Frequently Asked Questions on REACH by Industry

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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 REACH Helpdesk Correspondents' Network (REHCORN).

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.

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	5.6, 6.1.1, 6.3.9, 6.3.10, 6.3.11, 6.3.12	-	06/11/2008

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

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1 General

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

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 creates 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 will manage the registration, evaluation, authorisation and restriction processes for chemical substances to ensure consistency across the European Union.

- **The** REACH Regulation is available in the Official Journal on the website of the European Union.
- **About REACH** - for concise and basic information on REACH, you may want to refer to the "About REACH" section of the ECHA website;
- **REACH guidance documents** - provide explanatory and supplementary information to the legal text. The guidance available on the ECHA REACH guidance website at this stage is the result of both consultation of relevant stakeholders and close co-operation between the Competent Authorities of the EU Member States and the European Commission. Please see the most up-to-date list of all the final guidance documents.
- **SEARCH function** – allows you to search through the available documents. Using the keyword search you will be directed to the most relevant chapters in the guidance documents or sections on the ECHA website.
- **NAVIGATOR tool** - The Navigator tool will help you to identify your specific obligations under REACH.
- **REACH – IT and IUCLID 5** - IUCLID 5 is a software tool that allows you to enter, manage, store and exchange information on intrinsic and hazard properties of chemical substances. The guidance: "Where to enter the data requirements for EU REACH Regulation," is included in this software tool. It implements the Harmonised Templates developed by the OECD (Organisation for Economic Co-operation and Development - For further details, see FAQ 5.3 and 6.6). REACH IT will provide an on-line company homepage to submit registration dossiers on chemicals. It also allows ECHA and Member State authorities to review the dossiers. ECHA will make non-confidential information accessible on its website. More information on REACH-IT and IUCLID 5 is available on the ECHA website.
- **NATIONAL HELPDESKS** - are the points of contact in each EU member state when looking for REACH-related assistance (for full details see FAQ 1.5). A list of the national helpdesks is available on the

ECHA website. This also includes information on the helpdesk services provided by ECHA itself and on IUCLID 5 support.

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

The objective of Corrigenda to REACH of 29 May 2007 was to rectify linguistic errors but not to make changes on the content of the text. Most of the changes should be applicable to language versions other than English. One change to be mentioned here is in 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 When does the REACH Regulation start to apply?

Article 141 of the REACH Regulation provides the dates of entry into force and application of the REACH obligations and provisions.
On 1 June 2007, the REACH Regulation entered into force and those provisions not mentioned in Article 141 (2) to (4) started to apply.
On 1 June 2008, most of the main provisions started to apply, i.e. Title II on Registration, Title III on Data Sharing, Title V on Downstream Users, Title VI on Evaluation, Title VII on Authorisation, Title XI on Classification and Labelling Inventory and Title XII on Information. Articles 128 on Free movement and 136 on Transitional measures regarding existing substances.
Title VIII and Annex XVII on Restrictions will apply from 1 June 2009.

1.4 Who is responsible for the enforcement of REACH?

In accordance with Articles 125 and 126 of the REACH Regulation, Member States are responsible for preparing national provisions defining controls and sanctions for non-compliance of the REACH Regulation by 1 December 2008. We recommend that you contact the relevant enforcement authorities in your country to learn about the national control procedures to be put 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 sources of assistance and information available:

- National helpdesks established in every EU member state shall be contacted for advice on responsibilities and obligations under REACH. They provide services in their local language(s) knowing the national conditions (e.g. national legislation, organisation of enforcement authorities, etc.). According to Article 124 of the REACH Regulation

the national helpdesks should be operational in all Member States from 1 June 2007. The list of contact details is available on the ECHA website.

- For advice on fulfilling the obligations of REACH, trade associations, sector groups, chambers of commerce and other organisations have set up stakeholder helpdesks to provide tailor-made support for their industrial sectors and products; e.g. plastics, minerals, mineral oils, paints and they are familiar with sector-specific terminology.
- In addition, ECHA provides a service to companies registering a substance. ECHA assists registrants with questions on REACH provisions but also IUCLID 5, REACH-IT (once it is available) and the administration of submitted dossiers. A network between the national REACH helpdesks and ECHA has been established with the overall objective of achieving the best, consistent and harmonised advice possible to manufacturers, importers, downstream users and interested parties, in particular SMEs, across the EU. In this respect therefore, you can equally contact the national helpdesk of your country for advice on REACH.

Non-Community companies do not have direct obligations under the REACH Regulation. However, if they are looking for general information on REACH they may approach ECHA. If their questions are related to the particular national conditions, they may turn to a specific Member State helpdesk.

1.6 How can I get to know about job opportunities in ECHA?

ECHA selects its staff by open selection procedures following the publication of a vacancy notice or call for expressions on interests on the ECHA website, and also on the website of the European Personnel Selection Office (EPSO). You are kindly requested to check these sites regularly for future job opportunities in the ECHA.

2 Scope

2.1 Does REACH apply to substances (either on their own, in preparations 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 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 apply if the substance falls within the scope of REACH. These obligations also depend on the characteristics of the substance (e.g. is it classified as dangerous or not). In addition, obligations under REACH will differ depending on your role in relation to the substance (e.g. whether you import it or buy it from an EU manufacturer and use it). The Guidance for the Navigator as well as the Guidance on Registration (Section 1.6 – What to Register) will help you to

decide whether the substance falls under the scope of REACH by providing definitions of the terms used.
For help in identifying your obligations, the use of the Navigator tool is recommended. If the substance falls within the scope of REACH, you should check for the restriction obligations as restrictions contained in Annex XVII apply irrespective of the volume. Similarly, if the substance is included in Annex XIV and is therefore subject to authorisation, an authorisation is needed for its use, and again this is irrespective of the volume.
Following the Navigator further, you will find that you may also have obligations to notify the Agency on classification and labelling of the substance as well as providing Safety Data Sheets and information to your customer again, regardless of the tonnage.
By following the Navigator to the end, you will notice that substances (either on their own, in preparations or in articles) manufactured or imported in volumes below 1 tonne per registrant per year do not need to be registered.
Please note that restriction and/or authorisation obligations also apply to producers and/or importers of articles.

2.2 Does REACH apply to substances used in biocides and plant protection products (PPP)?

Active substances for use in biocidal products are regarded as registered as biocidal products and their active ingredients are covered by Directive 98/8/EC (Biocidal Products Directive). 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 the Guidance on Registration (Section 1.6.5.1 - Biocides). Please note that only the quantities of the active substance for use in the biocidal products are considered as registered, but co-formulants used in biocides are not regarded as registered.
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 they do not qualify for the exemption. This is further explained in the Guidance on Registration (Section 1.6.5.2 - Plant Protection Products).

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 used other than 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. Examples of the calculation of tonnages can be found in the Guidance on Registration (Section 1.6.5.1 – Biocides and Section 1.6.5.2 - Plant Protection Products).

2.3 Does REACH apply to substances occurring in nature?

REACH generally applies to substances occurring in nature as defined by Article 3 (39) of the REACH Regulation . A substance occurring in nature means a naturally occurring substance, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by floatation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means. Annexes IV and V list substances occurring in nature that are exempted from registration. Full details can be obtained from these annexes:

- Annex IV contains a list of substances, for which sufficient information shows that they cause minimum risk because of their intrinsic properties, and which are therefore exempted from registration. These substances are also exempted from Titles V (downstream user obligations) and VI (evaluation) of the REACH Regulation.
- Annex V covers substances, for which a registration is considered inappropriate or unnecessary. Among other things this Annex states, that the following substances occurring in nature are exempted from registration if they are not chemically modified: minerals, ores, ore concentrates, cement clinker, natural gas, liquefied petroleum gas, natural gas condensate, process gases and components thereof, crude oil, coal and coke. 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. The term “not chemically modified substance” is defined in Article 3 (40) of the REACH Regulation.

Please note that Commission is committed carrying out a review of these Annexes.
You may use the Navigator to learn about your obligations for substances occurring in nature.

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. This list must be updated by the Commission. 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 Do substances at nano-scale fall under the scope of REACH?

Yes and their health and environment properties must be assessed following the provisions of the REACH Regulation.
Potential registrants should first consider whether they have obligations under REACH, irrespective of the 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 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 to the Community

3.1 To which territories does REACH apply?

REACH is an European Community Regulation that directly applies in all Member States of the European Union. As REACH is of EEA (European Economic Area) relevance, Iceland, Liechtenstein and Norway will apply REACH after it has been incorporated into the agreement of European Economic Area. Substances imported in the Community from Switzerland (a non EU country belonging to EFTA (European Free Trade Association) but not to EEA) are treated under REACH in the same way as substances imported from any other non-EU country.
Member States are best placed to explain how REACH applies to their territories (autonomic areas or overseas territories). We therefore recommend contact with the national helpdesk of the relevant country to clarify specific requirements.

3.2 What are the obligations of non-EU companies?

Non-Community manufacturers do not have direct obligations under the REACH Regulation. It is the importer established within the Community, 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 EU companies exporting substances on their own, in preparations or in articles to the Community 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 the Guidance on Registration (Section 1.5.3.4 – Only representatives of "non-Community manufacturer") or see also FAQ 4 for details.

3.3 What are the obligations of importers of substances in articles?

Under some circumstances substances in articles have to be pre-registered, registered or notified to ECHA by producers or importers (see Article 7 of the REACH Regulation). The terms "import" and "article" are defined under Article 3 (3) and (10) of the REACH Regulation). In order to establish whether a registration or notification is required, any importer of articles needs to carry out the following actions:

- Determine:
  - whether any of the substances in the article is intended to be released under normal or reasonably foreseeable conditions of use and, if this is the case,
  - whether the total amount of this specific substance imported within all those articles is one tonne or above / year. If both conditions are fulfilled, the importer has registration obligations in accordance with Article 7(1) of the REACH Regulation.

- Determine whether any of the substances listed according to Article 59 of the REACH Regulation (the candidate list of substances meeting the criteria for being of very high concern) could be contained in the imported article above a concentration of 0.1 % w/w[1]. If this is the case and the substance is present in the imported articles in quantities totalling one tonne or above/ year, the importer will have notification duties in accordance with Article 7(2) of the REACH Regulation.

- A registration or notification of a substance in an article is not required if the substance has already been registered for that use (Article 7(6) of the REACH Regulation). Consequently, a potential registrant or notifier of a substance in articles should check whether a substance has been registered 'for that use'. This refers to any registration of that use of the substance up the same supply chain or any other supply chain. It needs to be ensured that it is the same substance that has been registered according to the rules set out in the Guidance for identification and naming of substances under REACH.

Independent of the duties such as listed above, a number of additional duties apply to importers of articles:

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1 Dissenting views (http://reach.jrc.it/docs/guidance_document/dissenting_en.pdf), questioning the application of the 0.1 % threshold to the entire article have been notified by 6 Member States. Please consult the Guidance on requirements for substances in articles for further information (http://reach.jrc.it/docs/guidance_document/articles_en.htm).

- Respond to any decision requiring further information as a result of the dossier or substance evaluation process by ECHA and the Member States in case registration duties apply.

- Respond to any Agency requirement to submit a registration for a substance contained in an article in quantities of over 1 tonne/ year, that is released and that ECHA suspects presents a risk to human health or the environment.

- Comply with any restrictions on placing on the market and use of substances in articles as set out in *Annex XVII* of the REACH Regulation.

- In the case of SVHC (Substances of Very High Concern) substances listed in the candidate list in accordance with Article 59(1) of the REACH Regulation and present in articles at a concentration above 0.1% (w/w), provide the recipient of the article - or on request the consumer that uses the article - with sufficient information to allow safe use of the article, including, as a minimum the name of the substance (see Article 33 of the REACH Regulation).

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 legal or natural person that manufactures a substances (to be used on its own, in preparations and/or to produce articles), formulates preparations or, if the substances in their articles are required to be registered, produces articles, outside of the EU can nominate an only representative located within the EU to carry out the required registration of their substances that are imported into the Community. 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 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-EU 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 Community 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 the Guidance on Registration (Section 1.5.3.4 – Only representatives of "non-Community manufacturer").

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 establish 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. When the only representative submits the registration(s) he is advised to submit copy(-ies) of the letter(s) officially assigning him. More information on the duties of the only representative is provided in the Guidance on Registration (Section 1.5.3.4 – Only representatives of "non-Community manufacturer").
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-EU companies that manufacture substances, formulate preparations or produces articles exporting to the Community, even for the same substance. More information on the duties of the only representative is provided in the Guidance on Registration (Section 1.5.3.4 – Only representatives of "non-Community manufacturer").

5 Pre-registration

5.1 When can I pre-register phase-in substances?

In order to benefit from the extended registration deadlines for phase-in substances, they need to be pre-registered between 1 June 2008 and 1 December 2008 (inclusive), as detailed in the Guidance on Registration (Section 2.2 on Pre-registration) and in the Guidance on Data Sharing (Section 3.5 - Deadline for pre-registration) or laid down in the REACH Regulation, Article 3 (20), Article 23 and 28. Chapter 1.7 of the Guidance on Registration (Section 1.7.1.1 – Phase-in Substances) advises potential registrants when they should submit their registrations to the ECHA.

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

Yes, but only in the case of a first-time manufacturer or importer who manufactures or imports a substance in quantities of 1 tonne or more per year for the first time or manufactures or imports more than one tonne for the first time after the pre-registration deadline (1 December 2008) has passed. 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 for the production of articles and imported articles that contain a phase-in substance for which registration is required and that is used by the company for the first time.

5.3 How can I pre-register my substances and is there a format to fill in?

As described in the Guidance on Data Sharing (Section 3.8 – How to pre-register a substance), starting from the 1 June 2008, there will be two possibilities to submit pre-registration information:

1. by direct encoding of the information on the REACH-IT website (On-line pre-registration)
2. by uploading one or more pre-registration files prepared off-line

In order to pre-register many substances in a single step, it is possible to submit a pre-registration prepared separately in a file format specified by ECHA in accordance with Article 111 of the REACH Regulation. The IUCLID 5 pre-registration plugin can be used for the preparation of the XML files or, alternatively, the files may also be created by other applications, as long as they implement the required format. The specific XML format is necessary in order to facilitate and validate the submission of your pre-registration data. The format can be downloaded from the IUCLID website. For more information, please refer to the Question, "How will IUCLID 5 help me with the pre-registration process?" on the IUCLID 5 download website under the Get Support/FAQ section.

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 will be 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 shall publish on its website the list of pre-registered substances by 1 January 2009. Downstream users of substances not appearing on this list of pre-registered substances may notify ECHA of their interest in these substances and provide their contact details and, if relevant, the contact details of their suppliers (Article 28 (5)).

6 Registration

6.1 Who has to register substances?

Only a natural or legal person established within the Community can be a registrant. Registration must take place when this person:
(1) manufactures a substance within the Community,
(2) is responsible for import into the Community or
(3) has been appointed as an only representative according to Article 8 of the REACH Regulation.
The national law of each EU Member State provides the specific provisions concerning natural or legal personality and when such a natural or legal person is established in its territory.
It is very important that companies correctly identify their role (or roles) in the supply chain for each substance they handle, because this will be a decisive

factor in determining their registration obligations. More information on roles as a potential registrant can be found in Article 3 (7) to (11) of the REACH Regulation, in the Guidance on Registration (Section 1.5 – Who has to register) or when using the Navigator.
Please note that non-Community companies that are not established within the Community do not have direct obligations under REACH. It is the importer established within the Community that needs to comply with the obligations of REACH. However, to relieve the importers of their obligations, the company not established within the Community may decide to appoint an "only representative" (see FAQs 4).

6.1.1 Who is the registrant in case of toll manufacturing of substances?[2] (NEW)

A toll manufacturer is normally understood to be a company that manufactures a substance (on its own, in a preparation or in an article) in its own technical facilities following the instructions of a third party in exchange for an economic compensation. The substance is generally put on the market by the third party. 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 a multinational 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 Community, often spread over several Member States. If these subsidiaries of the parent companies are separate legal entities to 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.

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

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;
- unless they are explicitly exempted from the scope of registration according to Article 2 (1) to (3) and Annexes IV and V or partially exempted according to Article 2 (5-9) 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 the Guidance on Registration (Section 1.6 – What to register). This guidance provides definitions, explanations and you will also find information on substances exempted from registration. In addition to the guidance, the use of the Navigator is recommended to find out whether you have any obligations under REACH for a given substance. The Navigator helps to clarify the registration obligations of your specific substance.

6.3.1 Do I have to register alloys?

Alloys are regarded as preparations according to Article 3 (2) of the REACH Regulation. This implies that only the single chemical elements in the alloys have to be registered but not the alloys itself.

The Guidance on Registration (Section 1.4 – on definitions) provides further information on the definition of a preparation and the distinction between a preparation and a multi-constituent substance. Guidance shall be developed for preparations, including assessment of substances incorporated into special preparations, such as metals incorporated in alloys (see also Recital 31 of the REACH Regulation).

6.3.2 Do I have to register intermediates?

According to Article 3 (15) of the REACH Regulation, an intermediate is defined as a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance(s). Therefore an intermediate should not be present in the final manufactured substance (except as an impurity). It then depends under which type of intermediate as described in REACH your intermediate falls whether you have registration obligations. Different types of intermediates are defined under REACH:

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

- Isolated intermediates:
  - 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 on 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, e.g. extracting wool wax from wool fibres?

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 or classified as dangerous in accordance with Directive 67/548/EEC. For answering the question, if a process can be applied to extract such a substance without the need for registration, it has to be verified if 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.

Applied to the example above, there is at first sight no obligation to register wool wax as such, as it is a substance occurring in nature. To remove the wool wax from the wool fibre, a process may be applied that may include a treatment with detergents as wool wax is insoluble in water. When detergents are used during the process, the question is if the extracted wool wax can still be considered as a substance which occurs in nature. As mentioned, it has to be verified, if 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. If, for example, the wool wax is processed by using "flotation" which is a well defined process mentioned in Article 3(39) and may include treatment with detergents, the wool wax still can be regarded as a substance which occurs in nature. However, 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 preparations or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance".
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 preparations, 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 Will PORD exemptions under Directive 67/548/EEC be transferred into REACH?

National Process Orientated Research and Development (PORD) exemptions for the notification of substances under Directive 67/548/EEC will no longer be valid under REACH after 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 1st June 2008, will need to submit a PPORD notification according to Article 9 of the REACH Regulation, to benefit from the registration exemption. PPORD (Product and Process Oriented Research and Development) notifications will only be accepted by the Agency from 1st June 2008. In practice, a PPORD notification dossier can be submitted on-line through the Agency web-site (REACH IT) either by directly entering the information into REACH-IT or by uploading a prepared file complying with the IUCLID format (e.g. prepared for example by using IUCLID 5). The Agency and the Commission are developing, in collaboration with Member States, a solution that would allow beneficiaries of PORD exemptions to continue their activities while their PPORD notification is being processed. It is recommended to take contact with your national REACH helpdesk or the national REACH competent authority for further information.
More information on PPORD can be found in the Guidance on Scientific Research and Development (SR&D) and Product and Process Oriented Research and Development (PPORD)

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 EU but exported 100% outside of the EU?

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 EU. Therefore, substances manufactured in the EU 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 EU 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 EU.

Please note that substances which have been registered, exported and then re-imported are exempted from registration and evaluation under certain conditions. See the Guidance on Registration (Section 1.6.4.6 – Re-imported substances).
More information on registration obligations can be found in the Guidance on Registration (Section 1.5.2 – Actors in the supply chain with registration obligations).

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 preparation 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?[3] (NEW)

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

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 Are there registration obligations for manufacturers and importers of natural polymers that have not been chemically modified?[4] (NEW)

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

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.

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.

6.3.11 Are there registration obligations for manufacturers and importers of natural polymers that have been chemically modified?[5] (NEW)

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.

6.3.12 For how long is it allowed to sell phase-in substances from stock without registration?[6] (NEW)

Article 5 of the REACH Regulation (“no data, no market”), that applies from 1 June 2008, states 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 Title II where this is required. 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).

Based on these articles, it follows that:

Substances manufactured before 1 June 2008 but not placed on the market in accordance with the definition above, need to be pre-registered (or registered as non phase-in substance) for being placed on the market after 1 June 2008.

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

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

Quantities of substances on their own, in preparation or in articles that have already been placed on the market or imported before 1 June 2008 may be further used without (pre)registration provided that the placing on the market before 1 June 2008 can be documented.

6.4 When do I have to register my substances?

Various aspects need to be taken into account when thinking of the registration deadlines. These include tonnage, dangerous properties, or whether it is a phase in or a non-phase in substance. Chapter 1.7 of the Guidance on Registration (Section 1.7.1.1 – phase-in substances) provides information on this matter.

- The REACH Regulation creates a special transition regime for phase-in substances (Section 1.7.1.1 – phase-in substances). In order to benefit from the extended registration deadlines for phase-in substances (Section 1.7.2 – deadlines for registration), these substances must be pre-registered (see also FAQ 5) between 1 June 2008 and 1 December 2008. Depending on the intrinsic properties of the substance, along with its tonnage, it will then need to be registered by 1st December 2010, 1st June 2013 or 1st June 2018.
- Phase in substances which have not been pre-registered must be registered before manufacture or import can continue. Therefore, if a phase-in substance is not pre-registered it should be registered if a company wishes to continue to manufacture or import. 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 the Agency regarding any previous registration for that substance.
- Non-phase in substances must be registered before they can be manufactured or imported. This obligation will start on 1st June 2008. Prior to registration of such substances, the manufacturer or importer has a duty to make an inquiry to the Agency regarding any previous registration for that substance.
- Within six months after first manufacture or import above the one-tonne threshold, and no later than 12 months before the relevant deadline for registration in the case of a first-time manufacture or import after the pre-registration deadline (1 December 2008) has passed (see FAQ 5.2).

To identify your specific obligations regarding each of your substances under REACH you may like to use the Navigator.

6.4.1 What are the requirements and procedures for new substances placed on the market before the registration obligations of REACH apply (1 June 2008)?

The placing on the market of new substances until 1 June 2008 is regulated by Directive 67/548/EEC on the Classification, Packaging and Labelling of Dangerous Substances, as amended by Directive 92/32/EEC. Thus if a new substance is placed on the market in quantities of 10 kg or more per year it has to be notified to the Competent Authority (CA) of the Member State where the substance is manufactured or where the notifier is established in case of a manufacturer located outside the Community. Please contact the relevant CA (Notification-Units) directly for further information on the notification procedure under Directive 67/548/EEC.

Article 24 of the REACH Regulation provides that notifications according to Directive 67/548/EEC are regarded as registrations for the purposes of REACH. ECHA will assign a registration number to those notifications regarded as registrations by 1 December 2008. Please note that a notification under Directive 67/548/EC is nominal so that only the notifier benefits from his substance being considered as registered (see FAQ 6.3.6). The Guidance on Registration (Section 1.6.5.3 - Notified substances) provides further information on this issue.

Transitional measures regarding requests to notifiers to provide further information on notified substances can be found in Article 135 of the REACH Regulation.

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

All registrations shall be submitted to ECHA. REACH-IT provides an online company homepage to submit data to ECHA. For more information please visit the ECHA website at: http://echa.europa.eu/reachit_en.asp
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 for their registration to the ECHA. Registrants

are not obliged to use the IUCLID system, but they must submit their registration in the IUCLID format.
The IUCLID 5 software is downloadable free of charge from the IUCLID website .

6.7 How much is the registration fee?

Article 74 of the REACH Regulation lays down the basic provisions on the requirements for fees. The fees are specified in a Commission Regulation No. 340/2008 on fees and charges payable to the ECHA. However, a fee is not required for the registration of substances in a quantity of 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. A reduced fee is set for SMEs. For more information we kindly advice you to consult the European Commission website: http://ec.europa.eu/enterprise/reach/reach_fees_en.htm

6.8 Can a Non-Community manufacturer of a substance register under REACH?

No. The obligation to register a substance applies only to actors established in the EU. Thus, the registration of substances imported into the EU on their own, in preparations or, in certain cases, in articles will have to be done by the importer established in the EU. 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 preparations or producers of articles established outside the EU, can nominate an Only Representative (OR) established within the EU to carry out the required registration. This will relieve the individual EU importers within the supply chain of that non Community manufacturer from their registration obligations for these substances. They will be regarded as downstream users of this Only Representative. However, the registration obligation may still apply if the EU-importers import the same substance from other non – Community manufacturers.

More information on the Only Representative role can be found in Chapter 4 of this FAQ document and in the Guidance on Registration in Section 1.5.3.4 p. 21.

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

The REACH registration obligations apply to substances on their own and in preparations. Thus, to fulfil his duties as a registrant an EU-based importer of preparations has to have information on the composition of the preparations he imports into the EU. 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 preparations he imports that could exceed the amount of one tonne/ year.

If the non Community formulator is not willing or not able to provide the required information, the importer has the following options:

- establish the composition of the preparation by analytical means,
- contact the non-community formulator and propose to him that he appoints an Only Representative in accordance with Article 8 of the REACH Regulation,
- find an alternative supplier who is prepared to provide all required information for the preparation,
- if sufficient information on the identity of the substance is available, pre-register but cease the import of the preparation when the relevant registration deadline according to Article 23 of the REACH Regulation arrives. Note, however, that if a pre-registration is not made an immediate registration of the substances would be required, unless the substance is imported for the first time by that importer in accordance with Article 28(6) of the REACH Regulation.

6.10 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. This appointment is for the purpose of joint submission of data for registration and data sharing and enables the registrant to remain anonymous when negotiating with other parties, in particular within a SIEF. Unlike an Only Representative, a third party representative only plays a part in the negotiations between the (potential) registrants, while the individual registrant retains full responsibility for complying with his obligations under the REACH Regulation.

[Note that this answer refers to a “third party representative” in the meaning of Article 4 of the REACH Regulation. “Third parties” in a general sense (e.g. consultants working on behalf of a company) can of course do work under normal commercial arrangements as for any other activity.]

7 Polymers and monomers

7.1 Do I have to register polymers?

Polymers do not have to be registered according to Article 2 (9) of the REACH Regulation 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);
- 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 the polymer in Article 3 (5) and the monomer in Article 3 (6).
If the monomer substances and/or any other substances from which the polymer is derived are phase-in substances (Section 1.7.1.1 of Guidance for Registration – phase-in substances), they can also be pre-registered and thus benefit from the registration deadlines for phase-in substances (section 1.7.2 of Guidance for Registration – deadlines for registration)

The Commission may according to Article 138 (2) of the REACH Regulation also 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?

A monomer used in chemical processing is a substance intended to be utilised for polymerisation purposes. This substance is therefore by definition an intermediate. Note however that 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, a stabiliser or an anti-oxidant?

Some substances are commonly added to polymers for the purpose of adjusting or improving their appearance and/or the physicochemical properties of polymeric material. Examples of polymer additives include stabilisers (for heat or light), anti-oxidants, pigments, lubricants, thickeners, antistatic agents, compatibilisers, antifogging agents, nucleating agents, flame retardants, etc.

In accordance with the definition of a substance in Article 3 (1) of the REACH Regulation any additive necessary to preserve the stability of a polymer substance is regarded as a constituent of that polymer. However, a mixture of a polymer and any unbound additive other than polymer stabilisers must be treated as a preparation. The importer of a polymer containing additives does not need to register these additives provided that the additive is added to preserve the stability of the polymer. Additives contribute to the substance composition (but not to the naming) and should therefore always be fully identified. Note however that there is the general obligation to register an additive substance manufactured or imported on its own or in the polymer preparation (see the Guidance on Registration) 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.

8 Requirements for substances in articles

8.1 Do I have to register substances in articles?

The registration requirement under the REACH Regulation according to Article 7(1) applies to substances in articles for which all the following conditions 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

Notification is required for substances of very high concern (SVHC) present in articles under certain conditions. For details, see the following FAQ 8.2.

8.2 When do I have to notify substance of very high concern (SVHC) in articles? (Timing, pre-conditions, same use)

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 substances of very high concern (SVHC) present in articles and for which the following conditions are met:

(1) the substance has been included in a candidate list for eventual inclusion in the list of substances subject to authorisation (Annex XIV) and
(2) the substance is present in those articles above a concentration of 0.1% weight by weight (w/w)[7] and
(3) the total amount in those articles 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 SVHC in articles shall be made at the latest 6 months after it has been included on

7 Dissenting views (http://reach.jrc.it/docs/guidance_document/dissenting_en.pdf), questioning the application of the 0.1 % threshold to the entire article have been notified by 6 Member States and publication of this part of the guidance document was not endorsed by these Member States. Please consult the Guidance on requirements for substances in articles for further information (http://reach.jrc.it/docs/guidance_document/articles_en.htm).

the candidate list for authorisation but only starting from 1st June 2011. Information on substances on the candidate list contained in articles is to be forwarded by the supplier of the article to the recipients of the article directly after a 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.

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. More detailed information will be provided in The Guidance on Requirements for Substances in Articles, once available.

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.
It is recommended that importers of articles pre-register any substance in articles for which the conditions of Article 7 (1) REACH Regulation are met, as this is a pre-condition to be able to benefit from the extended phase-in deadlines for registration. If the producer/importer has not pre-registered the substance, he will have to register the substances intended to be released from articles as a non phase-in substance and cannot benefit from the phase-in deadlines. See also FAQ 5.2 for additional information.

8.5 How to distinguish between intended and accidental release of a substance from an article?

As a general rule, intended release relates to the function or quality of an article. The release of substances from articles is considered "intended" when it is essential for the end use function or "adds value" to the article.

Example: Release of perfume from a perfumed eraser (function = to erase, added value / function for convenience = quality of smelling good).

A release is not considered to be intended in the following cases:

- A release occurs during removal of 'impurities' from a semi-finished or finished article during its production process. *Example: A size is added to a fabric to improve its process ability. Sizes are released during further wet processing of the textile.*

- A release occurs during use or maintenance of the article and is meant to improve the product quality in a wide sense or the safety as a side effect but the released substances do not contribute to the function of the article.
  Example: Washing of clothes by the consumer where remnants of different chemicals (dye, softener, starch etc.) from processing are removed over some washing cycles.

- A release of substances is an unavoidable side-effect of the functioning of the article. *Examples: wear and tear of materials under conditions with high friction, e.g. break linings, tyres.*

- A release of substances formed in a chemical reaction is an unavoidable side-effect of the functioning of the article *Examples: ozone released from copy machines.*

- A release is incidental or caused by undue use. This also includes any form of misuse and inappropriate use which is not in accordance with the use instructions or functionality, even if it could have been anticipated
  Examples: release of substances from a thermometer which drops and breaks.

For further details please consult the Guidance on Requirements for Substances in Articles.

9 Data-Sharing

9.1 What is the purpose of data-sharing?

The rules on data sharing and avoidance of unnecessary testing are provided in Title III of the REACH Regulation. The objective of these rules as laid down in Article 25 of Title III is to avoid vertebrate animal testing so that it is carried out as the last resort. Therefore, as a general rule, REACH requires the sharing of information for the purposes of registration in exchange for compensation.
As registration requires the submission of relevant and available data on intrinsic properties of substances and exposure scenarios and, when not available, the generation of data, including testing, specific mechanisms and procedures have been introduced in REACH to enable companies to share existing data before submitting a registration (data sharing and joint submission). This is aimed at increasing the efficiency of the registration system, to reduce costs and to reduce testing on vertebrate animals.

The data sharing will take place within a Substance Information Exchange Forum (SIEF) according to Article 29 of the REACH Regulation.
Detailed Guidance on Data Sharing has been prepared and is available on the ECHA website. Examples on cost sharing are also provided.

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

The aim of a SIEF is to facilitate the exchange of information that is needed for registration between potential registrants of the same substance to avoid duplication of studies. The other aim is to agree on the classification and labelling of the substance. Moreover, when the available information is not sufficient for registration, SIEF collectively identifies the needs for further studies. Each SIEF shall be operational until 1 June 2018.
Sharing of existing data in the case of registered substances is governed by Article 27 of the REACH Regulation. Detailed Guidance on Data Sharing giving background on the objectives of the SIEF is available on the ECHA website . Examples on cost sharing are also provided.

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. REACH includes provisions related to a Lead Registrant for testing and joint submission purposes (see REACH Article 11(1)) and it would be helpful if the "Lead Registrant" or another participant takes the initiative at the SIEF formation stage. While there are no specific provisions in REACH to that effect, REACH IT will offer the possibility for potential registrants to indicate their willingness to act as a "SIEF Formation Facilitator" when pre-registering so as to facilitate the identification of a potential leader.

The role of a facilitator should start in the "pre-SIEF" phase, during which pre-registrants exchange information to ensure they all belong to the same SIEF. For example, the facilitator can contact all potential registrants and organise the exchange of information on the identity of the substance. As a second step, when the SIEF is formed, they can propose means of organising exchange of substantial information on the substance. Alternatively, 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.

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), the facilitator or designated lead registrant can propose a confidentiality agreement or the use of an

independent Third Party or trustee who can handle the confidential information on behalf of Potential Registrants.

Detailed Guidance on Data Sharing has been prepared to facilitate the functioning of the SIEF and is available on the ECHA website. Examples on cost sharing are also provided.

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?

The Guidance on Data Sharing (Section 4.5 – How and when will a SIEF be formed ?) explains how and when a SIEF will be formed covering issues such as how to determine the sameness of substances, how to facilitate communication within a SIEF and when data holders will join the SIEF based on Article 29 of the REACH Regulation.
All potential registrants and data holders for the "same" phase-in substance shall be participants in a SIEF. However, the REACH Regulation does not define "sameness" and it does not foresee any formal step to confirm the establishment of sameness and the formation of a SIEF.
The assessment of the exact nature of an EINECS entry and the different substances it may cover can only be carried out by the manufacturers or importers who should be aware of the composition of the substance. It is,

therefore, up to them to take the responsibility for defining precisely the substance for which a SIEF will be formed.
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 pre-registration list, actually agree that they effectively manufacture or import, intend to manufacture or import a substance that is sufficiently similar to allow a valid joint submission of data.
Data holders (see also FAQ 9.7) will not be involved in pre-SIEF discussions. They will be considered as members of a relevant SIEF once it is formed as a consequence of the pre-SIEF discussions between pre-registrants of the same identifier (e.g. EINECS entry). Since data holders do not know the contact details of the potential registrants who have pre-registered under the same identifier, it is the role of the potential registrants to evaluate for which substance(s) within this identifier the data are relevant and to which SIEF(s) the data holder participates.
ECHA will not participate in the discussions between potential registrants and ECHA will not play a role in confirming or rejecting the creation of a particular SIEF.

9.6 How is a Substance Information Exchange Forum (SIEF) managed?

The pre-SIEFs are supported by REACH-IT via substance web pages. It will allow posting information on the creation of SIEFs in two dedicated free fields on the substance web-page. In the first free field, writing rights will only be given to the SIEF Formation Facilitator. In the second free field, all pre-registrants of the substance will have writing rights. All messages in these two free fields will be the exclusive responsibility of the authors and ECHA will neither verify nor approve or disapprove 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 field will allow other pre-registrants to give comments (e.g. in case of disagreement with the SIEF Formation Facilitator). Both free fields will 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.
Potential registrants should work towards forming SIEFs as soon as possible to ensure that sufficient time remains available to organise data sharing and prepare the registration dossiers, in particular for high volume substances considering the registration deadline of 30 November 2010. The Guidance on Data Sharing (Section 4.5 – How and when will a SIEF be formed ?) explains in more detail how and when a SIEF will be managed.

9.7 How can data holders get information about a SIEF that is already formed or in the process of formation to offer their data?

The Guidance on Data Sharing (Section 4.2.2) explains in detail who are SIEF participants and discusses the role of data holders.
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-EU 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-EU 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 cost sharing for tests without an agreement between registrants and/or downstream users 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 30 of the REACH Regulation requires any applicant or group of applicants to refer to previous testing data on vertebrate animals. 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 will be put into contact with the existing SIEF to facilitate data sharing.
The Guidance on Data Sharing (Annex 2, example 4 – late registrant) contains examples of pre-registration and data sharing and also addresses the issue of a late registrant.

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 SIEF members according to 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 different 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 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, 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) that may take place in the SIEF, nor is it required to participate in any additional related costs.

Every SIEF remains operational until 1 June 2018 (see Article 29(3) of the REACH Regulation). SIEF participants shall provide other participants with existing studies, react to requests by other participants for information, collectively identify needs for further studies for the purpose of avoiding duplication of studies and arrange for such studies to be carried out (Art. 29(3) of the REACH Regulation).

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.

10 Information requirements, test methods and quality of data

10.1 According to which test methods, should new tests be performed?

New tests, if necessary, to generate information on intrinsic properties of substances, must be conducted in accordance with the test methods laid

down in Commission Regulation No. 440/2008 laying down test methods pursuant to REACH Regulation or in accordance with other international test methods recognised by the Commission or the Agency. Commission Regulation No. 440/2008 was published on the 30 May 2008 and entered into force on the 1 June 2008. This Regulation replaces the Annex V to Directive 67/548/EEC. The work on the preparation of the first adaptation to technical progress for new test methods will start soon.
In addition, as mentioned in Article 13 of the REACH Regulation, it should be recalled that information on intrinsic properties of substances may be generated using sources of information other than in vivo testing, provided that the conditions set out in Annex XI of the REACH Regulation are met. The registrant may use a variety of alternative methods such as (Q)SARs ((Quantitative) Structure Activity Relationships), in vitro tests grouping of substances/category approach and read-across approach. All these different sources of information can also be used in a weight of evidence approach. Underpinning this is that if a scientific justification can be given, demonstrating that the available information has an information content equivalent to the internationally accepted test method, then the information requirement can be met using this available information. Testing strategies can also be adapted (waiving or triggering of tests) on the basis of the envisaged exposure of the substance.

The OECD (Organisation for Economic Co-operation and Development) Guidelines for the Testing of Chemicals provides a collection of the most relevant internationally agreed testing methods

Guidance on the obligations that apply to registrants regarding the information to be submitted in the registration dossier is available in the Guidance on Registration (Section 8.1.3 – Process of fulfilling information requirements). Guidance on information requirements and Chemical Safety Assessment under REACH was developed to assist the registrants to consider all types of information and their potential sources to meet their information requirements.

10.2 Which standards are accepted for new ecotoxicological and toxicological test?

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 test guidelines recognised by the Commission or the Agency. 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. This includes *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 for more information).

Moreover, a specific requirement is introduced in Article 13(4) of the REACH Regulation which states that ecotoxicological and toxicological tests and analysis shall be carried out in compliance with the principles of Good Laboratory Practice provided for in Directive 2004/10/EC or other international standards that will be in the future recognised as being equivalent by the Commission or the ECHA and with the provisions of Directive 86/609/EEC , if applicable. More information can be found in the Guidance on information requirements and Chemical Safety Assessment under REACH that is available on the ECHA web site.

Good Laboratory Practice is currently the internationally recognised quality assurance system through the OECD's mutual acceptance of data decision.
Guidance on how to fulfil this information requirement is available in the Guidance on Registration (Section 8.1.3 – Process of fulfilling information requirements).

10.3 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.

10.4 Is there a list of approved testing laboratories in Europe?

Good Laboratory Practice certification of laboratories is the responsibility of Competent Authorities in the Member States, that are administering the national GLP monitoring programmes. The list of the Competent Authorities responsible for GLP is available at the website of DG Enterprise and Industry of the European Commission.

10.5 Are data from reference books regarded as reliable sources of information e.g. for physicochemical data of substances?

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.

There are several public sources of information on physicochemical properties of substances. Much of this is data compiled from other sources. Useful reference books and data compilations containing peer reviewed physicochemical data are listed in the Chapter 7 a of the Guidance on the Information Requirements and Chemical Safety Assessment ". It includes, for example, the Merck Index, the IUPAC Solubility Data Series and the

Beilstein Database which are also available as online data bases (see the Table R.7.1-2 Sources of physico-chemical data).

11 Authorisation

11.1 Are any substances already subject to authorisation?

No, not yet. When either an Authority (Commission or Member State) considers that a substance may meet the criteria for identification as a substance of very high concern (SVHC), the Authority (Agency or Member State) will prepare an Annex XV dossier. Following completion of an Annex XV dossier the substance may be included in the candidate list for possible inclusion in Annex XIV. As specified in Art. 59 of the REACH Regulation the consultation of the Member States and interested parties is required. The candidate list will be made available on the ECHA website. The Agency shall indicate within this candidate list which substances are on its work programme.
Once the candidate list is established, some substances of very high concern will be prioritised. ECHA shall make its first recommendation of priority substances from the candidate list to be included in Annex XIV of the REACH Regulation by 1 June 2009. The Agency shall make further recommendations on substances to be included to Annex XIV at least every second year. Priority will normally be given to substances with PBT or vPvB properties that have a wide dispersive use or are manufactured or imported in high volumes.

11.2 Does the candidate list including the substances of very high concern (SVHC) already exist?

So far no candidate list exists. Once the candidate list is established some SVHCs on this candidate list will be prioritised. ECHA shall make its first recommendation of priority substances from the candidate list to be included in Annex XIV of the REACH Regulation by 1 June 2009. The candidate list will be made available on the ECHA website.

12 Information in the supply chain

12.1 Can downstream users continue to use the substance, if it has not been pre-registered?

The downstream user can use and place on the market, without limitation in time, any batches of the substance that were supplied before the registration obligation of REACH started to apply, i.e. before 1 June 2008, as these batches were not subject to the registration obligation.
Any batches that were manufactured, imported or supplied to downstream users after the start of the pre-registration period may be subject to

enforcement. In this respect, it should be noted that enforcement of the obligations under REACH is a matter for the national authorities.
Downstream users are recommended to contact their suppliers as soon as possible and well before the end of the pre-registration period (1 December 2008) in order to find out about the supplier's intentions and, where necessary, look for alternative future suppliers. Downstream users may wish to make appropriate contractual arrangements with their suppliers to ensure that pre-registration takes place within the pre-registration period.
This concerns substances that have not been registered and that are manufactured or imported in quantities of at least 1 tonne per year per manufacturer/importer, as otherwise there is no need to (pre-)register. Additional information can be found in the Guidance on Data Sharing (Section 3.2 – The benefits of pre-registration).

12.2 Does REACH require any changes in Safety Data Sheets?

According to Articles 31 and 32 of the REACH Regulation some changes in the Safety Data Sheet (SDS) are required.
The main rules concerning when a SDS is required, who needs to prepare a SDS and to whom and when it is to be submitted do not change. However, there are some changes, such as the exposure scenarios developed by registrants as part of a chemical safety assessment which where required, need to be annexed to the SDS. Another main change is that, in addition to substances or preparations that meet the criteria for classification as dangerous, SDSs are required for PBTs and vPvBs under the Annex XIII criteria and for substances included on the candidate list of substances for potential inclusion in Annex XIV. With regard to the company/undertaking information the e-mail address of the competent person for the SDS has to be given. In addition, the order of Chapters 2 and 3 of SDS is reversed. Hazard Identification is now Chapter 2 and Composition/Information on ingredients is now Chapter 3. These changes are also explained in more detail in the Guidance on Registration (Section 3.1.1 – Provide a safety data sheet to customers).

12.2.1 What are the differences between a SDS prepared according to "old" legislation and a SDS in line with the REACH requirements?

The current duties and responsibilities for Safety Data Sheets (SDSs) remain. In addition, 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 ES should provide advice on how risks can be adequately controlled for that use or group of uses. Risk management measures should be an integral part of the ES. Another important change is that, in addition to substances or preparations that meet the criteria for classification as dangerous, SDSs are additionally required for products containing substances classified as PBTs (Persistent,

Bioaccumulative and Toxic) and vPvBs (very Persistent and very Bioaccumulative) under the Annex XIII criteria and for substances included in the candidate list for potential inclusion in Annex XIV of the REACH Regulation.

The main body text of the Safety Data Sheet is to be adapted to take into account the information in the exposure scenario. This means in particular:

- 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) of the extended safety data sheet (see Annex II of the REACH Regulation - Guide to compilation of Safety Data Sheet). This includes consumer related measures communicated to a downstream user producing consumer preparation or articles. Also the relevant DNELs and PNECs should be presented here.

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

- 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 single ES.

- 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 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).

- 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.

In addition, the structure of the SDS has been changed (see Annex II of REACH):

▪ The section on Hazards Identification is now listed before the section on Composition and Information on Ingredients (previously listed after it).

▪ The naming of the section (12) on Environmental information has been changed to "Ecological information".

Also, some additional information shall be provided for in the SDS, e.g. the registration number for substances subject to registration, the e-mail address of a contact person or information on when the emergency telephone number is reachable.

Importantly, an SDS has to be updated on the occasions specified in Article 31(9) of the REACH Regulation, e.g. when new information becomes available on risk management measures or hazard classification, once an authorisation has been granted or refused or when a restriction has been imposed. The new SDS format (as described in Annex II of REACH) applies as of 1 June 2007. However, Member State authorities for the enforcement of the SDS provision agreed that the first priority for enforcement should be the correctness of the content of the SDS.

For further details please consult the Guidance on Information Requirements and Chemicals Safety Assessment *(part G*), available at the ECHA Guidance website 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 124).

12.3 How soon do the changes in the format of the SDS need to be implemented?

The new format for the SDS as described in Article 31 of and Annex II to the REACH Regulation entered into force on 1 June 2007. In principle, the changes in format are to be implemented by that date. However, enforcement of this provision is a matter for the national authorities. If new information, for example, on hazards or risk management measures, becomes available, the safety data sheet should be updated without delay according to Article 31 (9) of the REACH Regulation and the new format should be used.

12.4 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 preparation 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).

12.5 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 preparations 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 preparations occurring exclusively within an industrial plant is covered by REACH, even if this includes transportation carried out by an external company.

12.6 How to get assurance that a substance has been/will be pre-registered?

The REACH Regulation foresees the publication of a list of all pre-registered substances by 1st January 2009 that will help downstream users to verify whether the substances they use have been pre-registered. The list of pre-registered substances will neither include any company names nor provide any information concerning the preparations in which the substances are used or may be used.

In order to be able to compare this list with the substances (as such or in preparations) bought from a supplier, the downstream user should set up an inventory of the substances he receives. Substances a downstream user buys as components of a preparation will however often be difficult to identify. Thus it may be difficult to compare the published list of pre-registered substances with the substances in the products supplied to a specific downstream user. It is therefore advisable to make early contact with the relevant suppliers and ask for confirmation that the supplied substances (as such or in preparations) will be or have been pre-registered.

After the publication of the list a downstream user may notify ECHA of his interest in substance(s) that do not appear on the list. ECHA will then publish the names of such substances on its website and on request provide contact details of the downstream user to any potential registrants (see Article 28(5) of the REACH Regulation).

12.7 What information can a Downstream User communicate to his suppliers in order to cooperate in preparing for REACH?

Downstream users may make uses known to the suppliers in their supply chain, before the manufacturer or importer submits its registration. In some situations this may be best done as a collective action in a sector facilitated by the sector organizations (e.g. coatings industry, lubricants industry, detergent industry). However, where a company is not part of a trade association or

where very specific uses need to be addressed, 1:1 communication between a downstream user and his supplier may be required. One of the rights enshrined in Article 37(2) of the REACH Regulation is that an individual downstream user can make his use known to the manufacturer, importer, downstream user or distributor who supplies him with a substance or preparation with the aim of making this an identified use,

In making a use known, the downstream user must provide sufficient information to allow the manufacturer, importer or downstream user who has supplied the substance to prepare an exposure scenario for his use,

If the downstream user wishes to keep his use confidential from his supplier, he has two options:

1. The use is described in a generic way (see use descriptor system in chapter R12 of the Guidance on Information Requirements and Chemicals Safety Assessment available at www.echa.eu). The conditions of use are described to a sufficient extent to allow the manufacturer to carry out a Chemicals Safety Assessment. This does not necessarily require disclosure of technical details of the use.

2. Another party may be involved. It is anticipated that suppliers offer such mechanisms in order to maintain their markets.

Please note that according to Article 37(4) of the REACH Regulation, a downstream user shall normally prepare his own chemical safety report to demonstrate the safe use only where:

- he has any use outside the conditions described in an exposure scenario communicated to him in a safety data sheet, or

- he is using the substance for an application for which his supplier advices against

More detailed information can be found in the Guidance for downstream users. In addition, it is advisable for a downstream user to contact his respective industry association for assistance.

13 Downstream users

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

Only manufacturers of substances within the EU, or, importers of substances or preparations or articles from outside the EU, producers of articles or Only Representatives have registration duties. In this context, it is important to note that the role of your company may differ with respect to the different substances you use, i.e. it is possible that a legal entity has multiple roles under REACH depending on its activities especially where these activities involve many different substances and/ or articles. It is therefore important that companies carefully identify the suppliers of all substances they use in

order to establish if they (the companies) have registration or notification duties, e.g. because they are importing a substance.

You may use the Navigator tool on the ECHA website that is designed to help companies to establish their roles and duties under REACH for the substance(s) they use to help identify your obligations. Companies may also use the Guidance for Downstream users (Section 2.5 – Identification of roles and obligations) that can help to distinguish between the different roles under REACH.