Guidance on registration

June 2007

Guidance for the implementation of REACH

LEGAL NOTICE

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

PREFACE

This Guidance 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 of the Registration 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 or authorities need to make use of under REACH.

The guidance documents were drafted and discussed within the REACH Implementation Projects (RIPs) lead 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 (http://echa.europa.eu/reach_en.html). Further guidance documents will be published on this website when they are finalised or updated

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PART I

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 in general and registration in particular?
- 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 the Agency?
- When does a registration dossier have to be submitted to the Agency?
- What does it mean to submit jointly with other registrants of the same substance?
- 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 the Agency 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 process are offered, providing references to relevant guidance documents and other useful tools.

All of the references to the relevant Articles, Annexes or legal text quotation from the REACH Regulation are always indicated in italics (i.e. *Article 23*).

Whenever in the text of this document "the Agency" is mentioned it is meant The European Chemicals Agency in Helsinki (ECHA).

Whenever in the text of this guidance "legal entity" is mentioned it is meant a natural or legal person established in the EU and after ratification of REACH under the EEA Agreement, in the European Economic Area (EEA).

Whenever in the text of this guidance an "Annex" is mentioned it is meant an Annex of the REACH Regulation.

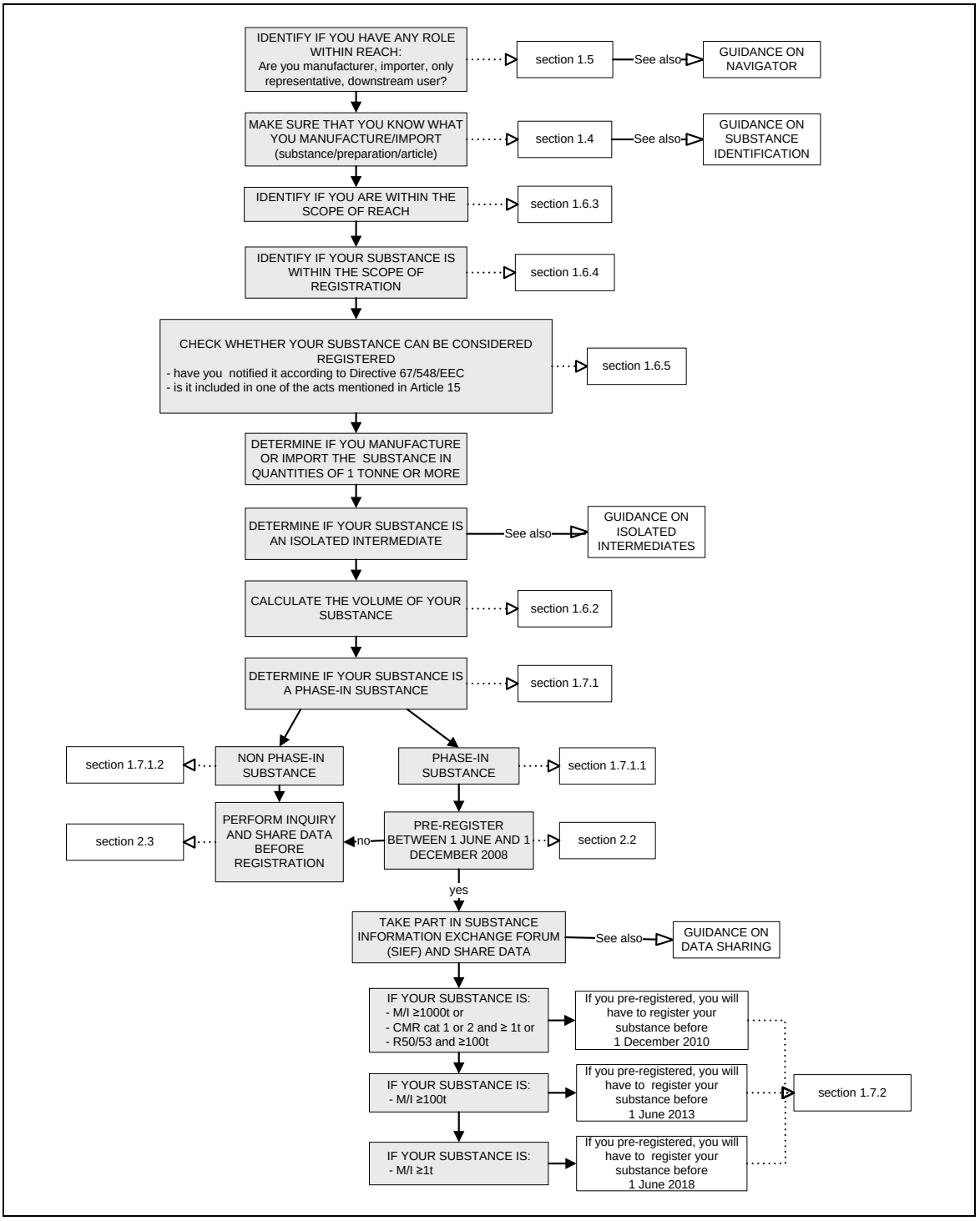
The first part of the document is addressed to all potential registrants with and without an expert knowledge in the fields of chemicals and chemicals assessment. It explains what the registration requirements are, who is responsible for them and how and when they must be fulfilled.

The second part of the document provides detailed guidance on how to prepare and update a registration dossier.

Figure 1 guides the reader within this document, through different steps helping him identifying his registration obligations.

A tool, called the Navigator, has been developed by the Commission services to help the users identifying their obligations under REACH. It can be found on http://echa.europa.eu/reach_en.html .

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



1.2 AIM OF REGISTRATION

In REACH the responsibility for the management of the risks of substances lies with the natural or legal persons that manufacture, import, place on the market or use these substances in the context of their professional activities. Therefore, the registration provisions require manufacturers and

importers to 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 ensure that they actually meet these obligations, as well as for transparency reasons, the registration provisions require them to submit a Registration Dossier containing information in accordance with *Article 10* to the Agency. Registered substances should be allowed to circulate on the internal market (*see Recitals 18 and 19*)."

Unless the regulation indicates otherwise, registration obligations apply to substances manufactured or imported in quantities of 1 tonne or more per year. Normally, the registration must be done 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", see section 1.7.1.1 for the definition of phase-in substances) a special transitional regime applies which allows their manufacture or import to continue (see section 1.7.2 – Deadlines for Phase-in substances.).

1.3 APPROACH IN CHEMICALS ASSESSMENT

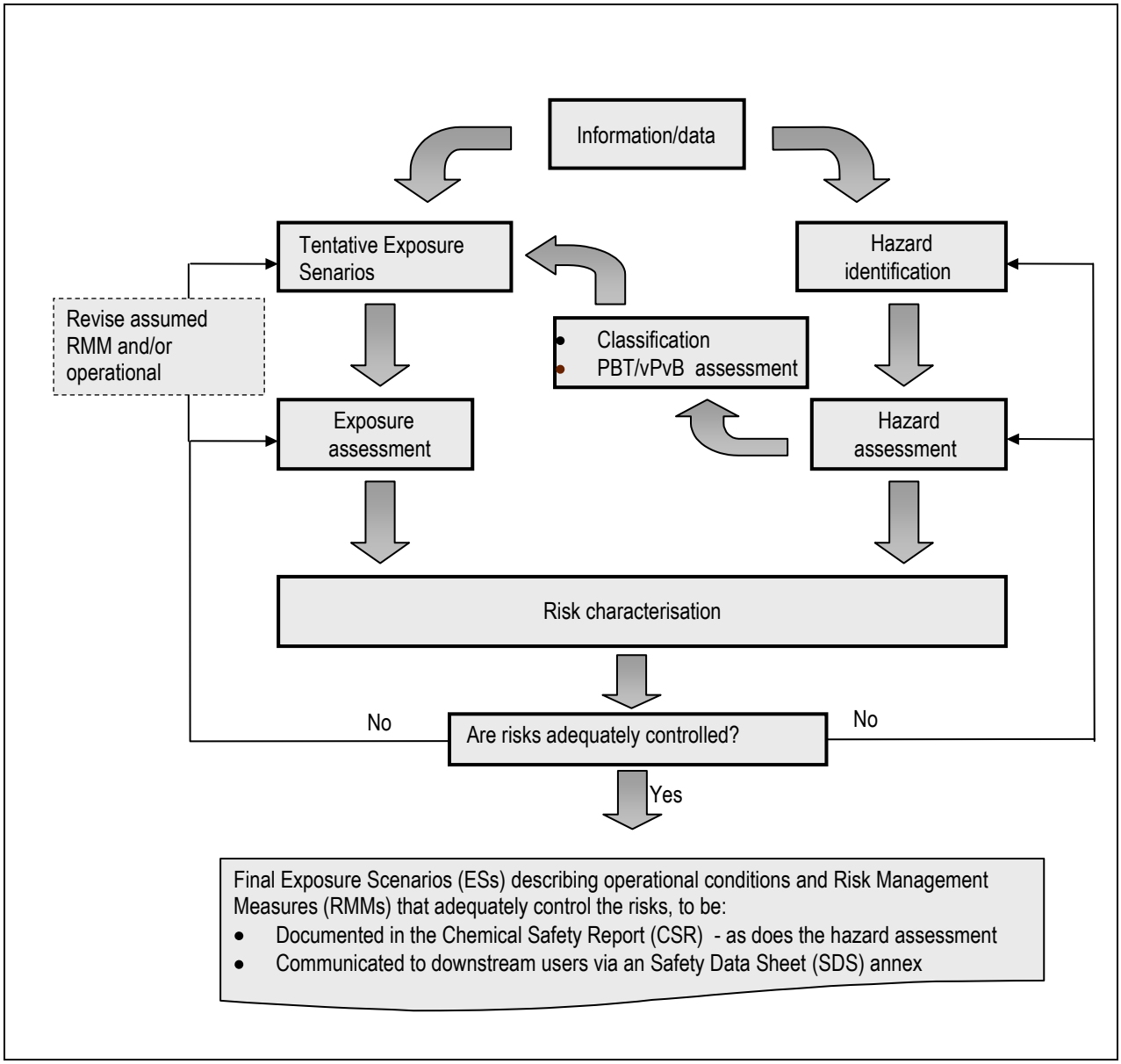
REACH is based on the principle that industry should manufacture, import or use substances or place them on the market in a way that, under reasonably foreseeable conditions, human health and the environment are not adversely affected.

In order to ensure this, manufacturers and importers need to collect or generate data on the substances and assess how risks to human health and the environment can be controlled by applying suitable risk management measures. The responsibility for the management of these risks lies 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 identification of measures required to manage risks is an integrated part of the safety assessment concept. In general this is the result of an iterative process where the aim is to demonstrate how risks identified for the manufacturing or use processes can be adequately controlled by suitable risk management measures. This process includes an assessment of all available relevant information on the hazardous properties of a substance and on the conditions under which it is used. For all substances that are manufactured or imported in volumes greater than 10 tonnes per year, a more formal Chemical Safety Assessment needs to be carried out and documented in a Chemical Safety Report.

The principles of the safety assessment concept are summarised in **Figure 2**. More detailed explanations on the conditions under which the Chemical Safety Assessment needs to be carried out as well as details on the contents of the individual steps are provided in Section II of this guidance document.

Figure 2 Principles of the Chemical safety Assessment (CSA)



PBT – Persistent, Bioaccumulative, Toxic substances; vPvB – very Persistent and very Bioaccumulative substances

Information/ data

The starting point for the chemical safety assessment is the gathering of all available data on the hazard of the substance and information on its manufacture and uses, as well as human and environmental exposures occurring in relation to the conditions under which the substance is used.

Hazard identification, Hazard assessment, Classification, PBT and vPvB assessment.

Based on the available data the hazard of the substance is identified and assessed including determination of its classification in accordance with Directive 67/548/EEC, establishment of *Derived No Effect Levels* (DNELs) for relevant routes of human exposure and *Predicted No Effect Concentrations* (PNECs) for environmental targets. In addition, an assessment of the persistency, bio-accumulative and toxic properties of the substance is performed to conclude whether or not the substance fulfils the criteria given in *Annex XIII* of REACH (PBT, vPvB assessment).

Exposure assessment

The conduction of an exposure assessment is required for substances meeting the criteria for classification as dangerous or assessed to be a PBT or vPvB substance and is a prerequisite for conducting a risk characterisation. However, the collection and assessment of use and exposure information will also be useful for the registrant to identify whether he falls under any specific regime for registration (e.g. intermediates) or whether this information can be used to waive any information required. Hence, even for substances that are not (yet) classified, the registrant may decide to focus first on gathering and assessing his use and exposure information. If a given test is waived according to the principles set out in REACH *Annex XI.3*, an exposure assessment is also required.

The exposure assessment consists of two steps: the generation of exposure scenario(s) (ESs) and estimation of exposure for each ES developed (see section 8.2.3.2). The exposure estimation is based on the ES, which provides a set of parameters that are the main drivers of exposure. The ES is a placeholder of these parameters and contains specifications of the conditions of the use. The conditions of use cover Operational Conditions (OC) (e.g. the applied amount of substance, duration of use, process temperature, pH etc.) and Risk Management Measures (RMM) (e.g. exhaust ventilation, waste water treatment plant, personal protective equipment), which the registrant has implemented or, where relevant, recommends the Downstream User(s) to implement. The first 'tentative' ES will normally reflect the current practice (current OCs and RMMs).

The exposure assessment needs to consider all life-cycle stages of the substance resulting from the manufacture and identified uses and covers each human population and environmental compartment known to be, or supposed to be, exposed.

Risk Characterisation

In the risk characterisation the exposure of each human population and environmental compartment being exposed are compared with the appropriate DNEL or PNEC. Concern is indicated if the estimated exposure is higher than the appropriate DNEL or PNEC.
If the first estimate indicates risks, the registrant has a choice to either

- refine the hazard assessment by obtaining more data;
- refine the exposure assessment by ensuring that the exposure estimation is realistic and reflects the use conditions defined in the initial Exposure Scenario (ES). Models or monitoring data can be used to this end; or
- refine the ES by introducing more stringent RMM or changing the OC in the ES.

This iteration continues until it can be demonstrated that risks are adequately controlled.

It should be noted that for some substances, it is not possible to derive a DNEL or PNEC. This may be due to lack of data or due to specific properties of the substance (including so-called non-threshold effects like some types of carcinogenicity as well as substance with PBT/vPvB properties). In these situations, the same basic steps as set out have to be followed in deriving appropriate ES, but the risk characterisation will be more qualitative and/or semi-quantitative.

Further guidance on iterative nature of Chemical Safety Assessment process will be available in the Guidance on the Chemical Safety Report.

Final exposure scenario and communication in SDS

The final output of this process is an ES that specifies the conditions of use (RMMs and OCs) where risks are adequately controlled for the manufacturing and use processes covered by this ES. This is, if required, summarised and communicated in an exposure scenario attached to the Safety Data Sheet that is provided to the user in the supply chain of the substance (see section 8.2.3.2).

1.4 SUBSTANCES, PREPARATIONS AND ARTICLES

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

- **Substance** means a chemical element and its compounds. The term substance includes both substances obtained by a chemical manufacturing process (for example formaldehyde or methanol) and substances in their natural state (for example dried lavender heads). 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 where the distinction is made between the three following types of substances: mono-constituent substances, multi-constituent substances and UVCB substances.
    - A mono-constituent substance is a substance, defined by its quantitative composition, in which one main constituent is present to at least 80% (w/w).
    - A multi-constituent substance is a substance, defined by its quantitative composition, in which more than one main constituent is present in a concentration ≥ 10% (w/w) and < 80% (w/w). A multi-constituent substance is the result of a chemical reaction in a manufacturing process. A multi-constituent substance is named as a reaction mass of two or more main constituents.
    - A UVCB substance (substances of **U**nknown or **V**ariable composition, **C**omplex reaction products or **B**iological materials) cannot be sufficiently identified by its chemical composition, because: the number of constituents is relatively large and/or the composition is, to a significant part, unknown and/or the variability of composition is relatively large or poorly predictable. As a consequence, UVCB substances require other types of information for their identification, in addition to what is known about their chemical composition.
- **Preparation** *means a mixture or solution composed of two or more substances* (Article 3(2)). Typical examples of preparations include paints, varnishes, inks. Preparations can contain several substances. Preparations are not the same as multi-constituents substances. The difference between preparation and multi-constituent substance is that a preparation is gained by blending of two or more substances without any chemical reaction occurring, whereas a multi-constituent substance is the result of a chemical reaction. REACH obligations apply individually to each of those substances depending on whether the individual substances are within the scope of REACH. Within the Globally Harmonised System for classification and labelling (GHS), a preparation is named a "mixture"[1].

1 Definition in GHS: “Mixture means a mixture or solution of two or more substances which do not react”

- An **article** is the term for any object that has been given a specific 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). The same requirements apply to new and used imported articles. Detailed guidance on articles and how they are dealt with under REACH can be found in the Guidance for articles.

As stated above, only substances have to be registered, preparations or articles do not.

When contained in a preparation, each individual substance needs to be registered, either by the substance manufacturer or the importer of the substance or preparation when reaching the threshold of 1 tonne per year. On the other hand, substances that have been registered by the manufacturer or the importer and that are being mixed into a preparation by a downstream user, do not need to be registered again by the downstream user.

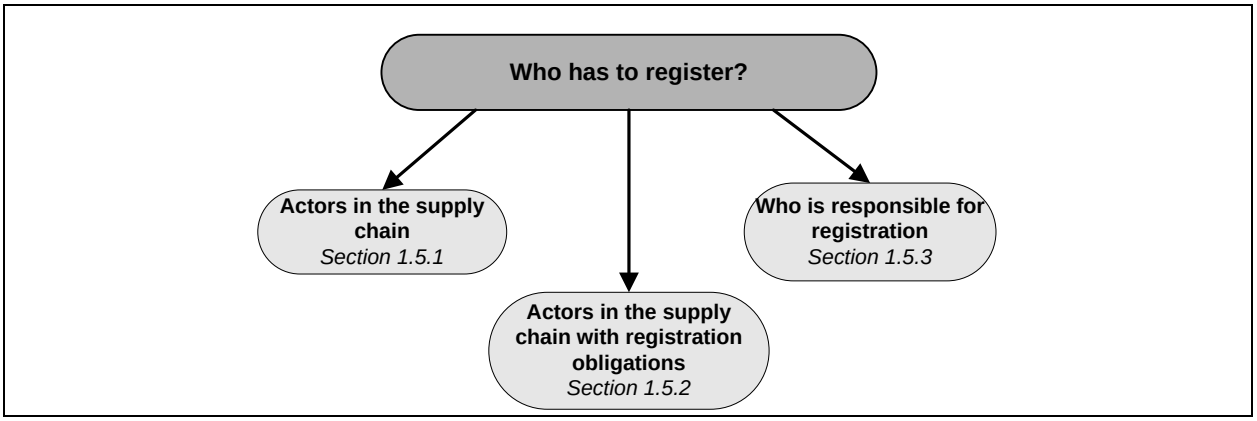
Individual substances in articles are also potentially subject to registration under certain circumstances as detailed in the Guidance for articles.

This document therefore focuses on the registration of **substances** alone or in preparations, and to substances in articles under certain conditions.

1.5 WHO HAS TO REGISTER?

Aim: The aim of this chapter is to explain which actors in the supply chain have registration obligations and responsibilities

Structure: The structure of this chapter is as follows:



1.5.1 Actors in the supply chain

The obligation to register a substance applies only to some actors in the EU. Before explaining the obligations of registrants under REACH, it is important to have a clear understanding of each of the 'actors in the supply chain' and their various roles and responsibilities.

One legal entity (see section 1.5.3.1) may have various roles depending on its activities, even for the same substance (e.g manufacturer and importer or manufacturer and downstream user). 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.

Therefore, for each substance a company has to define its role or roles under REACH

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

Manufacturing: means production or extraction of substances in the natural state (Article 3(8)). It is a case by case decision to establish which steps of the synthesis of the end product lead to substances which need to be registered (e.g. different purification or distillation steps).

Importer*: means any natural or legal person established within the Community who is responsible for import (Article 3(11)).*
Import: means the physical introduction into the customs territory of the Community (Article 3(10)). In other words, all substances on their own, in preparations or in articles manufactured or produced outside the European Community and put in the European market are considered as imported.

Downstream user*: means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, 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)).

An important point to bear in mind is that the terms used in REACH to describe the various actors in the supply chain 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 preparations (e.g. paints) would be regarded as a downstream user. 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.

Customs boundaries for Manufacture and Import:

Iceland, Liechtenstein, Norway and Switzerland are members of the **European Free Trade Agreement** (EFTA). The EFTA Convention established a free trade area among its Member States in 1960. Iceland, Liechtenstein and Norway entered into the Agreement on the **European Economic Area** (EEA) in 1992, which entered into force in 1994. Therefore, the EEA is composed of Iceland, Liechtenstein, Norway and the 27 EU Member States.

As soon as REACH is implemented by the EEA EFTA-States (which means EFTA States covered by EEA agreement), imports from Norway, Iceland and Liechtenstein will be considered as intra-Community trade for the purposes of REACH. EFTA is preparing a proposal for an EEA Joint Committee Decision, incorporating the Regulation and establishing the conditions for the EEA EFTA participation in the EU Chemicals Agency. EFTA is targeting to have the Regulation incorporated by 1 June 2008. Therefore an importer of a substance from an EEA country would not be required to register the substance under REACH and would simply be regarded as a downstream user. However, his supplier in the EEA EFTA-States will have to register the substance as a manufacturer under REACH with all associated obligations like any other manufacturer within the EU.

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

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 will be considered as an Importer.

1.5.2 Actors in the supply chain with registration obligations

The only actors in the supply chain with registration obligations are:

- EU **manufacturers and importers of substances on their own or in preparations**.
- EU **producers and importers of articles** meeting the criteria explained in the Guidance for articles.
- EU-based **"only representatives**" appointed by a manufacturer, formulator or article producer outside the EU to fulfil the registration obligations of importers.

Although polymers are exempted from registration, manufacturers or importers of polymers have, in certain circumstances, registration obligations (see e.g. Guidance for polymers for further information)

Please note that after ratification of REACH by the EEA EFTA-States, the actors of those countries will have the same obligations as the EU actors.

Only representatives of non-EU manufacturers

Registration of substances imported into the EU on their own, in preparations or, in certain cases, in articles will have to be done by the EU importer. This implies that each individual importer needs to register the substance. However, manufacturers of substances, formulators of preparations or, if the substances in their articles are required to be registered, producers of articles outside of the EU who export to the EU can nominate an **only representative** located within the EU to carry out required registration of the substance they export to EU. The only representative will have to comply with all obligations of importers under the registration title of REACH.

A non EU manufacturer will therefore appoint an only representative so that this only representative registers the full volume of the substance exported to EU by this non EU manufacturer, taking into account all uses from the importers of this non EU manufacturer. An "only representative" should have sufficient background in the practical handling of substances and the information related to the relevant substances to fulfil the obligations of a registrant (importer). In this case, all importers will be regarded as downstream users of the only representative.

The only representative can represent one or several manufacturers, formulators or producers of articles outside of the EU and exporting to the EU.

Who is an only representative?

According to *Article 8(1) "A natural or legal person established outside the Community who manufactures a substance on its own, in preparations or in articles, formulates a preparation or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on importers under this Title".*

When the registration is submitted by an "only representative" he will have to enclose (a) copy(ies) of the letter of the non-EU manufacturer(s) officially assigning him as "only representative". For phase-in substances the "only representative" will also have to pre-register the substance and will

subsequently become participant of the Substance Information Exchange Forum (SIEF) (see Guidance on data sharing).

Moreover, an "only representative" will have to keep available and up-to-date information on quantities imported, the list of EU customers of the exporter he represents, as well as information on the supply of the latest update of the safety data sheet. The non-EU manufacturer has to inform all the EU importers in the same supply chain that he has appointed an EU representative as his "only representative".

The only representative is legally responsible for his registration. Nevertheless, it can be anticipated that in most cases, it will be the non EU exporter who will provide him with all necessary data for his dossier. If a non EU manufacturer decides to change his only representative, the newly appointed only representative can, in agreement with the former only representative, update the registration dossier, by changing the registrant identity, and if necessary any other issues (e.g. change of tonnage band).

Example of when registration is needed:

- A manufacturer of a substance who uses the manufactured substance himself is a manufacturer and a downstream user. He 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 preparation has to register those substances which are present in the imported preparation 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 preparation. There is no obligation for importers of preparations to register the preparations themselves; indeed preparations cannot be registered.

Example of when registration is NOT needed:

- Any person, who is using substances which he has not manufactured or imported, is a downstream user and has no obligation to register these substances.
- An importer of a substance, a preparation 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 Title II of REACH has no obligation to register that substance.

1.5.3 Who is responsible for registration

It should be noted that only a natural or legal person established in the European Union can be a registrant. Because Community law does not operate a complete harmonisation of civil and company law, it is the national law of each EU Member State which provides when one is faced with a natural or legal person. The following guidance may be useful:

- 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" (in French "succursales") 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 be established in the EU to respect the provisions of REACH.
On the other hand, a legal person can also open "daughter companies" or "subsidiaries" in the EU (in French "filiales") 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 this guidance the term legal entity is used to refer to such a natural or legal person having rights and obligations under REACH.

1.5.3.1 Legal entity

Each legal entity established within the Community manufacturing or importing a substance is required to submit its own registration.

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 registrations. However, they need to submit parts of the dossier jointly, as outlined in section on Joint submission of data by multiple registrants (see section 1.8.4). 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 of situation:

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.

1.5.3.2 Consequences of changes in legal entities

When there is a change in the details of a legal entity such as a merger, spin-off, bankruptcy, acquisition, business partially sold, change of address or contact details, then in accordance with the provisions of *Article 22,* the registrant, without any undue delay, shall update the registration dossier. When updating the registration dossier he has to state that the update is linked to a "change of company identity". In the case of a merger where the individual legal entities have previously registered the same substance, attention has to be paid that if the total tonnage of the manufactured/imported substance after the merger reaches a higher tonnage band, then the registration dossier has to be updated accordingly.

If a registrant has ceased the manufacture or import of the substance, or the production or import of an article, he shall inform the Agency of this fact with the consequence that the registered volume in his registration, if appropriate, shall be put to zero. He should keep the relevant information for 10

years after last manufacture and make it available on request. In the case when he restarts the manufacture or import of the substance or he restarts the production or import of the article he has to notify the Agency accordingly.

1.5.3.3 Who is responsible of the registration in case of import?

In case of import (see definition in section 1.5.1, 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 but only acting as a kind of facilitator, a letter-box transmitting an order from a buyer to a 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 purposes of REACH. The sales agency is not responsible for the physical introduction of the goods.

The non-EU manufacturer or supplier, who is exporting the substance or preparation, has no responsibilities under REACH, and the shipping company that is transporting the substance or preparation is exempt from REACH (*Art. 2(1)(d)*).

1.5.3.4 Role of Industry associations and other types of service providers

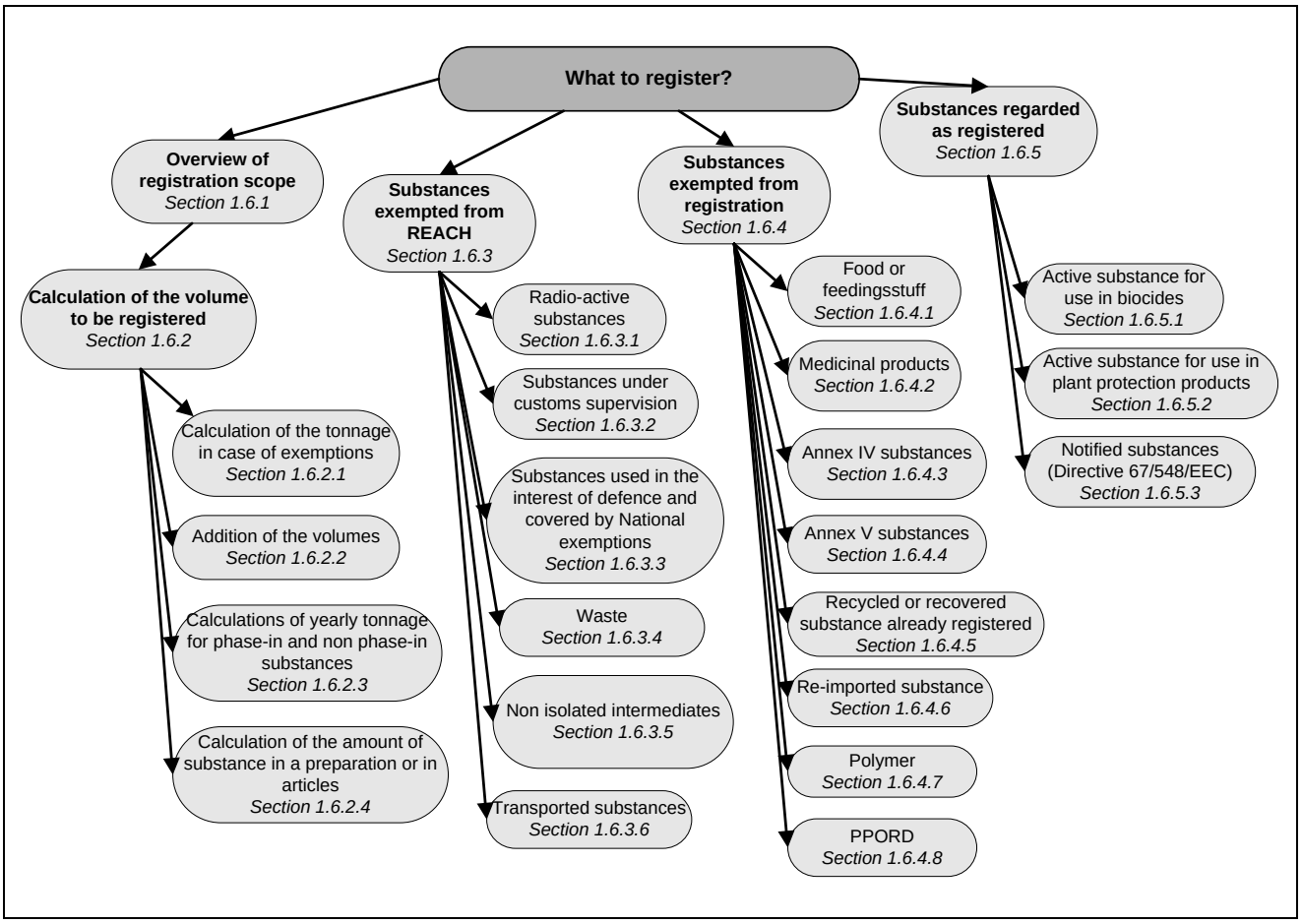
The actual registration can only be done by the manufacturer, importer or producer of an article or only representative and cannot be done by any third party including Industry associations, unless they act as the only representative for one or more non-EU companies.

However, Industry associations can provide very valuable assistance to registrants for the preparation of registration dossiers, and can help co-ordinating the process. In addition they may have valuable data on the substance that could be submitted to the SIEF (cf. Guidance on data sharing). 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.

1.6 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:



1.6.1 Overview of registration scope

The basic definition of a substance is a very broad one which includes not only potentially hazardous industrial chemicals, but every type of chemical substance manufactured in or imported into the EU. It therefore includes substances which are already closely regulated by other legislation such as medicines, biocides, pesticides, cosmetics or radioactive substances. Because of this, there are some complete or partial exemptions from REACH requirements.

Registration is required for all substances manufactured or imported in quantities of 1 tonne or more per year unless they are explicitly exempted from the scope of registration. This requirement applies irrespective of whether the substances are classified as hazardous or not. A technical dossier shall be prepared for all registrations and a chemical safety report (CSR) is required if the quantity manufactured or imported reaches or exceeds the 10 tonnes per year threshold. For substances manufactured or imported in quantities between 1 tonne per year and 10 tonnes per year some specific exposure information will have to be provided in addition to the information in the technical dossier.

Completely excluded from REACH are radioactive substances; substances under customs supervision and non-isolated intermediates. Waste is specifically exempted. A number of other substances are exempted from parts of the REACH provisions, where other equivalent legislation applies (for example substances used in medicinal products). In addition, polymers are exempted from registration, substances used for process and product oriented research and development only require a notification, non-isolated intermediates are excluded from REACH (but a special regime applies for the registration of isolated intermediates).

In addition, certain identified (categories of) substances and substances from certain identified processes, which are considered as causing minimum risk to human health and the environment, are exempt from registration. These substances are typically of natural origin and the list of exempted substances includes, for example, corn oil and nitrogen. *Annex IV* and *V* describe these substances and more guidance is given in sections 1.6.4.3 and 1.6.4.4. The Commission will carry out a review of these two annexes by 1 June 2008 with a view to proposing amendments, if appropriate.

1.6.2 Calculation of the volume to be registered

There are different rules to be applied on how to calculate a yearly tonnage for the registration dossier for phase-in and non phase-in substances (see *Article 3(30)*). The paragraphs below describe how to calculate the volume (tonnage value) to be used in order to decide whether a registration must be submitted for a substance (the threshold being 1 tonne per year), what are the information requirements that have to be fulfilled (in accordance with the different annexes) as well as, in the case of phase-in substances, to identify when the registration of the substance is due.

1.6.2.1 Calculation of the tonnage in case of exemptions

In principle a registrant needs to calculate the total volume of the substance he manufactures or imports and based on that decide whether the registration must be submitted and within which tonnage band. However if certain **exemptions to registration** apply to the specific substance, the potential registrant does not need to include those quantities in his calculation to determine the volume he has to register.

- Some substances or specific uses of some substances are totally exempted to registration. These exemptions to registration can be found in section 1.6.3.

Example 1: When a use is exempted from registration
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 count the quantities for the other uses. E.g., company A is a manufacturer manufacturing 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 preparation. The 50 tonnes used for the formulation of the preparation will be subject to the provisions of the REACH Regulation, while the 70 tonnes used in medicinal products are exempted from registration under REACH Regulation. As the total tonnage to be counted for registration purposes is 50 tonnes, the company must register in the 10-100 tonnes band.

- Substances manufactured or imported for the purpose of Product **and Process Orientated** Research **and Development (PPORD)** can also be exempted from registration under certain conditions (see Guidance for PPORD) as long as a PPORD notification is submitted to the European Chemicals Agency and any conditions set by the Agency are fulfilled (see *Article 9*).

Example 2: Tonnage to consider for the registration dossier in case of PPORD use
If a company manufactures 11 t/a of a substance, of which 2.0 t/a are for PPORD, the registration obligation is defined by the 9.0 t/a, i.e. the information requirements in *Annex VIII* do not pertain.

- Manufacturers or importers of **isolated intermediates** can, under certain conditions (see Guidance for intermediates) submit a registration dossier containing a limited set of information (see *Article 17* and *18*).

When a substance is manufactured or imported for several of these uses (for PPORD, as intermediate and for other uses) the registrant has the possibility to submit:

- one notification dossier for the use under PPORD
- one registration dossier covering both the use as isolated intermediate and the other uses. If the manufacture or use(s) as intermediate are not under strictly controlled conditions, then the manufacturer or importer needs to submit a "standard" registration dossier according to *Article 10*. If part of the tonnage manufactured or imported is for uses as intermediate under strictly controlled conditions, this tonnage will not need to be taken into account for the information requirement of the registration dossier. Nevertheless the use as intermediate should be documented in the dossier, including the volume manufactured or imported for this purpose.

Example 3 Tonnage to consider for the registration dossier
A company manufactures 2300 tonnes of substance A, of which 1700 tonnes are used as intermediate in strictly controlled conditions. This company will submit a registration dossier for substance A, where the volume of the remaining 600 tonnes not used as intermediate is used to determine the information requirements. This means that the information requirements for 100-1000t substances will be used as a basis for this dossier. The fact that the substance is also used as an intermediate should be indicated in the dossier and the volume of 1700 tonnes used as intermediates will also need to be documented in the dossier.

1.6.2.2 Addition of the volumes

In any case, it will be necessary to sum up all volumes of the substance that are intended to be manufactured and imported by the given registrant and that are not exempted from registration. This means, for example, that if a substance is imported in several preparations, the volumes of the substance in each preparation (calculated using the amount of the substance present in these preparations) will have to be added.

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 substance to be registered is the total of the volumes of the substance manufactured and/or imported at the different sites, because the sites are not separate legal entities.

Moreover, if a substance manufactured by a single non EU-manufacturer is imported in several articles from which it is intended to be released, the potential registrant needs to sum up all volumes 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 whole amount present in that article needs to be counted and not only the amount intended to be released.

Example:
If a company X imports 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, 40 out of 60 tonnes are released under normal conditions
- in article C 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.

1.6.2.3 Calculations of yearly tonnage for phase-in and non phase-in substances

Tonnage for **non phase-in substances** in the registration dossier

The volume of a non-phase-in substance to be reported in a registration dossier is the estimated quantity that is expected to be manufactured and/or imported in the calendar year (1 January – 31 December) of registration (see *Article 3(30)*). The definition of non phase-in substances can be found in the section 1.7.1.2.

Calculation of the tonnage for the registration of **phase in-substances** that have been pre-registered

The definition of **phase-in substance** can be found in section 1.7.1.1.

In the case of a phase-in substance that has been imported or manufactured for at least three consecutive years, the quantities per year shall be calculated on the basis of the average production or import volumes for the three preceding calendar years (see *Article 3(30)*). If the substance has not been manufactured or imported for 3 consecutive years then the calendar year tonnage 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. This value is to be used for the purpose of pre-registration as well as for registration. The highest yearly tonnage calculated after 1 June 2007 determines the deadline for registration. To know more about registration deadlines for phase in substance see section 1.7.2

Example 1:
If a company, based on its manufacture previsions, has determined that it should register a phase-in substance by the 1st June 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 according to *Article 23* can be confirmed based on the highest tonnage calculated starting in 2007.

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

The tonnage for 2013 (calculated as the average over 2010-2012) has to be used in the registration dossier.

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 the 1st June 2007. The tonnage to take into account in the registration dossier will be the 2013 tonnage calculated as the average over 2010-2012.

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/year, but the "3 year-average" tonnage in 2011 is 1433 tonnes/year. In this case the 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 at 30 November 2010.

1.6.2.4 Calculation of the amount of substance in a preparation or in articles

Specific situations may occur for substances present in preparations of in articles:

Amount of a substance in a preparation

In order to be able to calculate the amount of a substance in a preparation, the total volume of the preparation is multiplied by the fraction of the constituent substance. This value can for example be obtained from the safety datasheet of the preparation. When only a range of concentrations of a substance in a preparation is available then the maximum volume of the substance is calculated using the highest possible content of that substance in the preparation. Without more precise information on the composition, this volume should be used for the purpose of registration.

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.

1.6.3 Substances exempted from the REACH Regulation

1.6.3.1 Radio-active substances

Radio-active 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.

Radio-active substances were already exempted from notification under Directive 67/548/EEC on classification, packaging and labelling of dangerous substances, and the REACH Regulation exempts them from its application altogether. The reason for this exemption is that there is specific legislation applicable to them, so that there is no need to apply the REACH Regulation in addition.

Legal reference: Article 2 (1) (a)

1.6.3.2 Substances under customs supervision

If substances (on their own, in a preparation or in an article) in temporary storage, in transit, in a free zone or in a free warehouse on the EU territory are only transiting through the EU and remain under customs supervision while waiting to leave the EU, they are not subject to the provisions of the REACH Regulation.

Importers of substances meant to leave the EU again, who wish to rely on the exemption from REACH are therefore advised to ensure that the substances, while on the EU territory, 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 (including formulation, consumption, filling into containers, transfer from one container to another, mixing or production of an article) during their stay in the EU. For that purpose a free zone or a free warehouse on the EU territory is regarded as being part of the EU.

In the 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 community customs code which may be applied to substances merely passing through the EU.

Legal reference: Article 2 (1) (b)

1.6.3.3 Substances used in the interest of defence and covered by National exemptions

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

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

At the time of writing this guidance, no Member States had fixed an exemption in the interests of defence. It can be expected that Member States who decide on such an exemption will inform their suppliers concerned; however, if in doubt, manufacturers, importers and producers of preparations 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 was granted which may cover their substance, preparation or article.

Legal reference: Article 2 (3)

1.6.3.4 Waste

Waste is 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 industry (e.g. tires, slag, window frames that are discarded).

The REACH Regulation does not exempt waste from its provisions, but clarifies that waste is not a substance, a preparation or an article within the meaning of REACH. This is because when the holder discards, intends or is required to discard something, it loses its status as a substance, preparation or article which is used by its holder for a specific purpose. For practical purposes, this clarification can be considered as an exemption for waste from the REACH requirements. Note that when a Chemical Safety Assessment is required, this must include the whole lifecycle of the substance including the waste stage (cf. *Annex I, 0.7 and 5.1.1*). If necessary to manage risks from

chemical substances, recommended waste management measures have to be communicated through the supply chain via SDSs (heading 13). However, waste treatment is not a downstream use under REACH and waste treatment operators will not receive SDSs on how to handle the substance during the waste phase. As long as residues from waste treatment operations are waste, i.e. that they are disposed of (e.g., landfilled or stored in salt mines), they do not fall under REACH. Residues which are recovered as any other substances or preparations fall under REACH.

It is important to note that once waste is recovered and in this recovery process another substance, preparation or article is produced, the REACH rules will in principle apply again, as they would to any other substance, preparation or article manufactured, produced or imported in the EU. In specific cases, where a substance which has already been registered is recovered, an exemption from the registration obligation may apply. More guidance on recovery is available in section 1.6.4.5.

Legal reference: Article 2 (2)

1.6.3.5 Non isolated intermediates

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

Non-isolated intermediates falling within the above definition are not covered by 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 intermediate". 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.

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

1.6.3.6 Transported substances

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

EU transport legislation (for example, Council Directive 94/55/EC of 21 November 1994 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road, and relevant amendments) already regulates the safety conditions of transport of dangerous substances by various means of transport and thus such transport is exempted from the provisions of the REACH Regulation.

Legal reference: Article 2 (1) (d)

1.6.4 Substances exempted from registration

The Regulation exempts certain substances that are adequately regulated under other legislation, like medicinal products, or that generally present such low risks as not to require registration, like water, oxygen, certain noble gases, and specific types of cellulose pulp. In other cases substances occurring in nature such as minerals, ores and ore concentrates, cement clinker etc are not required to be registered as long as they are not chemically modified. Although polymers are exempted as well from the requirement to register, since they usually are not very hazardous, it is required to register monomer substances contained in the final polymer in ≥ 2% as monomer units, which have not already been registered and provided that those monomers make up ≥ 1 tonne/year.

The substances exempted from registration are described in detail below.

1.6.4.1 Food or feedings stuffs

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

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, feed for animals 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, feeding stuffs additives and animal nutrition, specific pieces of Community legislation already create a system for authorisation of substances for those particular uses. Therefore, registration under REACH would have little added value.

Accordingly, it is in the interest of manufacturers and importers of substances which may be put to food - or feeding stuffs-related uses to be aware if their own legal entity or their clients actually use the substance in food or feeding stuffs in accordance with the Food Safety Regulation, since in that case they will not have to register this use or obtain authorisations, at least for the quantities of the substance which are used in this way. Thus, if a downstream user makes such a use known to his supplier in accordance with *Article 37(2)*, he should be advised to consult the Food Safety Regulation.

Note however that quantities of the same substance may be used for other uses than food and feeding stuffs, so those quantities are not exempted. Only the quantities of the substance used in food and feeding stuffs are exempted from the registration obligation under REACH.

> **Example:**
> A manufacturer manufactures 100 tonnes of sulphuric acid in year X. 50 tonnes are used to produce foodstuffs in accordance with the Food Safety Regulation, 50 tonnes are used for the formulation of a non-food preparation. The 50 tonnes used for the formulation of the non-food preparation will be subject to the registration provisions of the REACH Regulation and can, if their properties warrant so, be made subject to authorisation, while the 50 tonnes used to produce foodstuffs are exempted from registration, evaluation and authorisation.

Legal references: Article 2 (5) (b), Article 2 (6) (d)

1.6.4.2 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.

Accordingly, it is in the interest of 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 to produce pharmaceuticals covered by this legislation, since in that case they will not have to register or obtain authorisations, at least for the quantities of the substance used in this way.

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 however that quantities of the same substance may be used for other uses than pharmaceuticals, so those quantities are not exempted. Only the quantities of the substance used in medicinal products are exempted from the registration obligation and REACH authorisation.

Example:
A manufacturer manufactures 100 tonnes of salicylic acid in year X. 50 tonnes are used to produce 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 preparation. The 50 tonnes used for the formulation of the non-medicinal preparation will be subject to the registration provisions and can, if their properties warrant so, be made subject to authorisation, while the 50 tonnes used to produce medicinal products are exempted from registration, evaluation and authorisation.

Legal references: Article 2 (5) (a), Article 2 (6) (a)

1.6.4.3 Substances included in Annex IV of the REACH Regulation

Annex IV currently lists 68 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, corn oil and nitrogen (N_2). 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, but more substances were added. The registration exemption applies to the substance as such, not to a particular use.

The Commission is required, by 1 June 2008, to review this Annex and, if appropriate, propose amendments to it. As this provision may lead to the inclusion of additional substances into Annex IV or the exclusion of substances from it, manufacturers and importers are advised to regularly check the list of substances in *Annex IV*. In the Navigator, a search engine has been implemented to help the user check whether his substance is listed in *Annex IV*.

1.6.4.4 Substances covered by Annex V of the REACH Regulation

Annex V currently lists nine broad categories of substances for which registration is deemed inappropriate or unnecessary. They are exempted from the registration provisions, but not necessarily from authorisation or restrictions. For the full list see below.

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*. For example, for hydrates or hydrated ions, copper (II) sulphate pentahydrate formed by association of copper (II) sulphate with water, will not require registration by its manufacturer provided the copper (II) sulphate was registered (or exempted) from registration.

The Commission is required, by 1 June 2008, to review this Annex and, if appropriate, propose amendments to the Annex. As this provision may lead to the inclusion of additional categories or substances into *Annex V* or the exclusion of categories from it, manufacturers and importers are advised to regularly check the list.

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, preparation or article.*

3. *Substances which result from a chemical reaction occurring upon end use of other substances, preparations 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, cement clinker, natural gas, liquefied petroleum gas, natural gas condensate, process gases and components thereof, crude oil, coal, coke.

8. *Substances occurring 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.*

9. Basic elemental substances for which hazards and risks are already well known: *hydrogen, oxygen, noble gases (argon, helium, neon, xenon), nitrogen.*

1.6.4.5 Recycled or recovered substance already registered

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

Recovery is defined in EU law (Waste Framework Directive 2006/12/EC (Article 1(f)) as one of the operations included in the following list:

- Use principally as a fuel or other means to generate energy
- Solvent reclamation/regeneration
- Recycling/reclamation of organic substances which are not used as solvents (including composting and other biological transformation processes)
- Recycling/reclamation of metals and metal compounds
- Recycling/reclamation of other inorganic materials
- Regeneration of acids or bases
- Recovery of components used for pollution abatement
- Recovery of components from catalysts
- Oil re-refining or other reuses of oil
- Land treatment resulting in benefit to agriculture or ecological improvement
- Use of wastes obtained from any of the operations numbered 1 to 10
- Exchange of wastes for submission to any of the operations numbered 1 to 11
- Storage of wastes pending any of the operations numbered 1 to 12 (excluding temporary storage, pending collection, on the site where it is produced)

The REACH Regulation sets conditions which have to be respected in order to benefit from the exemption, as follows:

(1) The recovered substance must have been registered. This means that if, for some reason, the substance has not been registered at manufacturing or import stage the recovered substance has to be registered following the recovery operation before being put to a new use.

On the other hand, the person who performs the recovery should check whether an exemption applies to the recovered substance. If an exemption applies which frees the recovered substance from the registration obligation, then that exemption can of course be invoked.

(2) The substance already registered must be the same, i.e. have the same chemical identity and properties, as the substance being recovered. For example, if the substance itself was modified in the recovery then the recovered substance has to be registered.

(3) The legal entity who did the recovery must ensure that information on the registered substance is available to it, and that information must comply with the rules on information provision in the supply chain.

This means that the person who did the recovery must have obtained one of the following:

- a safety data sheet, as required by *Article 31 (1) or (3)*, on the registered substance,
- other information sufficient to enable users to take protection measures, as required by *Article 31 (4)*, for the registered substance, or
- an information package comprising the status of the registered substance under the authorisation part of REACH, any applicable restrictions under REACH, other information necessary to allow appropriate risk management measures and the registration number, as required by *Article 32 (1)*.

Companies undertaking recovery operations and wishing to avail themselves from this exemption are advised to ensure as much as possible that the information on the registered substance which was put together to comply with the REACH Regulation, is available to them as well, as otherwise they will have to register the recovered substance.

It is worth noting that this exemption does not require that the substance has been registered by an actor in the same supply chain. Therefore, it is sufficient that a registration was filed for the substance, either by a registrant in the same supply chain or by a registrant in another supply chain.

Note that if the recycled substance is a phase-in substance, it is recommended that the recycler pre-registers that substance in order to benefit from the transitional provisions laid down in Article 23 and eventually be later on exempted from the registration requirements if another pre-registrant registers the substance.

Legal reference: Article 2 (7) (d)

1.6.4.6 Re-imported substance

The registration obligation of *Article 6* applies to manufacturers and importers of a substance, on its own or included in a preparation. However, in cases where a substance is first manufactured in the EU, then exported – for example, to be formulated into a preparation – 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 Community, 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 and evaluation 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 Community. 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.

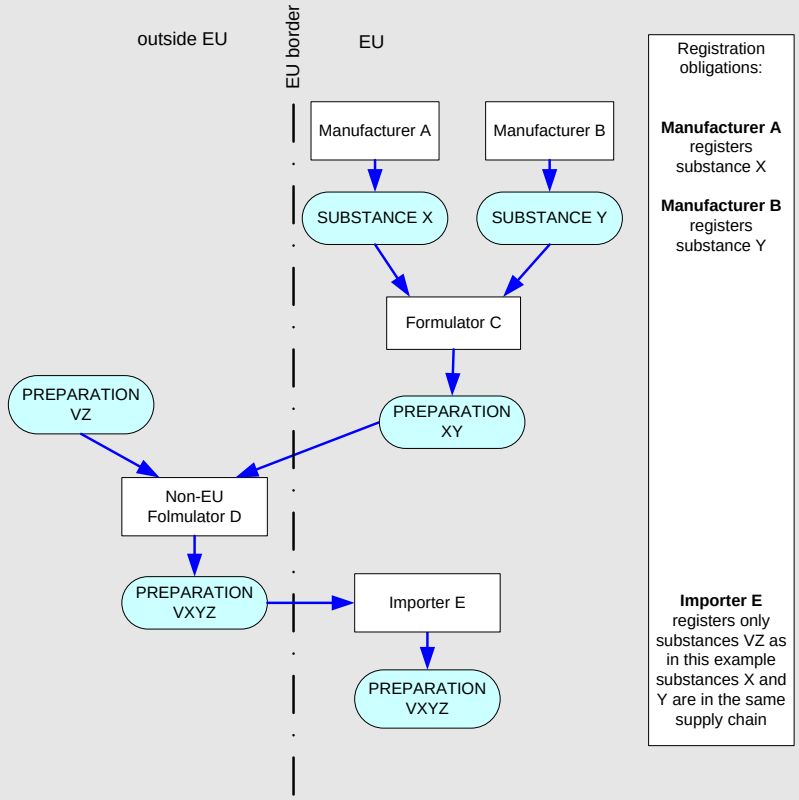
(2) The substance already registered and exported must be the same, i.e. have the same chemical identity and properties, as the substance being re-imported, on its own or in a preparation. For example, if the exported substance itself was modified outside the EU and

therefore it is not the same substance which is now being re-imported, the re-imported substance has to be registered.

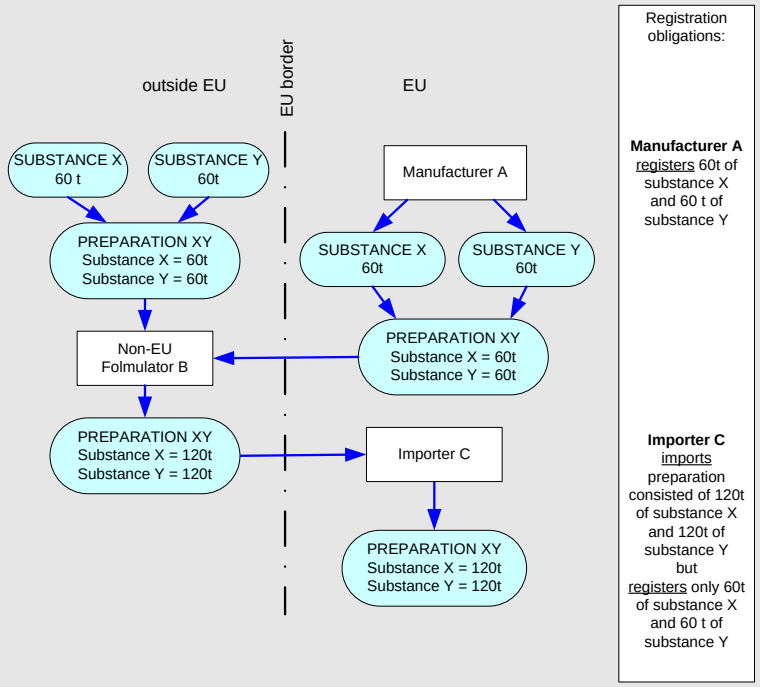
Again, the reason is clear: if the substance does not have the same chemical identity, it has not yet been registered (the registration information will be different), and therefore there will not be duplication of registrations. Note that the re-importer has to be able to prove that the substance is still the same. For more details on substance identification see the Guidance on substance identification.

(3) The substance must not only be the same, i.e. have the same chemical identity and properties, but it must actually be the same batches of the substance which are exported from and re-imported back to the Community (whether or not processed). This is meant by the requirement that the re-importer is "in the same supply chain".

Example (1):



Example (2):



(4) The re-importer must have been provided with information on the exported substance, and that information must comply with the rules of REACH on information provision in the supply chain.

This means that the re-importer must have been supplied with one of the following:

- a **safety data sheet**, as required by *Article 31 (1) or (3)*,
- other information sufficient to enable users to take protection measures, as required by *Article 31 (4)*, or
- an information package comprising the status of the substance under the authorisation, any applicable restrictions, other information necessary to allow appropriate risk management measures and the registration number, as required by *Article 32 (1)*.

Note that the re-importer has to be able to prove that he was provided with one of these pieces of information.

If the re-importer can avail himself of the exemption, he will be considered as a downstream user. Therefore, he is advised to check what downstream user obligations are applicable to him.

Note that the re-import exemption is not available if the substance is being re-imported in articles.

Legal reference: Article 2 (7) (c)

1.6.4.7 Polymer

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 may nevertheless be required to proceed with the registration of the

monomers or other substances used for the manufacture of the polymers. Specific guidance is available for polymers. See i.e. Guidance for polymers.

1.6.4.8 Substances use for purpose of product and process oriented research and development (PPORD)

To support industry's capacity for innovation, one of the objectives of REACH is to promote research and development. This results in a number of exemptions from the obligations under REACH.

Scientific research and development under REACH 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 such research and development is exempted from registration.

Product and process orientated research and development: means any scientific development related to product development or the further development of a substance, on its own, in preparations 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 product and process orientated research and development (PPORD) will receive exemption from **registration** if they are notified to the Agency. The notifier must pay a fee to the Agency when applying for this.

This exemption can be for up to 5 years and applies only to the quantity of substance being used for PPORD by the manufacturer or importer himself in cooperation with a limited number of listed **customers**. The Agency may extend the exemption period for up to a further 5 years (or 10 years in the case of medicinal products or substances not put on the market) upon request, as long as this can be justified by the programme of research and development presented by the applicant.

The Agency will check the completeness of the information supplied by the notifier.

The Agency could 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 Guidance for PPORD.

1.6.5 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:

- active substances in biocidal products as described below,
- active substances in plant protection products as described below ,
- substances already notified in accordance with Directive 67/548/EEC (NONS).

1.6.5.1 Active substance for use in biocides

Active substances for use in biocidal products are regarded as registered as biocidal products and their active ingredients are covered by Directive 98/8/EC (Biocidal Products Directive). To benefit from the exemption, several conditions have to be fulfilled:

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

An active substance in the context of biocides is a substance or micro-organism 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, without co-formulants, or it may be a preparation including one or more active substances.

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

- Annex I to Directive 98/8/EC – this is the list of active substances which are authorised for use 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 are authorised for use 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 are authorised for use as 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.
- 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 one of the active substances on the lists 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, since its manufacturer will not have submitted the required information to allow full assessment under Directive 98/8/EC. 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.

Note however that only the quantities of the active substance for use in biocidal products are exempted from the registration obligation. If they are used in another non-biocidal product, they are not exempted. It means that in the case when a manufacturer who manufactures only for the purpose of biocides puts the same substance on the market but for other purposes (not exempted from registration) he has to prepare a full registration dossier, including all relevant information including, if fulfilling conditions, the Chemical Safety Report (CSR).

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. The latter use is within the scope of REACH and has to be registered; the former use is exempted from registration.

The Agency has been charged with including the information submitted in the framework of Directive 98/8/EC, which is equivalent to registration dossier data, into its databases. This is to ensure that this data can be valorised where appropriate.

Legal references: Article 15 (2), Article 16, Article 56 (4) (b)

1.6.5.2 Active substance for use in plant protection products

Active substances and co-formulants for use in plant protection products (pesticides) are regarded as registered as the plant protection products and their active ingredients and co-formulants are covered by Directive 91/414/EEC (Directive on plant protection products) and in principle undergo a thorough assessment, on the basis of already submitted substantial information, before they can be placed on the market. To benefit from the exemption, several conditions have to be fulfilled:

(1) The substance must be 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, 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, without co-formulants, or it may be a preparation including one or more active substances.

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

Therefore, it appears that all substances contained in plant protection products are eligible for the exemption. However, since only active substances can meet condition (2) below, only active substances can qualify for the exemption.

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

- Annex I to Directive 91/414 – this is the list of active substances which are authorised for use 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 1991 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 and micro-organisms already on the market on 26 July 2003 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 1991 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 however that quantities of the same active substance may be used for other uses than plant protection products, so those quantities are not exempted. Only the quantities of the active substance for use in plant protection products are exempted from the registration obligation. If they are used in another product, they are not exempted. It means that in the case when a manufacturer who manufactures only for the purpose of biocides puts the same substance on the market but for other purposes (not exempted from registration) he has to prepare a full registration dossier, including all relevant information including, if fulfilling conditions, the Chemical Safety Report (CSR).

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 another use. The latter use is within the scope of REACH and has to be registered; the former use is exempted from registration.

The Agency has been charged with including the information submitted in the framework of Directive 91/414/EEC, which is equivalent to registration dossier data, into its databases. This is to ensure that this data can be valorised where appropriate.

Legal references: Article 15 (1), Article 16, Article 56 (4) (a)

1.6.5.3 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 a lot 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. The Agency is instructed to assign registration numbers to notifications considered as registrations. It must do so by 1 December 2008.

Legal entities are therefore 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/EC 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. Moreover in case when the manufacture/import volume of the notified substance reaches the next tonnage threshold as defined in *Article 12*, an update of the registration for that substance will have to be submitted to the Agency. For more details on registration update go to section 4 and 9 of this Guidance Document.

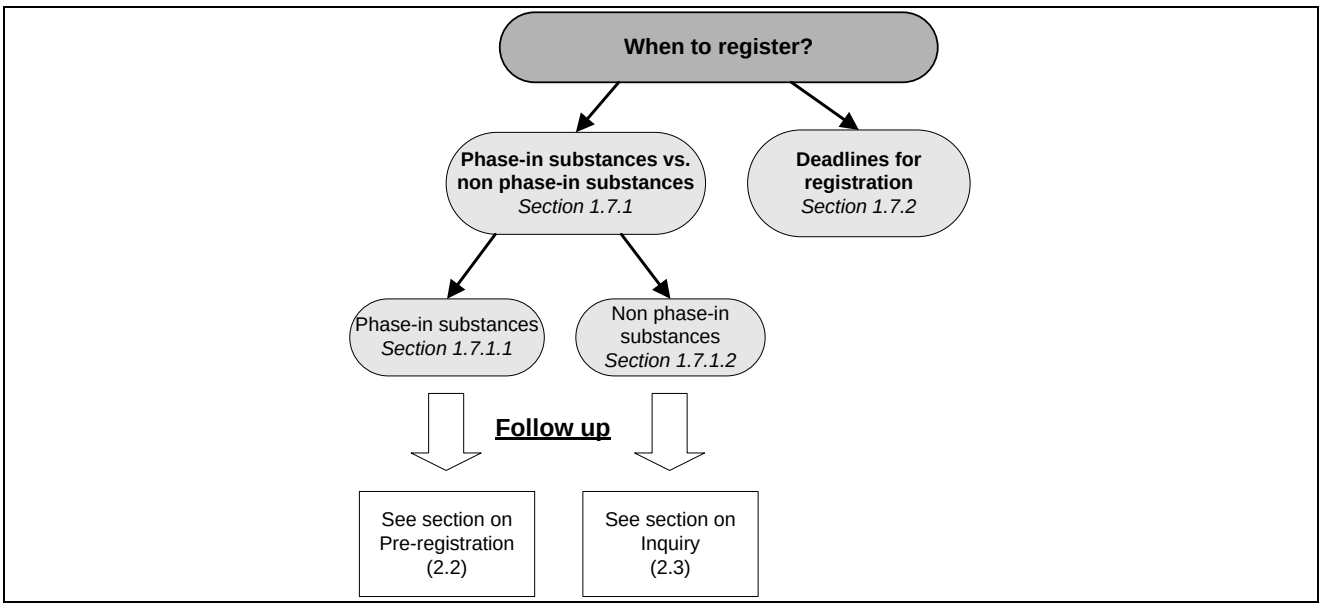
Please note that a notification under Directive 67/548/EC is nominal so that only the notifier benefits from being considered registered; any other parties manufacturing or importing the substance but who have not notified it, must register, unless there is another exemption that applies to them.

Legal reference: Article 24

1.7 WHEN TO REGISTER?

Aim: The aim of this chapter is to inform potential registrants when they should submit their registrations to the 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:



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

1.7.1.1 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 1.7.2.

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 is that the phase-in substance is being pre-registered within between the 1st June 2008 and the 1st December 2008.

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://ecb.jrc.it/esis/. Note that the list has been "frozen" and no more substances can be added to it or removed from it.
- The substance was manufactured in any of the current Member States of the EU (except Bulgaria and Romania), at least once after 31 May 1992, without being placed on the EU market by the manufacturer or importer, 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 was placed on the market, 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". A NLP is a substance which was placed on the EU market between 18 September 1981 and 31 October 1993 inclusive, was considered as notified under Article 8 (1) of the 6th amendment of Directive 67/54/EEC (and hence did not have to be notified under that Directive), but which does not meet the REACH definition of a polymer (which is the same as the polymer definition introduced by the 7th amendment of Directive 67/548/EEC). Also in this case, the manufacturer or importer must have documentary evidence that he placed the substance on the market in the relevant territory and that it was considered as NLP (and as such considered as notified under Article 8 (1) of the 6th amendment). 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://ecb.jrc.it/esis; 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.

Note also that manufacturers and importers of phase-in substances who do not pre-register on time will not be able to benefit from the transitional regime provided for in *Article 23.* Consequently, they will have to register their substance before continuing their manufacture or import as for any non phase-in substances (see section 1.7.1.2), at latest on the 1st December 2008.

Legal references: Article 3 (20)

1.7.1.2 Non phase-in substance

All substances that are not fulfilling any of the criteria for phase-in substances as presented in section 1.7.1.1 are considered as **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 1.6.5.3).

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 2.3.

1.7.2 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 or placed on the market (including import) in the EU. The substances, which have long been on the EU market (phase-in substances), and the non-phase-in substances have **different timelines** for registration.

Substances which have not previously been placed on the EU market (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 1 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 for the registration of phase–in substances have been set based on the volume manufactured or imported per manufacturer or importer or producer of articles. This is based on 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 like carcinogenic, mutagenic and toxic substances (CMR) and substances which are very toxic and may cause long-terms effects in the aquatic environment.

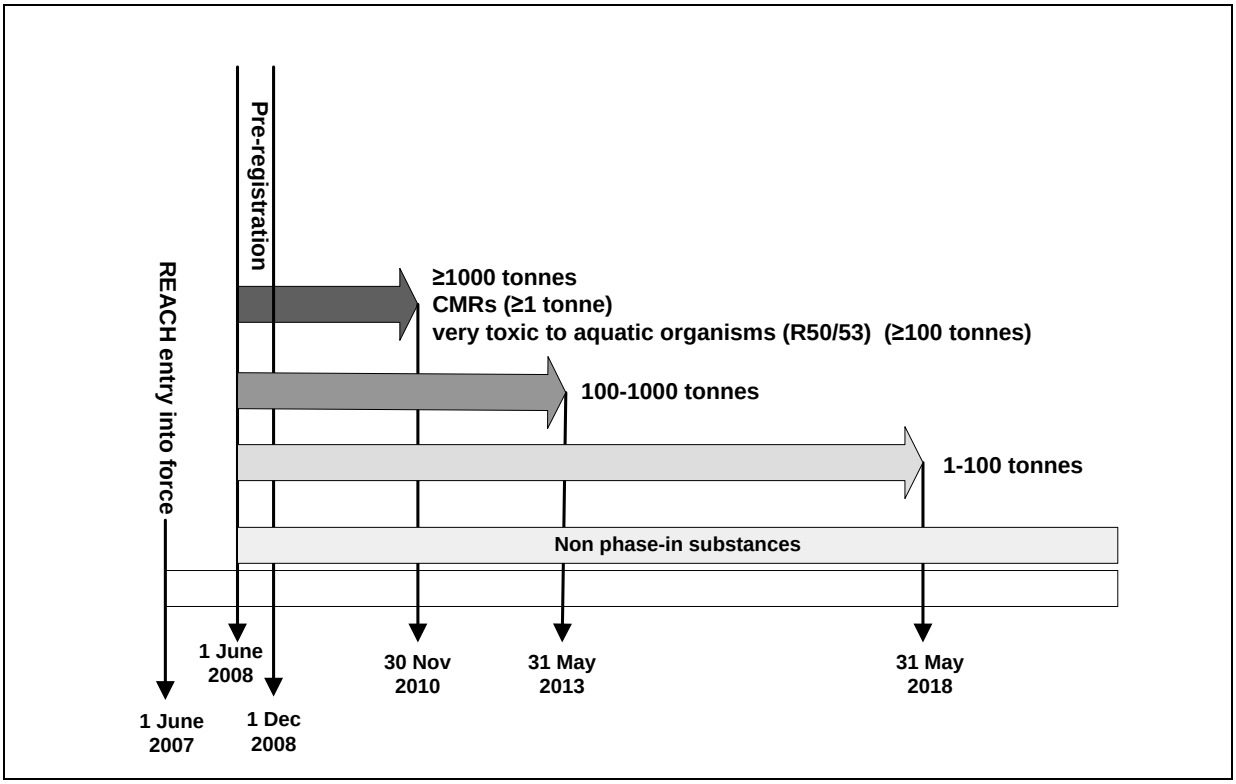
The **'phase-in' deadlines** after entry into force of the Regulation are presented in the following Table:

Deadline to submit registration dossier to ECHA	Criteria for substances
30 November 2010 (at the latest)	Phase-in substances manufactured in the Community 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 the latest)	Phase-in substances classified 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 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 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 the latest)	Phase-in substances manufactured in the Community or imported in quantities of 1 tonne or more per year per manufacturer or per

	importer at least once after 1 June 2007.

Figure 3 is presenting the registration deadlines in a graphical way.

Figure 3 Registration deadlines



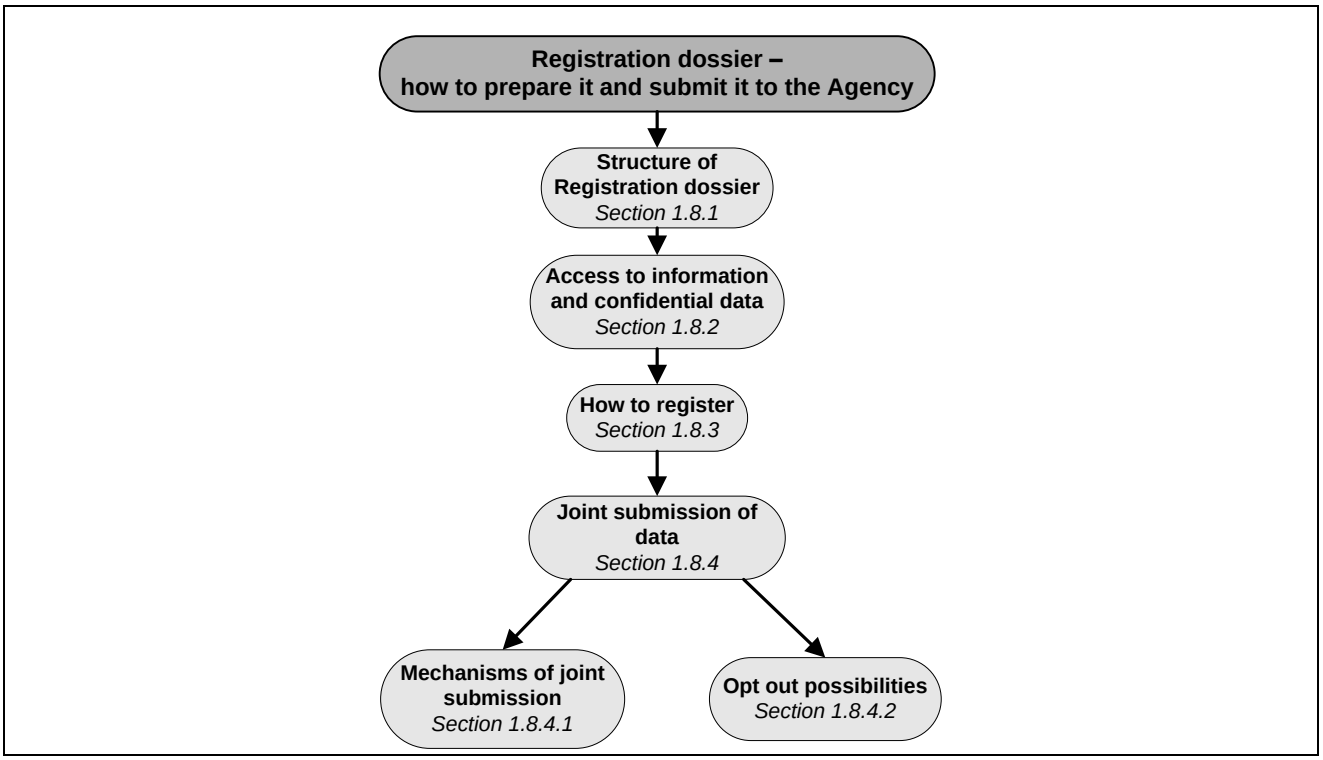
Therefore, if you are a manufacturer or importer of a phase-in substance, your registration deadline will depend on the above tonnage criteria.

Legal references: Article 23

1.8 REGISTRATION DOSSIER – HOW TO PREPARE IT AND SUBMIT IT TO THE AGENCY

Aim: The aim of this chapter is to present the structure of the registration dossier and to explain briefly how to prepare it. It also explains what a joint submission of registration data is and how to submit jointly the registration information to the Agency.

Structure: The structure of this chapter is as follows:



1.8.1 Structure of 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:

(i) a **technical dossier**, always required for all substances subject to the registration obligations,

(ii) a **chemical safety report**, required if the registrant manufactures or imports a substance in quantities of 10 tonnes or more per year, except for substances present in preparations in a concentration below the concentration limits in Directive 1999/45/EC (concerning the classification and labelling of preparations) for which there is no need to submit a CSR with the registration dossier, even if the tonnage is above 10 tonnes per year.

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

- the identity of the manufacturer/importer;
- the identity of the substance and information on the manufacture and use of the substance;
- the classification and labelling of the substance;
- guidance on its safe use;
- (robust) study summaries of the information on the intrinsic properties of the substance derived from applying *Annexes VII* to *XI*;
- 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;
- proposals for further testing, if relevant;
- for substances registered in quantities between 1 and 10 tonnes, the technical dossier shall also contain exposure related information for the substance (main use categories, type of uses, significant routes of exposure).

The information required to determine the properties of the substances varies according to the tonnage in which the substance is manufactured or imported. The higher the tonnage the more information on the intrinsic properties of the substance is required. The information requirements are set out in the Annexes VI to XI of the Regulation. REACH foresees data sharing between registrants to gather the required information.

Article 111 requires that the format of the technical dossier shall be IUCLID (International Uniform Chemical Information Database). This means that also other IT tools could be used to prepare the dossiers as long as they produce the exact same format. In this document only the preparation of the registration dossier using IUCLID is described. The last version of this software is IUCLID 5 which will be used as the reference in this document and for which a specific guidance is available (Guidance on IUCLID). The IUCLID 5 software will be downloadable from the IUCLID website at http://iuclid.eu for free by all parties, if used for non-commercial purposes.

The **chemical safety report (CSR)** is the documentation of the registrant's chemical safety assessment (CSA) for his substance (or of relevant substances if the chemical safety report has been developed for a category of substances having similar properties). Annex I reports general provisions for assessing substances and preparing CSR. This chemical safety report contains a detailed summary of information on the environmental and human health hazard properties of the substance, together with an assessment of exposure and risk where such an assessment is required.

If the substance is classified as dangerous or fulfils the PBT or vPvB criteria in Annex XIII, then an exposure assessment and risk characterisation shall be performed and included in the CSR to demonstrate that the risks are adequately controlled. This exposure assessment is done using exposure scenarios for each use of the substance.

Exposure scenarios are sets of conditions that describe how substances are manufactured or used during their life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment.

Substances manufactured or imported in quantities of less than 10 tonnes per year do not require a chemical safety report, but do require the submission of basic information on exposure.
More detailed guidance on when and how to conduct a CSA and when and how to report it to the Agency can be found in the Guidance on the Chemical Safety Report. That document describes also in more detail the cases when a chemical safety assessment does not need to be performed, such as:

- for a substance present in a preparation in a concentration below the concentration limits that apply for the classification of substances in preparations;
- for on-site or transported isolated intermediates (for more details see the Guidance for intermediates);
- for Product and Process Oriented Research and Development (PPORD) even if manufactured at more than 10 tonnes per year;
- when the specific use of the substance is already regulated under more specific legislation and the substance is therefore exempted from registration (e.g. biocides, pesticides, pharmaceuticals)

For uses in food contact materials and cosmetics, the CSA need not address human health aspects because these are addressed under other legislation.

A more extensive description of the contents of the technical dossier, the guidance on the preparation and submission of the registration dossier and use of IUCLID can be found in Part II of this document and in the Guidance on IUCLID.

Legal references: Article 10, Annex VI and Annex I

1.8.2 Access to information and confidential data

Although the REACH Regulation requires information to be provided to the Agency, and potentially exchanged with the other manufacturers and importers, some provisions to protect commercially sensitive information are foreseen. *Articles 118* and *119* mention information of which disclosure to the public could be harmful to the concerned party's commercial interest.

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 Agency website.
- A registrant may identify certain information in his registration as commercially sensitive in accordance with *Article 10(a)(xi)*. If the justification with regard to information listed in *Article 119(2)* is accepted as valid by the Agency, then this information will be marked as commercially sensitive in REACH–IT. Such information must not be published on the Agency website.
- Access to such pieces of information and other pieces of information may be granted by the Agency on request on a case by case basis whenever this is foreseen in Regulation 1049/2001. Regulation 1049/2001 defines cases in which access to information has to be denied e.g. for reasons related to commercial interests. It also requires the Agency to check with companies that have submitted information to it whether the company claims that the information asked has to be kept confidential. The Agency then has to take a decision.

According to *Article 119(2)* the following information can be claimed commercially sensitive 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, 100-1 000 tonnes or over 1 000 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 are dangerous within the meaning of Directive 67/548/EEC for a period of six years;*
- *the name in the IUPAC Nomenclature for dangerous substances within the meaning of Directive 67/548/EEC 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 Agency 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 preparation;*
- *without prejudice to Article 7(6) and Article 64(2), the precise use, function or application of a substance or preparation, including information about its precise use as an intermediate;*
- *the precise tonnage of the substance or preparation manufactured or placed on the market;*
- *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 the Agency on substances whether on their own, in preparations or in articles, shall be made publicly available, free of charge on the Agency website:

- *the name in the IUPAC Nomenclature, for dangerous substances within the meaning of Directive 67/548/EEC, 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;*
- *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.*

1.8.3 How to register

This section should be developed when the submission module of REACH-IT will be ready. It should explain briefly how the electronic dossier submission will work.

1.8.4 Joint submission of data by multiple registrants

Each manufacturer, importer or only representative is individually obliged to submit a registration for each of his substances. However in cases where a substance is manufactured or imported by more than one company, they are required to submit certain information together. This is called the joint submission of data. Registrants are required to jointly submit information on the hazardous properties of the substance and its classification and labelling and a testing proposal (if any), and can, if they agree, also jointly submit the chemical safety report and guidance on safe use (*Article 11*). The intention is that registrants will save money by co-operating on the preparation of the dossier. For more practical information on how to gather and share existing information see also Section 8.1.3.1.

It is important to stress that an only representative shall also be part of a joint submission when other manufacturers, importers or representatives exist for the same substance.

Any manufacturer, importer, or where relevant, downstream user, may, whilst retaining full responsibility for complying with his obligations under this Regulation, appoint a third party representative for all “joint submission of data” 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 the Agency to other manufacturers, importers, or, where relevant, downstream users. It is nevertheless 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.

1.8.4.1 Mechanisms of joint submission

The information that needs to be submitted jointly is submitted by one lead registrant on behalf of the others. Other information needs to be submitted by all registrants individually. This pertains to; information on each legal entity identity, the substance identity, information on the manufacture and on the use(s) of the substance including tonnage as well as some exposure information for substances registered in quantities of 1 to 10 tonnes.

The lead registrant of a joint submission could for example be the largest producer (i.e. one producer in the higher tonnage range), as he in any case will have to register the entire data set by the first deadline. However, this is not obligatory: the joint submission registrants have the possibility to appoint a leader 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 like that, a lead registrant in a lower tonnage band has to provide a complete dossier anyway (i.e. with studies for the higher tonnage) meeting the first 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.

In terms of timing, the lead registrant will have to submit first his registration dossier. The other registrants covered by this joint submission will be identified in this dossier. The other registrant(s) will then have to submit their own registration dossier containing, as a minimum, the information they need to submit separately.

In case the lead registrant ceases manufacture, the other registrants have to appoint a new lead registrant.

The registration fees, set by a Commission Regulation at the latest by 1 June 2008, will take into account whether the submission is joint or separate.

Legal references: Article 11

1.8.4.2 Opt-out possibilities

A manufacturer or importer may submit common parts of the registration dossier separately (opt-out of joint submission) in case when at least one of the reasons listed in *Article 11(3),* or for substances in intermediates respectively in *Article19(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 a* ***Confidential Business Information (CBI)****, 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 was likely to lead to substantial commercial detriment or the nature of the disagreement, as the case may be. More detailed guidance on the opting out possibilities and mechanisms can be found in the Guidance on data sharing.

2 DATA SHARING PROCEDURES

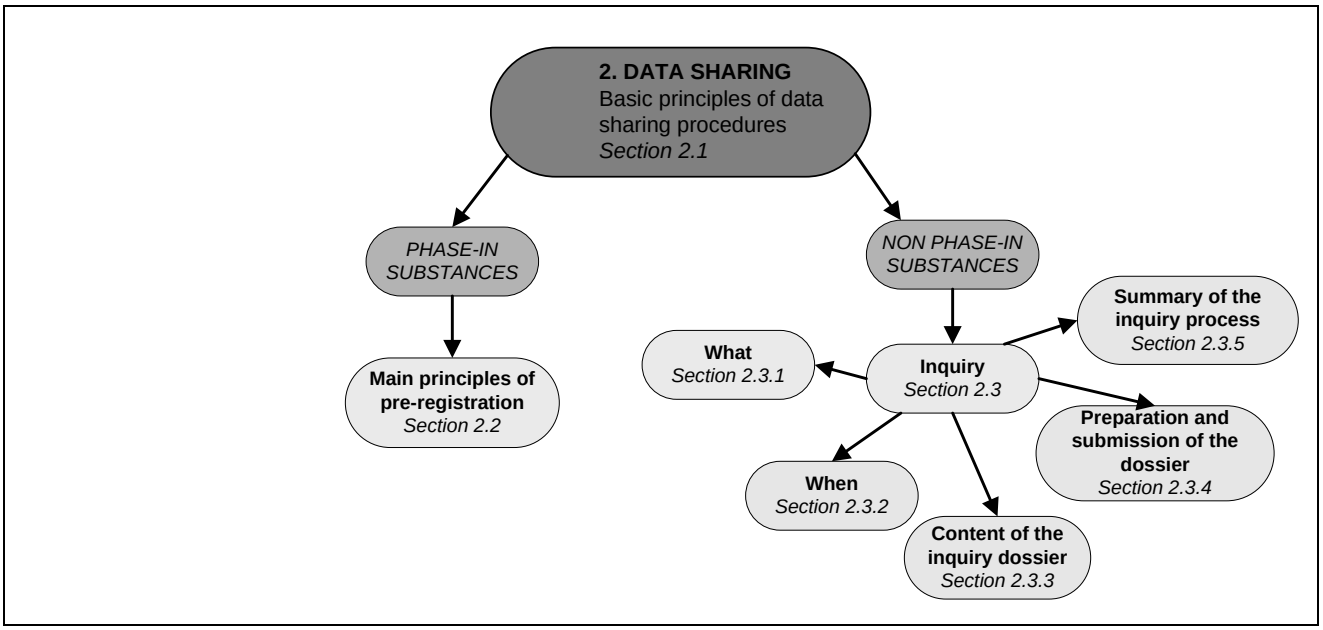
Aim: REACH has several provisions to facilitate the sharing of data between registrants. This reduces testing on vertebrate animals and costs to industry. For both phase-in and non-phase-in substances, data collected through vertebrate animal testing must be shared, in exchange for payment.

The main communication mechanism for phase-in substances is the establishment of the Substance Information Exchange Forum (SIEF) following pre-registration. For non-phase in substances the mechanism is the inquiry process. The difference between phase-in and non-phase in substances is outlined in Section 1.5.4.

Detailed guidance is provided in the Guidance on data sharing, especially for phase-in substances. Therefore in this chapter:

- the main principles of data sharing are described;
- the main principles of pre-registration are described for phase-in substances;
- the inquiry process is described in detail: when and how to prepare and submit an inquiry dossier.

Structure: The structure of this chapter is as follows:



2.1 BASIC PRINCIPLES OF DATA SHARING PROCEDURES

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 the inquiry for non-phase-in and phase-in substances that have not been pre-registered.

This applies to all potential registrants, including those who have a full set of data covering their information requirements and those that have to make a testing proposal to the Agency in accordance with *Article 12(1) (d) and (e)*.

One of the objectives of REACH is to avoid unnecessary testing, especially animal vertebrate testing, as far as possible, while balancing this with the generation of necessary information to identify the hazard of substances and manage the resulting risks. Duplicate animal testing has to be avoided and tests on vertebrate animals shall only be undertaken as a last resort (*Article 25*). To meet this objective, data sharing mechanisms have been developed and incorporated in the legislation (*Title III: Data sharing and avoidance of unnecessary testing*).

With respect to data sharing, 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, potential registrant must request it 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 data sharing mechanisms aim to ensure that sharing of costs of studies which are already available is agreed amongst potential registrants in a fair, proportionate and non-discriminatory way. In cases where the sharing of costs cannot be resolved amongst potential registrants, a provision to assign costs equally is included in the Regulation. 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.

2.2 MAIN PRINCIPLES OF PRE-REGISTRATION OF PHASE-IN SUBSTANCES

Each potential registrant of a phase-in substance manufactured or imported in quantities of 1 tonne or more per year must take part in the pre-registration process in order to benefit from the delayed registration deadlines outlined in section 1.7.2.

In order to be able to maintain manufacture, import and marketing of a phase-in substance during the transitional period, pre-registration is a one time process that has to take place in the period from 1 June 2008 to 1 December 2008. All manufacturers and importers of phase-in substances who wish to take advantage of the transitional registration deadlines will need to submit their pre-registration dossier during this period. This will allow companies to continue manufacturing and importing their phase-in substances for several years until the registration deadline is reached. Moreover, it will allow manufacturers and importers of the same substance(s) to initiate date sharing processes.

Manufacturers or importers not submitting a pre-registration dossier will have to register their substance before being allowed to continue manufacture or import. They will have to submit an inquiry dossier to the Agency, following the rules for non phase-in substances as described in section 2.3 and then restart manufacture or import of their substance once a registration is completed. Thus, failing to register a phase-in substance within the pre-registration period means that the manufacturer/importer cannot benefit from the delayed deadlines under the transitional regime.

In addition to this main pre-registration period, there is also a facility for potential registrants who for the first time manufacture or import a phase-in substance in a quantity of 1 t/y or more after the pre-registration deadline (later than 1 December 2008) to 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 the Agency a pre-registration dossier within six months of first manufacturing or importing or using the substance and no later than 12 months before the relevant registration deadline, i.e. the deadline given in *Article 23* for his tonnage band.

Detailed guidance on pre-registration can be found in the Guidance on pre-registration.

2.3 INQUIRY FOR NON PHASE-IN SUBSTANCES

This section explains in detail the Inquiry processes.

Legal references: Article 26 and 27

2.3.1 For which substances an inquiry has to be submitted

Inquiry is the process by which every potential registrant must inquire from the Agency 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**. It also applies to **phase-in substances** that have not been pre-registered.

2.3.2 When to inquire

An inquiry must be submitted before proceeding with substance registration, even in cases where the potential registrant possesses a full set of data for meeting the information requirements, and in cases where the potential registrant has to make a testing proposal to the Agency in accordance with *Article 12(1) (d) and (e)*.

Therefore, in cases where the potential registrant desires rapid access to the market it will be in his interest to submit an inquiry as early as possible.

2.3.3 Content of the inquiry dossier

When submitting an inquiry, potential registrants are required to submit contact details, information on substance identity and on relevant information requirements (*Article 26* and *Annex VI, Sections 1 and 2*).

2.3.3.1 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.

Pre-registration, inquiry and data-sharing procedures enable, for confidentiality purposes, to appoint a third party representative for all activities related to the data sharing processes except for contacts with the Agency. Any manufacturer, importer or where relevant downstream user who has used this opportunity of being represented by the third part representative, retains full responsibility for complying with his obligations under REACH but their identity should not normally be disclosed by the Agency to other actors of REACH. It is nevertheless up to the manufacturer or importer of the substance to register it, as a third party cannot register the substance for the company he represents in the data sharing discussions.

Legal reference: Article 4

2.3.3.2 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, and is outlined in the Guidance on substance identification.

It should be noted that providing thorough and accurate information on substance identity, taking full account of the current guidance in this area will be essential to enable the Agency to identify previous and potential registrants and so to minimise the burden on the registrant to generate new data.

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

The information requirements for a specific substance will depend on the proposed **tonnage band**. The potential registrant needs to identify the list of information requirements for their particular substance in order to facilitate the subsequent data sharing stage.

The potential registrant shall identify:

- which information requirements would require new studies involving vertebrate animals to be carried out by him;
- which information requirements would require other new studies to be carried out by him.

Guidance on the information needed for general registration purposes, including information requirements under the various tonnage bands can be found in Part II of this document and in the Guidance on information requirements.

2.3.4 Preparation and submission of the inquiry dossier

The inquiry dossier is to be prepared on line using the REACH IT web application. Guidance will be updated as soon as REACH IT is developed.

2.3.5 Summary of the inquiry process

Upon receipt of the inquiry dossier:

- The Agency will perform a substance identification check in order to identify previous registrants or potential registrants.
- After performing the substance identification check, if the Agency 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), the Agency shall inform the potential registrant accordingly and he may proceed with their registration.
- If the same substance has been previously registered less than 12 years earlier, the Agency shall 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. The Agency shall simultaneously inform the previous registrant(s) of the name and address of the potential registrant and the data sharing process will be initiated. Further details on data sharing including cost sharing can be found in Guidance on data sharing.
- Any study summaries or robust study summaries submitted in the framework of a registration under this Regulation at least 12 years previously can be used freely for the purposes of

registration by another manufacturer or importer. In addition, it is important to note that there may be instances where the information is generated for the purposes of complying with other regulations which may foresee a shorter data protection period. REACH will not extend the period of data protection under those specific legislations. 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 freely available for the purpose of registration, starting 12 years after the notification date.

Such study summaries and the robust study summaries will be available for download on the Agency's website 12 years after the corresponding registration. Once downloaded by a company the summaries can be imported and used in that company's local IUCLID database.

If several potential registrants have made an inquiry with respect to the same substance, the Agency shall 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 submit this as part of a joint submission as outlined in section 1.8.4.

- If the Agency 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 outlined in the Guidance on data sharing are met. If they are, they can submit the relevant information to the Agency, participate in the data sharing mechanisms facilitated by the Substance Information Exchange Forum (SIEF) and register in accordance with the relevant extended registration deadlines of *Article 23*. However, if the conditions for late pre-registration are not met, registration must take place before the substance is manufactured, imported or marketed in the EU.

3 OTHER DUTIES OF REGISTRANTS

3.1 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 could be used for the communication with the DU in order to refine the ES.

3.1.1 Provide a Safety Data Sheet (SDS) to customers

When supplying a substance or a preparation to another party or parties, the supplier has to provide a safety data sheet to all the downstream users and distributors he supplies as of 1st June 2007 as soon as the substance on its own or in the preparation falls within one of the following categories:

- it meets the criteria for classification as dangerous under Directive 67/548/EEC or the preparation 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 which may be subjected to authorisation, established according to *Article 59(1)*.

In addition a supplier of a substance could be requested at any time by his customer to provide him with a safety data sheet for any preparation which does not meet the criteria for classification as dangerous but which contains (Article 31(3)):

- ≥1% (by weight) for non-gaseous preparations (or ≥0.2% by volume for a gaseous preparation) of a substance posing human health or environmental hazard, or
- for non gaseous preparations, ≥0.1% (by weight) of a persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) in accordance with Annex XIII of the REACH Regulation or has been included in the candidate list of substances which may be subjected to authorisation, established according to *Article 59(1)*, or
- a substance for which there are Community workplace limits.

It is therefore highly recommended that each supplier of such substances prepares a safety data sheet for those preparations.

When supplying a substance on its own, the Safety Data Sheet has to be prepared for the substance itself. When supplying a substance in a preparation, the Safety Data Sheet has to be prepared for the preparation.

There is no obligation to provide a safety data sheet for dangerous substances or preparations being offered or sold to the general public as long as sufficient information to enable safe use of the substance is provided, unless this is requested by a downstream user or distributor.

Annex II of the REACH Regulation gives guidance for the compilation of Safety Data Sheets. The classification in accordance with Directive 67/548/EEC or Directive 1999/45/EC and the relevant occupational exposure limit values and/or biological limit values, DNELs and PNECs will also be communicated in the SDS.

In particular 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 adequate control of risks.

The SDS will have to be updated with the new information required by REACH for the first supply of the substance or preparation as soon as this information is required by the different title of REACH.

3.1.2 Provide other information to customers.

When supplying a substance or a preparation for which a Safety Data Sheet is not required (see section above), the supplier still has to provide some information to all the downstream users and distributors he supplies as of 1st June 2007 (*Article 32*).

If the substance is subject to authorisation or subject to restriction he will have to provide the following information to the recipient of his substance:

- the registration number, if available
- if the substance is subject to authorisation and the details of the granted authorisation or appropriate information if authorisation has been denied
- the details of the restriction

In addition he must provide any available and relevant information about the substance that is necessary to enable appropriate risk management.

3.2 CLASSIFICATION AND LABELLING NOTIFICATION

If the substance is a substance to be registered or is within the scope of Article 1 of Directive 67/548/EEC, meets the criteria for classification as dangerous and is placed on the market on its own or in a preparation above the concentration limits specified in Directive 1999/45/EC, the registrant must electronically notify to the Agency the information related to its classification and labelling if (*Article 113)*:

- he puts the substance on the market, and
- he has not already submitted a registration.

This has to be done before the 1st December 2010 for substances already on the market at that date or as soon as he puts the substance on the market for substances not on the market yet on the 1st December 2010 (*Article 116*).

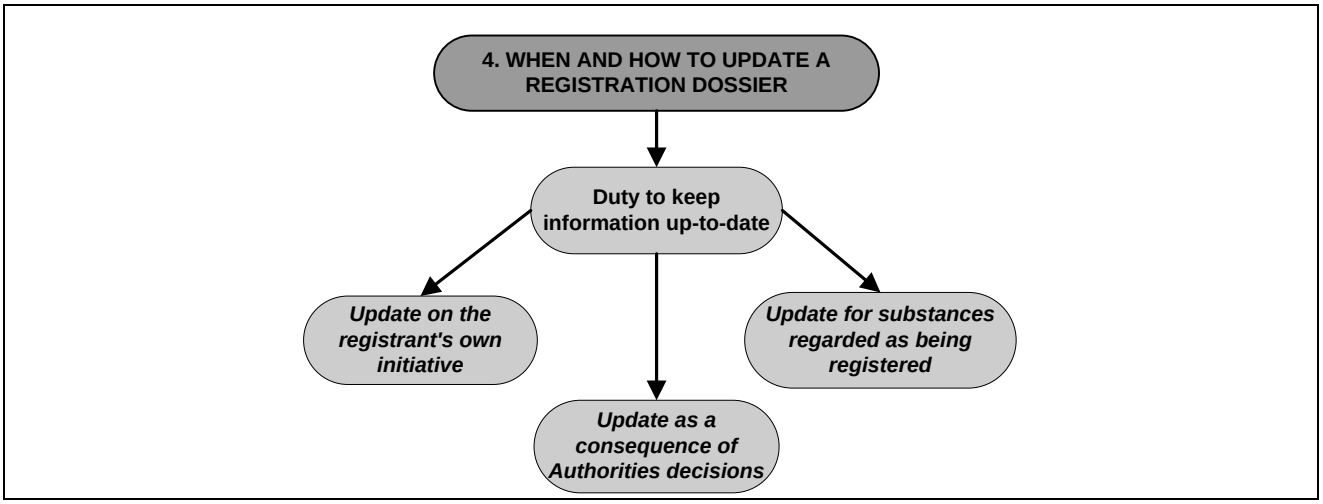
For substances registered before 1st December 2010 the classification and labelling will be reported in the registration dossier so that no separate notification is required.

The Agency will collate all this information on classification and labelling into a classification and labelling inventory. Parts of this inventory will be publicly accessible, other parts will only be accessible to notifiers and registrants who have submitted information on the same substance. This inventory will indicate the relevant registration number(s) and whether the classifications submitted for the same substance by different registrants or notifiers differ. In the latter case, the registrants and notifiers are required to make every effort to come to an agreed classification, and update their registrations/notifications as appropriate (the Guidance on C&L notification will be developed separately).

4 WHEN AND HOW TO UPDATE A REGISTRATION DOSSIER

Aim: The aim of this chapter is to explain when and how to update a registration dossier. 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.

Structure: The structure of this chapter is as follows:



The information submitted in the registration dossier to the Agency will have to be kept up-to-date. It is the responsibility of the registrant to update his registration dossier when needed. If the information to be updated is part of jointly submitted information, it is recommended that the lead registrant updates his dossier.

There are basically two types of situations where a registrant needs to update his registration and re-submit it to the Agency:

- Update on the registrant's own initiative

  Registrants are required to inform the Agency about new relevant available information on the registered substance or on their registration dossier (*Article 22(1)*). Any new information has to be submitted without undue delay to the Agency in the form of an updated version of the registration dossier. For more information see section 9.1.3.

- Update as a consequence of a decision made by the Agency or the Commission

  The registrant has to update his registration as a consequence of the Agency or Commission decision under the evaluation procedure. These updates have to be performed within the deadline specified by the Agency/Commission in the decision. The registrant should also consider updating his registration taking into account any decision made in accordance with *Article 60 (Granting of authorisation)* and *Article 73 (Commission decision on Restrictions).* For more information see section 9.1.4.

Moreover, according to *Article 20(6)* whenever additional information for a particular substance is submitted to the Agency by a new registrant, the Agency is responsible to notify the existing registrants that this information is available on the database. As a consequence the registrant has to take this information into account and if relevant update his registration dossier. An update shall be accompanied by the relevant part of the fee required in accordance with *Title IX Fees and charges*.

– Update of substances regarded as registered

For substances regarded as registered because a notification according to Directive 67/548/EEC has been submitted, updating of the registration dossier needs to be performed if the quantity reaches the next tonnage threshold as defined in *Article 12* (cf. *Article 24*). In such a case, not only the additional information corresponding to the tonnage threshold reached has to be submitted, but also any information corresponding to lower tonnage thresholds that had not yet been submitted.

There is no requirement to update a registration dossier (*Article 16(2)*) for substances in plant protection and biocidal products (*Article 15*).

Legal references: Article 22

5 APPEAL PROCEDURES

In case when registrant or potential registrants or registrants disagree with the Agency decisions, they can appeal against those decisions to the Agency's Board of Appeal.

The body to revise and take decisions on the appeals brought up against Agency decisions will be the Board of Appeal.

Related to the registration process, an appeal may be brought against Agency decisions in 5 cases:

1) in the completeness check - decision of the Agency to ask completion of a registration and set a deadline for submission of the required information, or to reject a registration if the registrant failed to complete his registration within the deadline set by the Agency (see section 7.3 on rejection of the registration dossier and *Article 20 (5)*).
2) in the inquiry process – the decision of the Agency to give permission to the potential registrant to refer to the information submitted by the previous registrant in his registration dossier (*Article 27(6)*).
3) in the data sharing for phase-in substances - decision of the Agency to appoint a registrant or downstream user to carry out the test on behalf of other registrants in a case where this test is not available within the SIEF (*Article 30(2)*).
4) in the data sharing for phase-in substances - decision of the Agency to give permission to all relevant registrants to refer to the information submitted by the registrant who during the data sharing procedures refused to provide either proof of the cost of the study or the study itself (*Article 30 (3)*).
5) in updating procedures – the decision of the Agency or the Commission requesting the submission of additional information as a consequence of the evaluation procedure as referred to in section 3 above.

All appeals must contain a statement of the grounds on which the appeal is based.

As underlined in *Article 92*, the appeal may be filed in writing by the registrant himself to the Agency, at the latest 3 months after the notification of the decision (to reject the registration, to give permission to information submitted by another registrant, to appoint a registrant to carry out a test, to request submission of additional information) to the person concerned by the decision.

The appeal may also be filed in writing by a person other than the registrant, to whom the decision was addressed or for whom the decision is of direct and individual concern. This may for instance be the case of a downstream user of the substance who was appointed to carry out a test on behalf of others. The appeal must be submitted at the latest 3 months after the date at which the person became aware of the Agency decision. For the fee information please consult the Fee Regulation which is foreseen to be available at latest on 1 June 2008.

The appeal is examined in the Agency. If, after consultation with the Chairman of the Board of Appeal, the Executive Director of the Agency 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. During the appeal procedures all parties to the appeal procedure must have the possibility to present orally their argumentation. The Board of Appeal may exercise any power which lies within the competence of the Agency or remit the case to the competent body of the Agency for further action.

If the result is still not to the liking of the party concerned, an action may be brought before the Court of First Instance or the Court of Justice, contesting a decision taken by the Board of Appeal or, in any cases where no right of appeal lies before the Board, by the Agency.

Legal references: Article 90, Article 91 and Article 92

6 FEES

Title IX of the REACH Regulation describes the framework for establishing a separate fee regulation and the basic principles to be observed when creating the regulation are described. Exact details of the fee regulation are not yet known since this fee regulation is still to be adopted, at the latest by 1 June 2008.

6.1 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 the Agency and competent authorities (see *Article 19 (3)*). In order for the Agency 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 uploaded a registration dossier to the REACH-IT system through the web-portal of the Agency, 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 ranges;
- An SME reduction if applicable; for this purpose the registrant will be asked to make a declaration on-line on the web portal of the Agency;
- A reduction for joint submission, if applicable;
- The items flagged according to (the provisions on required restrictions to electronic public access to information listed under) *Article 119 (2)*.

As soon as possible after the submission of the registration dossier, normally in the course of the next working day, the Agency will issue an invoice for the registration dossier(s) submitted. Upon receipt of the invoice, the registrant shall carry out the payment as indicated in the invoice.

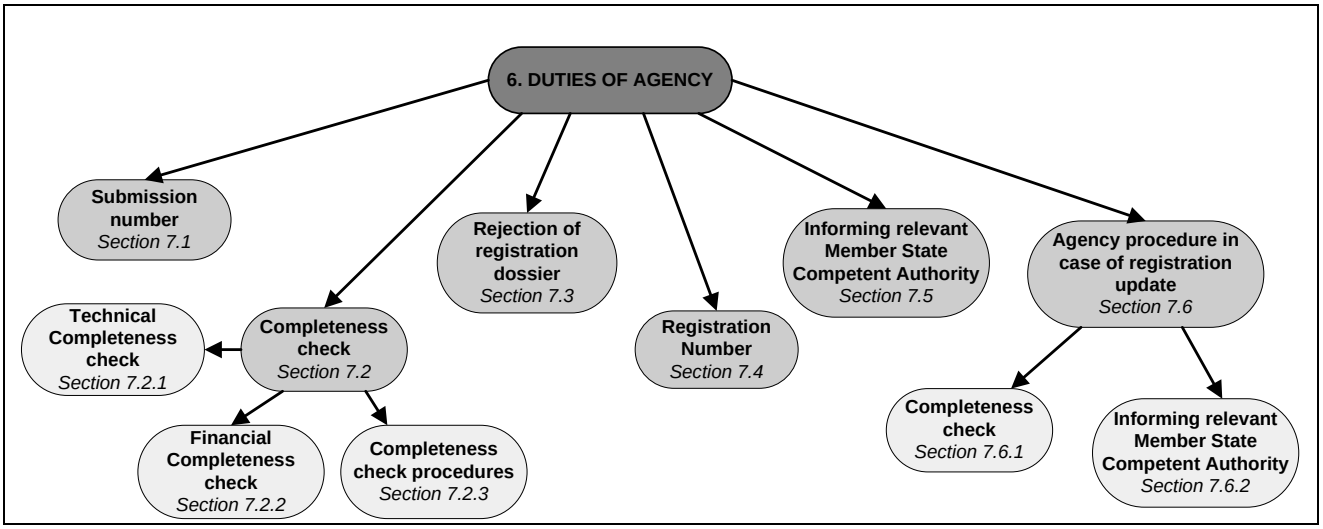
6.2 FEE FOR UPDATING OF A REGISTRATION DOSSIER

An update shall be accompanied by the relevant part of the fee as indicated in *Article 22 (5)* of the REACH Regulation. As with a first time registration, the registrant has to submit the updated dossier through the web-portal of the Agency and the REACH-IT system will automatically compute the applicable fee for the update and send the relevant invoice to the registrant.

7 DUTIES OF THE AGENCY

Aim: The aim of this chapter is to explain, for reasons of transparency, what are the duties of the Agency after the submission of the registration dossier. It explains how the submission number and date are assigned, what is the completeness check, what is the registration number and how and when the relevant Member State Competent Authorities will be informed about registrations.

Structure: The structure of this chapter is as follows:



7.1 ASSIGNING SUBMISSION NUMBER

Once the registration is submitted, the REACH IT system at the Agency automatically assigns a submission number to the registrant for the substance and submission concerned and a submission date. The Agency 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 (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.

7.2 COMPLETENESS CHECK AND INVOICING PROCEDURES

The completeness check process comprises two distinct sub-processes:

- Technical completeness check
- Financial completeness check

According to the REACH legislation the technical completeness check should be performed for the following dossier types: registration dossier (including intermediates), updated registration and PPORD notification. The Financial completeness check should be performed for those dossier types for which a fee is required.

7.2.1 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 depending on the tonnage range all elements as required in the legislation, in particular in *Articles 10, 12 and the relevant Annexes* have been provided.

After submission to the Agency each received dossier is screened for the 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 that all testing proposals, derogation statements, waving statements etc. are included. In the case of a negative result, the Agency will verify the outcome of the completeness check to make sure that the decision is fully correct.

Considering that the rejection of the registration dossier will not be without consequences for the registrant, the Agency intends to provide a tool within the IT system that will allow the registrant to perform a check for the completeness of his registration dossier before its submission to the Agency.

7.2.2 Financial completeness check

The Agency will monitor the payment of the fee as specified in the invoice. If a registrant fails to pay by the deadline indicated on the invoice, the Agency shall set a second reasonable deadline. If the registrant fails to meet the second deadline, the registration dossier shall be rejected

7.2.3 Completeness check procedures

The Agency shall undertake the completeness check of a registration dossier within three weeks of the submission date, or within three months of the relevant deadline of *Article 23*, as regards registrations of 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, the Agency shall inform the registrant, before expiry of the given period, as to what further information is required in order for the registration to be complete (*Article 20(2)*).

The negative decision on the outcome of the completeness check will be notified to the registrant in the form of a report indicating the points that are missing, while setting a reasonable deadline for providing the necessary information. This decision can be challenged through the appeal procedure.

The registrant must complete his registration accordingly and submit it once more to the Agency within the deadline set. The Agency will confirm the submission date of the further information to the registrant and will perform a further completeness check, considering the further information submitted.

A registrant may start or continue the manufacture or import of a substance or production or import of an article, if there is no indication to the contrary from the Agency within 3 weeks after the submission date (*Article 21(1)*).

7.3 REJECTION OF THE REGISTRATION DOSSIER

In case the registrant fails to complete his registration for the second time within the deadline set, the Agency will reject his registration. This decision can be challenged through the appeal procedure. The registration fee will not be reimbursed and the company will not be allowed to manufacture or import this substance within the EU (*Article 20(2)*).

7.4 ASSIGNING A REGISTRATION NUMBER

Once the registration is complete the REACH IT system at the Agency 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. The Agency 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)*). Moreover, the registration number will have to be incorporated in the SDSs for any supply after reception of that registration number.

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 C&L number and a registration number in the second above example.

7.5 INFORMING THE RELEVANT MEMBER STATE COMPETENT AUTHORITY

According to *Article 20(4)* within 30 days of the submission date, the Agency 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 registration dossier together with the submission or registration number and date as well as the result of the completeness check is available in the Agency database.

If the manufacturer has production sites in more than one Member State, all relevant Member States will be notified.

The Agency should also notify about any request for further information including deadlines set and when any further information submitted by the registrant is available on the Agency database.

7.6 AGENCY PROCEDURE IN THE CASE OF A REGISTRATION UPDATE

Whenever a new registrant submits to the Agency additional information for a particular already registered substance, the Agency shall notify the existing registrants that this information is available in the database (*Article 20(6)*). As a consequence, this may lead to the update of the existing registrations (see section 4 and 9).

7.6.1 Completeness check of a registration update

The completeness check of an updated dossier will include a comparison with the previously submitted version of the dossier.

7.6.2 Informing relevant Member State Competent Authority about an update

As soon as the updated dossier(s) is complete the Agency shall inform the relevant Member State Competent Authority about an update (*Articles 22(1), 22(2)*).

PART II

8 PREPARATION OF REGISTRATION DOSSIER

This part of the guidance describes how to prepare a registration dossier. It does not take into consideration whether the dossier is prepared as part of a joint submission or not. Joint submission processes are described in section 1.8.4. In addition the Guidance on data sharing can also be consulted.

8.1 FULFILLING THE INFORMATION REQUIREMENTS

8.1.1 Introduction

In this section, guidance is provided on the obligations that apply to registrants regarding the information to be submitted in the registration dossier according to *Article 10*. Most of the information to be submitted, particularly in the technical dossier relates to the intrinsic properties of the substance even if registrants have also to gather information on uses and exposure. Therefore this document provides mainly guidance on registrants' obligations regarding the general process of submission of information in particular related to intrinsic properties. Further detailed guidance is provided in the Guidance on information requirements.

It is recognized that in the case of import of a preparation, it can be difficult to obtain information on the composition of the preparation from the non EU supplier. However, also under existing Community legislation (e.g. for classification and labelling of preparations) importers need to know which substances are present in the preparations 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 preparation may have consequences, the non EU exporter has the possibility to appoint an only representative, as explained in section 1.5.2

Manufacturers and importers have to collect all available existing information on the intrinsic properties of a substance regardless of tonnage manufactured or imported as well as on its manufacture and uses. This information has in turn to be compared with the standard information requirements, which depend on the quantity of the given substance for each manufacturer or importer. As indicated in *Annex VI* this is done following a four step process which will be further described in the following sections.

Annexes VII to X specify the standard information requirements according to four tonnage bands from 1 tonne per year to ≥ 1000 tonnes per year (cf. *Article 12*). For the lowest tonnage level, the standard requirements are in *Annex VII*, and when a new tonnage level is reached, the requirements of the corresponding Annex have to be added. The Annexes thus need to be considered as a whole and in conjunction with the overall requirements of registration, evaluation and the duty of care as detailed in Table 1. These standard requirements may, however, be adapted (waived or increased) when appropriately justified (*Annexes III* and *VI* to *XI*). Accordingly, for each substance the precise information requirements may differ, according to the available information on inherent properties as well as to tonnage, use and exposure.

Table 1 Annexes requirements depending on tonnage bands

Tonnage bands	Annex VI	Annex VII	Annex VIII	Annex IX	Annex X	Annex XI
1 – 10 t/y	x	x (+ Annex III)				x
10 – 100 t/y	x	x	x			x
100 – 1000 t/y	x	x	x	x		x
≥1000 t/y	x	x	x	x	x	x

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 Guidance on data sharing).

Information on intrinsic properties of substances may be generated by using sources of information other than *in vivo* testing, provided that the conditions set out in *Annex XI* are met. The registrant may use a variety of alternative methods such as (Q)SARs ((Quantitative) Structure Activity Relationships), *in vitro* tests and grouping of substances / category approach and read across approach.

All these different sources of information can be used also in a weight of evidence approach.

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 a Commission Regulation (to be adopted) or in accordance with other international test methods recognised by the Commission or the Agency. Ecotoxicological and toxicological tests and analyses must be carried out in compliance with the principles of good laboratory practice (GLP) or other international standards recognised as being equivalent by the Agency or the Commission and with the provisions of Directive 86/609/EEC.

A key feature of REACH is the close parallel and iterative relationship between the Chemical Safety Assessment (CSA), the Risk Management Measures and the process of gathering and/or generating information on the properties of a substance as explained in section 1.3. Each of these must inform and feed-back to the others. Accordingly, the registrant should provide appropriate information on the intrinsic properties of substances that is useful for performing the Classification and Labelling (C&L) and the Chemical Safety Assessment (CSA) as required by *Article 12* and *section 0.5 of Annex I*. The results of the CSA may indicate that in the next iteration further information needs to be generated. Extensive guidance on the Chemical Safety Assessment is available in Guidance on the Chemical Safety Report.

8.1.2 Use of information from other assessments

As stated under Annex I Chapter 0.5, *"Available information from assessments carried out under other international and national programmes shall be included…..Deviations from such assessments shall be justified"*. 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 Community 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 is the OECD HPV (Organisation for Economic Co-operation and Development High Production Volume) chemicals programme where a lot of similarities exist with

REACH. Therefore in order to avoid duplicative efforts and to save resources coordination between this programme and the REACH regulation is clearly needed.

In Annex I of chapter 1 of the "OECD Manual for Investigation of HPV Chemicals" (http://www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_1,00.html), a document has been developed highlighting the synergies between REACH and the OECD HPV Chemicals Programme. From this document it is clear that the output of the OECD HPV Chemicals Programme can contribute to REACH implementation in specific REACH processes and particularly for the formation of Substance Information Exchange Fora (SIEFs) as well as for registration. Many of the requirements to manufacturers/importers when preparing a registration dossier in the framework of REACH are similar or identical to the requirements of the OECD HPV Chemicals Programme such as:

- All substance related information will be reported in IUCLID 5: the templates of IUCLID 5 have been harmonised with OECD and as such key study data are reported in the OECD Robust Study Summaries format.
- Consistent guidance is applied when waiving information requirements using the chemical category approach or (Q)SARs
- New information is generated using the OECD Test Guidelines, when available
- When writing the CSR, formats and the content requirements for the hazard assessment part are fully compatible with those of the OECD SIDS Initial Assessment Report (SIAR).

The technical similarities between REACH and the OECD HPV Programme are listed in the OECD document.

As a consequence, OECD SIDS Dossier and SIDS Initial Assessment Report (SIAR) can be used to prepare a REACH registration dossier, though for the purposes of REACH that dossier will necessarily need to contain additional information. This also means that parts of a SIDS Dossier and SIAR can be directly extracted from a REACH registration dossier.

The technical similarities between the two programmes allow for writing the hazard assessment part of a CSA (CSR) for registration under REACH using and moderately modifying a SIAR. Similarly a SIAR can be written using the hazard assessment part of the CSR, with deletions and minor modifications.

The OECD document also proposes a way forward on how to use the SIDS documents/REACH registration dossiers for the preparation of respectively REACH registration dossiers/SIDS documents and three cases have been differentiated depending on the registration deadline for REACH and therefore the presence or absence of a SIDS dossier.

In conclusion, in order to avoid duplicative efforts of both registrants and Agency/Member States, similarities between the REACH regulation and the OECD HPV Chemicals Programme should be taken into account when preparing or evaluating registration dossier where an OECD SIDS/SIAR is available.

8.1.3 The process of fulfilling information requirements

Annex VI describes a general scheme on the process and four steps to be followed by the registrant to fulfil the information requirements for a given substance:

Step 1: Gather and share existing information

Step 2: Consider information needs

Step 3: Identify information gaps

Step 4: Generate new information or propose a testing strategy

A comprehensive guidance document on information requirements under REACH has been developed. It contains a general guidance on these four steps. A General Decision Making Framework (GDMF) has been developed and describes in more detail the four steps listed above. In addition it includes endpoint specific guidance including endpoint specific Integrated Testing Strategies (ITS) (e.g. for aquatic toxicity, mutagenicity). It is recommended to consult this guidance before compiling a registration dossier and in particular before performing any testing, or in case of tests included in Annex IX or X before submitting a testing proposal.

The Guidance on information requirements has been developed to assist registrants meet the information requirements for their substance by considering all types of information and their potential sources. Advice is given on identification of information sources and how to ensure the reliability of the information used as well as its adequacy and fitness for purpose. It also explains when and how to use *in vitro* and non-test information, approaches for grouping substances in categories and the use of "read across" of information between substances.

The Guidance on information requirements provides assistance in developing a reasoned justification for applying adaptations (i.e. derogations/waiving) from the standard testing regime, and, in some cases also identifies the need for additional testing (which may be triggered by available data showing hazardous effects at a lower information level). For each of the endpoints, the requirements of the relevant Annexes are explained and an interpretation of the different descriptors for exposure considerations used in these annexes is provided.

In the present document, only the obligations and main processes to be followed according to the four steps procedure of *Annex VI* will be addressed. For more information the Guidance on information requirements should be consulted.

In case of joint submission, communication between the registrants within a SIEF is required before going into these different steps (see section 1.8.4 on joint submission).

8.1.3.1 Step 1: Gather and share existing information

The registrant has to gather all existing available information on the substance, both from in-house files and from any other sources, which may be useful to inform on the properties of that substance. *Articles 11 or 19* require that, when several legal entities need to register the same substance, registrations are submitted jointly enabling test data to be shared. In case of joint submission information on intrinsic properties of the substance should be shared as far as possible and submitted by the lead registrant on behalf of the others. More guidance on this issue can be found in the Guidance on data sharing.

The information to be gathered refers to:

- Testing data: i.e. all *in vivo* or *in vitro* testing data,
- Non-testing data: from computational tools i.e. data obtained with (Q)SAR models, or obtained by grouping of substances or read across etc. Further information on the use of these non-testing methods is available in the Guidance on information requirements (Section 6)
- Information on manufacture, uses and risk management measures and resulting exposures

The registrant must perform a thorough, reliable and well documented information gathering.

Information generated from (Q)SAR or by the application of a read across from one chemical to another should be treated like any other information when gathering information. The process on how to fill and submit a registration dossier will not be different when such information is provided. However, registrants who want to submit a registration dossier for a substance as part of a **chemical category** need to consult the specific guidance developed in the Guidance on information requirements (section 6) where a stepwise approach for developing chemical categories is proposed (see also the text box below).

Information required when grouping of substances/category approach is applied

Registrants have to submit a registration dossier for each substance that they need to register, regardless of whether the substance is part of a category or not. Nevertheless, all available and relevant necessary information on all members of the category, including those not intended to be registered, need to be gathered in the registration dossier, as this information is the basis to justify the relevancy and adequacy of the data reported on the properties of the registered substance.

IUCLID5 offers special features to facilitate the work of the registrant in developing categories (see Guidance on IUCLID).

The building of a chemical category may involve one or several registrants depending on the given situation:

- The registrant builds a chemical category for his own substances
- The registrant builds a chemical category for his own substances but with input from other registrants with similar substances.
- The registrant builds a joint category together with registrants of other substances for a number of substances that can be used by all registrants.

The data for each substance being part of a category should be shared with other registrants. The registrants of the different substances that can form a category can decide to prepare together the data set for the full category, which could be used for the registration of all individual substances. In case there are disagreements between registrants, there is a possibility for one or more registrant to opt out from the joint registration and build its own category. For details, see the Guidance on data sharing.

For each available piece of information the registrant must evaluate its adequacy**,** relevance and reliability. Thus the registrant must for each endpoint assess whether the available information gathered:

- is relevant and of sufficient quality,
- fulfils the specific requirements triggered by tonnage as described in *Annex VII* to *X*, and
- is appropriate for hazard classification, identification of Persistent Bioaccumulative and Toxic substances (PBT) or very Persistent and very Bioaccumulative substances (vPvB) as well as for risk assessment.

The outcome of this assessment should allow the registrant to determine which studies can be used in the hazard assessment, whether a specific study should be used as a key study (see text box below) for an endpoint or as supporting information and which studies can be used as part of a weight of evidence approach (more guidance on weight of evidence approaches can be found in the Guidance on information requirements).

Determination of the key study or key studies
A key study is the study that has been identified as the most suitable to describe an endpoint from the perspective of quality, completeness and representativity of data[2]. When several results are available for a given endpoint there can be several key studies.
For substances with more than one study available for an endpoint, the study or studies giving rise to the highest concern, taking into account quality, adequacy (reliability and relevance) and a weight of evidence approach 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.

All the relevant available information should then be documented in the form of a study summary or a robust study summary in IUCLID format. More guidance on when to provide a robust study summary or a study summary is available in section 8.2.2.6.

8.1.3.2 Step 2: Consider information needs

The registrant must identify precisely what the information requirements for the substance are. REACH requires the submission of information on:

- Substance identity
- Physicochemical properties
- Mammalian toxicity
- Ecotoxicity
- Environmental fate, including abiotic and biotic degradation.
- Information on manufacture and use(s) as well as risk management measures

Regardless of tonnage, the registrant must always provide all relevant physicochemical, toxicological and ecotoxicological information that is available to him even if not required (e.g. information he holds himself or that he can obtain from other information sources). He has to fulfil the standard information requirements on intrinsic properties as laid down in column 1 of *Annexes VII* to *X* for substances manufactured or imported in a certain tonnage band, and when a new tonnage level is attained, the information requirements of the corresponding Annex must be added. In addition he needs to submit information on manufacture and use(s) as laid down in *Article 10* and *Annex VI.*

In each of the *Annexes VII* to *X*, column 2 lists specific criteria, e.g. exposure or hazard characteristics, according to which the standard information requirements for individual endpoints may be modified (adapted), i.e. specifying possibilities for waiving the requirements for certain information or in certain cases defining the need for additional information. When waiving information, i.e. not providing the information requested in one of the Annexes, based on the condition in column 2 of the relevant Annex, the registrant must provide adequate justification and include this in the registration dossier.

In addition to these specific rules, the registrant may adapt the required standard information requirements according to the general rules contained in *Annex XI* which refers to situations where:

- testing does not appear scientifically necessary. This can be the case when appropriate information can be obtained using existing data, non-testing methods ((Q)SARs, on read-across or a grouping approach), and *in vitro* methods;

[2] OECD (2006) Manual for investigation of HPV Chemicals. Chapter 2: SIDS, the SIDS plan and the SIDS Dossier.

- testing is technically not possible;
- a test may be omitted based on exposure information (note that this only applies to information requirements in *Annex IX-X* and in *sections 8.6* and *8.7* in *Annex VIII*).

In all cases adequate and reliable documentation supporting the adaptation of the information requirement must be provided. Further guidance on these rules/conditions is detailed in the Guidance on information requirements and in Guidance on the Chemical Safety Report. Furthermore, the Commission must adopt criteria for what constitutes adequate justification for waiving of testing based on exposure information as described in *Annex XI section 3* by 1st December 2008.

It should be noted that a registrant of a substance for which the information requirement based on the tonnage band is in *Annexes VII* or *VIII* might have to prepare a testing proposal for higher tier tests of *Annexes IX* or *X*, if he considers this necessary, in order to gain more information on the hazardous properties of its substance, as in the following examples:

- The available information on an endpoint is inconclusive on the hazard.
- Further testing is triggered by structural alerts.
- The chemicals safety assessment (CSA) indicates that there is a risk and the registrant decides to refine the DNELs/ PNECs or the PECs (requesting further environmental fate information) instead of applying RMM.
- There is a need to identify or refine the assessment of a certain hazardous property and this could have an impact on the classification and labelling of the substance.
- There is a need to improve the PBT/vPvB assessment (e.g. when the PBT assessment is based only on screening test results like log Kow, ready biodegradability test results).

Considerations for phase-in substances manufactured or imported between 1 to 10 tonnes per year.

In case of phase-in substances between 1 to 10 tonnes, the information requirements in *Annex VII* (except for physico/chemical properties) can be waived if none of the criteria laid down in *Annex III* are met. More guidance is available in Guidance on information requirements. It should be borne in mind, however, that the requirement to submit all available information applies also in these cases.

8.1.3.3 Step 3: Identify information gaps

In this step the registrant has to compare the information requirements identified in step 2 with the information gathered in step 1 and identify where there are information gaps and consider how missing information can be generated. The registrant has therefore first to assess the information gathered by using usually a weight of evidence approach in order to determine whether the information requirements are already met or if this not the case.

If at the end of the assessment process the information is considered insufficient, then the registrant should go to step 4.

Registrants have also the flexibility to provide data beyond their obligations as listed in *Annexes VII* to *X*, when they consider it necessary to fulfil their obligations to ensure safe handling and use of their chemicals. It should be noted, however, that when these tests concern the tests listed in *Annexes IX-X* a testing proposal has to be submitted prior to performing any test and a scientific justification for the need of these test should be included. This testing proposal has to be evaluated by the Agency.

8.1.3.4 Step 4: Generate new information or propose a testing strategy.

When there is an information gap which cannot be filled by any of the non-testing methods mentioned in step 2, the registrant has to take action depending on the missing test/information identified in step 3:

- when *Annexes VII* or *VIII* apply the registrant has to **generate** new information according to the guidance given in the Guidance on information requirements;
- when *Annexes IX* or *X* apply the registrant has to prepare a **testing proposal** in any case and submit this as part of his registration dossier to the Agency for its consideration (note that this also applies to non-vertebrate animal tests listed in *Annexes IX and X*). The choice of the relevant test to be performed should be made based on the application of so-called Integrated Testing Strategies (ITS) developed for each endpoint. For further guidance on ITS chapter 7 of the Guidance on information requirements should be consulted. In this case, the registrant has to implement and/or recommend to downstream users interim risk management measures while awaiting the outcome of the Agency decision regarding the test proposal and the subsequent conduction of the test proposed.

When new testing is carried out, procedures in accordance with Good Laboratory Practice (GLP) must be followed for environmental (including ecotoxicity and fate) or toxicological tests (*Article 13(4)*) and the test methods used must be *in accordance with the tests methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the Agency as being appropriate (Article 13(3))*. Other methods may also be used provided that the conditions set out, in *Annex XI* and exemplified in the Guidance on information requirements, are met, in particular:

- they are adequate for the purpose of classification and labelling and/or risk assessment;
- sufficient documentation is provided to assess the adequacy of the study;

It is important to stress that testing on animals should be seen as the last resort. Testing on animals should only be proposed when the registrant considers it necessary to obtain additional information for assessing and documenting that risks are adequately controlled.

All the above conditions should be considered, not only to design fit-for-purpose *in vivo* tests, but also for providing a justification for not performing *in vivo* testing under certain circumstances.

When preparing a testing proposal, the registrant must provide a justification that:

- the testing is necessary:
    - for the purpose of bringing the registration dossier into compliance (i.e. the testing proposal is needed to fulfil the REACH information requirements);
    - as the results will increase the knowledge on the dangerous properties of the substance in order to protect human health or the environment. This is particularly important when additional testing for endpoints beyond the standard information requirements are proposed (See more information in section 2.1 of the Guidance on evaluation).
- the testing proposal is adequate, i.e reliable and relevant (as defined in the Guidance on information requirements);

Following the examination by the Agency of the testing proposal, the registrant receives a formal decision and has to take appropriate action within the deadlines set by the Agency (unless he decides to appeal against the decision of the Agency). For more details see the Guidance on evaluation.

8.2 GENERATION OF THE REGISTRATION DOSSIER

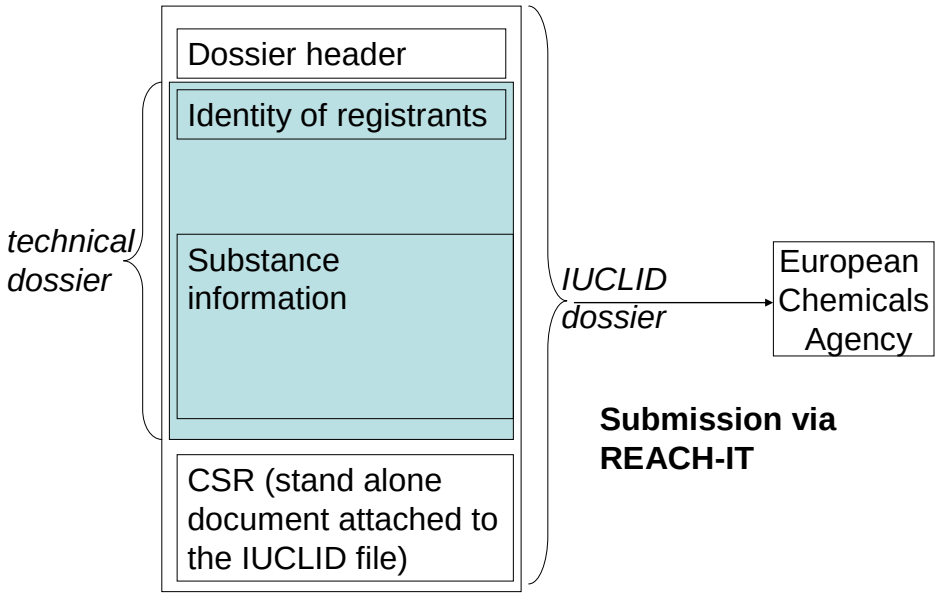
All relevant and available information has to be documented in both the technical dossier and for substances manufactured or imported in quantities of 10 tonnes or more per year per registrant in the chemical safety report (CSR). At least all the information required under *Article 10(a)* for the technical dossier and under *Article 10(b)* for the chemical safety report (CSR) needs to be documented in the recommended reporting formats which must be, for the technical dossier, IUCLID (*Article 111*).

Tasks to be undertaken:

- Document the technical dossier with all relevant and available information according to *Article 10* and *Annexes VI* to *XI* in IUCLID (see section 8.2.2)
- Carry out the Chemical Safety Assessment (CSA) for substances manufactured or imported in quantities of 10 tonnes or more per year per registrant (see section 8.2.3)
    - Carry out the hazard assessments (human health, environment, physico-chemical properties) and the PBT/vPvB assessment
    - If the substance is dangerous according to the criteria of Directive 67/548/EEC or assessed as PBT/vPvB document:
        - Define and carry out the exposure assessment(s) (including exposure scenario(s)).
        - Carry out the risk characterisation.
- Record the results of the CSA in the Chemical Safety Report (CSR) format

Once generated the registration dossier is submitted to the Agency using REACH IT as described in **Figure 4**.

Figure 4 Structure and format of the registration dossier prepared using IUCLID



8.2.1 IUCLID

This part of the document gives more detailed guidance on how to use IUCLID 5 for the preparation of the registration dossier. IUCLID 5 software will be downloadable from the IUCLID website [http://iuclid.eu] for free by all parties, if used for non-commercial purposes.

IUCLID 5 was developed for entering, storing and disseminating information on the properties and uses of substances. In particular, for each endpoint, harmonised data templates[3] have been developed in cooperation with the OECD so that IUCLID 5 can be used in different chemical assessment programmes, like the OECD HPV Chemicals Programme, US HPV Challenge Programme, Japan Challenge Programme, EU Biocides Directive as well as the EU REACH regulation. More information, such as information on exposure can also be stored in less structured but specific fields.

IUCLID 5 can also be used for preparing parts of the assessment reports. In particular, there are endpoint summary sections which allow the user to report the justification and summary of the assessment at each endpoint level that could be used for the equivalent section in the Chemical Safety Report (CSR). Some of these endpoint summary sections also exist at (eco)toxicological properties level, to report DNELS and PNECs.

All available and relevant information has to be reported in IUCLID. The decision of what is relevant is up to the registrant but the some issues can be taken into consideration as detailed in section 8.2.2.

[3] An OECD harmonised template is a standard format for reporting a summary of the results of a test on a chemical to determine its properties or effects on human health and the environment (e.g. hydrolysis, skin irritation, repeat dose toxicity, etc.). These templates can be used for reporting summary results for testing on any type of a chemical(e.g. pesticides, biocides, industrial chemicals).

8.2.2 Generation of the technical dossier

8.2.2.1 Level of detail of information to be reported in the technical dossier

It is recommended to report all available data, whether valid or not, so that all the work of gathering data is documented. The level of detail when reporting those data may vary considerably depending on the data as discussed further in this section. This might be in particular important when the registrant is confronted with several tests with conflicting results.

The registrant should make every effort to report original data rather than results obtained from literature reviews. This, in particular, to avoid reporting the same results several times.

The **level of detail** needed to be reported in IUCLID depends 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.

Guidance on assessing the reliability of the studies is available in section 4.2 of the Guidance on information requirements. In particular, a scoring system developed by Klimisch *et al* (1997) to assess the reliability of data, particularly from toxicological and ecotoxicological studies, that may be extended to physico-chemical and environmental fate and behaviour studies is described. This system distinguishes 4 level of reliability which can be reported in IUCLID:

1: reliable without restrictions; 2: reliable with restrictions; 3: not reliable; 4: not assignable

All information needs to be reported in an endpoint study record in IUCLID 5. When there are several sources of information on a given endpoint several 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 are detailed in the box below and more information is available in section B4.2.2 of the Guidance on iuclid.

Endpoint study record

An endpoint study record as defined in IUCLID5 should contain all the pieces of information related to one given endpoint study. The information is entered and stored in the fields provided on the data entry window of IUCLID. In other words, 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.

Endpoint summary

An endpoint summary includes the summary of the evaluation made of all relevant study summaries or robust study summaries compiled in a specific IUCLID section. On the endpoint level (e.g. short-term toxicity to fish), an endpoint summary should focus on the most important information, i.e., most critical results and conclusions, and justify the use of certain studies for this hazard identification. This information can come directly from a key study, but it can also be derived from a weigh of evidence approach or any other means.
The purpose of endpoint summaries is to describe and summarise the result 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 a higher level of the IUCLID hierarchy, such as "ecotoxicological information", and their purpose is to document information that is needed for the chemical safety assessment, such as PNECs or DNELs.

8.2.2.2 IUCLID templates

The registrant needs to report in the technical dossier all relevant and available information on the substance. As the standard information requirements depend on the tonnage manufactured or imported, the registrants can select the appropriate template depending on the tonnage level of registered substance. In these dossier templates all relevant sections to be filled for fulfilling the requirements under *Article 10(a)* are highlighted. The different templates for the technical dossier available in IUCLID 5 are reported in Table 2.

As REACH requires that all relevant available information shall be gathered in the technical dossier, the registrant should document all the studies he has and not only those required by a specific tonnage band. As a consequence the registrant should not rely only on the highlighted fields in the selected IUCLID 5 template to be sure to comply with REACH and should anyway document all relevant available information gathered. The REACH template in IUCLID 5 should be used only as a starting point in the preparation of the technical dossier but, as it is only based on the tonnage, the registrant should still check if he is in compliance with the REACH requirements, that is, if he does not need to provide additional information as explained in section 8.1.3.4.

Table 2 IUCLID5 templates for the registration dossier

IUCLID5 registration dossiers
REACH registration 1 – 10 tonnes, physico-chemical requirements
REACH registration 1 – 10 tonnes, standard requirements
REACH registration 10 – 100 tonnes
REACH registration 100 – 1000 tonnes
REACH registration above 1000 tonnes
REACH registration member of a joint submission – general case
REACH registration member of a joint submission – intermediates
REACH registration on-site isolated intermediates above 1 tonne
REACH registration transported isolated intermediates 1 – 1000 tonnes
REACH registration transported isolated intermediates above 1000 tonnes

The registrant must then fill IUCLID 5 fields by using the information gathered earlier in the process. The way to fill the different fields as well as the level of details needed is described in the following sections. In order to facilitate the work of the registrant this guidance for preparing the technical dossier has been developed in following the structure of IUCLID 5 but with clear links to the information requirements described in *Article 10* and *Annex VI*. Furthermore a summary of the information listed in *Article 10* and the corresponding sections in *Annex VI* and IUCLID5 file is provided in Table 3.

When filling the technical dossier (using IUCLID 5) the registrant has to remember that this is closely linked to the assessment of the substance and that some parts (e.g. hazard assessments) of

the chemical safety assessment might have been performed even for substances below 10 tonnes per year (See also section 1.3).

Table 3 Relation between information required under Article 10 and the corresponding sections in Annex VI and IUCLID5 file

Article 10	***Annex VI***	**IUCLID 5**
(a) technical dossier		
(i) identity of the manufacturer or importer	*Section 1: General registrant information*	Legal entity & Section 1.1
(ii) identity of the substance	*Section 2: Identification of the substance*	Sections 1.1, 1.2, 1.4
(iii) manufacture and use(s) of the substance and if relevant use and exposure categories	*Section 3: Information on manufacture and use(s) of the substance(s)*	Section 3
(iv) classification and labelling	*Section 4: Classification and labelling*	Section 2
(v) guidance on safe use	*Section 5: Guidance on safe use*	Section 11
(vi) study summaries of information derived from the application of Annexes 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		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 [4]
(ix) proposals for testing		Sections 4, 5, 6 and 7
(x) exposure information for substances in quantities of 1 to 10 tonnes	*Section 6: Information on exposure for substances registered in quantities between 1 and 10 tonnes per year per manufacturer or importer*	Section 3.5
(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		Attachment

[4] The dossier header consists of strictly administrative information

8.2.2.3 General information on the registrant and on the registered substance

General information consists mainly of:

- Registrant(s) identification information
- Substance identification information

Information regarding registrant identification as specified in *Article 10(a)(i)* and *Annex VI* (section 1) must be reported in the technical dossier under the legal identity section of the IUCLID 5 file. Guidance on how to document legal entity in IUCLID is available in section D9.2 of the Guidance on iuclid.

As far as possible all fields and all information specified in *section 1 of Annex VI* have to be documented in IUCLID 5 for the technical dossier to be complete. It includes: registrant's name, address, telephone number, fax number and e-mail address, the details about the contact person and when appropriate the 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.

In case of a joint submission the lead registrant has to identify himself but also all the other registrants who are part of the joint submission (see also section 1.8.4). The same applies to the other registrants who have to identify themselves in their technical dossier but also the lead registrant who submits the technical information on their behalf.

The registrant also needs to submit under this section of IUCLID5 all the information required in the technical dossier dealing with the identification of the substance as referred to in *Article 10(a)(ii)* and *section 2 of Annex VI*.

A substance is identified by its chemical identity, molecular and structural formula, chemical composition and content of each constituent in the substance. Required information listed in *section 2 of Annex VI* shall be documented as far as possible including the information on the substance, its composition, degree of purity, nature of impurities and information on the analytical methods.

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. 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. Guidance is given in section 8 of the Guidance on substance identification.

8.2.2.4 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.

The final Classification and Labelling decision 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 endpoint summary sections. For example the classification for the environment should be justified under the endpoint summary for ecotoxicological information, the classification for physico-chemical properties and human health should be justified under the relevant endpoint summary (e.g. under acute toxicity, flammability,

etc.). For more guidance on where information on classification and labelling should be provided the Guidance on IUCLID should be consulted.

All references to classification and labelling terminology, criteria and Directives are going to be amended as soon as the new EU regulation, implementing the Globally Harmonised System (GHS) for classification and labelling, is entering into force. This is foreseen to happen in 2008.

To ensure that hazard classifications and labelling of dangerous substances are available to all stakeholders and the general public, the Agency will record the classification and labelling proposed in the registration dossier within the classification and labelling inventory established and maintained by the Agency. 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 Directive 67/548/EEC which meet the criteria for classification of that Directive and which are placed on the market (*Article 112*).

It is recommended that registrants, before classifying their substance consult Annex I of Directive 67/548/EEC (where all harmonised classification and labelling of dangerous 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 Annex I of Directive 67/548/EEC (and therefore harmonised at Community level) they should follow this harmonised classification. If already listed in the inventory but not in Annex I of Directive 67/548/eec, 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.

8.2.2.5 Manufacture, use and exposure

Information on the manufacture and use(s) of the substance as mentioned under *Article 10 (a)(iii)* and specified under *section 3 of Annex VI* shall be documented in section 3 of IUCLID5.

The registrant has the possibility to record substantial amounts of information in IUCLID5 file regarding manufacture, use and exposure (e.g. technological processes, estimated quantities, exposure and uses categories, wastes). It is up to the registrant to decide on the level of detail to report, however all fields required under *section 3 of Annex VI* have to be filled.

The exposure scenario(s) will be attached to the IUCLID5 file as an integral part of the CSR, if the CSR is required. However, the exposure scenario(s) could also be attached to the IUCLID5 file under section 3 dealing with manufacture, use and exposure..

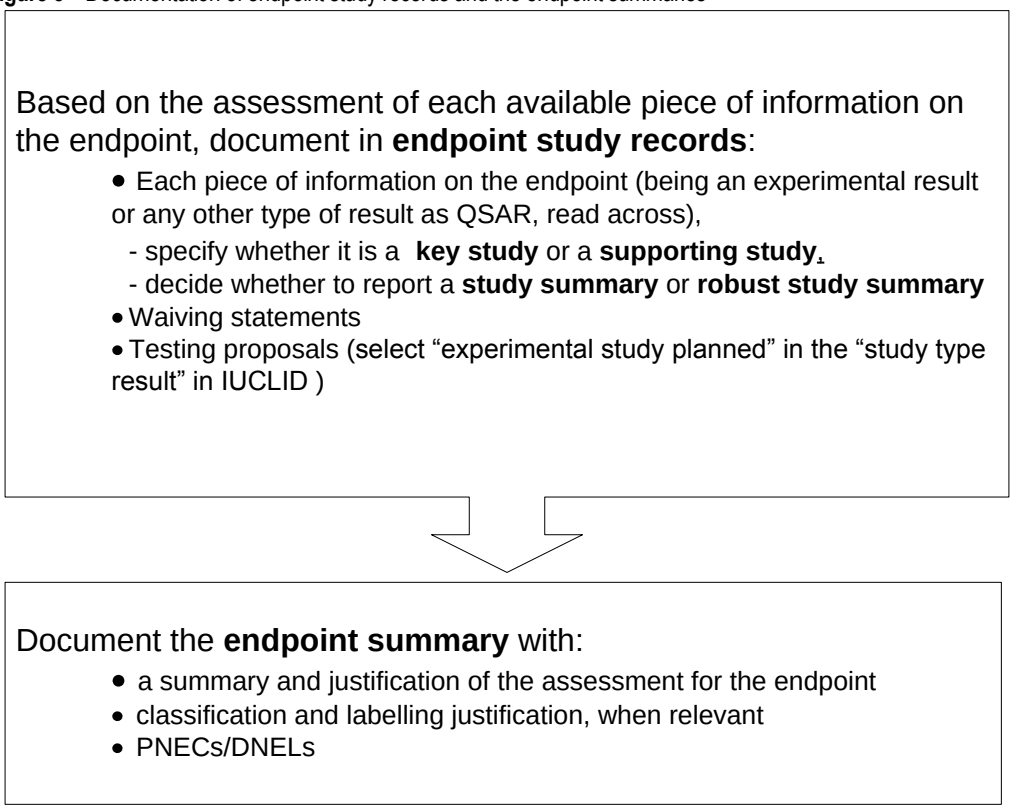
In addition for substances manufactured or imported between 1 and 10 tonnes for which no chemical safety report is required, registrants need to provide the information described in section 6 of *Annex VI* such as main use category, specification for industrial and professional use, significant routes of human and environmental exposure as well as the pattern of exposure. This information needs to be documented in section 3.5 of IUCLID (Identified uses and exposure scenarios).

8.2.2.6 Information requirements on inherent properties (*Annexes VII to X*)

All relevant available information on physicochemical, environmental fate and pathways, ecotoxicological and toxicological properties as specified under *Annexes VII* to *XI* have to be provided in IUCLID5 in the endpoint study record of their respective fields in the form of study summaries and robust study summaries (*Article 10(a)(vi) and (vii)*).

Figure 5 summarises the different steps to follow when filling endpoint study records and endpoint summaries in IUCLID 5 with the relevant information on the inherent properties of the substance.

Figure 5 Documentation of endpoint study records and the endpoint summaries



More guidance on the required level of detail and on when it is recommended to provide a complete robust study summary or just a study summary is described below.

8.2.2.6.1 Guidance on when to provide a robust study summary or a study summary when filling the technical dossier with information on each specific endpoint

A **robust study summary** should reflect the objectives, methods, results and conclusions of a full study report. The information included must be provided in sufficient detail to allow a technically qualified person to make an independent assessment of its reliability and completeness – minimising the need to go back to the full study report. Furthermore, it should contain sufficient information to determine whether the right key study(ies) has been chosen for an endpoint.

It is required to provide robust study summaries only for information derived from the application of *Annexes VII* to *XI* if required under *Annex I* in the technical dossier (*Article 10 (a)(vii*)). Robust study summaries need to be provided in the technical dossier only when a chemical safety report is required, therefore only for substances above 10 tonnes per year, and only for key studies (*Article 10 (a)(vii)*). However, it is recommended to provide robust study summaries in the technical dossier for all key studies including for substances manufactured and produced at less than 10 tonnes per year as this would facilitate the evaluation work made by the Agency and eventually Member States in the frame of substances evaluation and may eventually avoid them to request further information.

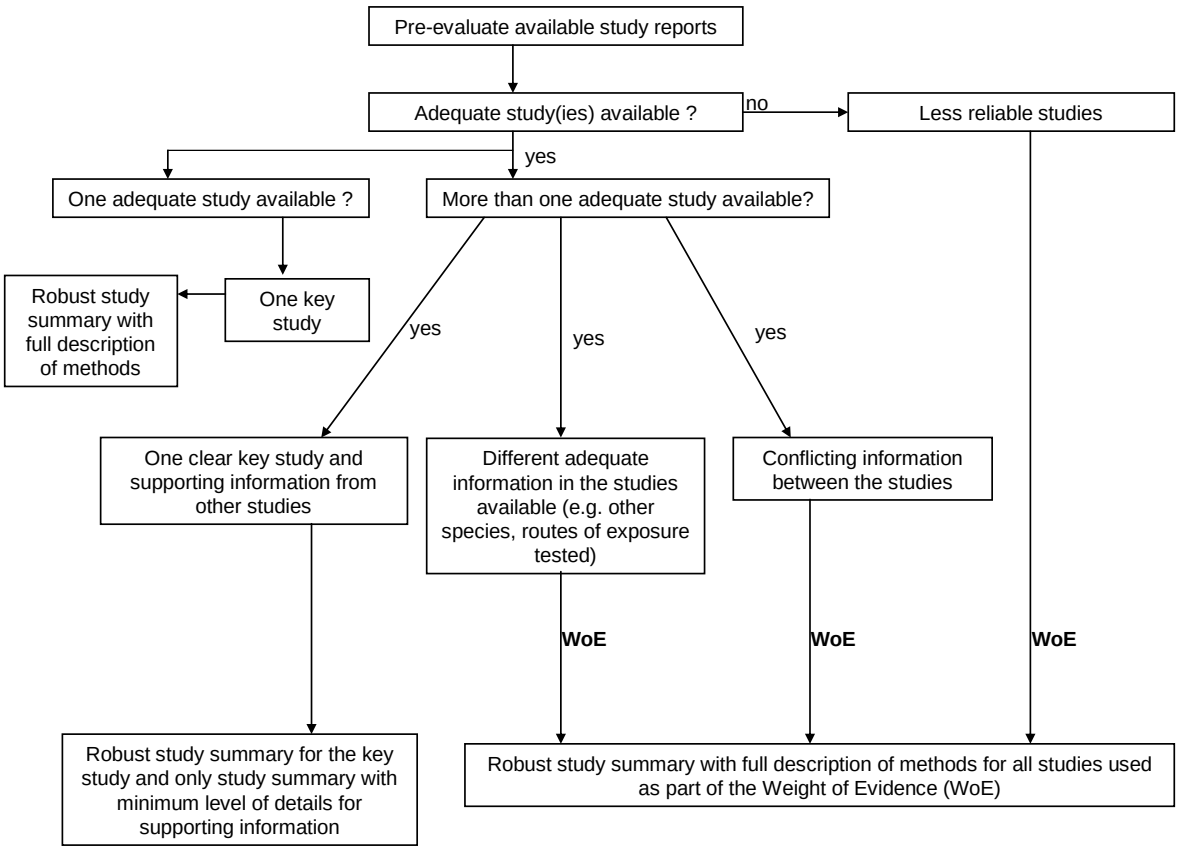
In addition there might be cases where it could be useful to provide robust study summaries for non key studies. For example, in case the key study is not the one giving rise to the highest concern it might be useful to prepare a robust study summary for this study as well as for all the studies

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.

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 technical 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 higher concern.

Substances may have more than one study available for an endpoint and among these studies more than one might be adequate. The registrant might therefore encounter one or more of the situations described in the following **Figure 6**.

Figure 6 Decision tree on when to document a study with a robust study summary or a study summary



It is reasonable to expect that there will be cases where several *inadequate or less adequate* data on a given REACH endpoint may exist.

It has to be underlined that when using a weight of evidence approach there might be cases where several less adequate/reliable studies on a given endpoint may exist (tests not performed in accordance with the test methods referred to in *Article 13(3)* for example). If a rationale can be presented to show that such tests adequately describe the endpoint of concern, a further test for that particular endpoint may not be necessary. For example there may be several repeated dose studies available on a chemical, none of which would be acceptable by itself due to some deficiency (e.g. small group sizes, insufficient number of dose groups, insufficient parameters, etc). Collectively, however, the different studies show effects in the same target organ at approximately the same dose and time.

- Only one adequate (reliable and relevant) study is available on the endpoint assessed.

When only one adequate study is available this is the key study and a robust study summary should be provided. The studies considered as less adequate (e.g. studies for which the reliability is considered as lower than the reliability of the key study but which is nevertheless a valid study) should nevertheless be documented as supporting information or as part of the available information but for these the registrant only needs to provide less detailed study summaries.

- More than one adequate study is available on the endpoint assessed.

When several adequate studies are available there might be more than one key study. The studies available can be used as part of a weight of evidence approach (see also the Guidance on information requirements - chapter 5 for general information and chapter 7 for information on specific endpoints). The use of a weight of evidence approach is common practice when more than one study is available on an endpoint. This might be particularly useful in the following cases:

- There is more than one adequate study but with conflicting information available as well as other less adequate studies.

  In that case it is highly recommended to prepare robust study summaries for all studies used as part of the weight of evidence approach even for those less adequate studies.

- There is more than one adequate study in which different species were tested or different exposure routes were used.

  In this case more than one study can be considered as key study to be used in the assessment. In this case it is very useful to prepare a robust study summary for each of these studies to facilitate the understanding of the choices made in the evaluation.

- Only studies considered as less adequate/reliable are available

  In case where the available information is individually considered as not completely adequate, the registrant might nevertheless consider that by using a weight of evidence approach the information is sufficient for the intended purpose. In that particular situation a robust study summary should be prepared for each study used as part of the weight of evidence approach.

8.2.2.6.2 Further recommendation on when to provide robust study summaries for non key studies

- When the study is performed according to non-standard protocols

For studies not performed according to standard protocols it is recommended to provide a robust study summary to allow the evaluation of the specific conditions used during testing. The summary should in particular give enough information and highlight points that justify the choice of this protocol rather than a standard protocol as well as sufficient information regarding the adaptations made due to the intrinsic properties of the substance. This is particularly relevant for substances requiring special considerations during testing (see Guidance on information requirements, section 5.2.2) that often need specific adaptation of testing protocols.

- When the study gives ambiguous results

Sometimes tests performed according to accepted guidelines might give ambiguous results for which more explanations might be needed (e.g. tests without clear dose-response relationship). In such cases it is recommended to give the necessary information particularly if this study is to be used in the hazard assessment of the substance.

For each endpoint the registrant has to fill the endpoint study record. Moreover it is strongly recommended that when available the registrant should also fill the endpoint summary in IUCLID5 as detailed below.

8.2.2.6.3 How to document the endpoint study record

When filling IUCLID5, in order to fulfil his requirements, the registrant could be in the following situations:

- Information is available in the form of the results of a study report. The type of information can be *in vivo* tests results but also results from any alternative methods (QSARs, *in vitro* methods, read across).
- There is no information on the endpoint available, but information is available to justify the possibility for waiving (e.g. information cannot be provided because it cannot be technically obtained or information does not need to be provided because lack of exposure can be demonstrated).
- Information is not available and is necessary, and as this information is listed under *Annexes IX* and *X* a testing proposal has to be submitted.

How to document the endpoint study record with available information (study reports and alternatives methods)

IUCLID5 allows the user to highlight if only a study summary is provided on an endpoint or a full robust study summary. However it is up to the registrant to decide which field to fill and the level of detail of information to give. In case of a robust study summary the detail level 'all fields' should be used. It is recommended to provide at least the type and amount of information in the respective fields that is relevant for the assessment of the reliability and completeness of the study report (e.g. depending on the type of test performed, physico-chemical properties of the substance).

Furthermore it should be specified in IUCLID5 for each study if it is used as a key study, as a supporting study or as part of a weight of evidence approach[5]. This is a way to document the evaluation that has been made by the registrant and might be useful for IT tools developed for the preparation of the CSR (e.g. in order to report the main results in the CSR) and may also facilitate the evaluation by the Agency.

In case of use of alternative methods the registrant has also to fill the endpoint study record with sufficient information to allow proper evaluation. Particularly in case of use of QSARs it is recommended to fill as much information as possible in the IUCLID5 structured fields but also to attach in the endpoint study record the completed report format to be found in the Guidance on information requirements (section 6.1) for QSARs.

The rationale for using read across from another substance needs to be well documented and justified in the endpoint study record.

[5] In IUCLID the user can select in the "Purpose flag" filed in the section on "Administrative data", whether it is a key study, a supportive study or a weight of evidence approach. If it is neither of those, nothing should be selected for this field.

How to document the endpoint study record with waiving statements

If the registrant waives the data this should be also recorded in the endpoint study record. A clear justification for waiving shall be given.

How to document a testing proposal

The registrant shall document the testing proposal in the endpoint study record. Since no test results are available the registrant has just to fill the "study result type" field explaining that an "experimental study is planned". When submitting a testing proposal, the registrant need to submit sufficient information to the Agency so that the Agency can take a decision as whether to accept the testing proposal as such or not. Most of the information that needs to be submitted concerns the testing protocol, i.e. the materials and methods part of the study record. In order to avoid subsequent work it is possible for the registrant to already submit all this information in the structured fields of IUCLID so that part of the endpoint study record is already filled when the registrant will update his dossier with the result of the test.

8.2.2.6.4 How to document the endpoint summary

The registrant needs also to fill the endpoint summary in order to summarise what the conclusions are of the overall assessment of an endpoint (e.g. aquatic toxicity, repeated dose toxicity) or of a more general section such as ecotoxicological information or toxicological information.

In order to be able to fill the endpoint summaries the registrant has to assess the information reported in the different endpoint study records. Depending on the situation, the registrant may be in possession of only one study on an endpoint or may have several studies.

If only one study is reported on an endpoint:

The registrant has to use the information available in the robust study summary for that study and to conclude on the endpoint in the endpoint summary. If the endpoint study record has been documented sufficiently the registrant would only need to use information already summarised in the endpoint study record.

If more than one study is available on an endpoint:

The registrant has to use all available relevant information reported in the different endpoint study records in order to conclude on the endpoint. Usually the first information to be used should be the robust study summary(ies) of the key study(ies) documented in the endpoint study record(s). The other information should be used only as supporting evidence. However there might be cases where there will be more than one key study on a specific endpoint or no key study as developed before. In these situations the assessment should be done by using all available information in a weight of evidence approach. In such situations the endpoint summary should be well documented and all studies discussed to justify the final conclusion.

The three following types of information can be reported in the endpoint summary:

- A summary of the data available on a specific endpoint as well as a conclusion regarding the assessment of a specific endpoint of the substance (e.g reprotoxicity, acute toxicity to fish, biodegradation)
- The classification and labelling of the substance (for human health, environment and physico-chemical properties) as well as the justification for this classification
- PNECs and DNELs values as well as the justification of the reported values.

Guidance on how to technically fill the endpoint summaries is given in the Guidance on IUCLID. It should be noted that information included in the endpoint summaries in IUCLID5 can be automated extracted to generate specific sections of the chemical safety report.

8.2.2.7 Guidance on safe use

The registrant has to report information required under *section 5 of Annex VI* in section 11 of IUCLID5 file and this information must be consistent with the information in the Safety Data Sheet (SDS), where an SDS is required. More information on the level of information needed in the SDS and therefore in this section is available under *Annex II (Guide to the compilation of Safety Data Sheets)*. Furthermore it is recommended to follow in-house current practices or guidance to make SDS when filling this section of the technical dossier.

In case the CSR contains exposure scenarios the latter need to be annexed to the SDS. The information on safe use in the ES, in the technical dossier and in the SDS has to be consistent. The same applies to the summary of the physico-chemical properties hazard assessment, the summary of the environmental hazard assessment, environmental fate as well as the calculated PNECs, the summary of the human health hazard assessment as well as the calculated DNELs, and, if the substance is considered PBT/vPvB to the report on PBT/vPvB properties as required under *Article 31* in the SDS (see section 1.2.3.2).

8.2.2.8 Others

Review by an assessor

Further information shall also be provided in the technical dossier as referred to in *Article 10*. This relates particularly to the need to highlight in the technical dossier if the information submitted under (iii), (iv), (vi), (vii) or subparagraph (b) has been reviewed by an assessor chosen by the manufacturer or importer and having appropriate experience as referred to in *Article 10 (viii)*. This must be recorded in the dossier header in IUCLID5.

Confidential information

The registrant has the possibility in IUCLID5 to flag as confidential all sections or endpoint study records or any other information mentioned in *Article 119 (2)*(containing the list of information that would normally be made publicly available by the Agency over the Internet). The registrant can request not having this information published on the Internet. In case of endpoint study records, it is possible to flag as confidential specific fields for information listed under *Article 119(2)*. However a clear justification shall be provided to allow the Agency to accept this information as confidential. It should be clear however that this applies only to information listed under *Article 119(2)* and that all information mentioned in *Article 119 (1)* shall be made publicly available in any case. For information not mentioned in *Article 119, Article 118* as well as the rules on access to documents (Regulation (EC) No 1049/2001) apply.

Registrants are entitled to claim confidentiality for information not to be disclosed on the Agency's website pursuant to *Article 119 (2)* against fee payment (*Article 74 (3)*). As this claiming of confidentiality is part of compiling a registration dossier, IUCLID 5 is build in such a way that industry can flag all 7 items (a – g) listed in *Article 119 (2)* (see also section 1.8.2).

8.2.3 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 1.8.1. The Chemical Safety Report is a stand alone document which will be attached to the IUCLID registration dossier and will contain partly information that should already have been reported in the technical dossier. The structure of IUCLID 5 gives the possibility to extract information already included in the technical dossier, e.g. within the endpoint summaries, to build automatically some parts of the chemical safety report. A format for the reporting of the CSR is available in *Annex I*.

The CSR is the document reporting the Chemical Safety Assessment (CSA). Therefore, to prepare this CSR the registrant has to perform a CSA and for this:

- Perform and document hazard assessments in the relevant reporting format
    - the human health hazard assessment
    - the physicochemical hazard assessment
    - the environmental hazard assessment
    - the PBT/vPvB assessment

If the substance is classified as dangerous in accordance with Directive 67/548/EEC or assessed to be a PBT/vPvB in accordance with the criteria in *Annex XIII* then the registrant has to:

- Perform and document the exposure assessment including exposure scenarios
- Perform and document the risk characterisation

A specific guidance on how to do a chemical safety assessment is available in the Guidance on the Chemical Safety Report and should be consulted by registrants. Several tools are available or will be developed to perform the chemical safety assessment and generate the chemical safety report. Some of these tools are listed in the Guidance on the Chemical Safety Report.

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

8.2.3.1 Hazard assessments

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

As mentioned previously the hazard assessments 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 before in the guidance.

8.2.3.1.1 Human health hazard assessment

The objective of the human health hazard assessment for the registrant is to classify and label their substance and to determine a derived no-effect level(s) (DNEL) for workers and the general population. The DNEL is regarded as an exposure level (internal or external) below which an adverse effect will not occur. The DNEL is derived from toxicity test results using appropriate assessment factors. These toxicity results should be reported in the technical dossier in the different endpoint study records and the result of the assessment should be reported in the endpoint summary once the assessment is finalised as well as the DNELs values calculated. The guidance on how to derive a DNEL is available in the Guidance on the Chemical Safety Report.

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 8.2.2.4.

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 IUCLID5 and then to use this information as a basis for section 5 of the CSR.

8.2.3.1.2 Physicochemical hazard assessment

The objective of the physicochemical hazard assessment is for the registrant to determine the classification and labelling of their 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 can be consulted in the Guidance on the Chemical Safety Report.

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 8.2.2.4.

A summary of the different effect and at least the explosivity, flammability and oxidising potential shall be reported in section 6 of the CSR on the basis of the information available in the technical dossier under the relevant IUCLID 5 endpoint study records.

8.2.3.1.3 Environmental hazard assessment

The objective of the environmental hazard assessment for the registrant is to classify and label their substance and to determine a predicted no effect concentration (PNEC) below which adverse environmental effects in the environmental compartments are not expected to occur. The guidance on how to derive a PNEC is available in the Guidance on the Chemical Safety Report.

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 8.2.2.4.

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 IUCLID5 endpoint study record. The result of the assessment, once finalised, should also be reported under the relevant endpoint summaries in IUCLID5 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 as this information is used, for example, when determining the classification and labelling of the substance or for exposure assessment.

8.2.3.1.4 Persistent bioaccumulative and toxic (PBT)/ very persistent and very bioaccumulative (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 within the Guidance on the Chemical Safety Report.

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 (as described in the Guidance on the Chemical Safety Report).

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.

8.2.3.2 Exposure assessment

When the result of the hazard assessments indicates that the substance meets any criteria for classification as dangerous (in accordance with Directive 67/548/EEC) or is assessed to be a PBT or vPvB (in accordance with criteria in *Annex XIII*) the registrant shall 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 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 (as such, in a preparation or in an article) 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 adequately 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 the Chemical Safety Report.

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

8.2.3.3 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 adequately controlled. The registrant shall compare no effect levels (DNELs) and predicted no effect concentrations (PNECs) with calculated exposure concentrations to human and the environment respectively. 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. Guidance on how to characterise risk is available in the Guidance on the Chemical Safety Report.

This step shall be carried out for each exposure scenarios 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 adequately controlled it is expected that the results of the risk characterisation should not indicate a risk in the CSR.

9 WHEN AND HOW TO UPDATE A REGISTRATION DOSSIER

9.1.1 Duty to keep information up-to-date

The information submitted in the registration dossier to the Agency will have to be kept up-to-date. It is the responsibility of the registrant to update their registration dossier when needed. There are basically two types of situations where a registrant needs to update his registration and re-submit it to the Agency:

- *update on the registrant's own initiative*

  The registrants are required to inform, without undue delay, the Agency about new relevant available information (e.g. new tonnage band) on the registered substance or on his registration dossier (*Article 22(1)*) and therefore to submit an updated version of the registration dossier.

- *update as a consequence of a decision made by the Agency or the Commission*

  The registrant has to update his registration as a consequence of the Agency or Commission decision under the evaluation procedure but also, when relevant, following any decision made in accordance with *Article 60 (Granting of authorisation) and Article 73 (Commission decision on Restrictions).* These updates have to be performed within the deadline specified by the Agency/Commission in the decision.

Moreover, according to *Article 20(6)* whenever additional information for a particular substance is submitted to the Agency by a new registrant, the Agency is responsible to notify the existing registrants that this information is available on the database. As a consequence the registrant has to take this information into account and if relevant update his registration dossier.

For substances regarded as registered because a notification according to Directive 67/548/EEC has been submitted, updating of registration dossiers needs to be performed if the quantity reaches the next tonnage threshold as defined in *Article 12* (cf. *Article 24*).

There is no requirement to update a registration dossier (*Article 16(2)*) for substances in plant protection and biocidal products (*Article 15*).

An update shall be accompanied by the relevant part of the fee required in accordance with *Title IX* Fees and charges.

9.1.2 Brief overview of the updating process

New relevant information prepared either on the registrant's own initiative or in response to a request by the authorities has to be communicated by updating the registration dossier and submitting it to the Agency. Once such an update is submitted to the Agency it has to undergo a completeness check within three weeks of the submission date. For more details on completeness check process see section 7.2.

As soon as the updated registration dossier is available in the Agency data base, the Agency should inform the relevant Member State Competent Authority about the update (*Articles 22(1), 22(2)*).

Manufacture/import may continue if there is no indication to the contrary from the Agency within 3 weeks after the submission of the registration update (*Article 21(1)).*

9.1.3 Required update on the registrant's own initiative

A registrant is responsible on his own initiative for updating his registration dossier without undue delay with relevant new information and resubmitting it to the Agency. The following cases are identified in *Article 22(1*). Further interpretation and guidance is given below for each case when appropriate.

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

This requires that any changes in the status of the registrant as well as any change related to the registrant's contact details, appointed contact person(s) and location of the registrant's production and own use site(s) should trigger update of the registration dossier.

b) Any change in the composition of the substance as given in section 2 of Annex VI

Section 2 of Annex VI addresses what information is useful to identify each substance. *Section 2.3* specifies the information on 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 the Agency. It is important that the registrant evaluates whether the change on the composition of its substance has some influence on its properties (being, physico-chemical properties or fate or hazard properties).

Further guidance on when a change in for example the degree of purity would trigger an update is available in Guidance on substance identification.

(Number the indents below 2.3.1-2.3.7)

- Degree of purity (%),
- Nature of impurities, including isomers and by-products,
- Percentage of (significant) main impurities,
- Nature and order of magnitude (…ppm, … %) of any additives (e.g. stabilising agents or inhibitors), and other information why are changed.
- Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum)
- High-pressure liquid chromatogram, gas chromatogram
- Description of the analytical methods or the appropriate bibliographical references for the identification of the substance and, where appropriate, for the identification of impurities and additives. This information shall be sufficient to allow the methods to be reproduced.

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 is reaching a higher tonnage band, the information requirements of the registration dossier change, i.e. at 10, at 100 and at 1000 tonnes per year the registrant has to inform the Agency of the change(s) in the quantities (*Article 22 (1) (c)* as well as the additional information that he would require to comply with the information requirements for the new tonnage level (*Article 12(2)*).

As stated in *Article 12(2*) upon receipt of this information, the Agency should act as in an inquiry process (*Article 26(3)*) and if the substance has previously been registered less than 12

years earlier, the Agency shall inform the registrant of the names and addresses of the previous registrants and of any relevant (robust) study summaries already submitted by them in order to allow sharing existing data and to ensure that studies on vertebrate animals are not unnecessarily repeated. For more information on inquiry/data sharing see Guidance on data sharing.

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 make a chemical safety report (CSR), he can assess the chemical safety for this use, and include that use in his chemical safety report if the results of the chemical safety assessment indicates that risks to human health and the environment from that use are adequately controlled. He will then, when relevant, provide the downstream user with a revised SDS, including the new use as well as the exposure scenarios describing the operational conditions for which the substance can be used safely. If on the basis of the chemical safety assessment he is unable to include that new identified use for reasons of human health or environmental protection, he shall provide the Agency in writing with the reason for this decision. The registrant can consider to update the SDS indicating the use(s) advised against, if he deems this of importance.

- If the registrant has registered in a tonnage band less than 10 tonnes per year, he has no obligation to perform a chemical safety assessment. 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.

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.

Therefore, if the ‘new’ use is covered by an ES that is already included in the registrant's CSR (and annexed to a SDS) the registrant does not need to update his registration even if the 'brief general description of use' in accordance with *section 3.5 of Annex VI* does not exactly correspond to that use.

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 safety data sheet or the chemical safety report

If the registrant becomes aware of information that could lead to other or different risks for the human health or the environment caused by the substance he manufacture or import, 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 international review such as IPCS review or OECD SIDS, 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 CSA/CSR or SDS. There are various triggers for the need to update the CSA or SDS and thus the Registration Dossier such as:

- Ongoing obligation: regularly screen data bases for new substance information that would change the results of the CSA.
- New or additional study reports become available that would change hazards or have identified new hazards.

For example where a substance has been identified as a substance of a very high concern and included in the candidate list for eventual inclusion in *Annex XIV*, the registrants of such substance need to update their registration dossier to take this fact into account if they did not previously do so.

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

Any registrant is required to submit to the Agency classifications for all substances subject to registration.

In cases, where a harmonised classification and labelling has been adopted in accordance with *Article 115*, the registration dossier needs to be updated accordingly.

Furthermore, any manufacturer, producer of articles or importer who places a substance on the market must (independent of the quantity for classified substances) notify to the Agency information on identity of the substance and information on the hazard classification of the substance, including labelling and specific concentration limits. The Agency will collate all this information on classification and labelling into a publicly available classification and labelling inventory. This inventory will indicate the relevant registration number(s) and whether the classifications submitted by different registrants or notifiers differ. In the latter case, the registrants and notifiers are required to make every effort to come to an agreed classification, and update their registrations/notifications as appropriate (Guidance on C&L notification will be developed separately).

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

g) Any update or amendment of the chemical safety report or section 5 of Annex VI (Guidance on safe use concerning):

Apart from the reasons mentioned in the previous points there can be also a need to update CSA/CSR due to i.e.:

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

Moreover an update of the CSR can be triggered also by an increase of the production and/or import.

Above mentioned needs for updating CSA/CSR can be identified internally by the manufacturer or importer, by the downstream user or Agency/MS. Although the need for updating CSA/CSR

may result from the information from down the supply chain, the M/I has the choice whether to support any reported revisions to the CSR:

- If the changes are supported the CSR and any existing SDS (and/or other downstream information) are revised and if necessary the registration dossier is updated.
- If the manufacturer or importer decides not to support the revisions, the original source of the information should be informed so they can take appropriate action and the reasons for advising against that unsupported conditions of use should be specified in section 16 of the SDS and the Agency must be informed in writing of those reasons. Moreover, the registration must be updated by including the non supported use under the heading uses advised against (*Article 37(3)*).

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 case when the higher level studies are not required by the legislation due to i.e. lower tonnage band, in some cases such studies still might be necessary in the opinion of the registrant in order to adequately control the risks arising from the manufacture and use(s) of the substance.

In case when the registrant identifies the need to perform the higher level study listed in *Annexes IX* and *X*, he will have to submit to the Agency an update of registration dossier including the testing proposal for this test.

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

Encouraging registrants to share data in order to save resources and avoid unnecessary repetition of the animal tests it is very important to keep up-to-date information about ownership and permission to use of the relevant data.

This point is especially relevant in light of the joint submission of information. In joint submission of information the lead registrant should submit the full set of data on behalf of the whole group of registrants who are all registering the same substance while all the others should in their own separate registrations submit only limited a set of information, while referring to the lead registration for the rest of the information. To "protect" his submission on behalf of all registrants, the lead registrant is obliged to update his lead registration whenever there is a change in the composition of the group of registrants covered by the joint submission or whenever there is any change in the right of access granted to the other registrants to information in lead registration. To save time and resources related to this task, the REACH IT system will enable the lead registrant whenever necessary to update online only a company related part of the lead registration.

9.1.4 Update as a consequence of Agency or Commission decisions

The registrant has to update his registration as a consequence of the Agency or Commission decision under the Evaluation Title, or to take into account decisions made in accordance with *Article 60 (Granting of authorisation) and Article 73 (Commission decision on Restrictions).* This task has to be performed within the deadline specify by the Agency/Commission in the 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 decisions taken under the provision of this Title that can have an impact on the updating obligations of registrants will be analysed 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 the Agency within certain timelines. The examination of testing proposal by the Agency could trigger the need for the registrant to update the registration dossier when a decision requesting one or several tests to be carried out is taken by the Agency or the Commission. For more details see the Guidance on evaluation.

All tests carried out based on a decision of the Agency under *Article 40* (*Examination of testing proposals*) have to be submitted in a form the study summary, or the robust study summary if required by *Annex I* in 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, the Agency 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 the Agency 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 chemical safety report, 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 competent authority considers that additional information is necessary for clarifying the suspicion, the draft decision stating the reasons for this request will have to be prepared by it.

When a decision is taken by the Agency or the Commission, the registrant has to submit the requested information by way of an update of his registration dossier to the Agency by the deadline set. In the case of multiple registrants, they have to agree who is going to carry out testing on behalf of all other registrants and to share the costs of testing equally.

b) Authorisation/Restrictions

If 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.

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

Substances notified in accordance with Directive 67/548/EEC

Under the REACH Regulation, the substances notified in accordance with Directive 67/548/EEC 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 as soon as the manufactured/imported quantity reaches the next tonnage threshold under *Article 12* (10, 100 or 1000 tons). This 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 the Agency of the additional information that he would require to comply with the information requirements for the new tonnage level. Upon receipt of this information, the Agency should act as in an inquiry process (*Article 26(3)*) and 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, for more information on Inquiry see section 2.3and the Guidance on data sharing.

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 Chemical Safety Report and to prepare Exposure Scenarios to attach to t heir Safety Data Sheet when relevant.

Apart from the update required when reaching the next tonnage threshold, the updates described under sections 9.1.3and 9.1.4 above must also be submitted if and when relevant.

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 *Article 15*) updating requirements in *Article 22* do not apply (*Article 16(2)*).

APPENDIX 1 : ROLES AND DUTIES OF THE MAIN STAKEHOLDERS OF REACH.

I. Industry

A first glance at currently existing duties, which will continue after REACH enters into force:

Manufacturers/importers/downstream users need to:

- Comply with any restrictions on marketing and use of substances and preparations (restrictions as set out in directive 76/769/EEC will be taken over by REACH in *Annex XVII*).
- Classify and label substances and preparations that are placed on the market according to Directive 67/548/EEC and Directive 1999/45/EC.
- Prepare safety data sheets (SDS) for substances and preparations (requirements in Directive 91/155/EEC will be taken over by REACH in *Article 31* and *Annex II*).
- Conduct risk assessments and reduce risks for any chemical agent occurring at the workplace (Directive 98/24/EC on chemical agents at work).

A glance at the duties after entry into force of REACH

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

- Classify and label substances and preparations that are placed on the market.
- Notify classification of dangerous substances to the Agency for the classification and labelling inventory for all substances placed on the market.
- Prepare and supply safety data sheets for substances and preparations as required by *Article. 31* and Annex II to downstream users and distributors.
- Prepare and supply information on non-classified substances as required by *Article 32* to direct customers.
- Conduct risk assessments and reduce risks for any chemical agent occurring at the workplace (Directive 98/24/EC on chemical agents at work).
- Comply with any restrictions on manufacture, placing on the market and use of substances and preparations as set out in *Annex XVII*.
- Apply or decide not to apply for authorisation for use(s) of substances listed in *Annex XIV*.
- In the case of having relevant data 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:

- If you wish to secure the phase-in status of your substance, pre-register it to the Agency
- In case your substance is a non phase-in substance send an inquiry to the Agency whether the 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 isolated intermediates)
- Prepare CSA and CSR (for each chemical ≥ 10 tonnes/y per manufacturer).
- Prepare CSA and CSR including exposure scenarios and risk characterisation (for each chemical ≥ 10 tonnes per year per manufacturer, which are dangerous or fulfil the criteria as a PBT or vPvB).

- Implement appropriate RMMs for own manufacture and use.
- Submit registration for substances (≥ 1 tonne/y per manufacturer).
- Keep the information submitted in the registration up-to-date and submit updates to the Agency.
- Classify and label substances and preparations that are placed on the market.
- Notify/register classification of dangerous substances with the Agency for the C&L inventory for all substances placed on the market.
- Prepare and supply safety data sheets for substances and preparations as required by *Article 31* and *Annex II* to downstream users and distributors.
- Recommend appropriate RMMs in SDS.
- Communicate ESs developed in CSA as Annex to the SDS (≥ 10 tonnes per year per manufacturer).
- Prepare and supply information on non-classified substances as required by *Article 32* to downstream users and distributors.
- Conduct risk assessments and reduce risks for any chemical agent occurring at the workplace (Directive 98/24/EC on chemical agents at work).
- 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 preparations as set out in *Annex XVII*.
- Apply for authorisation for use(s) of substances listed in *Annex XIV*.

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

- If you wish to secure the phase-in status of your substance,, pre-register it to the Agency
- In case your substance is a non phase-in substance send an inquiry to the Agency whether the 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 isolated intermediates)
- Prepare CSA and CSR including exposure scenarios and risk characterisation (for each chemical ≥ 10 tonnes per year per manufacturer, which are dangerous or fulfil the criteria as a PBT or vPvB).
- Implement appropriate RMMs for own use.
- Submit registration for substances, on their own or in preparations (≥ 1 tonne/y per importer)
- Keep the information submitted in the registration up-to-date and submit updates to the Agency..
- Classify and label substances and preparations that are placed on the market.
- Notify/register classification of dangerous substances with the Agency for the C&L inventory for all substances placed on the market.
- Prepare and supply safety data sheets for substances and preparations as required by *Article 31* and *Annex II* to downstream users and distributors.
- Recommend appropriate RMMs in SDS.
- Communicate ESs developed in CSA as Annex to SDS (≥ 10 tonnes/y per importer)
- Prepare and supply information on non classified substances as required by *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 preparations 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/y per producer and per article type). Comply with C&L, 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/y per producer and per article type).
- When receiving SDS with ESs annexed for dangerous substances and preparations to be incorporated into the articles:
  1. If the use is covered by the ES, implement RMMs as set out in ES, or
  2. If the use is not covered by the SDS annex, 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 DU tonnage ≥ 1 tonne/y) notify the Agency.
- Implement those RMMs as set out in SDS for dangerous substances and preparations which are applicable when incorporated into the articles.
- Conduct risk assessments and reduce risks for any chemical agent occurring at the workplace (Directive 98/24/EC on chemical agents at work).
- 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 preparations 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/y per importer and per article type). Comply with C&L, 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/y per importer and per article type).
- 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 preparations as set out in *Annex XVII*.
- Apply for authorisation for use(s) of substances listed in *Annex XIV*.

(6) Downstream Users:

- Check if the substance is placed on the list of pre-registered substances published by the Agency. If not, and considered relevant, ask the Agency to add the substance to the list
- In the case of having relevant data act as data holder in Substance Information Exchange Fora (SIEF).

- Implement RMMs as set out in SDS.
- When receiving SDS with ESs annexed:
  1. If DU use is covered by the ES, implement RMMs as set out in ES annexes to SDS; or
  2. If DU use is not covered by the SDS annex, 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 DU tonnage ≥ 1 tonne/y) notify the Agency.
- Prepare and supply SDS(s) and recommend appropriate RMMs in them and annex ES(s) for further downstream use.
- Prepare and supply information on non-classified substances as required by *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.
- Conduct risk assessments and reduce risks for any chemical agent occurring at the workplace (Directive 98/24/EC on chemical agents at work).
- 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 preparations as set out in *Annex XVII*.
- Use authorised substances as set out in the authorisation (this info should be found in the suppliers' SDS) or apply for authorisation for use(s) of substances listed in *Annex XIV*.
- Notify about using an authorised substance to the Agency

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.
- Suggest harmonised C&L for CMRs and respiratory sensitizers.
- Identify substances of very high concern for authorisation.
- Suggest restrictions.
- Nominate candidates to membership of Agency committees on risk assessment and socio-economic analysis.
- Appoint member for "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. Agency:

Day to day management of technical, scientific and administrative aspects of REACH.
Responsibilities:

- Provide technical and scientific guidance and tools for the operation of REACH in particular to assist the development of chemical safety reports by industry and especially by Small and Medium Sized Enterprises (SMEs).
- Provide technical and scientific guidance on the operation of REACH for Member State competent authorities and provide support to the competent authorities' help desks.
- Receive and check requests for research and development (PPORD) exemptions.
- Pre-registration:
  1. Receive information and grant access to all manufacturers and importers who have submitted information on one substance. When foreseen decide about conflicting issues.
  2. Publish a list of pre-registered substance on the Agency 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:
  1. Ensure a harmonised approach. Set priorities and take decisions.
  2. Conduct dossier evaluation of registrations including testing proposals and other selected registrations.
  3. Substance evaluation: Propose draft Community rolling action plans, coordinate the substance evaluation process.
  4. Take decisions on testing proposals.
- Substances in articles: take decisions on notifications.
- Authorisation/restrictions: manage the process and provide opinions. Suggest priorities.
- Secretariat for forum and committees.
- Take decisions on access to submitted data.
- Publish certain specified data on a publicly accessible database.
- Deal with appeals - registration, R&D, evaluation, confidentiality, etc.

IV. Commission:

- Take decisions on further information needs under the evaluation process where there is no unanimous agreement by Member States.
- Include substances into the authorisation system.
- Take decisions on granting or rejecting authorisations.
- Take decisions on restrictions.
- If decision making fails at the Agency take decisions on testing proposals

V. All stakeholders including trade or industry associations, NGOs, and the public:
Note: The following are possibilities/options for stakeholders:

- Access to non-confidential information via the Agency website.
- Request access to information.
- Evaluation: submit scientifically valid, relevant information and studies addressed by the testing proposal published on the Agency website.
- Authorisation:
  1. Provide comments on substances which the Agency has proposed to be prioritised and on uses which are to be exempted from the authorisation requirement.
  2. Provide information on possible alternatives.
- Restrictions:
  1. Provide comments on restriction proposals.
  2. Provide socio-economic analysis for suggested restrictions, or information to contribute to one.
  3. Provide comments on draft opinions from Agency's committee for risk assessment and Committee for socio-economic analysis.