chemical safety report, guidance on safe use and an indication that information included in the dossier has been reviewed by an assessor)
- It is important to carefully read the relevant Data Submission Manuals during the creation of your substance dataset/dossier. Special attention should be given to:
  - Data Submission Manual 4: How to Pass Business Rule Verification ("Enforce Rules");
  - Data Submission Manual 5: How to complete a Technical Dossier for Registrations and PPORD Notifications;
  - Data Submission Manual 18: How to report the substance identity in IUCLID 5 for registration under REACH.
- If a chemical safety report (CSR) is relevant for your registration, it may be partly or fully covered in a joint CSR submitted by the lead registrant on your behalf. For detailed instructions, please refer to Data Submission Manual 19: How to submit a Chemical Safety Report as part of a joint submission . Other relevant links:
  - Chesar tool – Software to support the chemical safety assessment and generate the chemical safety report.
  - CSR Template – Document structured according to the format specified in Annex I of REACH.
  - CSR plug-in – Plug-in for IUCLID that generates the chemical safety report.
- When your substance dataset is complete (i.e. the relevant IUCLID 5 fields have been filled in with the necessary information), create the final dossier following the instructions as prompted by the IUCLID 5 'Dossier Creation wizard'. When the dossier has been created it is then ready to be exported to your computer
- Before submitting your dossier as a member of a joint submission to ECHA, you are advised to run the following IUCLID 5 plug-ins on your substance dataset and on the final dossier (plug-ins are available at the IUCLID 5 website – "Download" section):
  - IUCLID 5 TCC plug-in: checks the technical completeness of the substance dataset and dossier as a member (however, it is worth noting that ultimately the completeness of your dossier is dependant on the completeness of the lead registrant dossier).
  - IUCLID 5 Fee Calculation plug-in: calculates the fee payable on the successful submission of your dossier
  - IUCLID 5 Dissemination plug-in: simulates which information from your dossier ECHA will make available over the internet

*Member registrants are strongly advised to take into consideration the "Practical guide 9: How to do a registration as a member of a joint submission" available on the ECHA website. This document outlines the basic steps for preparing a registration dossier in IUCLID 5 and the*

*submission of the dossier via REACH-IT.*

**c) Individual registration**

(http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/registration)

- Potential registrants of the same substance have to share data and submit information jointly. However, there might be situations where only one company intends to register a particular substance. In this situation, an individual registration (not linked to any joint submission) should be prepared and submitted to ECHA. It will always be possible to create a joint submission at a later stage in case of a second company intending to register the same substance
- Collect all data needed according to your tonnage band (REACH *Annexes VI-X*)
- It is important to carefully read the relevant Data Submission Manuals during the creation of your substance dataset and the final dossier. Special attention should be given to:
  - Data Submission Manual 4: How to Pass Business Rule Verification ("Enforce Rules");
  - Data Submission Manual 5: How to complete a Technical Dossier for Registrations and PPORD Notifications;
  - Data Submission Manual 18: How to report the substance identity in IUCLID 5 for registration under REACH.
- As an individual registrant you may need to prepare a chemical safety report (CSR). For detailed instructions please refer to:
  - Chesar tool – Software to support the chemical safety assessment and generate the chemical safety report.
  - CSR Template – Document structured according to the format specified in Annex I of REACH.
  - CSR plug-in – Plug-in for IUCLID that generates the chemical safety report.
- When your substance dataset is complete (i.e. the relevant IUCLID 5 fields have been filled in with the necessary information), create the final dossier following the instructions as prompted by the IUCLID 5 'Dossier Creation wizard'. When the dossier has been created it is then ready to be exported to your computer.
- Before submitting, you are advised to run the following IUCLID 5 plug-ins on your substance dataset and on the final dossier (plug-ins are available at the IUCLID 5 website – "Download" section):
  - IUCLID 5 TCC plug-in: checks the technical completeness of the substance dataset and dossier
  - IUCLID 5 Fee Calculation plug-in: calculates the fee payable on the successful submission of your dossier
  - IUCLID 5 Dissemination plug-in: simulates which information from your dossier ECHA will make available over the internet

## 11.4 How to submit a dossier

All REACH registration dossiers are submitted through REACH-IT. For detailed instructions please refer to the Industry User Manual - Part 6: Dossier Submission.

*Please note that in case of a Joint Submission, the dossier of the Lead Registrant (which includes the joint information needed for registering) needs to be successfully submitted before the member registrants can submit their registrations. More precisely, member registrants can only submit their dossiers once the lead registrant dossier has been accepted for processing (i.e the dossier passes the business rules verification step – see section 10).*

## 11.5 Update of the registration dossier

Once a registration dossier has been submitted to ECHA and accepted for processing, any resubmission of the dossier has to be identified as an update for technical reasons.

There are two different kinds of updates related to a registration dossier:

- **Requested update** (as a result of an incomplete initial submission or as a consequence of a decision made by ECHA or the Commission).
  - In case of a requested update (e.g. due to an incomplete dossier, or more information needed for the scientific assessment etc.), you need to submit an updated dossier via REACH-IT. The updated version of your initial IUCLID 5 dossier should include all the information initially submitted plus the additional information that is requested in the official communication sent by ECHA.
  - In the dossier header of the IUCLID 5 dossier the checkbox "The submission is an update" must be selected followed by the checkbox "Further to a request/decision from regulatory body" (dossier creation wizard step 6). The last submission number and the annotation number in the communication letter sent by ECHA must be entered in their respective adjacent fields.
  - If the requested update is for a previously registered substance (i.e. a registration number has already been granted for this substance), please ensure that the registration number is included in section 1.3 of your IUCLID 5 substance dataset.
  - After creating your 'update by request' dossier, please submit it via REACH-IT in the same manner as described in the above chapters.
- **Spontaneous update** (on the registrant's own initiative).
  - If you need to include additional information in your dossier that has been already submitted and accepted by ECHA (i.e. a registration number has already been granted for your substance), you have to submit a spontaneous update via REACH-IT.
  - In the dossier header of the IUCLID 5 dossier the checkbox "The submission is an update" must be selected followed by the checkbox "Spontaneous update" (dossier creation wizard step 6). The last submission number and a justification must be entered in their respective adjacent fields.
  - Please ensure that the registration number is included in section 1.3 of your IUCLID 5 substance dataset.
  - After creating your 'spontaneous update' dossier, please submit it via REACH-IT in the manner as described in the chapters above.

More information on how the dossier header of your IUCLID 5 dossier should look - depending on the type of registration (individual, lead registrant, member of a joint submission) and the type of update - can be found in Data Submission Manual 4: How to Pass Business Rule Verification ("Enforce Rules").

# 12 PPORD notification

*If your substance is subject to product and process oriented research and development (PPORD), you can submit a PPORD notification to ECHA in order to be exempted from the obligation to register* (http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/ppord).

- Prepare your PPORD notification by first creating a substance data set in IUCLID 5.
- It is important to read carefully the relevant Data Submission Manuals before creating your substance dataset and dossier. Special attention should be given to:
  - Data Submission Manual 1: How to prepare and submit a PPORD notification;
  - Data Submission Manual 4: How to Pass Business Rule Verification ("Enforce Rules");
  - Data Submission Manual 5: How to complete a Technical Dossier for Registrations and PPORD Notifications.
- When your substance dataset is complete (i.e. the relevant IUCLID 5 fields have been filled in with the necessary information), create the final dossier following the instructions as prompted by the IUCLID 5 'Dossier Creation wizard'. When the dossier has been created it is then ready to be exported to your computer (Chapter D8 of the IUCLID 5 End User Manual).
- Before submitting, you are advised to run the IUCLID 5 TCC plug-in to verify the technical completeness of your dossier. It also includes a pre-check for certain "business rules".
- Submit your PPORD notification dossier via REACH-IT. You can find detailed instructions in the Industry User Manual - Part 6: Dossier Submission.

# 13 Inquiry dossier

*Every potential registrant of a non-phase-in substance (or a phase-in substance which has not been pre-registered), must inquire to ECHA as to whether a registration has already been submitted for the same substance. Similarly, a company is obliged to inform ECHA of the additional information that they would require for an update of a registration due to a tonnage band increase* (http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/inquiry).

- There are two different options to create an inquiry:
  - Enter the information required for the inquiry directly online in REACH-IT, following a step-by-step procedure until the final validation and submission.
    For guidance on how to create an inquiry dossier following this option, please refer to the Industry User Manual - Part 11: Online dossier creation and submission for inquiries.
  - Alternatively, you can create a IUCLID 5 dossier containing the information required for the inquiry and submit this dossier through REACH-IT. Before submitting your inquiry, apply the Technical Completeness Check (TCC) tool plug-in to identify possible fields of your dossier from which information may be missing.
    For guidance on how to create an inquiry following the IUCLID 5 dossier option, please refer to Data Submission Manual 2: How to prepare and submit an inquiry dossier.
- Submission to ECHA:
  - If you choose to create your inquiry online in REACH-IT, the submission is integrated as the final step in this process.
  - If you create a IUCLID 5 dossier, then Industry User Manual - Part 6: Dossier Submission will provide you with step-by-step instructions on how to submit your inquiry dossier.
- It is recommended to also refer to:
  - Guidance on substance identification;
  - Data Submission Manual 18: How to report the substance identity in IUCLID 5 for registration under REACH;
  - Questions and answers on inquiry and substance identification.

# 14 Late pre-registration

*Please note that the official pre-registration period is over. As explained in section 4.2 of this guidance, late pre-registration is only allowed under specific circumstances* (http://www.echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/pre-registration).

For more information please refer to the Questions and Answers on Pre-Registration. Practical instructions on how to pre-register can be found in Industry User Manual - Part 4: Online Pre-Registration.

# Appendix 1. Acronyms

| | |
|---|---|
| C&L | Classification and Labelling |
| CBI | Confidential Business Information |
| Chesar | Chemical Safety Assessment and Reporting tool |
| CMR | Carcinogenic, Mutagenic and Reprotoxic substance |
| CSA | Chemical Safety Assessment |
| CSR | Chemical Safety Report |
| CWG | Commission Working Group |
| DNELs | Derived No Effect Levels |
| DU | Downstream User |
| ECHA | European Chemicals Agency |
| EEA | European Economic Area |
| EFTA | European Free Trade Agreement |
| 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 |
| IP | Intellectual Property |
| IPCS | International Programme on Chemical Safety |
| ITS | Integrated Testing Strategies |
| 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 |
| OECD SIDS | OECD Screening Information Data Set |
| OECD SIDS SIAR | OECD SIDS Initial Assessment Report |
| PA | Publicly Available |
| 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 |
| SDS | Safety Data Sheet |
| SIEF | Substance Information Exchange Forum |
| SME | Small and Medium Sized Enterprise |
| 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. It should be noted 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, 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.
- 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.
- 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:**

- Under some circumstances 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 todate.
- Under some circumstances 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 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:**

- Under some circumstances 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.
- Under some circumstances 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*.
- Apply for authorisation for use(s) of substances listed in *Annex XIV*.

**(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 to resolve divergences of opinion on decisions following evaluation, consider proposals for harmonised classification and labelling, and identify substances for authorisation.
- 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.
  - 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.
- 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.

# Appendix 3. Update of the document

The changes introduced to the document are listed in the table below except for minor changes such as corrections of typographical errors, minor amendments of wording for improved language usage or addition or updates of links to other documents or web pages.

| Section (Version 2) | Section (Version 1.6) | Change made |
|---|---|---|
| 1.1.<br>Figure 1 | 1.1<br>Figure 1 | - The step regarding the calculation of the volume of the substance has been moved prior to the determination of the use of the substance as an isolated intermediate.<br>- Reference to the expiry of the first registration period for phase-in substances has been included. |
| 1.2 | 1.2 | - The concepts of data sharing and joint submission have been introduced.<br>- The consequences of not registering within the required deadline are explicitly highlighted. |
| - | 1.3 | - Previous section 1.3 has been deleted. |
| 1.3 | 1.4 | - The explanation regarding the different types of substances (mono-constituent, multi-constituent and UVCB) has been deleted. A reference to the Guidance on substance identification is included instead.<br>- Information regarding the registration requirements in the case of alloys has been added.<br>- More detailed information regarding the registration of substances in articles is provided. |
| 2.1.1 | 1.5.1 | - The title has changed.<br>- The roles of the only representative, article producer and distributor have been included.<br>- The term 'formulator' is clarified.<br>- The subsection regarding customs boundaries have been moved to Section 2.1.2.2. |
| 2.1.2 | 1.5.2 | - The title has changed.<br>- The reference to the registration obligations of polymers in certain circumstances has been deleted. |
| 2.1.2.1 | 1.5.3<br>1.5.3.1 | - The new section merges the content of the two previous sections.<br>- The term 'legal entity' is further clarified. |
| - | 1.5.3.2 | - The content of section 1.5.3.2 has been moved to section 7.2.a. |
| 2.1.2.2 | - | - The content originates from the previous subsection on customs boundaries within section 1.5.1. |
| 2.1.2.3 | - | - New section explaining the registration obligations in case of manufacturing.<br>- Responsibilities in case of toll manufacturing are also described. |
| 2.1.2.4 | 1.5.3.3 | - A new example to illustrate the responsibility of registration in the case of import has been added.<br>- Further clarification regarding the term 'importer' has been included. |

| Section (Version 2) | Section (Version 1.6) | Change made |
|---|---|---|
| 2.1.2.5 | 1.5.3.4 | - The need for a non-EU manufacturer to provide the only representative with up-to-date information on the list of EU importers has been reworded as a recommendation. Other options are considered to keep the only representative informed.<br>- The scope of the previous subsection on the tasks of the only representative has been changed to cover exclusively the registration obligations.<br>- The information regarding pre-registration by an only representative has been moved to section 4.2.<br>- The requirement to submit a new registration dossier in case of change of only representative without agreement of the earlier one has been eliminated.<br>- The requirement to submit separate registrations by an only representative is further clarified. |
| 2.2.1 | 1.6.1 | - The content has been restructured.<br>- The requirement to provide information of the substances in the bulk and nanoform where applicable has been included. |
| 2.2.2.1 | 1.6.3.1 | - The content has been streamlined.<br>- A reference to the specific legislation applicable to radioactive substances is included in a footnote. |
| 2.2.2.4 | 1.6.3.4 | - The content has been streamlined. |
| 2.2.2.5 | 1.6.3.5 | - The definition of intermediates has been included. |
| 2.2.3 | 1.6.4 | - The content has been restructured.<br>- Reference to the authorisation and restriction obligations is included. |
| 2.2.3.1 | 1.6.4.1 | - The scope of the exemption in substances used for food or feedingstuffs is further clarified.<br>- The application of the exemption to exports and imports is clarified. |
| 2.2.3.2 | 1.6.4.2 | - The application of the exemption in medicinal products to exports and imports is clarified.<br>- References to the authorisation requirement under REACH are deleted to avoid misunderstandings. |
| 2.2.3.4 | 1.6.4.4 | - The example regarding Annex V exemption has been deleted. A reference to the Guidance on Annex V is introduced instead. |
| 2.2.3.5 | 1.6.4.5 | - Reference to the criteria to determine the sameness of substances has been introduced.<br>- The requirements to benefit from the exemption in the case of recovered substances are further clarified.<br>- Additional information on the Guidance on waste and recovered substances is added. |
| 2.2.3.6 | 1.6.4.6 | - Reference to the criteria to determine the sameness of substances has been introduced.<br>- The conditions to benefit from the exception regarding the supply chain of the re-imported substance have been clarified.<br>- Reference to the requirements regarding information in the supply chain has been introduced. |
| 2.2.3.7 | 1.6.4.7 | - A definition of polymer is provided.<br>- The conditions for the registration of monomers are explained. |
| 2.2.3.8 | 1.6.4.8 | - The title has changed.<br>- The threshold of one tonne per year for PPORD notification is |

| Section (Version 2) | Section (Version 1.6) | Change made |
|---|---|---|
| | | clarified.<br>- The requirement to identify the customers included in the exemption is included. |
| 2.2.4.1 | 1.6.5.1 | - The title has changed<br>- The fact that microorganisms are outside the scope of REACH is clarified in a footnote.<br>- The conditions under which substances used in biocidal products are regarded as registered are further clarified.<br>- Reference to the inclusion of information regarding substances used in biocides in ECHA's database has been deleted. |
| 2.2.4.2 | 1.6.5.2 | - The title has changed.<br>- The fact that microorganisms are outside the scope of REACH is clarified in a footnote.<br>- The conditions under which substances used in plant protection products are regarded as registered are further clarified.<br>- Reference to the inclusion of information regarding substances used in plant protection products in ECHA's database has been deleted. |
| 2.2.5 | - | - New section on intermediates. |
| 2.2.6 | 1.6.2 | - Further information is provided regarding the volume to be registered. |
| 2.2.6.1 | 1.6.2.1 | - Information regarding the calculation of the tonnage in case of intermediates has been moved to the next section 2.2.6.2. |
| 2.2.6.2 | 1.6.2.1 | - The information regarding the submission of information for a substance manufactured or imported for several uses (PPORD, intermediate and other uses) is deleted.<br>- Further clarification on the determination of the information requirements for intermediates is included.<br>- The information on the calculation of the volume in case a substance is intended to be released from an article has been moved to section 2.2.6.3. |
| 2.2.6.3 | 1.6.2.2 | - Information on the volume to be used for the definition of the information requirements has been added.<br>- Information on the calculation of the volume in case a substance is intended to be released from an article has been included here. |
| 2.2.6.5 | 1.6.2.3 | - The examples provided in section 1.6.2.3 have been moved to section 2.3.2. |
| 2.3.1.1 | 1.7.1.1 | - Reference to the pre-registration deadline has been deleted.<br>- The paragraph regarding NLP has been reworded. |
| 2.3.2 | 1.7.2 | - The latest time for dossier submission is defined for each deadline.<br>- The term 'classified in accordance with Directive 67/548/EEC' is clarified.<br>- An explanation of how to determine the deadline for registration is included.<br>- The examples from previous section 1.6.2.3 have been moved here.<br>- The tonnage to be used for the determination of the information requirements has been defined in each example. |
| 3.1 | - | - Introduction to the information requirements. |

| Section (Version 2) | Section (Version 1.6) | Change made |
|---|---|---|
| 3.1.1 | 8.1.1 | - The text has been streamlined.<br>- Table 2 compiling the standard information requirements has been added.<br>- A reference to the available guidance is included. |
| 3.1.2 | 8.1.2 | - The content has been streamlined. |
| - | 8.1.3 | - Section 8.1.3 has been deleted. |
| - | 8.1.3.1 | - Section 8.1.3.1 has been deleted. |
| - | 8.1.3.2 | - Section 8.1.3.2 has been deleted. |
| - | 8.1.3.3 | - Section 8.1.3.3 has been deleted. |
| - | 8.1.3.4 | - Section 8.1.3.4 has been deleted. |
| 3.2.1 | 1.8.1 | - The content has been streamlined.<br>- The information regarding the format of the registration dossier has been moved to section 3.2.2.<br>- The information regarding the different steps of the CSA has been deleted. All information on CSA can now be found in section 5.3. |
| 3.2.2 | 1.8.1<br>8.2.1 | - Section 3.2.2 gathers part of the information on IUCLID provided previously in section 1.8.1 and 8.2.1. |
| 3.2.3 | - | - Introduction to dossier submission. |
| 3.3 | 1.8.4 | - The text regarding 'Third Party Representative' has been moved to section 4.1.<br>- Clarification regarding the application of the joint submission requirement has been added. |
| 3.3.1 | 1.8.4.1 | - Explanation regarding the lead and member dossier has been added.<br>- A new table (table 3) showing the information requirements for the lead and member dossiers has been included.<br>- The requirement for a potential registrant to form part of a joint submission when there are one or more previous registrants for the same substance is explained. |
| 3.3.2 | 1.8.4.2 | - Further explanation regarding the chronology of dossier submission in case of opt-out is included. |
| 4.1 | 2.1 | - The purposse of data sharing is defined.<br>- The SIEF concept is introduced.<br>- The importance of substance identification is highlighted<br>- Information regarding 'Third Party Representative' is provided here. |
| 4..2 | 2.2 | - Information regarding the pre-registration deadline has been deleted.<br>- Information related to pre-registration of substances in articles has been added.<br>- Information regarding pre-registration by an only representative has been moved here from previous section 1.5.3.4. |
| 4.3 | - | - New brief section on SIEF formation. |
| 4.4 | 2.3<br>2.3.1<br>2.3.2 | - The content has been restructured. |
| 4.4.1 | 2.3.3<br>2.3.3.1<br>2.3.3.2<br>2.3.3.3<br>2.3.4 | - The content has been restructured.<br>- Information regarding substance identity has been added. |

| Section (Version 2) | Section (Version 1.6) | Change made |
|---|---|---|
| 4.4.2 | 2.3.5 | - The requirement for a registrant to form part of a joint registration if the same substance has been previously registered is explicitly included. |
| 5 | 8 | - The content has been restructured. |
| 5.1 | 8.2<br>Table 3 | - The content has been restructured. |
| 5.2 | 8.2.2 | - The content has been streamlined. |
| - | 8.2.2.1<br>8.2.2.2 | - These sections have been deleted. |
| 5.2.1 | 8.2.2.3 | - The content has been restructured.<br>- The recommendation to only representatives to include the list of importers in their registration dossiers is deleted. |
| 5.2.2 | 8.2.2.4 | - The possibility to submit several classifications in a joint submission is included. |
| 5.2.3 | 8.2.2.5 | - The minimum data to be reported in IUCLID on manufacture, use and exposure are defined.<br>- Information on how to report the tonnage has been moved to section 5.2.3.1. |
| 5.2.3.1 | 8.2.2.5 | - Information on how to report the tonnage has been moved here.<br>- The content has been streamlined. |
| 5.2.4 | 8.2.2.6<br>8.2.2.6.1<br>8.2.2.6.2<br>8.2.2.6.3<br>8.2.2.6.4 | - The information regarding the reporting of the intrinsic properties of the substance has been streamlined and is included now in section 5.2.4. |
| 5.2.5 | 8.2.2.7 | - The content is streamlined.<br>- The information to be included on the guidance on safe use is defined. |
| 5.2.6 | 8.2.2.8 | - The content is streamlined. |
| 5.2.7 | 8.2.2.8 | - The content is streamlined. |
| 5.3 | 8.2.3 | - Table 5 is included.<br>- Information regarding CSR IUCLID plugin has been deleted. |
| 5.3.1.1.1 | 8.2.3.1.1 | - Reference to the exemption for food contact materials and cosmetic products is included. |
| 5.3.1.1.4 | 8.2.3.1.4 | - A footnote regarding the inclusion of the assessment in IUCLID 5 has been included. |
| 5.3.1.3 | 8.2.3.3 | - The qualitative and semi-quantitative risk characterisation is mentioned. |
| - | 8.2.4<br>8.2.4.1<br>8.2.4.2 | - Practical instructions on how to prepare a dossier in case of a joint submission can be found now in section 11.3. |
| 5.3.2<br>5.3.2.1 | - | - New sections on Chesar tool. |
| 6.1.1 | 3.1.1 | - Reference to the responsibility of the supplier to keep the SDS updated is included. |
| 6.2 | 3.2 | - The information regarding the C&L inventory has been updated. |
| 7 | 4<br>9 | - The information in previous section 4 & section 9 has been streamlined and merged in section 7.<br>- The information regarding the update as a result of an incomplete initial submission has been deleted. This is included now in section 10.3.3 within the completeness check |

| Section (Version 2) | Section (Version 1.6) | Change made |
|---|---|---|
| | | procedures.<br>- The information regarding the change of legal entity has been moved here from previous section 1.5.3.2. |
| 8 | 5 | - The list of cases subject to appeal has been updated to include all cases defined in REACH. |
| 9 | 6 | - Clarification regarding the size of the company to be reported by only representatives is added.<br>- Reference to SME status verification by ECHA is included.<br>- Clarification related to the fee to be paid in the case of update is added. |
| 10.4 | 7.3 | - Information has been added regarding the consequences in case the registrant fails to submit or complete his registration dossier within a set deadline. |
| 10.7 | 7.6 | - Clarification regarding the process in the case of a registration update. |
| Part II | - | - Sections 11, 12, 13 and 14 in Part II provide practical information to registrants on how to prepare and submit a dossier to ECHA. |

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