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 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.

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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 start 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 1.6.1 – 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 ca 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 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 1.5.2 – Actors in the Supply Chain) or see also FAQ 4 for details.

4 Only Representative

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 1.5.2 – Actors in the Supply Chain).

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 1.5.2 – Actors in the Supply Chain).

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 can 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 1.5.2 – Actors in the Supply Chain).
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. An only representative representing more than one non-EU company must submit one registration dossier for the same substance. He must register the volume of the substance he is responsible for, that is exported by all of the non-EU companies that appointed him and fulfil all registration requirements.

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. In order to pre-register many substances in a single step, it is possible to submit a pre-registration prepared separately in a computer file format specified by ECHA in accordance with Article 111 of the REACH

Regulation. A specific format is necessary in order to facilitate and validate the submission of your pre-registration data. This XML format is produced by an IUCLID 5 plug-in, which is currently under development. Alternatively, pre-registration files may also be created by other applications, as long as they use the same format for submission, as the one produced by IUCLID 5. 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).

6.2 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.

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. By 1 June 2008, 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 or states that he has received confirmation from the user (being in the EU or outside the EU) that the substance is manufactured and used under strictly controlled conditions as described under Article 18(4).

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 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.

6.3.4 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 or producers of articles wishing to continue their PPORD (defined in Article 3(22)) activities need to submit a new notification to the European Chemicals Agency according to Article 9 of the REACH Regulation. In order to avoid interruptions of such activities, the notification should be made as soon as possible because, in the absence of an indication to the contrary, PPORD activities may not start earlier than after the notification. The exact date by when notification will be possible will be communicated at a later stage.
Please note also that even if the notification is made in advance of 1 June 2008, any activities covered by the notification can always only start on 1 June 2008, when the PORD rules under Directive 67/548/EEC have expired and the new rules under REACH have entered into force.
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)

6.4 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 in the period 1 June to 1 December 2008, the substance should be registered by 1st December 2008 at the latest if a company wishes to continue to manufacture or import. If registration occurs after 1 December 2008, then the company may have to wait for 3 weeks before continuing manufacture or import (Article 21). 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 is the procedure for new substances before the registration obligations of REACH apply (1 June 2008)?

The placing on the market of new substances is currently regulated by Directive 92/32/EEC amending for the Seventh Time Directive 67/548/EEC on the Classification, Packaging and Labelling of Dangerous Substances. That means if you plan to place a new substance in quantities of 10 kg or more per year on the market it has to be notified to the Competent Authorities (CA) of

the Member State where you place the substance on the market. Please contact the concerned CA (Notification units) directly for further information on the notification procedure under Directive 92/32/EEC.
Article 24 of the REACH Regulation provides that notifications according to Directive 92/32/EEC amending for the Seventh Time Directive 67/548/EEC are regarded as registrations for the purposes of REACH and the ECHA shall assign to them a registration number by 1 December 2008. Please note that a notification under Directive 67/548/EC is nominal so that only the notifier benefits from being considered registered; any other parties manufacturing or importing the substance but who have not notified it, must register, unless there is another exemption that applies to them. The Guidance on Registration (Section 1.6.5.3 – Notified substances) provides further information on this issue.

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 via the REACH IT web portal, which will be accessible through the ECHA website. REACH-IT provides an online company homepage to submit registration dossiers on chemicals.
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 at ECHA.

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 will be specified in a Commission Regulation to be adopted by 1 June 2008 in accordance with procedure referred to in Article 133(3). 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 shall be set for SMEs.

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) in bound or unbound form makes up 1 tonne or more per year.

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 of the polymer 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 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 – 3.4) provides further information on this issue.

8 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) 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 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.

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.

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 shall be submitted jointly whereas other information shall be submitted separately. Additionally there is information where the registrant might decide them self whether they submits it 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.

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 a Commission Regulation or in accordance with other international test methods recognised by the Commission or the Agency. The Commission Regulation was adopted on the 31 October 2007 and will be officially published in due course. This Regulation currently reproduces the test methods in 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 under REACH is being developed to assist the registrants to consider all types of information and their potential sources to meet their information requirements. This will be available on the ECHA web site in due course.

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 a Commission Regulation 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 under REACH that will be available on the ECHA web site in due course.

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.

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 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. This also means that the downstream users of the substances may be at risk. 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 31and 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).

12.3 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.