Frequently Asked Questions about REACH

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Version 4

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The questions and answers presented here address general situations and are intended to assist those who do not have a detailed knowledge on REACH, to provide context information and to guide the reader to the most appropriate information sources, such as the Navigator or a specific guidance document or the REACH text itself. This information is also available on ECHA's website at http://echa.europa.eu/.

LEGAL NOTICE

This Frequently Asked Questions document contains information on obligations under the REACH Regulation (hereafter referred to as REACH or the REACH Regulation) explaining how to fulfil them. This FAQ document has been agreed by and between the correspondents of the national helpdesks of the Member States, representatives of the European Commission and the European Chemicals Agency within the Help Net Steering Group.

However, users are reminded that the text of the REACH Regulation (Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC) 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.

Frequently asked questions about REACH (version 4)

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

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Document History

Update	New FAQ included	Revised FAQ	Date
FAQ 2.0	All	-	04/12/2007
FAQ 2.1	2.4, 6.3.3, 6.3.6, 6.3.7, 10.5, 12.4, 12.5	2.1, 3.2, 4.1,4.2, 4.4, 4.5, 6.3.2, 6.3.5, 6.4.1, 6.6, 7.1, 7.5, 9.4, 12.1	09/04/2008
FAQ 2.2	3.3, 6.3.8, 6.8, 6.9, 6.10, 8.5, 9.10, 9.11, 12.2.1, 12.6, 12.7, 13.1	-	04/06/2008
FAQ 2.2 Release 2	-	1.3, 2.4, 6.3.1, 6.4, 6.6, 6.7, 8.2, 10.1, 10.2, 10.5, 11.1	11/06/2008
FAQ 2.3	6.1.1, 6.3.9, 6.3.10, 6.3.11, 6.3.12	-	06/11/2008
FAQ 2.4	2.5*, 4.6, 13.1*, 13.2, 13.3	1.1, 1.6[1], 2.3, 2.4, 5.1, 5.5, 6.3.1, 8.3, 9.5, 10.1, 11.2, 12.2, 12.6, 12.7	20/03/2009
FAQ 2.5	9.12, 9.13, 9.14, 9.15, 9.16, 9.17, 9.18	4.1, 9.1, 9.2, 9.3, 9.5[1], 9.6, 9.7, 9.8, 9.9, 9.10, 9.11	29/06/2009
FAQ 3.0	3.4, 6.3.13, 6.11, 6.12, 6.13, 6.14, 10.6, 11.3, 11.4, 11.5	1.1, 1.3[1], 1.4, 1.5, 2.1, 2.2, 2.3, 2.5, 3.1, 3.2, 3.3, 4.2, 4.4, 4.5, 5.1[2], 5.2, 5.3, 5.4, 5.5, 6.1, 6.2, 6.3, 6.3.1, 6.3.2, 6.3.3, 6.3.5, 6.3.7, 6.4, 6.4.1[1], 6.6, 6.7, 6.8, 6.9, 6.10, 7.1, 7.4, 8.1, 8.2, 8.3, 8.4, 8.5, 10.1, 10.2[2], 10.4, 10.5, 11.1, 11.2, 12.1, 12.2, 12.3, 12.6[1], 12.7, 13.4	19/11/2009
FAQ 3.0.1	9.5		22/02/2010
FAQ 3.1	6.3.14, 6.15, 6.16, 7.8, 12.8, 12.9		07/06/2010
FAQ 3.2	4.7, 4.8, 6.6*, 6.18, 6.19, 10.1^, 10.2^, 10.3^, 10.4^, 10.5^, 10.6^, 10.7, 10.8		20/10/2010
FAQ 3.2.1		6.3.12	26/11/2010
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FAQ 3.2.4	11.7	11.4, 11.6	28/04/2011
FAQ 4	6.20, 6.21, 6.22, 8.7, 8.8, 8.9, 9.19, 9.20, 9.21, 9.22, 11.8, 14.5	12.2, 12.3, 12.4, 12.5, 13.3	23/06/2011

* Previous FAQs 2.5 and 13.1 were renumbered due to the insertion of the new FAQs. They are now numbers 2.6 and 13.4.

* By insertion of the new FAQ 6.6 the existing FAQs 6.6 – 6.16 have been renumbered

^ Previous chapters 10 – 13 are renumbered as new chapter 10 was included

[1] Deleted

[2] Merged with another FAQ

Note to FAQ (version 4):

Twelve (12) new FAQs have been introduced and five (5) existing FAQs have been edited.

The revision of existing FAQs is normally triggered by recent publication of related Commission Regulations or Guidance Documents.

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1 GENERAL

1.1 What is REACH and where do I find more information about it?

REACH stands for the Regulation for Registration, Evaluation, Authorisation and Restriction of Chemicals. The REACH Regulation entered into force on 1st June 2007 to streamline and improve the former legislative framework for chemicals of the European Union (EU). REACH also created the European Chemicals Agency (ECHA) which has a central co-ordination and implementation role in the overall process. ECHA is located in Helsinki, Finland and manages the registration, evaluation, authorisation and restriction processes for chemical substances to ensure consistency across the countries in which REACH applies.

The following sources of information about REACH are available:

- The REACH Regulation and other related pieces of legislation published in the Official Journal of the European Union; links to these texts can be found in the section on legislation of the ECHA website.
- The "About REACH" section of the ECHA guidance website provides concise and basic information on REACH.
- The REACH guidance documents provide explanatory and supplementary information to the legal text. They are the result of both consultation of relevant stakeholders and close co-operation between the National Competent Authorities and the European Commission. Final guidance documents as well as draft versions in the process of being updated are available on the ECHA guidance website.
- The Navigator tool will help you to identify your specific obligations under REACH.

1.2 What has been changed by the Corrigenda to REACH of 29 May 2007?

The objective of the Corrigenda to REACH of 29 May 2007 was to rectify mostly linguistic errors but not to make changes on the content of the text. Most of the corrections are applicable to language versions other than English. One change to be mentioned here is within Article 64 (8) where a printing error has been corrected: the reference to the procedure to arrive at a final decision on granting or refusing the authorisation has been corrected to Article 133(3), being the regulatory committee procedure.

1.3 (deleted)

1.4 Who is responsible for the enforcement of REACH?

In accordance with Articles 125 and 126 of the REACH Regulation, Member States shall enact national provisions defining controls and sanctions for non-compliance

with the REACH Regulation. It is recommended that you contact the relevant enforcement authorities in your country to learn about the national control procedures in place. You may also contact the customs authorities and the national helpdesk for further information.

1.5 Who should I contact if I have a question on REACH?

There are a number of contact points from which you can obtain assistance and information on REACH:

- The first point of contact for questions on REACH is the national helpdesks established in each country of the European Economic Area (EEA). They provide services in their local language(s) and know the national conditions (e.g. national legislation, organisation of enforcement authorities, etc.). The list of contact details of the national REACH helpdesks is available on the ECHA website.
- For advice on fulfilling the obligations of REACH, trade associations, sector groups, chambers of commerce and other organisations, which are particularly familiar with sector-specific terminology, have set up stakeholder helpdesks to provide tailor-made support for their industrial sectors and products; e.g. plastics, minerals, mineral oils, paints.
- ECHA provides assistance particularly to those companies that are registering substances who have questions on REACH provisions but also on IUCLID 5, REACH-IT and the administration of submitted dossiers. Although non-EEA companies do not have direct obligations under the REACH Regulation, they also may approach ECHA, if they are looking for information on REACH. If their questions are related to the conditions in a particular country, they may also turn to the corresponding national REACH helpdesk. A network between the national REACH helpdesks and ECHA has been established with the overall objective of achieving the best, most consistent and most harmonised advice possible to manufacturers, importers, downstream users and interested parties, in particular SMEs.

2 SCOPE

2.1 Does REACH apply to substances (either on their own, in mixtures or in articles) manufactured or imported in volumes below 1 tonne per year?

Yes, because there are several obligations under REACH. Registration requirements only apply to substances that are manufactured or imported in quantities of 1 tonne or more per year per registrant (see FAQ section 6 on registration). However if a substance is manufactured/imported at less than 1 tonne per year per registrant, other obligations under REACH may still apply if the substance falls within the scope of REACH. These obligations, which may apply irrespectively of the volume, include obligations concerning use of the substance, restrictions, authorisation and communication in the supply chain, such as the provision of safety data sheets.

For help in identifying your obligations, the use of the Navigator tool is recommended.

2.2 Do substances used in biocides and plant protection products (PPP) have to be registered under REACH?

Active substances for use in biocidal products are regarded as already registered, as biocidal products and their active ingredients are covered by Directive 98/8/EC (Biocidal Products Directive). However, several conditions have to be fulfilled to benefit from the exemption. These conditions are laid down in Article 15(2) of the REACH Regulation and explained in section 1.6.5.1 of the Guidance on registration.

Active substances for use in plant protection products (PPPs) are regarded as registered as the plant protection products and their active ingredients are covered by Directive 91/414/EEC (Directive on plant protection products). Please note that even though co-formulants are mentioned in Article 15(1) of the REACH Regulation, currently they do not meet the conditions laid down in this Article. Therefore co-formulants used in biocides do not qualify for the exemption and are not regarded as registered. This is further explained in section 1.6.5.2 of the Guidance on registration.

It is important to note, that only the quantities of the active substance for use in biocidal products and for use in PPPs are considered registered under REACH. Thus, if the substance is not used as an active ingredient in a biocidal product or a PPP, then the exemption would not apply to this other use and the quantity of the substance for the non-biocidal or non-PPP use would have to be registered.

2.3 Does REACH apply to substances occurring in nature?

REACH also applies to substances occurring in nature as defined by Article 3(39) of the REACH Regulation. However, Annex V of the REACH Regulation states that the following substances occurring in nature are exempted from registration if they are not chemically modified: minerals, ores, ore concentrates, raw and processed natural gas, crude oil and coal. Other substances occurring in nature are exempted from registration if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or unless they were identified in

accordance with Article 59(1) at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 57(f). The term "not chemically modified substance" is defined in Article 3(40) of the REACH Regulation.

Please note that Annex V of the REACH Regulation was amended by Regulation EC 987/2008 in October 2008. Additional guidance giving more explanations and background information on the different exemptions in Annex V will be included in the Guidance on registration. A draft version of this additional guidance is available on the ECHA Guidance website.

FAQ 6.3.3 provides guidance on substances occurring in nature that are obtained by extraction processes. For particular guidance on polymer substances occurring in nature you may consult section 3.2.1.3 of the Guidance for monomers and polymers.

2.4 Are modified substances derived from substances listed in Annex IV also exempt from registration?

According to Article 2(7)(a) of the REACH Regulation, substances listed in Annex IV are exempt from registration. Modified substances derived from a substance listed in Annex IV are also exempt if the modified substance is still covered by the same EINECS entry. Whether or not a modification of a substance is covered by the same EINECS entry as the non modified substance is a case by case decision. For example, for plant oils such as soybean oil (EINECS no 232-274-4; CAS no 8001-22-7) the **physically** modified derivatives of that substance are explicitly covered in the EINECS entry. Compared to that, **chemical** modification (e.g. hydrogenation) is not mentioned and hence considered not to be covered. Please consult Article 3, Definition 40, of the REACH Regulation and Guidance on Registration (Section 1.6.4.3 – Substances included in Annex IV of the REACH Regulation) for further information.

2.5 Are synthetic analogues of natural substances exempted from Registration in accordance with Article 2(7)b and Annex V?

No. In order to avail of the exemption foreseen in Article 2(7)(b) and Point (8) of Annex V, as amended, to the REACH Regulation, substances must occur in nature as defined in Article 3(39) of the REACH Regulation. Such substances will include substances derived from geological rocks, plants, animals, micro-organisms, etc. These substances can only be processed by certain means (e.g. dissolution in water, flotation) which are specified in Article 3(39) and do not include chemical modification (Article 3(40)).

Since the synthetic analogues of naturally occurring substances do not meet this criterion, any manufacturer or importer of these substances in quantities of 1 tonne or more per year is required to submit a registration to ECHA.

2.6 Do substances at nano-scale fall under the scope of REACH?

Yes, they do and their health and environment properties must be assessed according to the provisions of the REACH Regulation.

Potential registrants should first consider whether they have obligations under REACH, irrespective of the particle size of the substances. Once it is established that the substance falls within the scope of REACH, further investigation of the detailed provisions of REACH may indicate that different provisions apply according to the hazard properties associated with the particle size of the substances.

The evolving science of nanotechnology may necessitate further requirements in the future to reflect the particular properties of nano-particles.

3 IMPORT OF SUBSTANCES INTO THE COMMUNITY

3.1 To which territories does REACH apply?

REACH is a European Community Regulation that directly applies in all Member States of the European Union. REACH is of EEA (European Economic Area) relevance as it has been incorporated into the Agreement on the European Economic Area. This means that REACH also applies in Iceland, Liechtenstein and Norway. Substances imported into the EEA from Switzerland (a non EU country belonging to the European Free Trade Association but not to the EEA) are treated under REACH in the same way as substances imported from any other non-EEA country.

Member States are best placed to explain how REACH applies to their territories (autonomic areas or overseas territories). We therefore recommend contacting the national REACH helpdesk of the relevant country to clarify specific questions in this regard.

3.2 What are the obligations of non-EEA companies?

Manufacturers established outside of the European Economic Area (EEA) do not have direct obligations under the REACH Regulation. It is the importer established within the EEA who needs to comply with the REACH obligations.

According to Article 3(9) of the REACH Regulation, a manufacturer means any natural or legal person established within the Community who manufactures a substance within the Community. Non-EEA companies exporting substances on their own, in mixtures or in articles to the EEA may (but are not obliged to) appoint an "only representative" according to Article 8 of the REACH Regulation to fulfil the obligations of importers. More guidance on only representatives can be found in section 1.5.3.4 of the Guidance on registration or in the FAQ section 4.

3.3 What are the obligations of importers of articles?

Under some circumstances article importers have to register or notify substances in articles to ECHA (see Article 7 of the REACH Regulation); these obligations are in general the same as for producers of articles. When placing articles on the market in the European Economic Area, importers of articles may also have to communicate information on substances in their articles to their customers. In order to establish

whether registration, notification or communication duties apply, any importer of articles is advised to follow first the Guidance in a Nutshell on requirements for substances in articles.

3.4 Is the importer always to be considered the same legal entity as the consignee stated on the simplified administrative document (SAD) used by the customs authorities? Does this imply that the consignee is considered to be responsible for registration?

No. Article 3(11) of the REACH Regulation states that the importer is the natural or legal person established within the Community who is responsible for import, i.e. the physical introduction (of the goods) into the customs territory of the Community (Article 3(10) of the REACH Regulation). As stated in section 1.5.3.3 of the Guidance on Registration the responsibility for import depends on many factors such as who orders, who pays, who is dealing with the customs formalities, but these might not be conclusive on their own.

In many instances the ultimate receiver of the goods (the consignee) will also be the legal entity that is responsible for the import. However this is not always the case. If for example company A (established in one EEA country) orders goods from company B (established in another EEA country) who acts as a distributor, company A probably does not know where the goods originate. Company B may choose to order the goods from either an EEA-manufacturer or from a non-EEA manufacturer. In case company B chooses to order from a non-EEA manufacturer (company C) the goods may be delivered directly from company C to company A in order to save on transportation costs. Because of this company A will be stated as the consignee on the SAD form and customs handling will take place in company A's country. Payment for the goods is, however, settled between companies A and B. Also note that in the present example company B is not a “sales agency” as described in section 1.5.3.3 the Guidance on Registration, as the “sales agency” does not choose the manufacturer from which to order the goods.

Because the decision whether to order goods from an EEA or non-EEA manufacturer lies with company B, this company (and not company A) should be considered the legal entity responsible for the physical introduction of the goods into the customs territory of the Community, while company A is a downstream user. The registration obligation consequently would lie with company B. Company A on the other hand will have to be able prove through documentation to the enforcement authorities that it is a downstream user, for example by showing that the order was placed to company B.

In addition, it should be noted that when interpreting the term "importer" according to the REACH Regulation, it is not possible to fall back upon the Community Customs Code (Regulation (EEC) No. 2913/92) or the "INCOTERMS".

4 ONLY REPRESENTATIVE OF "NON-COMMUNITY MANUFACTURER"

4.1 Who can appoint an only representative?

According to Article 8(1) of the REACH Regulation, a natural or legal person established outside of the EU who manufactures substances (to be used on their own, in mixtures and/or to produce articles), formulates mixtures or produces articles, can nominate an only representative located within the EU to carry out the required registration of their substances that are imported (as such, in mixtures and/or in articles) into the EU. Distributors are not mentioned in Article 8(1) and thus cannot appoint an only representative.

The reference to the EU covers both the EU countries and the EFTA countries that have adhered to the EEA (European Economic Area) Agreement, that is Iceland, Liechtenstein and Norway.

The only representative will have to fulfil the registration obligations of importers (Title II of REACH) and comply with all other obligations of importers under the REACH Regulation. More information on the only representative role is provided in the Guidance on Registration (Section 1.5.3.4 – Only representatives of "non-Community manufacturer").

4.2 Who can be appointed as an only representative?

A non-EEA company (that can appoint an only representative, see FAQ 4.1) may, by mutual agreement, appoint a natural or legal person established in the European Economic Area (EEA) to act as his only representative. According to Article 8(2) of the REACH Regulation this representative shall comply with all obligations of importers under the REACH Regulation. Therefore the only representative is required to have sufficient background in the practical handling of substances and the information related to them. More information on the only representative is also provided in section 1.5.3.4 of the Guidance on registration.

4.3 What is meant by the "sufficient background" of an only representative?

There are no detailed requirements or criteria regarding what is regarded as "sufficient background in the practical handling of substances and the information related to them" other than what is laid down in Article 8(2) of the REACH Regulation.

4.4 Is there a special procedure to appoint an only representative?

The issue of becoming an only representative is a question of mutual agreement between the "non-Community manufacturer" and the natural or legal person

established in the European Community who is being appointed as an only representative.

"Non-Community manufacturers" need to send a letter confirming this appointment to their only representative who must have it available in case of inspection by the relevant Member State's enforcement authority. No such letter has to be sent to ECHA. However, when compiling the registration dossier in IUCLID 5 the only representative is advised to attach this letter of appointment to the registration dossier in the field "Official assignment from non EU manufacturer" in section 1.7. More information on the duties of the only representative is provided in section 1.5.3.4 of the Guidance on registration.

In addition the "non-Community manufacturer" shall inform the importer(s) within the same supply chain of the appointment of the only representative according to Article 8(3) of the REACH Regulation. These importers shall be regarded as downstream users.

4.5 Can an only representative represent more than one company?

Yes, an only representative can represent one or several non-EEA companies that manufacture substances, formulate mixtures or produce articles which are exported to the European Economic Area (EEA), even for the same substance. More information on the duties of the only representative is provided in section 1.5.3.4 of the Guidance on registration.

4.6 How can “non-Community manufacturers” help their only representative or importers to prepare for registration?

The importer or the only representative is responsible for submitting a registration dossier or a pre-registration to take advantage from the extended registration deadlines for phase-in substances. In order to assist these actors under REACH, the *“non-Community manufacturer”* may wish to make himself aware of the information requirements laid down in REACH and start to collect the relevant information. This may include correct identification (CAS or EINECS/ELINCS/NLP) number and naming of the substance and information on its composition. This is explained in more detail in the Guidance for identification and naming of substances under REACH available at: http://guidance.echa.europa.eu/guidance_en.htm. The *“non-Community manufacturer”* may also assist in providing all available information regarding the intrinsic properties of the substances (see REACH annex VII to XI). However, these supporting measures of the *“non-Community manufacturer”* cannot relieve the only representative or the importer from the duty to comply with all relevant obligations of the REACH Regulation.

More information for *“non-Community manufacturers”* can be found at: http://echa.europa.eu/about/form_reach/form_not_eu_location_en.asp

4.7 As an only representative, do I need to specify in the registration dossier the identity of the "non-Community manufacturer" I am representing?

An only representative must be able to document who he is representing (i.e. the name of the non-EU manufacture should be given in section 1.7 of IUCLID) and is advised to attach a document from the "non-Community manufacturer" appointing him as only representative in section 1.7 of IUCLID. It is not mandatory to include this information in the registration dossier, but it needs to be presented to the enforcement authorities upon request.

Furthermore an only representative is advised to include the "list of importers" in section 1.7 in IUCLID.

4.8 I have registered a substance as an only representative (OR) of a non-Community manufacturer. Does a change of the importers of the non-Community manufacturer trigger the need for an update of the registration, and would this update be subject to a fee?

The change of importers of a substance supplied by a non-Community manufacturer who appointed an OR to register this substance does not trigger the requirement to update the list of importers indicated in section 1.7 of the IUCLID 5 dossier. However, the OR is required, in accordance with Article 8 (2) of REACH, to keep available and up-to-date information on quantities imported and customers sold to.

Information on the importers may be reported in section 1.7 of IUCLID 5. Practical information on how to do this is provided in the Data Submission Manual 5, section 4.1.7. The update of this list of importers is not subject to any fee.

5 PRE-REGISTRATION

5.1 (merged with FAQ 5.2)

5.2 Is it possible to benefit from the specific provisions for phase-in substances, if the substance was not pre-registered by 1 December 2008?

In order to benefit from the extended registration deadlines for phase-in substances, they needed to be pre-registered between 1 June 2008 and 1 December 2008. However, in the case of a manufacturer or importer who manufactures or imports a substance in quantities of 1 tonne or more per year for the first time after the pre-registration deadline (1 December 2008) has passed a pre-registration may still be submitted. In this case, the manufacturer or importer can still benefit from the extended registration deadlines for phase-in substances even though he did not pre-register within the deadline for pre-registration. According to Article 28(6) of the REACH Regulation, first-time manufacturers or importers must pre-register within six

months after first manufacture or import over the one-tonne threshold, and not later than 12 months before the relevant deadline for registration. First-time manufacturers or importers will therefore have to submit their pre-registration before 1 December 2009, 1 June 2012 or 1 June 2017, whichever is relevant as described in chapter 3.6 of the Guidance on data sharing.

The same applies to phase-in substances for which registration is required and that are used in the production of articles or imported in articles for the first time.

5.3 I am a first-time manufacturer or importer. How can I pre-register my substances and is there a format to be respected?

Late pre-registrations can only be submitted via the REACH-IT portal by direct encoding of the information on the REACH-IT website (online pre-registration). The REACH-IT Industry User Manual - Part 4 provides step by step instructions on how to make an online pre-registration.

5.4 How much is the pre-registration fee?

There is no fee for pre-registration. However according to Article 74 of the REACH Regulation that specifies the requirements for fees there is a fee for registration. For more information on the registration fee please see FAQ 6.7.

5.5 How is it possible to find out whether a substance is pre-registered?

According to Article 28(4) of the REACH Regulation, ECHA has published on its website the list of pre-registered substances. This list does not contain the names of the pre-registrants. Thus, in order to find out whether a substance has been pre-registered in a particular supply chain, a downstream user should enquire to his supplier or other actors further up his supply chain.

6 REGISTRATION

6.1 Who has to register substances?

Only a natural or legal person established within the European Economic Area (EEA) can be a registrant. Registration must take place when this person:

(1) manufactures a substance within the EEA in quantities of 1 tonne or more per year,

(2) is responsible for import into the EEA of quantities of 1 tonne or more per year or

(3) has been appointed as an only representative according to Article 8 of the REACH Regulation.

The national law of each country provides the specific provisions concerning natural or legal personality and when such a natural or legal person is established in its territory.

Please note that a company that is not established within the EEA does not have direct obligations under REACH. It is the importers introducing the non-EEA company's products into the EEA that need to comply with the obligations of REACH. However, to relieve the importers of their obligations, a company not established within the EEA, which is a manufacturer of substances, formulator or producer of articles, may decide to appoint an "only representative" (see FAQ section 4).

6.1.1 Who is the registrant in case of toll manufacturing of substances?[1]

A toll manufacturer is normally understood to be a company that manufactures a substance (on its own, in a mixture or in an article) in its own technical facilities following the instructions of a third party in exchange for an economic compensation. The substance is generally put on the market by the third party. This construction is, for example, used for an intermediate step in the production process for which sophisticated equipment is needed (distillation, centrifugation etc.).

According to the REACH Regulation, manufacturers of substances are required to register the substances they manufacture above one tonne per year. Therefore, the trigger to consider whether a natural or legal person is required to register is whether they undertake a process of manufacturing a substance in accordance with the definition of Article 3(8) of the REACH Regulation.

In this regard, an entity that manufactures a substance on behalf of a third party is to be considered a manufacturer for the purposes of REACH and, consequently, is required to register. If the entity running the manufacturing process is different from the entity owning the production facility, nevertheless one of these entities must act as the registrant under REACH. More explanations on which actors in the supply chain have registration obligations and responsibilities can be found in the Guidance on Registration (Section 1.5 - Who has to register?).

6.2 In case of an international company, who is the registrant?

In the situation where a company group is composed of several natural or legal persons, each of those must determine if they qualify as registrants according to Article 3(7) of the REACH Regulation. International companies sometimes have several daughter companies in the European Economic Area, often spread over several countries. If these subsidiaries of the parent companies are separate legal entities from the parent company, (a natural or legal person as defined under applicable national law), then they may be a registrant under REACH. Please see FAQ 6.1 on who has to register a substance.

6.3 Which substances have to be registered?

Registration is required for all substances:

- as defined in Article 3(1) of the REACH Regulation;

- manufactured in or imported into the Community in quantities of 1 tonne or more per registrant per year;

[1] This FAQ has been agreed by the Competent Authorities of the Member States (REACH CA) in October 2008.

- unless they are exempted from registration or regarded as being already registered, according to provisions in Articles 2, 9, 15 or 24 of the REACH Regulation;

- irrespective of whether they are classified as dangerous or not.

If you want to know whether you have to register a substance you should first consult section 1.6 of the Guidance on registration, where you will also find information on substances exempted from registration. In addition, the Navigator tool can help to clarify the registration obligations for your specific substance.

6.3.1. Do I have to register alloys?

The REACH Regulation refers to alloys as "special mixtures" (Recital (31), Annex I (0.11.), as amended by Regulation (EC) No 1272/2008). Therefore, an alloy is to be treated in the same way as other mixtures under REACH, which means that the alloy as such is not subject to registration but the alloying elements (e.g. metals), irrespectively of the production process of the alloy are. However, components which are not important for the properties of the alloy should be considered as impurities (i.e. they are part of a substance in the mixture) and therefore need not be registered separately.

Please note that intermetallic compounds are often wrongly regarded as alloys, although they have a well defined stoichiometry. Such substances are listed in EINECS (e.g. “aluminium, compound with iron (1:1)”, “iron, compound with titanium (2:1)”, etc.) and cannot be regarded as mixtures, therefore these intermetallic compounds have to be registered as such. This means that e.g. separate (pre-)registrations of the substances Al and Fe do not cover the substances “aluminium, compound with iron (1:1)” or “aluminium, compound with iron (1:3)”. For each intermetallic compound with a different metal ratio a separate (pre-)registration is required.

6.3.2. Do I have to register intermediates?

It depends under which type of intermediate as described under Article 3(15) of the REACH Regulation your intermediate falls, whether you have registration obligations or not.

- Non-isolated intermediates:

For the use of a substance as a non-isolated intermediate, there are no obligations under the REACH Regulation.

- On-site isolated intermediates:

A manufacturer of on-site isolated intermediates in quantities of 1 tonne or more per year needs to register their substances (if they are not otherwise exempted from registration (see FAQ 6.3). However registrants of on-site isolated intermediates can provide reduced registration information according to Article 17(2) of the REACH Regulation if they confirm that the substance is manufactured and used under strictly controlled conditions as described under Article 17(3).

- Transported isolated intermediates:

A manufacturer or importer of transported isolated intermediates in quantities of 1 tonne or more per year needs to register his substances if they are not otherwise exempted from registration (see FAQ 6.3). However, a registrant of transported isolated intermediates can provide reduced registration information according to Article 18(2) of the REACH Regulation if he confirms that he is manufacturing and/or

using the substance under strictly controlled conditions and if he confirms or states that he has received confirmation from the user that the substance is used under strictly controlled conditions as described under Article 18(4). In this case, both the registrant and the users are each liable for their own statement regarding the strictly controlled conditions.

The specific Guidance for intermediates describes when and how the specific provisions for the registration of intermediates under REACH can be used.

6.3.3. Do I have to register a substance occurring in nature if I have to apply a process to extract this substance?

Substances occurring in nature are exempted from the duty to register in accordance with Article 2(7)(b) and Annex V, point 8 of REACH, as long as they are not chemically modified, not classified as dangerous in accordance with Directive 67/548/EEC, nor substances of very high concern, such as PBT or vPvB substances. If a process is applied to extract such a substance, it has to be verified whether the process applied is one of those listed in Article 3(39) of the REACH Regulation. If this is the case, the substance still qualifies as substance that occurs in nature that does not have to be registered.

The processes mentioned in Article 3(39) are manual, mechanical or gravitational processes, dissolution in water, flotation, extraction with water, steam distillation, heating solely to remove water and extraction from air. Please note that extraction with solvents other than water, like e.g. hexane or ethanol, are not covered by Article 3(39). Substances which are extracted with these solvents do not qualify as a substance that occurs in nature and cannot be exempted from registration on the basis of Annex V, point 8.

Lavender oil, for example, is extracted from flowers of certain species of lavender (which occur in nature) by means of steam distillation. The subsequent spontaneous separation of oil and water allows an easy isolation of the lavender oil. As this extraction process is mentioned in Article 3(39), the lavender oil can be regarded as a substance that occurs in nature.

On the contrary, chrysanthemum oil, for example, which is extracted from chrysanthemum blossoms and leaves (which occur in nature) with a solvent mixture of water and ethanol (1:10), cannot be regarded as a substance that occurs in nature.

In general, it is important to remember that it is up to the manufacturer to assess the process applied and to determine if the definition of Article 3(39) is applicable or not.

6.3.4. What falls under the definition of PPORD (Product and Process Oriented Research and Development)?

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

Any scientific development of a substance consisting of, for example, campaign(s) for the scaling-up, improvement of a production process in a pilot plant or in the full-

scale production, or the investigation of the fields of applications for that substance, falls under the definition of PPORD irrespective of the tonnage involved.

In order to promote innovation, Article 9 of the REACH Regulation specifies that substances manufactured or imported on their own or in mixtures, as well as substances incorporated in articles or imported in articles for the purpose of PPORD can be exempted from the duty to register for a period of 5 years. To be exempted a company needs to submit a PPORD notification to the ECHA. Upon request, ECHA may further extend this exemption for up to another 5 years, or 10 years for the development of medicinal products (for human or veterinary use) as well as for substances that are not placed on the market. The specific Guidance on Scientific Research and Development (SR&D) and Product and Process Oriented Research and Development (PPORD) provides further information.

6.3.5. Have PORD exemptions under Directive 67/548/EEC been transferred into REACH?

National Process Orientated Research and Development (PORD) exemptions for the notification of substances under Directive 67/548/EEC are no longer valid under REACH since 1 June 2008, because there are no such notifications under REACH. Therefore, manufacturers or importers of substances, or producers of articles wishing to continue their PORD activities after 1 June 2008, need to submit a PPORD (Product and Process Oriented Research and Development) notification according to Article 9 of the REACH Regulation, to benefit from the registration exemption. For guidance on how to prepare and submit a PPORD notification in practice, please consult the Data Submission Manual 1, which is available on the ECHA website.

6.3.6. Does a potential registrant have to register a substance he is manufacturing or importing if this substance has previously been notified under Directive 67/548/EEC by another manufacturer or importer and is, thus, regarded as registered under the REACH Regulation?

Yes, a notification under Directive 67/548/EEC as amended by Directive 92/32/EEC is nominal so that only the notifier benefits from the provision that notified substances are being considered registered. Therefore, any other parties manufacturing or importing the substance in quantities of more than one tonne per year who have not notified this substance, must register it unless another exemption from the duty to register applies. More information on notified substances can be found in the Guidance on Registration (Section 1.6.5.3 – Notified substances according to Directive 67/548/EEC) and in Article 24 (2) of the REACH Regulation.

6.3.7. Will a registration under the REACH Regulation be required for substances that are manufactured within the EEA but exported 100% outside of the EEA?

Yes. Article 6 of the REACH Regulation requires a manufacturer of a substance in quantities of more than 1 tonne per year to submit a registration, irrespective of whether this substance will subsequently be exported outside of the European

Economic Area (EEA). Therefore, substances manufactured in the EEA above this limit that do not meet any of the criteria for exemption from registration in accordance with Article 2 of the REACH Regulation and which are subsequently exported to non-EEA countries must be registered. The rationale for this duty is that the exposure resulting from manufacture and any other activity before export could be relevant for workers and the environment in the EEA.

6.3.8. Do I have to register chemically surface treated substances?

The surface treatment of a substance is a "two dimensional" modification of macroscopic particles. A "two dimensional" modification means a chemical reaction between the functional groups only on the surface of a macroscopic particle with a substance which is called a surface treating substance.

By this definition it becomes clear that this kind of modification means a reaction of only a minor part (surface) of a macroscopic particle with the surface treating substance, i.e. most of the macroscopic particle is unmodified.

Therefore a chemically surface treated substance cannot be regarded as a mixture nor be defined by the criteria of the Guidance for identification and naming of substances under REACH.

With the same reasoning, a chemically surface treated substance could not be reported for EINECS nor be notified according to Directive 67/548/EEC because it was covered by the separate EINECS entries of both the basis substance (macroscopic particle) and the surface treating substance.

Taking this decision up under REACH means a consequent continuation of former decisions. Using the same line of arguments, chemically surface treated substances should not be registered as such under REACH, but the following requirements should be fulfilled:

1. Registration of the basis substance (macroscopic particle)

2. Registration of the surface treating substance

3. Description of the use "surface treatment" in the registration dossier of the surface treating substance and in the registration dossier of the basis substance

4. Any specific hazards or risks of the surface treated substance should be appropriately covered by the classification and labelling and by the chemicals safety assessment and resulting exposure scenarios.

6.3.9. Do I have to register substances used in medicinal products?[2]

According to Article 2(5)(a) of the REACH Regulation substances used in medicinal products for human or veterinary use within the scope of the relevant Community legislation are exempted from the Registration Title of the REACH Regulation (Title II). More explanation is provided for in section 1.6.4.2 of the Guidance on Registration available at the ECHA website:

http://reach.jrc.it/docs/guidance_document/registration_en.htm

[2] This FAQ has been agreed by the Competent Authorities of the Member States (REACH CA) in October 2008.

Substances fulfilling the conditions of Article 2(5)(a) of the REACH Regulation are also exempt from the Titles on Downstream Users, Evaluation and Authorisation (Titles V, VI and VII of the Regulation).

Importantly, substances are exempted from these Titles only to the extent that they are used in medicinal products in accordance with Regulation 726/2004, Directive 2001/82 and Directive 2001/83. Quantities of the same substance used for other purposes are not exempted.

The exemption covers the manufacture (in the EU) of substances in medicinal products that are exported; and the manufacture (in the EU) of active substances within the scope of Community legislation on medicinal products that are exported. The exemption also applies to imports of substances in medicinal products and imports of active substances within the scope of the Community rules on medicinal products.

Intermediates that are not present in the medicinal product (as defined in Regulation 726/2004, Directive 2001/82 and Directive 2001/83) are not exempted from registration.

6.3.10. (moved to section 7, corresponds now to FAQ 7.6)

6.3.11. (moved to section 7, corresponds now to FAQ 7.7)

6.3.12. May pre-registered substances that are manufactured or imported before the relevant registration deadline be placed on the market after this deadline without a registration?

The answer to this question depends on the role of the entity at the time when the registration obligation applies.

Article 5 of the REACH Regulation provides that *"…substances shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title* ***where this is required****."* (emphasis added)

Articles 6, 7, 17 and 18 establish the registration obligation and specify to whom this registration obligation applies. These Articles only impose registration obligations on manufacturers or importers (and, in specific cases, on producers or importers of articles) and do not impose registration obligations upon downstream users, distributors or suppliers of substances. In principle a manufacturer/importer can simultaneously also fulfil the definition of a "supplier of a substance" when placing it on the market.

Hence, the registration obligation does not apply to manufacturers or importers that have manufactured or imported pre-registered substances before the registration deadline and ceased such activities and simply act as suppliers of these substances after the registration deadline. This equally applies for any downstream user, distributor or supplier down the supply chain.

On the contrary, if the manufacturing/importing activities have not ceased before the relevant registration deadline, the manufacturer/importer keeps his status and must submit a registration dossier for all quantities of the substance manufactured **before and after** the respective registration deadline to continue the manufacture/import and placing on the market of these substances. However, in case the manufacturer/importer has not submitted registration, any actor down the supply chain who is not subject to the registration obligation may continue to use and/or supply quantities of the substance that have been supplied to them by the manufacturer/importer before the registration deadline.

6.3.13. Is a metal hydroxide manufactured from the metal oxide covered by the exemption from registration in Annex V, point 6 of the REACH Regulation?

According to Annex V, point 6 of the REACH Regulation hydrates of a substance or hydrated ions, formed by association of a substance with water are exempted from registration, provided that the substance (i.e. the anhydrous form) has been registered by its manufacturer or importer.

Hydrates of a substance are characterised by the fact that water molecules are linked by molecular interactions, in particular by hydrogen bonds, to other molecules or ions of the substance. For the purposes of Annex V, hydrates and water free forms (anhydrous) of compounds shall be regarded as the same substance (e.g. $CuSO_4 \cdot 5H_2O$ and $CuSO_4$).

In contrast, a metal hydroxide (e.g. $Ca(OH)_2$) and a metal oxide (e.g. CaO) cannot be regarded as the same substance as both substances have different structures, regardless of the manufacturing process. The formation of the hydroxide involves forming new covalent bonds, which is different from forming a hydrate which only involves weak intermolecular bonds. Therefore a metal hydroxide manufactured from the metal oxide is not covered by the exemption from registration in Annex V, point 6.

6.3.14. Are substances that are banned under Regulation (EC) No. 2037/2000 (on substances that deplete the ozone layer) subject to (pre-) registration?

Yes. Substances are not exempted from (pre-)registration on the grounds that they are within the scope of Regulation (EC) No. 2037/2000 on substances that deplete the ozone layer. FAQ 6.3 explains which substances have to be (pre-)registered.

6.4 When do I have to register my substances?

Various aspects need to be taken into account when considering the registration deadlines. These include tonnage, dangerous properties, and whether it is a phase in or a non-phase in substance. Chapter 1.7 of the Guidance on registration provides information on these aspects.

- The REACH Regulation creates a special transition regime for phase-in substances (section 1.7.1.1 of the Guidance on registration). In order to benefit from the extended registration deadlines for phase-in substances (Section 1.7.2 of the Guidance on registration), these substances must be pre-registered (see also FAQs

5.1 and 5.2). Depending on its intrinsic properties and its tonnage, a pre-registered substance needs to be registered by 1 December 2010, 1 June 2013 or 1 June 2018.

- Non-phase-in substances and phase-in substances which have not been pre-registered must be registered before manufacture or import can continue. In this case the registrant may have to wait for 3 weeks before continuing manufacture or import (Article 21 of the REACH Regulation). Prior to registration of such substances, the manufacturer or importer has a duty to make an inquiry to ECHA regarding any previous registration for that substance.

6.4.1. (deleted)

6.5 How do I calculate the tonnage?

Each registrant has to calculate the yearly tonnage for the registration dossier. The yearly tonnage is calculated as the volume per manufacturer/importer per calendar year, unless stated otherwise. For phase-in substances that have been imported or manufactured for at the least three consecutive years, quantities are calculated on the basis of the average production or import volumes for the three preceding calendar years (Article 3 (30) of the REACH Regulation). Detailed guidance and practical examples are provided in the Guidance on Registration (Section 1.6.2 – Calculation of volume to be registered).

6.6 Can I register for a tonnage band higher than the actual tonnage of the substance?

Yes. Companies are free to register a substance for a tonnage band which is above the actual tonnage of the substance. This is also reflected in section 1.6.2.2 of the Guidance on Registration, which clarifies that companies are free to register a substance for the intended tonnage band. A registration at a higher tonnage band will trigger a higher registration fee in accordance with Regulation (EC) No 340/2008. In addition, the technical dossier will need to comprise all the information required for the registered tonnage band. Practical advice on how to complete a IUCLID dossier is provided in the Data Submission Manual: Part 4 and Data Submission Manual: Part 5.

6.7 How do I register my substances and do I need IUCLID 5?

All registrations shall be submitted to ECHA. This shall be done using the REACH-IT Portal. For more information please visit the REACH-IT section of the ECHA website.

According to Article 111 of the REACH Regulation, registration dossiers have to be submitted in the format of IUCLID (International Uniform Chemical Information Database). IUCLID 5 is a software tool for companies to store data on chemicals and prepare registration dossiers. Registrants are not obliged to use the IUCLID software, but they must submit their registration in the IUCLID format.

The IUCLID 5 software is downloadable free of charge from the IUCLID website.

6.8 How much is the registration fee?

The registration fee for a substance varies depending on the tonnage of registration, size of the company and type of submission. A fee is not required for the registration of substances in a quantity between 1 and 10 tonnes per year for which a registration dossier containing the full information in Annex VII to the REACH Regulation is submitted. Lower fees and charges apply to joint submissions as compared to separate submissions. Moreover, a reduced fee is set in all categories for SMEs. However, an additional fee is levied for confidentiality requests submitted in accordance with Article 10(a)(xi) of the REACH Regulation.

Article 74 of the REACH Regulation lays down the basic provisions on the requirements for fees. The fees are specified in the Commission Regulation No. 340/2008 on fees and charges payable to ECHA. Further FAQs on fees and charges payable to ECHA are provided on the European Commission's website.

6.9 Can a Non-EEA manufacturer of a substance register under REACH?

No. The obligation to register a substance applies only to actors established within the European Economic Area (EEA). Thus, the registration of substances imported into the EEA on their own, in mixtures or, in certain cases, in articles will have to be done by the importer established in the EEA. This implies that each individual importer needs to register the substance. However, according to Article 8(1) of the REACH Regulation manufacturers of substances, formulators of mixtures or producers of articles established outside the EEA, can nominate an only representative (OR) established within the EEA to carry out the required registration. This will relieve the individual EEA importers within the supply chain of that non-EEA manufacturer from their registration obligations for these substances. They will be regarded as downstream users of this OR. However, the registration obligation may still apply if the EEA-importers import the same substance from other non-EEA manufacturers.

More information on the OR role can be found in FAQ section 4 and in section 1.5.3.4 of the Guidance on registration.

6.10 What are the options for an importer of a mixture when he is unable to obtain the relevant information from his supplier on the components of the mixture?

To fulfil his duties as a registrant an EEA-based importer of mixtures has to have information on the composition of the mixtures he imports into the European Economic Area (EEA). This obligation already existed under the previous legislation as regards substances to be classified as dangerous. Under REACH, an importer needs to know at least the identity and percentage content of all substances in the mixtures he imports that could exceed the amount of one tonne/year.

If the non-EEA supplier is not willing or not able to provide the required information, the importer has the following options:

- identify the formulator of the mixture (if different from the supplier) and ask him directly for the required information,

- propose to the non-EEA formulator that he appoints an only representative in accordance with Article 8 of the REACH Regulation,

- establish the composition of the mixture by analytical means,

- find an alternative supplier who is prepared to provide all required information for the mixture.

6.11 Can a third party representative register?

No. According to Article 4 of the REACH Regulation a manufacturer, importer or downstream user may appoint a third party representative for all proceedings under Article 11, 19, Title III (Data sharing and unnecessary testing) and Article 53 of the REACH Regulation involving discussions with other manufacturers, importers or, where relevant, downstream users. These proceedings do not include the submission of registrations. Unlike an only representative, a third party representative only plays a part in the negotiations between the (potential) registrants, while the appointing company retains full responsibility for complying with its registration obligations.

6.12 A company who notified a substance under Directive 67/548/EEC fails to claim its registration number for the notified substance. Is this substance still considered as registered? If this is the case and an inquiry is subsequently submitted for this substance by a potential registrant can this notifier be listed as the registrant?

In accordance with Article 24 of the REACH Regulation, ECHA has assigned registration number(s) to each notification submitted under Directive 67/548/EEC. The owner of the notification needs to claim a registration number from ECHA via REACH-IT. If the notifier fails to claim the registration number, it does not mean that he is "losing" his registration number, and that his substance will no longer be considered as registered. It just means that in practise he may not be able to provide evidence that he has a valid registration for the previously notified substance. However, the substance will still be considered as registered.

If an inquiry is subsequently submitted for this substance by a potential registrant, the contact details of the notifier available to ECHA are communicated to the potential registrant in the same way as ECHA informs the potential registrant about the contact details of any previous registrants according to Article 26(3). When informing the previous registrants of the contact details of the potential registrant, the notifier is informed accordingly. In the same letter to the notifier ECHA will remind the notifier to claim its registration number.

Further information is provided in the Questions and Answers document for the registrants of previously notified substances.

6.13 What are the duties of registrants that cease manufacture and import?

If a registration for a substance has been submitted, the obligations to update the registration (Article 22) and to keep information (Article 36) apply. This means that a registrant ceasing manufacture and import of this substance has to inform the Agency about the new total tonnage manufactured and imported (in this case zero t/a). Furthermore this registrant has to keep available all the information he required to carry out his duties under REACH for a period of at least 10 years after he last manufactured, imported, supplied or used the substance (as such or in a mixture). In this regard, the period of at least 10 years does not start if the registrant, who ceased manufacture and import, still supplies or uses the substance.

6.14 If I already have notified a substance under Directive 67/548/EEC, what do I have to do if I increase my tonnages?

Under the REACH Regulation, substances notified in accordance with Directive 67/548/EEC are regarded as registered by the manufacturer, importer, or sole representative who submitted the notification. The owner of the notification receives, after successful claim, a registration number from ECHA for the tonnage notified. For practical details please see the Questions & Answers for the registrants of previously notified substances.

If the quantity of notified substance manufactured or imported per manufacturer or importer reaches the next tonnage threshold as defined in Article 12(2) of the REACH Regulation, that is 1, 10, 100 or 1000 tonnes/year, the registration dossier should be updated. Note that 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. According to Article 22(1), the update shall be submitted without 'undue delay'. The manufacturer/importer does not need to stop manufacturing/importing while his update dossier is processed unless otherwise indicated by ECHA.

Specifically, if a company has notified a substance at a tonnage lower than 1 tonne/year, they need to submit a registration update when they reach that tonnage. All information listed in Annex VII needs to be included in the update dossier.

If a company increases its tonnage to e.g. 10 tonnes/year or more, it is required to submit not only the information required under Annex VII (≥ 1 tonne) which has not yet been submitted but also the additional information in accordance with Annex VIII (≥ 10 tonne) to the REACH Regulation. Moreover an update for a tonnage band reaching 10 tonnes/year or more should also include a Chemical Safety Report.

The registrant is obliged to inform ECHA of the additional information he would require to comply with the information requirements for the new tonnage level (Article 12(2)). In order to facilitate this process and to accelerate the handling of the update dossier, we strongly recommend that the registrant submits an inquiry to ECHA whenever he requires such additional information. Upon receipt of this information, ECHA acts as in an inquiry process (Article 26(3) and (4); see Section 9.1.5 of the Guidance on registration) 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.

6.15 Does the phrase “classified as [...] in accordance with Directive 67/548/EEC” in Article 23(1)(a) and (b) of the REACH Regulation refer only to substances listed with a harmonized classification in Annex I of this directive?

The wording of Article 23(1)(a) and (b) of the REACH Regulation “classified as [...] in accordance with Directive 67/548/EEC” refers to both, substances listed in Annex I with their harmonised classification and to self-classified substances.

It may be inferred from Articles 4 and 6 of Directive 67/548/EEC that substances shall be classified (by manufacturers/importers) according to the criteria in Annex VI of that Directive. In addition, Annex I of that Directive contains the list of substances classified by the Commission, following discussions in expert groups. As the Directive covers both situations, substances should therefore be considered as classified in accordance with Directive 67/548 not only when listed with their harmonised classification in Annex I, but as soon as they meet the criteria for classification set out in Annex VI of that Directive, i.e. also when self-classified by the registrant, should the substance not (yet) be listed in Annex I. Both situations should be considered as “classification in accordance with Directive 67/548/EEC”.

This interpretation is borne out by the very spirit of REACH and in particular the aim and objective of the deadlines provided for in Article 23. The aim of the earlier deadline for registration of substances with properties of very high concern is to gather earlier the necessary information on the substances, on their uses and for industry to develop and recommend appropriate risk management measures. Given the specific health and/or environmental concerns in this case the objective was not to defer the application of the REACH provisions for further years. To this end, the aim of the legislature in setting the earlier registration deadlines was clearly to cover both cases, as there is no difference in the protected public interest. Substances with non-harmonized classification are equally a ground for the same concern as substances with harmonised classification.

A consequence of this interpretation is that, as from 1 December 2010, as soon as a manufacturer or importer obtains evidence that his substance fulfils the classification criteria set out in Art. 23(1)(a) or (b) after that date, he will be obliged to register that substance immediately.

6.16 Does a registration of an isolated intermediate pursuant to Article 17(2) or Article 18(2) have to be updated due to a change of tonnage band?

A manufacturer or importer who has registered an isolated intermediate pursuant to Article 17(2) or Article 18(2) does in general not have to update this registration in case of a change of tonnage band. However, such a registration would have to be updated due to a change of tonnage band in two cases.

Case 1: Where the registration is for a transported isolated intermediate and the 1000 t/a threshold is reached, the registrant must update his registration dossier by submitting the information specified in Annex VII of the REACH Regulation, if not already included in the dossier.

Case 2: Where the registrant ceases manufacture and import of the isolated intermediate, he has the duties described in FAQ 6.12, which include an update of the registration.

6.17 I plan to manufacture/import a phase-in substance for the first time either less than 12 months before the relevant registration deadline or after it. When do I have to register this substance in each case?

The "no data, no market" principle set out in Article 5 of the REACH Regulation applies to all substances that are manufactured or imported in quantities of 1 t/a or more where they have not been registered or pre-registered. This means that a company planning to start manufacture or import of 1 t/a or more of a phase-in substance after the relevant registration deadline given in Article 23 needs to have validly registered the substance before starting this activity.

According to Article 28(6) a first-time manufacturer or importer of a substance may submit a late pre-registration within 6 months of the date of first manufacture or import in quantities of 1 t/a or more of that substance and no later than 12 months before the relevant registration deadline given in Article 23. Therefore, a company planning to start manufacture or import of 1 t/a or more of a phase-in substance less than 12 months before the relevant registration deadline also needs to have validly registered the substance before starting this activity.

In both cases, prior to registration the company planning to start manufacture or import has to submit an inquiry according to Article 26. The subsequent data sharing and submission process is explained in chapter 6 of the Guidance on data sharing.

After the submission of the registration dossier it may take up to three weeks before ECHA informs the registrant whether his registration is complete or not. Manufacture or import of a substance cannot start before the end of this period and can only start once ECHA has informed the registrant that the registration is complete and a registration number has been assigned.

6.18 How can a registration dossier be corrected in case a mistake was made in the preparation of the dossier?

After you have submitted your registration dossier you may realise that your registration dossier has to be corrected or modified for reasons other than those triggering the need for an update of the registration according to Article 22 of the REACH Regulation. This might be the case, for example, if you accidentally introduced faulty information in the dossier (e.g. incorrect information in one of the study summaries, which however does not affect the assessment of the substance made) and noticed this only after you submitted the dossier to ECHA. In this case you should make a spontaneous dossier update via REACH-IT, indicating in the dossier header the reason(s) why you are spontaneously updating it as well as the references of the previous valid submission (i.e. the "last submission number"). Such an update would not be subject to a fee.

If the mistake leads to a failure in the business rule verification, then instead of a spontaneous update submission an initial submission has to be made, as if it was the first dossier submission. Part 4 of the REACH-IT Data Submission Manual describes how to pass the business rule verification.

6.19 If a dossier submission is rejected after the second technical completeness check, what are the consequences?

In case the registrant fails to complete his/her registration for the second time within the deadline set, the Agency will reject the registration and the registration fee will not be reimbursed. According to Article 5 of the REACH Regulation, substances may not be manufactured, or placed on the market unless they have been registered. By virtue of Article 23(1), 23(2) or 23(3), as applicable, neither Article 21 nor Article 5 apply to the registration dossiers for substances benefiting from the extended registration deadlines of Article 23 until the respective deadline in question. This means that if a registration is rejected before the respective deadline in Article 23, manufacturing or importing of this substance within the European Economic Area can continue until this deadline.

6.20 Is there any obligation according to Article 21 of REACH to interrupt the manufacture or import of the substance during the technical completeness check (TCC)? (New)

In case the manufacture or import is only to be started, e.g. in case of a non phase-in substance, the waiting period must be respected.
On the other hand, there is no requirement to interrupt manufacture or import of phase-in substances during the TCC. However, when the initial submission of a phase-in substance was incomplete, ECHA will give the registrant a deadline to complete the dossier. Until the end of this deadline, the registrant is allowed to continue his activities. If he does not update the dossier, the registrant must cease manufacture or import by this deadline at the latest. If he updates his dossier, the registrant can continue the manufacture or import of the substance until he receives the decision by ECHA on the outcome of the completeness check. If he receives a decision rejecting his registration, he must cease manufacture or import of the substance.

6.21 Are registration numbers assigned to active substances in biocidal products? Does ECHA disseminate any information on those substances? (New)

REACH does not provide for the assignation of registration numbers to active substances in biocidal products. It is reminded that registration numbers are assigned exclusively for substances:
-where complete registration dossiers were submitted to ECHA by the registrant according to Article 20 of REACH;
-which were notified under Directive 67/548/EEC and the registration number was claimed by the notifier according to Article 24 of REACH.

Regarding the information on active substances in biocidal products, this is held by the European Commission, and certain information is publicly available via its website at http://ec.europa.eu/environment/biocides. ECHA has access to the information necessary for data sharing purposes.

6.22 If a registrant decides to change its Third Party Representative (TPR) does it need to update the registration and is there a fee for this? (New)

If a registrant changes its TPR, the new TPR will have to create a REACH-IT account (provided he does not yet have a REACH-IT account).
In case of a change of TPR, the following steps shall be taken by the registrant in order to update the details of its TPR:
-Include the new TPR in the REACH-IT company information section. The registrant should select <Company> - <View> and add the TPR in the TPR tab.
-Select manually the new TPR for every single pre-registration and Joint Submission Object (JSO) where a registration dossier has not been submitted yet using the pre-registration and JSO functionalities respectively. If a registration number had already been assigned to a specific substance, the registrant will not be able to modify the TPR of its pre-registration but he is able to update its TPR in the JSO.

Since the inclusion of a TPR in a registration dossier is not required by REACH during the submission of a registration dossier, an update of the TPR related to a registration is also not legally required. Article 22 of REACH does not include the update of a TPR as a case where the registrant shall be responsible for update on his own initiative. However, if the registrant wishes to communicate a change of TPR for a specific registration, i.e. while submitting a registration dossier update for any of the reasons established in Article 22 of REACH, they may do so.

No fee is required if the TPR is updated in a registration dossier.

7 POLYMERS AND MONOMERS

7.1 Do I have to register polymers?

According to Article 2(9) of the REACH Regulation polymers do not have to be registered, but according to Article 6(3), the monomer substance(s) and other substances of the polymers that have not already been registered by an actor up the supply chain, are to be registered if both the following conditions are met:

- the polymer consists of 2 % weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s) (i.e. free or unbound monomers shall not be considered when checking this condition);

- the total quantity of such monomer substance(s) or other substance(s) makes up 1 tonne or more per year (the total quantity in this context is the total quantity of monomer or other substance ending up in the final polymer unbound or chemically bound to the polymer)

The REACH Regulation defines polymers in Article 3(5) and monomers in Article 3(6).

The European Commission may according to Article 138(2) of the REACH Regulation present legislative proposals with requirements for the registration of polymers once a practicable and cost-effective way of selecting polymers for

registration on the basis of sound technical and valid scientific criteria can be established.

Detailed guidance and practical examples are provided in the Guidance for monomers and polymers.

7.2 Can I register monomers as intermediates (in accordance with Article 17(2) or 18(2) of the REACH Regulation)?

According to Article 6 (2) of the REACH Regulation, the reduced registration provisions with regard to on-site isolated and transported intermediates do not apply to monomers. This means that a full registration dossier must be submitted even if a monomer is used as an intermediate under strictly controlled conditions.

7.3 What is an impurity in a polymer?

An impurity in a polymer is defined as an unintended constituent present in the manufactured polymer substance. It may originate from the starting materials, such as the monomers or any other reactants, or be the result of secondary or incomplete reactions during the production process. While it is present in the final substance it was not intentionally added. Examples of impurities in a polymer include unreacted monomers or other reactants, residual polymerisation catalyst, or any contaminant from the manufacturing process. The definition and detailed guidance on how to handle impurities can be found in the Guidance for Identification and Naming of Substances Under REACH (Sections 4.2, 4.3 and 5).

7.4 What is an additive in a polymer?

Some substances are commonly added to polymers for the purpose of adjusting or improving their appearance and/or the physicochemical properties of polymeric material.

Additives which are necessary to preserve the stability of a polymer must be regarded as a part of the polymer in accordance with Article 3(1). Any other unbound “additive” must be regarded as a component of a mixture and not as an additive in accordance with Article 3(1).

Thus, the importer of a polymer containing additives does not need to register these additives provided that the additives are added to preserve the stability of the polymer. Note however that there is the general obligation to register substances imported in a polymer mixture in quantities of at least 1 tonne per year. Detailed guidance and practical examples are provided in the Guidance for monomers and polymers.

7.5 Beside registration requirements, do I have other obligations for polymers under REACH?

The provisions under the REACH Regulation with regard to information in the supply chain (Title IV), authorisation (Title VII), restrictions (Title VIII) and classification and

labelling C&L (Title XI) may also apply to polymers. The Guidance for Monomers and Polymers (Sections 3.2.2 – 3.2.5) provides further information on this issue.

7.6 Are there registration obligations for manufacturers and importers of natural polymers that have not been chemically modified?[3]

Natural polymers are understood as polymers which are the result of a polymerisation process that has taken place in nature, independently of the extraction process with which they have been extracted (i.e. they may or may not fulfil the criteria set out in Article 3(39) of the REACH Regulation).

Following Article 2(9) of the REACH Regulation, any polymer meeting the criteria of Article 3(5) of the REACH Regulation does not have to be registered.

According to Article 6(3) of the REACH Regulation any manufacturer or importer of a polymer shall submit a registration for the monomer substance(s) or any other substance(s) that meet the criteria mentioned in the respective article. However, monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s) in natural polymers can, for practical reasons, be treated as “non-isolated intermediates” and do not have to be registered.

7.7 Are there registration obligations for manufacturers and importers of natural polymers that have been chemically modified?[4]

Natural polymers are understood as polymers which are the result of a polymerisation process that has taken place in nature, independently of the extraction process with which they have been extracted (i.e. they may or may not fulfill the criteria set out in Article 3(39) of the REACH Regulation).

Following Article 2(9) of the REACH Regulation, any polymer meeting the criteria of Article 3(5) of the REACH Regulation does not have to be registered. This includes natural polymers which are chemically modified (e.g. post-treatment of natural polymers).

Monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s) originating from the natural polymer can for practical reasons be treated as “non-isolated intermediates” and do not have to be registered. The substances used to chemically modify the natural polymer and which are chemically bound within the final polymer need to be registered according to the REACH requirements.

7.8 An importer of a polymer has the obligation to register a monomer or other substance chemically bound to the polymer. Does he have to submit spectral data and

[3] This FAQ has been agreed by the Competent Authorities of the Member States (REACH CA) in October 2008.
[4] This FAQ has been agreed by the Competent Authorities of the Member States (REACH CA) in October 2008.

a chromatogram of the original substance used in the manufacture of the polymer?

Yes. The registration of a monomer or other substance chemically bound to a polymer shall include spectral data and a chromatogram of the original monomer or other substance used in the manufacture of the polymer. If it is not technically possible, or if it does not appear scientifically necessary to include this information, the reasons shall be clearly stated. Generic spectral data or a generic chromatogram cannot be accepted as this would not reflect the actual composition of the monomer or other substance used in the manufacture of the polymer.

It may be the case that a company imports a type of polymer from different sources, and thus a monomer or other substance used in the manufacture of this polymer probably also stems from different sources. Even when a company imports a polymer from just one source, it can happen that a monomer or other substance used in the manufacture of this polymer stems from different sources. In these cases the importer of the polymer is responsible for assessing the sameness of the monomer or other substance from the different sources. If he considers that the substances from the different sources are the same, he shall submit just one registration for this substance with one set of spectral data and one representative chromatogram. In this process he might still have found out that the substance from the different sources has different impurity profiles. He shall then refer to these different compositions of the substance in his registration dossier.

8 REQUIREMENTS FOR SUBSTANCES IN ARTICLES

8.1 Do I have to register substances in articles?

The registration requirement for substances in articles according to Article 7(1) of the REACH Regulation applies only if all the following conditions deriving from Articles 7(1) and 7(6) are met:

- the substance is intended to be released during normal and reasonable foreseeable conditions of use; and

- the total amount of the substance present in the articles exceeds one tonne per producer or importer per year; and

- the substance has not yet been registered for that specific use.

8.2 Under what conditions and when do I have to notify substances of very high concern in articles?

Substances meeting the criteria outlined in Article 57 of the REACH Regulation are commonly referred to as substances of very high concern (SVHC). Notification is required under Article 7(2) of the REACH Regulation for SVHC present in articles and for which the following conditions are met:

(1) the substance has been included in the candidate list of SVHC for authorisation and

(2) the substance is present in articles above a concentration of 0.1% weight by weight (w/w) and

(3) the total amount of the substance in those articles (i.e. those containing more than 0.1% (w/w) of the SVHC) exceeds one tonne per producer or importer per year and

(4) the substance has not yet been registered for that specific use.

However, there is no obligation to notify if the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use and disposal.

As indicated in Article 7(7) of the REACH Regulation the notification of a SVHC in articles shall be made at the latest 6 months after it has been included on the candidate list for authorisation but only starting from 1st June 2011. Information on a substance on the candidate list contained in articles is to be forwarded by the supplier of the articles to the recipients as soon as possible after the substance is included in that list (Article 33). The candidate list will be updated continuously when substances have been identified as meeting the criteria of Article 57 of the REACH Regulation. Further information can be found in http://echa.europa.eu/reach/sia/notification_in_sia_en.asp.

8.3 As Article 7(6) states "Paragraphs 1 to 5 shall not apply to substances that have already been registered for that use" does it refer to the same supply chain or to different supply chains?

Provided that the substance has been registered by any manufacturer/importer for that specific use, paragraphs 1 to 5 of Article 7 of the REACH Regulation shall not apply. This means that it is not relevant whether the registration was done within the same supply chain or within another supply chain.

8.4 Can I already rely on the provisions of Article 7(6) when a substance in an article has been pre-registered?

No, because Article 7(6) of the REACH Regulation only applies if the substance has already been registered for that use.

8.5 What is an intended release of a substance from articles?

A substance is intended to be released from articles if it fulfils an accessory function which would not be achieved if the substance were not released. Scented children's toys, for example, are articles with intended release of substances, because fragrance substances contained in the toys are released in order to fulfil an accessory function, namely to scent. Consequently, substances that are released because of ageing of articles, because of wear and tear or as an unavoidable side-effect of the functioning of the article, are generally not intended releases, as the release as such does not provide a function in itself.

An intended release of a substance from an article has furthermore to occur under normal or reasonably foreseeable conditions of use. This means that the substance release has to occur during the service life of the article. Hence, a substance release during the production or disposal phase of the article's life cycle is not an intended release. Similarly, a release in an accident or due to any form of misuse which is not in accordance with the use instructions or functionality of the article, does not occur under normal or reasonably foreseeable conditions of use and is therefore not considered to be an intended release.

8.6 May steel semi-finished products such as slabs, blooms and billets be considered as articles?

The transition point of steel and steel semi-finished products from substances/mixtures to articles during processing is to be determined by comparing the importance of physical and chemical characteristics for achieving the object’s function. If it can be unambiguously concluded that the shape/surface/design are more relevant for the function than the chemical

composition, the object that it is assessed is an article. If the shape, surface or design is of equal or less importance than the chemical composition, it is a substance or mixture. In case of doubt, the indicative questions given in section 2.4 of the Guidance on requirements for substances in articles can be used in order to better determine whether or not steel semi-finished products constitute an article. ECHA also advises industry to consult sector-specific guidance documents provided by business associations. However, it is up to the individual companies to examine their specific situation and determine whether their product may be considered as an article.

8.7 Is there any notification fee for the submission of a notification of Substances of Very High Concern (SVHC) in articles per Article 7 (2) of REACH? (New)

There is no fee charged for the notification of SVHC in articles.

8.8 I have stopped production/import of the article containing a Substance of Very High Concern (SVHC). Do I have to notify? (New)

If the production/import ended before the SVHC was included in the Candidate List or before the notification obligation starts to apply (i.e. 1 June 2011 for substances placed on the Candidate List before 1 December 2010 or 6 months after a substance has been included in the Candidate List) then you do not have to notify. However, you may still have obligation, under Article 33 of REACH, to provide the recipient of the article, or the consumer upon request, with sufficient information to allow safe use of the article, including, as a minimum, the name of that substance.

8.9 Do I have to consider the tonnage produced/imported before the Substance of Very High Concern (SVHC) was put on the Candidate List for the calculation of the tonnage in accordance with Article 7 (2) of REACH? (New)

For articles which have been produced/imported for at least three consecutive years, the tonnage to be reported must correspond to the average tonnage of the substance in the article produced/imported during these three full years. If the substance in the article has only been produced or imported for two full years, the average of these two full years must be notified. However, if the substance in the article has been produced or imported only since the previous calendar year, the tonnage will be calculated based on the previous calendar year only and no averaging will be made.

For instance, substances that were placed on the Candidate List before 1 December 2010 must be notified by the producer or importer of the article by 1 June 2011. The producer or importer shall provide the average tonnage of the three or two preceding years, or the tonnage of 2010, depending on for how many consecutive years they have imported or produced the article.

Thus, there are situations, where volumes of the substance predating the inclusion in the candidate list are considered in the tonnage calculation for the notification of a substance in an article.

Where production/import of the article starts in the current year, you are advised to notify as soon as the 1 tonne threshold is exceeded. In that case please indicate an expected tonnage range for the whole year.

9 DATA SHARING

9.1 What is the purpose of data sharing?

The rules on data sharing and avoidance of unnecessary testing are contained within Title III of the REACH Regulation. Article 25 sets out the objective of these rules, which is to reduce testing on vertebrate animals (such tests shall be carried out only as the last resort) and to avoid the duplication of tests, thus reducing the costs for industry and increasing the efficiency of the registration system.

9.2 What is the aim of a SIEF (Substance Information Exchange Forum)?

The aim of a SIEF is to facilitate the exchange between potential registrants of information necessary for the registration of the same substance in order to avoid duplication of studies and to agree on the classification and labelling (C&L) of the substance. The SIEF also serves as a platform for data holders to share their substance data/studies. Moreover, when the available information is not sufficient for registration, a SIEF collectively identifies the need for further studies.

9.3 How can communication within a SIEF be facilitated?

Exchange of information within a SIEF will be greatly facilitated if one participant agrees to play the role of a co-ordinator. This participant can propose means of organising exchange of information on the substance. Where the information to be exchanged is considered commercially sensitive by one or more potential registrants (e.g. because of an impurity content that can give indication on a production process), he could for example propose a confidentiality agreement or the use of an independent Third Party or trustee who can handle the confidential information on behalf of the potential registrants.

The SIEF can already at an early stage agree on a lead registrant who might take over the organisation of the information exchange and the preparation of the joint submission. Any other form of organisation is equally possible, as REACH does not set any conditions in this respect.

Detailed information on how to facilitate communication within SIEFs can be found in section 4.5.2 of the Guidance on data sharing.

9.4 Do the registrants have to submit all their data jointly?

No, the registrants do not have to submit *all* their data jointly. The Guidance on data sharing (Section 8.1) provides an overview of what shall and what may be jointly submitted for registration based on Article 11 of the REACH Regulation.

Some information of the registration has to be submitted jointly whereas other information needs to be submitted separately. Additionally, there is information the registrant(s) may decide themselves whether to submit jointly or separately.

The following information shall be submitted jointly: information on the classification and labelling of the substance, study summaries, robust study summaries and an

indication as to which of the submitted information on classification and labelling, study summaries and robust study summaries has been reviewed by an assessor. Under specific conditions, which should be explained in the dossier, a separate submission of these data is allowed.

Additionally each registrant shall submit separately: the identity of the manufacturer or importer, the identity of the substance, information on the manufacture and use(s), exposure information for substances in quantities of 1 to 10 tonnes and an indication of which of the submitted information on manufacture and use has been reviewed by an assessor. The registrants may decide to submit the following information jointly or separately: guidance on safe use of the substance, a Chemical Safety Report (CSR) when required and an indication which of the information submitted for the CSR has been reviewed by an assessor.

9.5 How is a Substance Information Exchange Forum (SIEF) formed and what is the role of EINECS in defining substance identity?

The Guidance on data sharing (Section 4.5 – How and when will a SIEF be formed?) explains principles on how and when a SIEF will be formed and how to determine the sameness of substances (i.e. whether the quantitative and qualitative composition of a substance leads to the conclusion that it needs to be considered as one and the same substance with one name for the purpose of REACH) and therefore whether they should be considered together in one SIEF. The Guidance also explains how to facilitate communication within a SIEF and at what point in time data holders should join the SIEF.

All potential registrants for the same phase-in substance shall form a SIEF on the basis of the rules laid down in REACH and further explained in the Guidance for identification and naming of substances under REACH. Wherever a phase-in substance has an EINECS number, this will normally mean that one SIEF will be formed for one EINECS entry. However, one EINECS entry may also correspond to several substances or several EINECS entries may correspond to one and the same substance. Establishing substance identity and determining whether substances should be considered the “same” substance and join the same SIEF is the matter for “sameness” discussions which should take place before a SIEF is formed. It should be noted that the REACH Regulation does not define "sameness" and it does not foresee at this stage any formal role for ECHA in confirming the establishment of sameness or in the formation of a SIEF.

In order to reach an agreement on the sameness of a substance, pre-registrants must enter into pre-SIEF discussions. As a consequence of this, a SIEF is formed when the potential registrants of a substance in the list of pre-registered substances actually agree that they effectively manufacture or import or intend to manufacture or import the same substance to allow a valid joint submission of data.

Any decision on the substance’s identity and substance name should be carefully examined to ensure that they are in line with the substance identity rules explained in the Guidance for identification and naming of substances under REACH. Refusal to share data within SIEFs may under certain circumstances lead to inability to register the substance. Failure to split one EINECS entry into several substances, where necessary, may result in invalid registrations, the need to prepare and resubmit registration dossiers for all concerned substances and to pay the registration fee again. Therefore, in case of doubt, it is recommended to share data as widely as possible within one EINECS entry (even if this is not strictly required by REACH) and,

at the same time, to interpret the substance definition narrowly, i.e. to rather submit several separate dossiers. Wherever a decision is taken not to split EINECS entries, care should be taken that the data submitted are adequate for all variants and forms of the substance.

In case of major problems, it is advised to contact ECHA to seek clarification.

For further information in relation to pre-SIEFs and SIEFs please refer to the SIEF – Key Principles document and to document CA/74/2009 rev.2.

9.6 How is a pre-SIEF managed?

The pre-SIEFs are supported by REACH-IT via substance web pages. These allow for the posting of information on the creation of SIEFs via two dedicated free-text fields on the substance web page. In the first free-text field, writing rights are only given to the SIEF Formation Facilitator; in the second free-text field, all pre-registrants of the substance have writing rights. All messages in these two free-text fields are the exclusive responsibility of the authors and ECHA will neither verify nor approve or disapprove of their contents.

It is recommended that the SIEF Formation Facilitator uses the first free-text field to post messages on the creation of a SIEF and to give contact details and information on further communication tools (e.g. dedicated industry websites). The second free-text field allows other pre-registrants to give comments (e.g. in case of disagreement with the SIEF Formation Facilitator). Both free-text fields allow only a limited number of characters and should therefore only be used for key messages and referring to further contact details and/or communication tools. In addition, pre-registrants can communicate that they are no longer interested in registering by de-activating themselves in the pre-SIEF (see also FAQ 9.14).

Potential registrants should work towards forming SIEFs as soon as possible, in order to ensure that sufficient time remains available to organise data sharing and prepare the registration dossiers; this is of particular relevance for high volume substances, in view of the registration deadline of 30 November 2010. The Guidance on data sharing (section 4.5) explains in more detail how and when a SIEF is formed.

9.7 Who can become a data holder in a SIEF?

The Guidance on data sharing (section 4.2) explains in detail who can be (and who must be) a SIEF participant and discusses the role of data holders.

A data holder is any person holding information/data relevant to a phase-in substance and willing to share it. They can sign up in REACH-IT with a view of becoming a participant in the SIEF for that substance and can provide information to other SIEF members by submitting to ECHA any or all of the relevant information listed in Article 28(1).

Data holders may include:

- Manufacturers, importers and only representatives of a non-EEA manufacturer of phase-in substances in quantities of less than 1 tonne per year who have not pre-registered.
- Downstream Users of phase-in substances
- Third Parties holding information on phase-in substances

In addition, the following parties will automatically be participants in SIEF, as they have already submitted information on phase-in substances either (1) as registrants or (2) in the framework of Community legislation on plant protection products and/or biocidal products:

- Any manufacturer or importer or only representative of a non-EEA manufacturer and any producer or importer of an article with intended release under normal or reasonably foreseeable conditions of use who has registered a phase-in substance before 1 June 2018 automatically becomes a data holder. This includes operators that do not pre-register as well as operators that, having pre-registered, decide to register before the relevant deadline.
- Any party for which ECHA has information submitted in the framework of the Plant Protection Product Directive (91/414/EC) or the Biocidal Product Directive (98/8/EC) that meet the conditions established in Article 15.

9.8 How are the costs shared?

As data gathering induces costs, data sharing implies some form of cost sharing. As required under Article 27(3) of the REACH Regulation, parties sharing data must make "every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way". Further information on sharing of cost for tests required as a result of a decision of the Agency can be found in Article 53 of the REACH Regulation.

Agreement on cost sharing usually requires parties to agree on:

(1) the reliability, relevance and adequacy of the data ("Data Quality")

(2) the economic value of the data ("Data Valuation"), and

(3) how the agreed value is shared among parties ("Cost Allocation and Compensation")

These elements should serve primarily as a checklist in order to ensure that all interested parties identify relevant factors when organising data quality review, data valuations and other cost sharing activities. Registrants are only required to share the costs of information that they are required to submit to satisfy their registration requirement. Therefore, companies cannot be forced to pay for studies that they do not need and they also cannot be forced to pay before they actually need them in their respective tonnage band. However whenever the (potential) registrant requests data earlier, he has to pay on receipt of the data. Other elements might be considered as well. In general, it is recommended that an agreement on cost sharing is reached prior to the disclosure of available information by participants.

The cost sharing guidance referred to in Article 27 and 30 of the REACH Regulation has been published by ECHA as chapter 7 of the Guidance on data sharing.

9.9 Who has the duty to inquire prior to registration and for which reason?

For non phase-in substances (and for phase-in substances that have not been pre-registered), a duty to inquire before registration applies. In particular, potential registrants must, according to Article 26 of the REACH Regulation, inquire from ECHA whether a submission has already been made for the same substance. This is to ensure that data are shared by the relevant parties.

Article 26(3) of the REACH Regulation in particular stipulates that studies involving vertebrate animals shall not be repeated and available studies shall be shared. Article 27 specifies further that available vertebrate animal studies have to be shared while other studies may be shared.

Thus, potential registrants have to refer in their registration to previous testing data on vertebrate animals wherever possible. Referring to submitted dossiers for information that has been generated by means other than tests on vertebrate animals is a possibility, but not obligatory.

In this regard, it is noteworthy that the SIEFs are active until 1 June 2018, and thereby a new registrant who makes an inquiry will be put into contact with the existing SIEF to facilitate data sharing.

9.10 What is the difference between a SIEF (a Substance Information Exchange Forum) and a consortium or other options for co-operation in the context of a SIEF?

A SIEF itself has no prescribed legal form. It is a group of potential registrants, downstream users and third parties (according to Article 29 of the REACH Regulation) that have an interest in the same substance and thus may have data sharing duties or data sharing opportunities under REACH. The REACH Regulation does not impose any obligation on SIEF participants to form or join a consortium or any other form of cooperation agreement. Thus, participation in a SIEF is mandatory for actors specified in Article 29 of the REACH Regulation, whilst membership of a consortium or any other form of cooperation agreement is entirely voluntary. If some or all participants of one or more SIEF(s) decide to form a consortium, they are free to determine their arrangements regarding scope, purpose, duration, conditions for membership or leaving etc. as long as these do not contravene Community competition rules. In addition, it is important to note that when a SIEF has members that are not part of a consortium or another form of agreement, the members of the consortium must nevertheless cooperate with the SIEF participants that are not participants in the consortium or agreement. Additional information can be found in chapter 10 of the Guidance on data sharing.

9.11 Is it possible to leave a SIEF? If not, what happens in case a company ceases its activities with regard to a pre-registered substance?

No, it is not. If a company which is a member of a SIEF subsequently ceases its activities with respect to the substance, that company still remains a participant in the SIEF. In particular, it will be required to share information it holds in accordance with the data sharing provisions of REACH. However, it is not required to participate in any submission (or update) made by the members of the SIEF, nor is it required to participate in any additional related costs.

Please note that during the pre-SIEF phase you can de-activate yourself from the pre-SIEF to indicate that you are not interested in registering the substance e.g. in a situation where you decide to cease manufacture or import of the specific substance. Note, however, that even as a non-active participant you still may be required to share your data.

9.12 Do I have to become a member of a SIEF, if I want to register a phase-in substance?

Article 11(1) of the REACH Regulation requires that when a substance is to be registered by multiple parties, a lead registrant has to make the joint submission of the registration dossier with the agreement of the other assenting registrant(s). The context in which this agreement is sought is the SIEF. Hence, all registrants have to become members of a SIEF in accordance with Article 29. Even in the particular case that a registrant opts out of the joint submission, the said registrant still remains a member of the SIEF (details on the conditions for opting out are provided in section 8.4 of the Guidance on data sharing).

In practice, REACH-IT automatically places companies who pre-registered phase-in substances with either the same name or same chemical identifiers, in the same pre-SIEF. According to Article 29 of the REACH Regulation, all potential registrants who have actually pre-registered the same phase-in substance shall become participants in a SIEF. In addition, parties who have registered a phase-in substance before 1 June 2018 without previous pre-registration, also enter the corresponding SIEF.

Every potential registrant of a phase-in substance who has not pre-registered this substance shall submit an inquiry to the Agency in accordance with Article 26.

Information on the categories of SIEF participants and their obligations is given in sections 4.2 and 4.3 of the Guidance on data sharing.

9.13 I have information on a substance that I do not intend to register, how can I become a member of the SIEF for this substance?

Parties holding information relevant to a phase-in substance, and willing to share it, can become members of the corresponding SIEF.

For this, parties who have not signed up yet as companies in REACH-IT have to sign-up as data holders. The functionality to indicate that you have data on a phase-in substance is called "provide information". The information as to which relevant studies/data you have can be put in the text field of the Remarks tab.

The "provide information" functionality is also available for parties that have signed-up already in REACH-IT as companies. Hence, these parties do not have to sign up as data holders separately.

As REACH does not provide for data holders to have an active role in the (pre-)SIEF, data holders have to wait until they are invited by the other participants to join a SIEF and share their studies/data with the potential registrants. Particularly data holders in possession of vertebrate animal test data for a substance have to be invited by the potential registrants of this substance to join their SIEF.

Further information on the role of data holders can be found in section 4.2.2 of the Guidance on data sharing.

9.14 I have pre-registered a substance which I do not intend to register. Can I become a member of the SIEF for this substance?

Yes, you will become a member of the SIEF. REACH-IT automatically placed companies who pre-registered substances with either the same name or chemical identifiers in the same pre-SIEF. Companies in each pre-SIEF must decide, based on detailed consideration of the substance identity, whether the substances they pre-registered can in fact be regarded as the same. Pre-registrants of the same substance will form one SIEF.

This, in principle, is irrespective of the intention to register, as pre-registration does not have to be followed by registration. However, pre-registrants should bear in mind that as SIEF members they may be asked by other participants in the SIEF for information required for the purpose of registration and, if they are in possession of such information, they will have to supply it.

If you are a member of a pre-SIEF for a given substance and have no intention to register this substance, you should deactivate your pre-SIEF membership to make this clear to the potential registrants who want to form a SIEF and prepare the joint submission. Guidance on how to deactivate your pre-SIEF membership is provided in section 2.5 of the REACH-IT Industry User Manual Part 5 - Pre-SIEF.

Additional information on SIEF Formation is provided in the SIEF – Key Principles document.

9.15 What is the role of ECHA in the formation of SIEFs?

ECHA will not participate in the discussions between potential registrants and will not play a role in confirming or rejecting the creation of a particular SIEF.

Each potential registrant should be aware of the identity of the substances manufactured and imported. It is therefore up to manufacturers, importers and only representatives to take the responsibility of defining precisely the substance for which a SIEF will be formed. They are furthermore free to choose how they communicate and organise themselves in the pre-SIEF.

9.16 Is a consortium necessary to organise the activities within a SIEF?

Consortia are a more formal type of co-operation between registrants set up in order to provide practical help with SIEF data-sharing obligations and the preparation of registrations. It is often claimed that "consortium" must be formed (or consortium agreements signed) to organise the activities within a SIEF such as data sharing and the joint submission of data. This is not the case. Neither the use of a full "consortium agreement" nor the use of another formal, written agreement is legally required by REACH.

However, under REACH, agreements of different parties have to be achieved on various issues, such as the sameness of substances, classification and labelling, sharing of data and cost, ownership of studies jointly developed or the selection of a lead registrant. When seeking agreements, the parties involved have to be mindful of intellectual property rights, confidentiality issues and always respect competition law. Therefore it is advisable that, whatever the form of the cooperation chosen, the

parties keep records of their agreements in writing (this can be by means of a contract but also even by email). Chapter 10 of the Guidance on data sharing provides information on different forms of cooperation under REACH.

9.17 How do the roles of SIEF Formation Facilitator and the Lead Registrant differ?

The SIEF Formation Facilitator (SFF) role was created in order to initiate and conduct discussions after pre-registration, and to facilitate the exchange of information and data which is required in order to form a SIEF. Sections 2.8-2.10 of the REACH-IT Industry User Manual Part 5 - Pre-SIEF explain the steps necessary to become SFF and the special means at the disposal of the SFF to communicate with the other members of the (pre-)SIEF. Any company volunteering to be a SFF must be willing to take the initiative to contact the other participants within its pre-SIEF, with a view to forming the SIEF.

It is to be noted that the SFF and the Lead Registrant (LR) have different roles within REACH. While the SFF plays a role during the pre-SIEF phase until a SIEF is formed, the LR acts within the SIEF and in the context of joint submission, as stipulated by Article 11(1) of the REACH Regulation.

The SFF does not have a formal recognition in the REACH Regulation, while the role of the LR is specifically foreseen in the Regulation and necessary for joint registrations. This means that potential registrants have no obligation to use a SFF to form a SIEF, and may even bypass the SFF in order to commence pre-SIEF discussions, should the SFF be inactive. Nevertheless, they must select a LR who submits the joint registration before the other registrants in the SIEF can submit their individual dossiers for registration.

A further difference between the SFF and the LR relates to the way in which potential registrants can assume these roles. To become SFF, a potential registrant has to volunteer via REACH-IT on a first-come first-served basis. A LR, on the contrary, must act with the agreement of the other registrants of the same substance. Therefore, a registrant can only become LR provided that the other SIEF members assent to it. The REACH Regulation does not specify rules as to how the LR should be selected and nominated. However, LRs are advised to inform ECHA of their nomination by using the web form in the section on Lead Registrants of ECHA's web site.

Additional guidance on the role of the SFF is provided in section 4.5.2 of the Guidance on data sharing and in the SIEF – Key Principles document.

9.18 I have received a request from a SIEF Formation Facilitator asking me to pay a fee. Do I have to comply with this request?

The role of a SIEF Formation Facilitator (SFF) is not defined in the REACH Regulation. He is supposed to take the initiative to contact other participants in the pre-SIEF in order to facilitate the exchange of information and data which is required in order to form a SIEF. However, SFFs have no management role beyond facilitating discussions, and they have no legal basis to force other pre-SIEF participants to cooperate with them. Consequently, SFFs cannot demand fees for their services unless mutually agreed.

9.19 Since the data-sharing and cost-sharing rules in Article 30 of REACH apply only within the same SIEF, can ECHA do anything to help in a situation where the conflict is between two different SIEFs? (New)

If a registration containing the relevant information has not already been submitted by another registrant, it is not mandatory for participants in different SIEFs to share data, even though it is encouraged by REACH in order to reduce animal testing and curb compliance costs. Every request for access to studies across different SIEFs will have to be negotiated on a case by case basis by the concerned companies. Further guidance on inter-SIEF rules can be found in section 4.6 of the Guidance on Data Sharing available on the ECHA website at:

http://guidance.echa.europa.eu/guidance_en.htm#GD_PROCC.

9.20 How to proceed when sharing data older than 12 years submitted for notifications under Directive 67/548/EEC? (New)

Following an inquiry, where a potential registrant indicates the data requirements needed for the tonnage band he intends to register, he is informed of the names of previous registrants/ notifiers and of whether data has been submitted more than 12 years previously (data that is available at ECHA). Simultaneously the previous registrants receive a communication that an inquiry about one of their substances has been placed at ECHA.

The potential registrant does not need to contact the previous registrants. Instead, the study summaries or robust study summaries submitted in the framework of a registration of the same substance under REACH at least 12 years previously are attached as annex to the ECHA communication sent to the inquirer. However, the information in the endpoint summaries that ECHA provides may not be sufficient to pass the technical completeness check (TCC) , because:

- certain data were not migrated into the IUCLID 5 format and will need to be manually corrected or/and

- certain administrative information may be missing in some fields or sections.

The potential registrant should carefully check and complete its registration dossier in order to fulfil the information requirements for his tonnage band. It is the responsibility of the potential registrant to submit a registration dossier (in IUCLID 5 format) properly filled in.

ECHA provides inquirers with instructions on how to fill in their registration dossier if they wish to make use of the available (robust) study summaries submitted more than 12 years ago.

Access to data does not provide ownership of the data. According to the REACH Regulation, these study summaries and/or robust study summaries may only be used by another manufacturer or importer for the purposes of registration (as per Articles 10 and 25(3)). The potential registrant must respect any property rights.

9.21 How can ECHA assist me in case I have an issue in sharing data? (New)

1. In the case of non-phase-in substances or phase-in substances that have not been pre-registered

If the previous and potential registrants cannot reach an agreement on sharing the data or the costs, the potential registrant, can ask ECHA to be granted permission to refer to the data, if he considers that he has made every effort to reach an agreement while the other party has not. In this case he can inform ECHA by filling in the following webform: https://comments.echa.europa.eu/comments/article275.aspx. He must ensure to follow all instructions given on the ECHA website.

2. In the case of pre-registered phase-in substances
2.1. If the joint registration dossier has already been submitted, and if the existing registrant(s) (or their representative) do not share the submitted data, a potential registrant who considers that he has made every effort to reach an agreement, can ask ECHA to grant him permission to refer to the vertebrate animals studies contained in the submitted joint registration and that he is required to also submit.

2.2. In the case of a joint registration which has not been submitted yet and the dossier is being prepared, if the owner of an existing vertebrate study within the SIEF is not willing to share his data or refuses to provide proof of its costs, the other potential registrants can ask permission from ECHA to proceed with their registration without fulfilling the relevant information requirements.

In both cases 2.1 and 2.2, the potential registrants can inform ECHA by filling in the following webform: https://comments.echa.europa.eu/comments/article303.aspx. They must ensure to follow all instructions given on the ECHA website.

2.3. In the case of a joint registration which has not been submitted yet and the dossier is being prepared, if a data gap has been identified by the SIEF participants, but none of the potential registrants is willing to conduct the necessary test, the SIEF participants who need this information (e.g. as per their tonnage band requirements) can ask ECHA to appoint one of them to conduct the missing test. In this case they can inform ECHA by filling in the following webform: https://comments.echa.europa.eu/comments/article302.aspx. They must ensure to follow all instructions given on the ECHA website.
For more information please consult the ECHA website at http://echa.europa.eu/datasharing_en.asp.

9.22 How can I be sure ECHA will consider my data sharing dispute? (New)

ECHA will review all claims that are submitted via the webforms (mentioned in FAQ 9.21).
However, in order to justify its claim, an applicant needs to demonstrate that he has made every effort to reach an agreement in the negotiation for the data. This includes that he has requested clear information, challenged the answers which were unsatisfactory to him, made reasonable proposal to resolve the aspects of disagreements and granted reasonable time to the other party to address its arguments and proposals. The applicant will have to provide ECHA with all the correspondence and supporting documents (e.g. SIEF agreement) available at the time of the claim to ECHA, and will have to describe the situation to the Agency. The applicant must have offered the other party the opportunity to discuss all the concerns he may have on the data sharing conditions.

For more detailed information please consult the Data Sharing section of the ECHA website at http://echa.europa.eu/datasharing_en.asp and more specifically the Questions and Answers on Data sharing and related disputes document.

10 JOINT SUBMISSION OF DATA BY MULTIPLE REGISTRANTS

10.1 When the lead registrant should create the joint submission in REACH-IT and is there a deadline for registrants to confirm their membership of the joint submission?

A lead registrant should create the joint submission in REACH-IT as soon as he is nominated by the SIEF.

A company, which has received the joint submission name and token from the lead registrant has to bear in mind that:
- the token needed for the membership confirmation in REACH-IT has a validity of 30 days only (the lead registrant can always generate a new token);
- the company has to confirm its membership of the joint submission before submitting its member dossier; and
- its member dossier has to be submitted before the registration deadline relevant for the member registrant (see FAQ 6.4).

10.2 As a member registrant, how will I be informed about the submission of the joint registration dossier by the lead registrant?

Information relating to the receipt and processing of the lead dossier is sent by ECHA only to the lead registrant. As a member registrant, you do not receive this information from ECHA.

ECHA recommends that member registrants develop contractual arrangements with their lead registrant specifying the items about which the lead registrant must keep them informed (e.g. about the submission of the lead dossier) and by which means (e.g. postal or electronic mail).

In any case, the “lead dossier status”, which member registrants can see on the joint submission details page in REACH-IT, indicates whether the lead dossier has been accepted for processing by ECHA (status depicted by a green tick) or not (status depicted by a red cross). Section 3.3 of part 7 of the REACH-IT Industry User Manual describes how to view the joint submission in REACH-IT.

10.3 Can a registrant submit all the information specified in Article 10 (a) (iv), (vi), (vii) and (ix) separately?

Registrants are allowed to submit the information specified in Article 10(a) (iv), (vi), (vii) or (ix) separately under the specific conditions listed in Article 11(3) of the REACH Regulation. Such an “opt out” can cover all information that the lead registrant submits on behalf of all member registrants, or it can cover only parts of this information.

10.4 If I opt out for all information submitted by the lead registrant on behalf of member registrants, does this mean that I still have to submit my dossier as part of the joint submission?

The REACH Regulation, and in particular Article 11, is based on the "one substance one registration" principle. In line with this principle Article 11(3) provides that certain information, but not the whole dossier, may under certain conditions be submitted separately. From this it follows that registrants that opt out should submit their registration dossier as part of the joint submission, even if they opt out for all information specified in Article 10(a)(iv), (vi), (vii) and (ix).

10.5 Can different classifications of a substance be included in the joint submission dossier?

According to Article 29(2) of the REACH Regulation, one of the main aims of the SIEF is to agree on classification and labelling where there is a difference in the classification and labelling of the substance between potential registrants. Nevertheless if all member registrants agree, the lead registrant may include different classifications of the substance in the joint part of the registration dossier, e.g. if different impurity profiles lead to different classifications. In this case, member registrants should leave empty the pertinent section of their member dossier in order to avoid being treated as an opt-out for the classification and labelling of the substance.

If no agreement is reached among the member registrants on the inclusion of all different classifications of the substance in the joint part of the registration dossier, one or more of the member registrants may decide to provide his substance classification separately (by filling in the respective section in the member dossier), in which case a justification in accordance with Article 11(3) is required. In addition, where a harmonised C&L for a substance is provided in Annex VI of the CLP Regulation, then that harmonised C&L must be used.

Section 4.2 of the Data Submission Manual No. 5 explains how to report the classification and labelling of a substance within a joint submission.

10.6 Does a joint submission dossier need to include all available studies?

Yes. According to Annex VII of the REACH Regulation any physicochemical, toxicological and ecotoxicological information that is available and relevant shall be provided in the registration dossier. In practice, after gathering and assessing all existing information, the registrant has to select the information that is reliable, relevant and adequate. For key studies, robust study summaries have to be provided; for supporting studies, study summaries are sufficient

Further guidance on Information gathering and evaluation is also provided in chapters R.3 and R.4 of the Guidance on information requirements and chemical safety assessment available at http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm?time=1283943789.

More information on the reliability, relevancy and adequacy of the selected information is provided in the section 2.1.1 of Practical Guide 4 “How to report data waiving” available at http://echa.europa.eu/doc/publications/practical_guides/pg_report_data_waiving.pdf.

10.7 Can member registrants of a joint submission submit the same generic spectral data or chromatograms?

According to Article 11(1) of the REACH Regulation, the information specified in Article 10(a)(ii), i.e. details on the substance identity including spectral data and chromatograms, have to be submitted separately by each member registrant of a joint submission.

This information is necessary in order for ECHA to be able to check the sameness of the substances of the different member registrants. Therefore, generic spectral data or chromatograms must not be used. Each member registrant of a joint submission has instead to provide specific spectral data and chromatograms for the substance he intends to register.

10.8 Can a company resign from its role as lead registrant?

REACH requires certain data of the dossier on the same substance to be jointly submitted by one lead registrant. The REACH Regulation as such does not prevent the change of a lead registrant. It is up to SIEF participants to agree on who shall be the lead registrant, which acts with the assent of the other registrants for the same substance.

From a technical point of view, a company cannot resign from its role as lead registrant unless it assigns the lead role to another member of the joint submission and the member accepts the assignment as lead registrant in REACH-IT. Section 3.3.1 of the REACH-IT Industry User Manual, Part 7 describes how to transfer the lead role in REACH-IT to another member of the joint submission. The new lead registrant is advised to identify himself via the lead registrant notification web-form to inform ECHA of his nomination. In parallel, the previous lead registrant should also update his nomination by informing ECHA of his resignation (using the same web-form). The lead registrant notification is voluntary and can/ should be updated at any time.

11 INFORMATION REQUIREMENTS, TEST METHODS AND QUALITY OF DATA

11.1 According to which test methods and standards should new tests be performed?

Article 13(3) of the REACH Regulation requires that new tests shall be carried out in accordance with the test guidelines included in Commission Regulation No. 440/2008 or in accordance with other international test methods recognised by the European

Commission or ECHA. In addition, in Annexes VII to X on standard information requirements, the use of various OECD test guidelines is required in cases where no EU test method exists (e.g. OECD TG 414, 421 and 422).

Article 13(3) also specifies that information may be generated using other methods provided the conditions defined in Annex XI of the REACH Regulation are met. These include *inter alia* that the result is sufficient for the purposes of classification and labelling and/or risk assessment, and that adequate and reliable documentation of the applied method is provided (see Annex XI of the REACH Regulation for more information).

Moreover, a specific requirement is introduced in Article 13(4) of the REACH Regulation for ecotoxicological and toxicological tests. Since 1 June 2008, new tests of this kind have to be carried out in compliance with the principles of Good Laboratory Practice (GLP) provided for in Directive 2004/10/EC, as no other international standard has so far been recognised as being equivalent. In case of physico-chemical testing it may be desirable but it is not mandatory to have tests performed according to GLP standard.

The Guidance on information requirements and chemical safety assessment contains specific Integrated Testing Strategies for each endpoint (e.g. for aquatic toxicity, mutagenicity), which should be consulted before new tests are performed.

11.2 (merged with FAQ 10.1)

11.3 Are there “other international test methods” recognised by the Commission or the ECHA and referred to in article 13(3)?

For the time being, no "other international test methods" within the meaning of Article 13(3) of the REACH Regulation have been recognised by the Commission or by ECHA.

11.4 Is there a list of GLP certified testing laboratories?

Good Laboratory Practice (GLP) certification of laboratories is the responsibility of national authorities that administer the national GLP monitoring programmes. If the laboratory is located in the EU, Norway or Switzerland, the corresponding authority can be found at the website of DG Enterprise and Industry of the European Commission. If the laboratory is located in another country, you should check the section on Good Laboratory Practice of the OECD website. After you have identified the relevant GLP monitoring authority, you can consult this authority in order to find out the laboratories with GLP certification in the corresponding country.

If the laboratory is located in a country which has not joined the OECD Mutual Acceptance of Data system, but the laboratory has been inspected by a GLP Monitoring Authority before the test has been carried out in this laboratory information on these laboratories can be obtained from the GLP Monitoring Authority who has inspected these laboratories (see also FAQ 11.7).

11.5 Are reference books and databases regarded as reliable sources of substance data?

In general, there is the possibility to use data from reliable, scientifically accepted reference literature or databases, provided that the substance to be registered and the substance described in the reference are comparable with regard to homogeneity, impurities, particle size etc. References to literature or databases often use secondary data sources. When such data is used, the original source should be cited and checked by an expert.

Useful reference books and data compilations containing peer reviewed physicochemical data are listed in section R.7.1.1.2 of the Guidance on information requirements and chemical safety assessment.

11.6 What is the OECD Mutual Acceptance of Data (MAD) system?

The OECD decision on Mutual Acceptance of Data (MAD) provides for data generated by testing of chemicals in an OECD member country in accordance with OECD test guidelines and OECD Principles of Good Laboratory Practice to be accepted in other member countries for purposes related to the protection of human health and the environment. This system also covers non-OECD countries which have requested adherence to the OECD GLP and to join the MAD system. These non-OECD countries can be divided in two groups:

1) Countries which are full adherents to the OECD MAD system.

2) Countries which are provisional adherents to the OECD MAD system.

Countries which are full adherents to the OECD MAD system will accept data from OECD member countries and other adhering countries generated under MAD conditions. In addition non-clinical safety data developed in these countries must be accepted by OECD and adhering countries.

Countries which are provisional adherents to the OECD MAD system need to accept data from OECD member countries and other adhering countries generated under MAD conditions. However, during the period of provisional adherence, GLP monitoring activities conducted by the GLP MA located in the country of the provisional adherence do not have to be accepted by the full members of the OECD MAD Decision.

11.7 What studies does ECHA accept as GLP studies?

In general, ECHA accepts data as GLP data where this data comes (i) from countries which are OECD member states or full adherents to the OECD Mutual Acceptance of Data (MAD) system and (ii) from countries which are provisional adherents to the OECD MAD system and in which laboratories have been inspected jointly by the GLP Monitoring Authority concerned and by an OECD GLP Monitoring Authority.

Studies that are conducted in a laboratory situated in a country which has not joined the OECD MAD system can be accepted by ECHA as GLP compliant studies under the following conditions:

1) Prior to the performance of the study the GLP compliance of the laboratory has been inspected by:

- an EU GLP Monitoring authority (including Norway through EEA agreement) or
- GLP Monitoring Authorities in Israel, Japan and Switzerland with whom the EU holds Mutual Recognition Agreements or
- other GLP Monitoring Authorities of OECD member states or full adherents to the OECD Mutual Acceptance of Data (MAD) system on a case-by-case basis

and

2) the laboratory has been found to be operating in compliance with GLP principles.

11.8 Registrants who submit a proposal for testing in accordance with Annexes IX and X of REACH may waive 28-day studies if certain conditions are fulfilled. However, if there are no results for a 28-day repeated dose toxicity study because a testing proposal for a 90-day repeated dose toxicity test is made, it is not possible to derive a DNEL. Which interim risk management measures (RMM) could be recommended in this situation? (New)

Interim RMM are to be included into the Chemical Safety Report (CSR) and to be communicated to the users of the substance (either under Article 31 or 32 of REACH, in form of Exposure Scenario (ES) or otherwise). Such RMMs need to describe how to handle a substance in an appropriate way in the absence of sufficient toxicological information and while waiting for the results of proposed testing for long-term hazards. If no Derived No-Effect Level (DNEL) is available, the registrant is expected to carry out a qualitative risk characterisation referring to the identified uses and the expected exposure and justifying that the measures are sufficient to control the risks (based on the available knowledge). Typical RMM applicable in such case are listed in the Table E.3-1 of Part E: Risk Characterisation of the Guidance on information requirements and chemical safety assessment available at:

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm?time=1301130958#E.

Where no or not enough hazard information on the substance is available, the registrant should demonstrate control of risks by minimizing the emission and/or exposure to the substance. In doing so, he can use a combination of containment and/or Local Exhaust Ventilation (LEV) and/or Personal Protective Equipment (PPE) as interim RMM to protect workers from exposure. Due to the interim nature of the measures, PPE may play a more prominent role compared to what is suggested in table E.3-1 of the abovementioned Guidance.

The registrant may need to update his CSR and ES once he receives the result of the test proposal and is able to derive a DNEL (or identify that minimisation of emission/exposure is required if "no threshold" effects had been identified in the testing). This applies in particular if the interim measures had been based on PPE instead of containment or other engineering measures.

12 AUTHORISATION

12.1 Are any substances already subject to authorisation?

Yes. On 17 February 2011 the European Commission adopted its first amendment to the List of Substances Subject to Authorisation (Annex XIV of the REACH Regulation) which now includes the first six (6) substances. This amendment entered into force on 21 February 2011. The link to the updated Annex XIV can be found on ECHA's website.

Substances will regularly be added to Annex XIV by the European Commission, on the basis of recommendations issued by ECHA.

Further details on the procedure for the inclusion of substances to Annex XIV of the REACH Regulation are available in FAQ n°12.4, as well as on ECHA's website.

12.2 Where do I find the Candidate List? (Updated)

The Candidate List of Substances of Very High Concern (SVHC) for authorisation (Candidate List) is available on ECHA's website at:

http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp.

Additional substances are regularly included in the Candidate List, once these have been identified as SVHC.

12.3 How is a substance included in the Candidate List? (Updated)

When the European Commission or a Member State considers that a substance may meet the criteria for identification as SVHC pursuant to Article 57 of REACH, ECHA (on request of the European Commission) or the Member State prepares an Annex XV SVHC dossier. With this Annex XV dossier ECHA or the Member State proposes the inclusion of the substance in the Candidate List by outlining the scientific evidence for identifying the substance as a SVHC.

ECHA's website includes a public registry of intentions in order to allow interested parties to be aware of the substances for which the authorities intend to submit Annex XV dossiers and thus facilitates timely preparation of the interested parties for commenting later in the process.

Once an Annex XV SVHC dossier has been prepared, a consultation of the Member States and interested parties is required, as specified in Article 59 of REACH. Further details on this consultation process are available on the ECHA website at http://echa.europa.eu/consultations/authorisation/svhc_en.asp. Following this consultation, the substance may be included in the Candidate List. The Candidate List is made available on ECHA's website at

http://echa.europa.eu/chem_data/authorisation_process/candidate_list_en.asp in its last updated version.

12.4 How is a substance from the Candidate List included in the "Authorisation List"? (Updated)

Substances included in the Candidate List may be prioritised for inclusion in Annex XIV of the REACH Regulation (the so called "Authorisation List"). The Authorisation List contains all substances which, after a certain deadline, may only be used and/or placed on the market after a specific authorisation has been granted.

ECHA has to make at least every second year a recommendation of priority substances for inclusion in Annex XIV to the European Commission. Interested parties are invited to submit comments during this process. In addition, the Member State Committee issues an opinion on the recommendation before it is submitted to the European Commission. The European Commission then decides using the comitology procedure which of the recommended substances are to be included in Annex XIV and specifies, based on ECHA's recommendation, the transitional arrangements and, where relevant, exemptions and review periods. Further details on the procedure for inclusion of substances in Annex XIV of the REACH Regulation are available on ECHA's website at

http://echa.europa.eu/chem_data/authorisation_process/annex_xiv_rec_en.asp.

12.5 How are authorisations granted for substances on the "Authorisation List"? (Updated)

Applications for authorisation need to be made within the deadline (the so called "latest application date") that is specified in the "Authorisation List" for the corresponding substance if the applicant wishes to use the substance without interruption after the sunset date.

Authorisation applications need to be submitted to ECHA. Third parties can provide information on alternative substances and technologies during public consultations on the uses that authorisation has been applied for. These are made available on ECHA’s web-site. The ECHA Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) give draft opinions on the application. Applicants will have the opportunity to comment on these draft opinions. RAC and SEAC will adopt final opinions and ECHA sends them to the European Commission.

The European Commission decides, using the comitology procedure, whether an authorisation is granted or refused. ECHA will establish a publicly available database that will contain summaries of the Commission decisions.

Further details on the application for authorisation procedure are available on ECHA's website at

http://echa.europa.eu/reach/authorisation_under_reach/authorisation_application_en.asp.

13INFORMATION IN THE SUPPLY CHAIN

13.1 Can downstream users continue to use a substance, if it has not been (pre-)registered?

Downstream users can use substances, irrespectively of whether they have been (pre-)registered or not. In this regard 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. Placing on the market is however not to be regarded as a use. FAQ 6.3.12 explains the need for substances to be (pre-)registered in order to be placed on the market.

Please note that for the use of substances (whether (pre-)registered or not) certain requirements related to restrictions, authorisation and risk management may apply. Guidance on how to comply with these requirements is provided in the Guidance for downstream users.

13.2 Does REACH require any changes in Safety Data Sheets?

Yes, according to Articles 31 and 32 of the REACH Regulation some changes in the Safety Data Sheet (SDS) are required. However, the duties and responsibilities for Safety Data Sheets (SDSs) remain largely the same. Guidance for the compilation of Safety Data Sheets is given in Annex II of the REACH Regulation.

The following list summarises the main changes:

- The risk management measures for the identified uses with regard to human health and the environment are to be summarised in section 8 (and 7). This includes consumer related measures communicated to a downstream user producing consumer mixtures or articles. Also the relevant Derived No-Effect Levels (DNELs) and Predicted No-Effect Concentrations (PNECs) should be presented here.

- The information on physicochemical properties, toxicology and eco-toxicology in the SDS is to be updated in line with the information requirements of Annex VI to XI of the REACH Regulation.

- The results of the PBT and vPvB assessment are to be presented in section 12.

- The information on uses advised against in section 16 of the SDS may need to be updated depending on the outcome of the manufacturer's Chemicals Safety Assessment (CSA).

- Where Exposure Scenarios (ES) are developed as a result of conducting a chemical safety assessment in accordance with Article 14 of the REACH Regulation they must be annexed to the SDS and thereby be appropriately passed down the supply chain. The information on uses of the substance in section 1.2 of the SDS must be consistent with the short titles of the ES in the annex, indicating which uses are covered by the ES.

- Since REACH includes a requirement to include the waste disposal considerations into the manufacturer's chemicals safety assessment, section 13 of the SDS may need to be updated with substance specific waste management advice as contained in the ES.

It is important to note that now SDSs are additionally required for substances assessed to be PBTs (Persistent, Bioaccumulative and Toxic) or vPvBs (very Persistent and very Bioaccumulative), for substances included in the candidate list for potential inclusion in Annex XIV of the REACH Regulation, as well as for mixtures containing any of these substances.

For further details on the obligation to provide an SDS please consult the Guidance on information requirements and chemicals safety assessment (part G) and the Guidance on registration (Section 3.1.1). In addition, the Guidance for downstream users provides an overview on the new information in an SDS (table 25 on page 123).

13.3 For substances or mixtures already placed on the market before 1 December 2010 or 1 June 2015 respectively does the Safety Data Sheet (SDS) need to be updated in accordance with the Commission Regulation (EU) No 453/2010? (Updated)

In principle, SDS need to comply with Annex I to Commission Regulation (EU) No 453/2010 since 1 December 2010 and until 1 June 2015, and with Annex II to Commission Regulation (EU) No 453/2010 as of 1 June 2015. However, there are specific transitional periods, so not all SDS need to be updated immediately.

According to Article 2 (6) of the Commission Regulation (EU) No 453/2010 the SDS of substances which were placed on the market before 1 December 2010 and which are not required to be relabelled and repackaged in accordance with Article 61 (4) of the CLP Regulation, need not be replaced with a SDS complying with Annex I to Commission Regulation (EU) 453/2010 before 1 December 2012.

However, if an update of the SDS is required by Article 31 (9) of REACH:

- if new information which may affect the risk management measures, or new information on hazards becomes available;

- an authorisation has been granted or refused; or

- a restriction has been imposed;

this transitional period does not apply.

For mixtures which are placed on the market before 1 June 2015 and which are not required to be relabelled and repackaged in accordance with Article 61 (4) of the CLP Regulation, Article 2 (6) of the Commission Regulation (EU) 453/2010 stipulates that the SDS need not be replaced with a SDS complying with Annex II of the Commission Regulation (EU) 453/2010 before 1 June 2017. Again, if an update of the SDS is required by Article 31 (9) of REACH for one of the abovementioned reasons, the transitional period does not apply.

For mixtures provided to any recipient at least once before 1 December 2010, Article 2 (7) of the Commission Regulation (EU) 453/2010 stipulates that SDS may continue to be used in the previous format and need not comply with Annex I to Commission Regulation (EU) 453/2010 until 30 November 2012. However, if an update of the

SDS is required by Article 31 (9) REACH for one of the abovementioned reasons, the transitional period does not apply.

13.4 In what language should the SDS be supplied?

According to Article 31(5) of the REACH Regulation, the safety data sheet (SDS) shall be supplied in an official language of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide otherwise. Placing on the market means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market (Article 3(12) of the REACH Regulation).

13.5 The workers of transport companies can be exposed to chemicals, for example while loading and unloading chemicals, or fitting and opening of transfer pipelines. Should transport companies be regarded as downstream users in these cases?

The carriage of dangerous substances and dangerous mixtures by rail, road, inland waterway, sea or air is exempted from the scope of the REACH Regulation (see Article 2(1)(d)). Transporting activities (including loading and unloading) by transport companies are not “uses” under REACH.

The loading and unloading operations performed by the workers of the transport company are covered by the Carriage of Dangerous Goods legislation, and hence they are outside of the scope of the REACH Regulation. Compared to that, the site related activities before loading and after unloading will often be “uses” under REACH which may need an exposure scenario and a chemicals safety assessment.

It is also important to note that the transfer of substances and mixtures occurring exclusively within an industrial plant is covered by REACH, even if this includes transportation carried out by an external company.

13.6 (deleted)

13.7 What information can a downstream user communicate to his suppliers in order to cooperate in preparing for REACH registration?

Downstream users may make uses known to the suppliers in their supply chain, before the manufacturer or importer submits his registration, with the aim of making these uses identified uses. This right is enshrined in Article 37(2) of the REACH Regulation. In making a use known, the downstream user must provide sufficient information to allow the manufacturer, importer, downstream user or distributor who has supplied the substance to prepare an exposure scenario for his use. This does not necessarily require disclosure of technical details of the use, as the use can be described in a generic way using the use descriptor system introduced in chapter R12 of the Guidance on information requirements and chemicals safety assessment.

In some situations communicating uses up the supply chain may be best done as a collective action in a sector facilitated by sector organizations. However, where a company is not part of a trade association or where very specific uses need to be addressed, direct communication between a downstream user and his supplier may be required.

More detailed information on requesting that a use becomes an identified use can be found in chapter 8 of the Guidance for downstream users. In addition, it is advisable for a downstream user to contact his respective industry association for assistance.

13.8 When does the registration number have to be communicated down the supply chain?

For a substance or mixture requiring a Safety Data Sheet (SDS) according to Article 31 of the REACH Regulation, Annex II of REACH requires that the registration number assigned in accordance with Article 20 be given in the SDS when it is available.

Article 31(9) gives specific occasions on which an updated SDS should be supplied without delay. Receipt of a registration number *per se* is not listed as one of these occasions. However as the assignment of a registration number is of major potential interest to downstream users of the substance it may be recommendable to send existing customers an updated SDS either immediately or on the next supply of the substance or of a mixture containing it. The SDS should of course be updated to incorporate the registration number(s) for customers who are going to receive the substance or mixture for the first time. Note in particular that the final sentence of Article 31(9) requires that “any updates following registration shall contain the registration number” (Please note that there are detailed provisions in the Regulation (EU) No 453/2010 amending Annex II of the REACH Regulation concerning when the part of the registration number referring to the individual registrant of a joint submission (the last four digits of the original full registration number) may be omitted by a supplier who is a distributor or a downstream user).

Similarly, Article 32(1)(a) indicates that when registration numbers have to be communicated to customers according to Article 32 (Communication duties for substances and mixtures not requiring an SDS; further guidance can be found in section 3.1.2 of the Guidance on Registration) the registration number, if available, should be supplied. The occasions on which an update without delay is required are given in Article 32(3). Again, receipt of a registration number *per se* is not listed as one of these occasions. For similar reasons it may be deemed to be desirable to nonetheless send updated information. Note again that the last sentence of Article 32(3) also requires that “any updates following registration shall contain the registration number”.

The provisions of Articles 31 and 32 apply irrespectively of whether the relevant registration deadline is still to come or has already elapsed.

13.9 When does a safety data sheet with annexed exposure scenario have to be provided to customers?

Where an Exposure Scenario (ES) is developed as a result of conducting a chemical safety assessment as required by Article 14 or 37(4) of the REACH Regulation, it must be annexed to the safety data sheet (SDS), provided it is relevant for the customer.

According to Article 31(9) a supplier shall update his SDS without delay as soon as new information which may affect the risk management measures or new information on hazards becomes available. An ES is considered to be such new information, which normally triggers the need to update a SDS as soon as it becomes available. The SDS with annexed ES resulting from this update has to be provided without delay to all customers who have been supplied with the particular substance or mixture within the preceding 12 months. This provision applies since the entry into force of the REACH Regulation and irrespectively of whether the substances are registered or not.

Where the information in an ES that becomes available does not affect the risk management measures and the ES contains no new information on hazards, the SDS does of course not have to be updated.

14 DOWNSTREAM USERS

14.1 What are my downstream user (DU) obligations as a DU of a substance for which an extended safety data sheet is required?

As a downstream user you should follow the risk management advice and the operational conditions of use described in the extended safety data sheet (eSDS) received from the supplier, including the exposure scenarios. If relevant, forward the advice to actors further down the supply chain. If you as a downstream user produce a mixture, you must ensure that the eSDS for that mixture includes all relevant information received from the suppliers of the individual components. Please note: This was also a duty of downstream users under previous legislation. The new element under REACH is the receiving and forwarding of **use-specific risk management advice and risk management measures relating to exposure to humans or the environment**.

If as a downstream user you receive information from your customers intended for the purpose of making a use known, you should forward this information to the supplier up the supply chain or assess if the use is covered in the existing exposure scenario for the mixture and eventually carry out your own downstream user Chemical Safety Assessment (CSA).

If you as a downstream user hold information that puts into question the hazard or risk management information received from a supplier, you should communicate this information to the supplier.

An overview of the possible obligations of downstream users can be found in the Guidance for downstream users (Section 2.5.5) available at the ECHA website: http://guidance.echa.europa.eu/guidance_en.htm

14.2 What are my downstream user obligations when my use is not covered by the eSDS?

If as a downstream user you use the substance (as such or in a mixture) outside the conditions communicated to you in the extended safety data sheet (eSDS), or the use is not covered at all in the eSDS, you may choose one of the following options:

- Adapt the conditions of use to those described in the eSDS.
- Implement or recommend an exposure scenario which includes as a minimum the conditions described in the exposure scenario communicated to you.
- Make the use known to the supplier with the aim of making it an identified use based on the manufacturer's chemical safety assessment.
- Perform your own chemical safety assessment for that particular use and record it in a Chemical Safety Report - CSR (if the total amount used is 1 tonne/year or more). Notify your use, including the information specified in Article 38(2) of the REACH Regulation to ECHA.
- Switch to another supplier of the substance if that supplier covers your specific use in his eSDS.

If as a downstream user you receive information from your customers intended to make a use known you should forward this information to the supplier up the supply chain or assess if the use is covered in the existing exposure scenario for the mixture and eventually carry out your own downstream user Chemical Safety Assessment (CSA).

If as downstream user you hold information that puts into question the hazard or risk management information received from the supplier you need to communicate this information to the supplier.

An overview of how to decide whether or not your use is covered by the exposure scenario can be found in the Guidance for downstream users (Section 6.1). Information on how to make a downstream user chemical safety report is given in Section 7 of the same guidance available at the ECHA website: http://guidance.echa.europa.eu/guidance_en.htm.

14.3 What are my downstream user obligations, when I use substances subject to authorisation?

If a substance is subject to authorisation (Annex XIV):

- You must use the substance according to the conditions laid down in the authorisation granted for that specific use to an actor up your supply chain or apply for an authorisation yourself if the authorisation of your supplier does not cover your use(s);
- You must notify to ECHA within 3 months after first supply, the use of the substance subject to authorisation.

If a substance is subject to restrictions: Comply with the restrictions for placing on the market or use of substances as listed in Annex XVII of the REACH Regulation.

An overview of the possible obligations of the downstream users related to authorisation can be found in the Guidance for downstream users (Section 12.0) available at the ECHA website: http://guidance.echa.europa.eu/guidance_en.htm

14.4 How can I make sure that I have no registration or notification obligations?

You do not have registration or notification obligations, for example, if all your suppliers are located within the EEA or have appointed an only representative, and you do not produce any new substance or article. However, there are also various other cases in which no registration and notification obligations apply.

In order to check whether in your particular supply chain situation you have registration or notification obligations or not you should use the Navigator tool on the ECHA website. This tool is designed to help companies to determine their obligations under REACH and find the appropriate guidance on how to fulfil these obligations.

14.5 I am a downstream user, when do I need to report the use of my substance to ECHA? (New)

You have to report to ECHA when you:

-Need to prepare a downstream user chemical safety report; or

-Wish to benefit from the exemption to prepare a chemical safety report either because:

❍ you use the substance in total less than 1 tonne per year; or

❍ you use the substance for product and process oriented research.

If reporting to ECHA is required, specific uses of less than 1 tonne per year do not need to be included in the report except from the following situation: if the reason you do not need to prepare a chemical safety report is that the total quantity you use is below 1 tonne, then all uses are to be reported.

You have six months to report to ECHA from the date you receive an extended safety data sheet with a registration number.

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