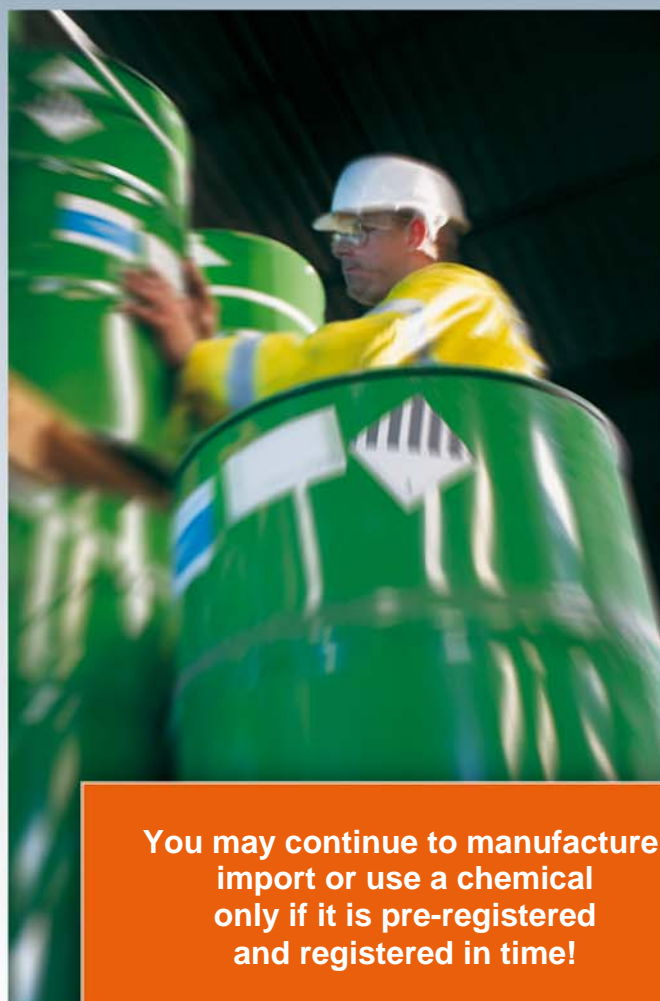


# REACH Pre-registration Questions and Answers

(RELEASE 2)



**You may continue to manufacture, import or use a chemical only if it is pre-registered and registered in time!**

**REACH Pre-registration**  
Questions & Answers

**Reference:** ECHA-08-QA-01-EN

**Date:** 30/05/2008

**Language:** EN

This document is available in the following 22 languages:

*Bulgarian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovakian, Slovenian, Spanish and Swedish*

If you have questions or comments in relation to this document please send them by e-mail to [info@echa.europa.eu](mailto:info@echa.europa.eu) quoting the reference, issue date and language version.

## QUESTIONS & ANSWERS ON PRE-REGISTRATION

This document provides easy access to commonly asked questions and answers (Q&As) covering general and IT-related issues when considering pre-registering your substance.

The EU's new chemicals legislation REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) entered into force on 1 June 2007. It has implications for all chemical substances, manufactured or imported into the EU, in quantities of one tonne or more per year. Mandatory registration of new ('non-phase-in') substances begins on 1 June 2008. Later deadlines exist for 'existing' ('phase-in') substances that have been pre-registered. These depend on the quantities involved and range from November 2010 to May 2018. A company that fails to pre-register a phase-in substance by 1 December 2008 may neither import nor manufacture it after that date until it has fully registered the substance with the European Chemicals Agency (ECHA).

The questions and answers presented here address situations directly related to pre-registration and are intended to assist those who do not have a detailed knowledge on this issue, to provide context information and to guide the reader to the most

appropriate information sources such as the [Navigator](#), specific guidance documents or the REACH text itself. This information is also available on ECHA's website at [echa.europa.eu](http://echa.europa.eu) and is complementary to the [Frequently Asked Questions on REACH by Industry](#) and [IUCLID 5](#). If after reading this document you still have questions on pre-registration you can obtain information from the following sources:

- Your industry association may be the best source of information for sector-specific questions.
- The national [REACH helpdesk](#) in your country provides you with wide ranging information on the provisions of REACH, your roles and responsibilities, and guidance made available by ECHA to the stakeholders. The national Helpdesk should be your first point of contact;
- The [ECHA Helpdesk](#) will also assist you with questions related to registration, REACH-IT or IUCLID and registration-related questions. You can submit your questions by filling in an information request form on the ECHA website.

**REACH Pre-registration**  
Questions & Answers

**TABLE OF CONTENT**

Questions & Answers on Pre-registration .....	3
Table of Content.....	4
<b>1. Questions related to practical pre-registration issues.....</b>	<b>6</b>
1.1. What is pre-registration? .....	6
1.2. What is meant with extended registration deadlines? .....	6
1.3. How do I calculate the tonnage for pre-registration in order to determine the envisaged registration deadline? .....	6
1.4. Which substances can be pre-registered? .....	7
1.5. What are phase-in substances? .....	7
1.6. Can I pre-register non-phase-in substances? .....	7
1.7. Must recycled substances be pre-registered?.....	7
1.8. What information do I have to submit when pre-registering?.....	7
1.9. What are the advantages of pre-registration? .....	8
1.10. Do I have to pay a pre-registration fee? .....	8
1.11. Who can pre-register? .....	9
1.12. May a non-Community manufacturer pre-register? .....	9
1.13. May a non-Community manufacturer of phase-in substances appoint an only representative for the purpose of pre-registration only? .....	9
1.14. How can a non-Community manufacturer help an only representative or an importer in preparing for pre-registration?.....	10
1.15. Does a downstream user have pre-registration obligations? .....	10
1.16. How do I as a downstream user, know whether my supplier will pre-register the substances that he supplies to me?.....	10
1.17. How can I find out which substances have been pre-registered?.....	10
1.18. Will the list of pre-registered substances be published only after pre-registration is closed? .....	11
1.19. What will happen to companies that do not pre-register a substance? .....	11
1.20. Is it possible to pre-register after 1 December 2008? .....	11
1.21. If I miss pre-registration and I submit a full registration dossier, do I have to wait to continue manufacturing or importing?.....	12
1.22. Is pre-registration of substances contained in articles required? .....	12
1.23. What if I, as an article producer, find out after 1 December 2008 that my supplier did not pre-register? What if I as an article importer have missed the deadline to pre-register? .....	12
1.24. If a substance has not been pre-registered, can a downstream user benefit from Article 28(6) of the REACH Regulation and become a first time importer in order to register the substance himself after 1 December 2008? .....	12

## REACH Pre-registration Questions & Answers

1.25. Should documentary evidence demonstrating the phase-in status of a substance without an EC number be submitted in parallel with pre-registration? .....	13
1.26. What are the duties following from pre-registration?.....	13
1.27. Can a downstream user participate in a SIEF and share data?.....	13
<b>2. Questions related to the use of IT Tools .....</b>	<b>14</b>
2.1. Is it possible to pre-register via e-mail? .....	14
2.2. How can pre-registrations be submitted to ECHA?.....	14
2.3. Which IT tools have to be used to prepare data for pre-registration? .....	14
2.4. When will the IT tools be available for use? .....	15
2.5. Will the contact details of my company be shown to other pre-registrants during pre-registration and when forming the pre-SIEF? .....	15
2.6. Which contact details will be used by ECHA – the REACH-IT registration contact details or the contact details defined in the IUCLID 5 pre-registration tool?.....	15
2.7. How can I identify a third party representative when pre-registering? .....	15
2.8. What will happen if I will try to pre-register the same substance several times? .....	16
<b>3. Questions on IUCLID 5.....</b>	<b>17</b>
3.1. How do I establish pre-registration lists per legal entity in the IUCLID 5 pre-registration tool?.....	17
3.2. Will information on the legal entity be stored in the pre-registration XML files? .....	17
3.3. Can a pre-defined CAS number coming from the EC inventory be modified in the IUCLID 5 pre-registration tool? .....	17
3.4. Will it be possible to carry out a bulk pre-registration of substances having no EC number? .....	17
3.5. Will a multi-constituent substance, where some of the constituents have no EC-number, be allowed into a bulk pre-registration? .....	18
3.6. Will there be a compliance check in the IUCLID 5 pre-registration tool?.....	18
<b>4. Questions on REACH-IT .....</b>	<b>19</b>
4.1. Is it possible to modify the data entered during pre-registration? .....	19
4.2. Will the ‘Super User’ functionality as mentioned in the Guidance on Data Sharing be available in REACH-IT? .....	19
4.3. Will there be a pre-registration number distributed to the pre-registrant?.....	19
4.4. Can I, as a downstream user, check on-line the pre-registration number and see if my supplier did pre-register? .....	20

## 1. Questions related to practical pre-registration issues

### 1.1. *What is pre-registration?*

Pre-registration is a REACH process taking place between 1 June and 1 December 2008. During this period all manufactures and importers of phase-in-substances in quantities of 1 tonne or more per year and producers/importers of articles containing substance(s) intended to be released in quantities of 1 tonne or more per year have the possibility to inform ECHA about which substances they intend to register. Companies taking this opportunity are granted extended registration deadlines for their substances (see also question 1.4). Without pre-registration, substances need to be registered before they are manufactured in the Community or placed on the market. These registration obligations apply from 1<sup>st</sup> June 2008.

### 1.2. *What is meant with extended registration deadlines?*

Article 23 of the REACH Regulation provides for a scheme with staggered registration deadlines for so-called 'phase-in substances', depending on the tonnage band and hazards of the substance:

- 30 November 2010 for CMR<sup>1</sup>  $\geq 1$  t/y, R 50-53<sup>2</sup>  $\geq 100$  t/y and other substances  $\geq 1000$  t/y; or
- 31 May 2013 for other substances  $\geq 100$  t/y; or
- 31 May 2018 for other substances  $\geq 1$  t/y;

### 1.3. *How do I calculate the tonnage for pre-registration in order to determine the envisaged registration deadline?*

The actual amount of production and/or import and the forecasted tonnages will define the relevant registration deadline (depending on the tonnage band and hazards of the substance 30 November 2010 or 31 May 2013 or 31 May 2018). This should be taken into account for pre-registration. The envisaged yearly quantity shall be calculated per calendar year. Detailed guidance and practical examples are provided in the [Guidance on Registration](#) (Section 1.6.2 – Calculation of volume to be registered and Article 3 (30) of the REACH Regulation).

When pre-registering substances that have different uses (intermediates, normal industrial use, PPORD<sup>3</sup>), only the estimated tonnage band corresponding to the quantities of the normal registration has to be filled in.

---

<sup>1</sup> Classified as carcinogenic, mutagenic or toxic to reproduction, categories 1 and 2, in accordance with Directive 67/548/EEC.

<sup>2</sup> Classified as very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment (R50-53) in accordance with Directive 67/548/EEC.

<sup>3</sup> Product and Process Orientated Research and Development.

#### **1.4. Which substances can be pre-registered?**

Pre-registration applies only to so-called 'phase-in' substances. If you wish to benefit from the extended registration deadlines set out in the REACH Regulation, and you are a potential registrant of a phase-in substance manufactured or imported in quantities of 1 tonne or more per year, you should pre-register the phase-in substances concerned in order to benefit from the extended registration deadline.

#### **1.5. What are phase-in substances?**

Substances fulfilling at least one of the following criteria are phase-in substances (Article 3(20) of the REACH Regulation):

- Substances listed in the **E**uropean **I**nventory of **E**xisting **C**ommercial chemical **S**ubstances (EINECS);
- Substances that have been manufactured in the EU (including accession countries on 1 January 2007) but have not been placed on the EU market after 1 June 1992;
- Substances that qualify as a so-called 'no-longer polymer';

Detailed information can be found in the guidance document '[Guidance on registration](#)' (section 1.7.1.1 – Phase-in substances).

#### **1.6. Can I pre-register non-phase-in substances?**

No, you cannot pre-register non-phase-in substances. Non-phase-in substances are substances that do not meet the definition of phase-in substances as provided in Article 3(20) of the REACH Regulation. Non-phase-in substances are therefore normally new substances. For such substances, it will be important to proceed with registration as soon as possible from 1 June 2008 in order to minimise disruptions of manufacturing, placing on the market or use.

#### **1.7. Must recycled substances be pre-registered?**

If the recycled substance is a phase-in substance, it is recommended that the recycler pre-registers this substance in order to benefit from the transitional provisions laid down in Article 23 and later on be exempted from the registration requirements if another pre-registrant registers the substance. Pre-registration of recycled substances is not obligatory but a decision against pre-registration may result in immediate registration obligations. Detailed information on recycled substances can be found in the guidance document '[Guidance on registration](#)' (section 1.6.4.5 - Recycled or recovered substance already registered).

#### **1.8. What information do I have to submit when pre-registering?**

Pre-registration takes place when the company submits electronically the required information to ECHA (Article 28(1) of the REACH Regulation). This information includes:

## REACH Pre-registration Questions & Answers

- The name of the substance identified by the EINECS, CAS, IUPAC-name or other identity codes.
- The name of your company, the address and the name of the contact person:
  - When your company consists of several legal entities, manufacturing in the EU or importing the same substance, each legal entity has to pre-register separately;
  - You can appoint a third party representative to represent you for all the proceedings involving discussions with other manufacturers, importers and downstream users. If you do not wish to make your contact details available to other pre-registrants you should use a third party representative.
- The envisaged registration deadline and the tonnage band;
- Optionally, identifiers of related substances which may be relevant for deriving data for the substance pre-registered. This is a way to indicate which data can be shared by read-across, (quantitative) structure-activity relationships ((Q)SARs) and grouping of substances.

Detailed information can be found in the guidance document '[Guidance on data sharing](#)'<sup>4</sup> (Section 3.8 – How to pre-register a substance) and in the document '[Practical Steps for Pre-registration](#)' (What information has to be provided for pre-registration?).

### 1.9. *What are the advantages of pre-registration?*

Besides the fact that pre-registration allows companies to benefit from extended registration deadlines, it also allows industry to adapt gradually to the new system. More specifically pre-registration:

- Allows you to continue manufacturing or importing phase-in substances until the relevant registration deadline;
- Gives you additional time to organise the collection and assessment of available data, the sharing of existing data, and the collective generation of missing information;
- Provides the basis to make existing information on substances e.g. non-testing information, substance to substance read-across, data from testing accessible to those who need the information for registration;
- Ensures that there will be no interruption in the supply to downstream users using your substances.

### 1.10. *Do I have to pay a pre-registration fee?*

**Pre-registration is free of charge** and does not establish any obligation to maintain production or import of substances.

---

<sup>4</sup> Guidance on pre-registration is covered by a specific chapter in the 'Guidance on data sharing'.

### **1.11. *Who can pre-register?***

Any company (legal entity) that is required to register a phase-in substance as of 1 June 2008 may pre-register. These companies include:

- Manufacturers and importers established within the European Community of phase-in substances on their own or in preparations in quantities of 1 tonne or more per year, including intermediates;
- Producers and importers established within the European Community of articles containing substances intended to be released under normal or reasonably foreseeable conditions of use and present in those articles in quantities of 1 tonne or more per year;

Conversely, companies that manufacture substances, formulate preparations or produce articles outside the Community cannot pre-register as they have no obligations under REACH. They can nominate an only representative established within the Community to carry out the required pre-registration of their substances that are imported into the Community.

Detailed information can be found in the guidance document '[Guidance on data sharing](#)' (Section 3.4 – Who can pre-register?).

### **1.12. *May a non-Community manufacturer pre-register?***

No, non-Community manufacturers cannot pre-register their substances that are imported into the EU. Either the pre-registration is done by their importer(s) or, alternatively, non-Community manufacturers may appoint an 'only representative', a natural or legal person located in the Community (Article 8 of the REACH Regulation). The only representative is then legally responsible to fulfil the REACH obligations of importers which, in turn, are regarded as downstream users.

Detailed information on the 'only representative' can be found in the guidance documents '[Guidance on registration](#)' (section 1.5.3.4 - Only representatives of 'non-Community manufacturer') and '[Guidance on data sharing](#)' (Section 3.4 – Who can pre-register?).

### **1.13. *May a non-Community manufacturer of phase-in substances appoint an only representative for the purpose of pre-registration only?***

Once appointed, the only representative shall be responsible for registration and thus also for all other obligations of importers under REACH, including pre-registration. This does not only pertain to registration, but also all other relevant obligations, such as communication in the supply chain, notification of substances of very high concern (SVHC), classification and labelling and any obligations resulting from authorisations or restrictions etc. (see Article 8(2) of the REACH Regulation). He will also become a participant of a Substance Information Exchange Forum (SIEF) (See [Guidance on data sharing](#) section 3.4 - Who can pre-register?). Detailed information on the 'Only Representative' can be found in the guidance documents '[Guidance on registration](#)' (section 1.5.3.4 - Only representatives of 'non-Community manufacturer').

**1.14. *How can a non-Community manufacturer help an only representative or an importer in preparing for pre-registration?***

In most cases it is anticipated that 'non-Community manufacturers' will provide all necessary data for the pre-registration by the only representative appointed by him or to his EU-based importer. The 'non-Community manufacturer' may wish to make himself aware of the information requirements laid down in REACH and start collecting the relevant information. This may include the correct naming of the substance and information on its composition. This is explained more in detail in the '[Guidance for identification and naming of substances under REACH](#)'. It also includes assessment of all information available to the non-Community manufacturer about the intrinsic properties of the substances (see REACH annex VII to XI).

**1.15. *Does a downstream user have pre-registration obligations?***

A downstream user who is not manufacturing or importing substances has no registration obligations and consequently he is not obliged to pre-register a phase-in substance. However, after the publication of the list of pre-registered substances by ECHA (1 January 2009), a downstream user of a substance that does not appear on the list may notify ECHA of his interest in the substance, his contact details and the details of his current supplier. Following this publication, ECHA can provide contact details of the downstream user to this potential registrant.

**1.16. *How do I as a downstream user, know whether my supplier will pre-register the substances that he supplies to me?***

If a supplier is located outside the EU, a downstream user established within the EU is reminded that he has registration obligations as an importer unless an only representative has been appointed (see also question 1.12). Downstream users established within the EU are encouraged to contact their EU-based suppliers as soon as possible and well before the end of the pre-registration period (1 December 2008) in order to find out about their intentions and to look for alternative future sources of supply in case the current supplier is not intending to register the substance. Likewise, manufacturers and importers are encouraged to inform their downstream users about their intention to (pre-) register the substance. The downstream users may wish to make appropriate contractual arrangements with their suppliers to ensure that they will comply with REACH and the pre-registration takes place within the pre-registration period.

We recommend consulting the [Navigator](#) that is designed to help companies to learn more about their roles and obligations under REACH.

**1.17. *How can I find out which substances have been pre-registered?***

ECHA will publish a list of pre-registered substances on its website by 1 January 2009 (Article 28(4) of the REACH Regulation). The published list will contain the names of substances and related identity codes. It will also include the names and

## REACH Pre-registration Questions & Answers

other identifiers of substances that pre-registrants have indicated as being related substances on which e.g. read-across of test results could be possible. The list to be published will not contain information on the companies.

### **1.18. Will the list of pre-registered substances be published only after pre-registration is closed?**

Yes, the list of pre-registered substances will be published after closure of the pre-registration. ECHA will publish on its website a list of pre-registered substances (Article 28(4) of the REACH Regulation) by 1 January 2009.

### **1.19. What will happen to companies that do not pre-register a substance?**

A company that has not pre-registered a phase-in substance must have submitted a complete registration dossier for the substance to ECHA and received a decision on registration, including a registration number<sup>55</sup>, from ECHA before it can further manufacture or import the substance.

### **1.20. Is it possible to pre-register after 1 December 2008?**

You may pre-register after 1 December 2008 if you are:

- manufacturing or importing phase-in substances (on their own or in a preparation) after 1 December 2008 in quantities of 1 tonne or more per year and be able to prove that you do this **for the first time**; or
- producing or importing articles with an intended release of substances after 1 December 2008 in quantities of 1 tonne or more per year and are able to prove that you do this **for the first time**

If this is the case, the following deadlines apply:

- At the latest six months after manufacturing or importing exceeds the one-tonne threshold; and
- At least 12 months before the relevant transitional deadline for registration.

In this context, the manufacture or import 'for the first time' means for the first time after the entry into force of the REACH Regulation (1 June 2007). Detailed information can be found in Article 28(6) of the REACH Regulation, in the guidance documents 'Pre-registration and Data-sharing' (Section 3.6 – First time Manufacturers or Importers?) and 'Guidance on requirements for substances in articles' (Section 6.4 - Time of checking compliance).

---

<sup>55</sup> To receive a decision, including a registration number, the company has to:

- File an inquiry to ECHA to determine whether a registration or an inquiry was previously submitted for the same substance;
- Obtain and assess relevant physico-chemical, health and environmental data and use information in order to compile your registration dossier
- Submit a complete dossier and pay the related fee in full to ECHA.

**1.21. *If I miss pre-registration and I submit a full registration dossier, do I have to wait to continue manufacturing or importing?***

In these circumstances, you will have to submit a registration dossier and receive a registration number for that substance before you can continue manufacturing or importing it in quantities of 1 tonne or more per year starting from 1 June 2008.

**1.22. *Is pre-registration of substances contained in articles required?***

Producers or importers of articles containing substances intended to be released<sup>6</sup> in quantities of 1 tonne or more per year have to pre-register between 1 June and 1 December 2008 and may benefit from the option that other registrants in the Substance Information Exchange Forum (SIEF) include their use of the substance in the article in their registration dossier (Article 7(6) of the REACH Regulation).

**1.23. *What if I, as an article producer, find out after 1 December 2008 that my supplier did not pre-register? What if I as an article importer have missed the deadline to pre-register?***

Please note that this only concerns articles containing substances intended to be released in quantities of 1 tonne or more per year. If an article supplier identifies a registration requirement after 1 December 2008 for a substance in articles he has been producing or importing already, he cannot submit a pre-registration any more and he has to limit his production/import to less than 1 tonne per year until:

- he has made a registration and received a registration number; or
- someone else registers his use of the substance.

**1.24. *If a substance has not been pre-registered, can a downstream user benefit from Article 28(6) of the REACH Regulation and become a first time importer in order to register the substance himself after 1 December 2008?***

Article 28(6) of the REACH Regulation also allows downstream users to become a first time importer, benefiting from the phase-in period corresponding to the respective tonnage band for substances that have not been pre-registered (the so called *late pre-registration* procedure). Article 28(5) of the REACH Regulation entitles downstream users to contact ECHA and indicate their interest in a missing substance. ECHA will relay this interest, and a manufacturer/importer will potentially

---

<sup>6</sup> A release of substances from articles is intended when the release contributes to a (accessory) function of the article, or, in other words the release contributes to the 'added value' of the article, which is not directly connected to the end use function. If the release did not happen, that function could not be fulfilled.

## REACH Pre-registration Questions & Answers

respond. The decision to pre-register and to further register, if taken, lies with the manufacturer/importer. Detailed information can be found in the '[Guidance on data sharing](#)' (see section §4.4 – What happens after the Pre-registration?).

### **1.25. *Should documentary evidence demonstrating the phase-in status of a substance without an EC number be submitted in parallel with pre-registration?***

The pre-registration of a phase-in substance without an EC number does not require the potential registrant to submit documentary evidence demonstrating the phase-in status of a substance within the meaning of Article 3(20)(c) of the REACH Regulation in his pre-registration (see Art. 28(1) of the REACH Regulation). The pre-registrant has nevertheless to confirm in the pre-registration that he is willing to claim phase-in status for his substance.

Manufacturers/importers need to keep this information at the disposal of the enforcement authorities of the Member States at any time.

### **1.26. *What are the duties following from pre-registration?***

All companies that pre-register will become a member of a Substance Information Exchange Forum (SIEF) for the substance concerned. The aim of a SIEF is to avoid duplication on the testing of substances and to agree on their classification and labelling. In a SIEF, companies are obliged to share animal testing studies to keep these tests to an absolute minimum. They may also share other data relevant for REACH. It is an opportunity to generate and obtain required information for registration required by the REACH Regulation in a cost-effective manner.

### **1.27. *Can a downstream user participate in a SIEF and share data?***

In accordance with the provisions of Article 28(7) of the REACH Regulation, downstream users may submit information on pre-registered substances as well as any other relevant information for those substances, with the intention of becoming a participant (Data Holder) of the corresponding SIEF.

When downstream users have data regarding safety, including hazard data, uses, exposure and risks, it is recommended that they communicate as early as possible with their suppliers in order to ensure the best possible use of their data. They can share data for fair recompense in the SIEF for that substance.

Detailed information can be found in the '[Guidance on data sharing](#)' (see section 4.5 – How and when will a SIEF be formed?- and section 7 – Cost sharing).

## 2. Questions related to the use of IT Tools

### 2.1. *Is it possible to pre-register via e-mail?*

Due to the high number of expected pre-registrations it is not possible to pre-register via e-mail. Pre-registration must be carried out electronically via the REACH-IT web application accessible from the ECHA website.

### 2.2. *How can pre-registrations be submitted to ECHA?*

All pre-registrations have to be submitted electronically via the REACH-IT web application accessible from the ECHA website in the format specified by ECHA. When you enter the pre-registration application access point you will be guided through dedicated pages where you can choose between the two following possibilities to pre-register your substances:

- **On-line pre-registration** by entering the required information directly, substance by substance into the REACH-IT system;
- **Submission of a pre-registration as an XML file** prepared separately in a specified electronic file format and uploaded at the moment of the pre-registration via REACH-IT. It allows you to submit one or more file(s) with the required pre-registration information for one or multiple substances.

These are the only alternatives to submit a pre-registration.

### 2.3. *Which IT tools have to be used to prepare data for pre-registration?*

There are three options to prepare your files:

- The first possibility is to encode all necessary information directly on-line with REACH-IT.
- The second option is to use IUCLID 5 and the ad-hoc functionality called 'pre-registration plugin'. This option allows the use of existing information in a local database. Pre-registration files can be produced in the required XML format either for several substances as 'bulk' export files, or for individual substances as 'single' export files.
- The third option for preparing pre-registration data is to use any other company specific tool, which is able to export the necessary information in the defined pre-registration XML format published on the [IUCLID 5](#) website.

The first option allows using information in any format, but encoding needs to be done manually online substance by substance. The last two options offer the possibility to prepare the information offline in advance using other tools. More information on the XML format is available on the IUCLID 5 website.

**2.4. *When will the IT tools be available for use?***

The REACH-IT web portal will be opened on 1 June 2008. The pre-registration XML schema and the pre-registration plugin for IUCLID 5 have been published respectively in February and March on the [IUCLID 5](#) website. This website can be accessed through the ECHA website.

**2.5. *Will the contact details of my company be shown to other pre-registrants during pre-registration and when forming the pre-SIEF?***

When specifying the contact details of your company in the pre-registration, there are three possibilities:

- You identify the contact person for pre-registration within your company. If you do not wish to enter a name of a person you can use a functional mailbox address as a contact detail. The information about your company will be shown accordingly in the pre-SIEF;
- You specify a third party representative according to Article 4 of the REACH Regulation. The contact details of your company will be kept confidential. The contact details of your third party representative will be shown accordingly in the pre-SIEF;
- You do not specify anything (neither the contact person nor the third party representative). Your company's general contact details will be displayed in the pre-SIEF.

**2.6. *Which contact details will be used by ECHA – the REACH-IT registration contact details or the contact details defined in the IUCLID 5 pre-registration tool?***

The contact details in the context of REACH pre-registration are the ones given at the REACH-IT signup. ECHA will use the contact details in the pre-registration for inquiries regarding specifically this dossier when appropriate. There is no obligation to provide substance specific contact details for pre-registration.

**2.7. *How can I identify a third party representative when pre-registering?***

When your third party representative signs up into REACH-IT, he will obtain a unique identifier 'UUID' (Universally Unique IDentification) that he will communicate to you. If you are using IUCLID 5, your third party representative can also download and distribute his Legal Entity Object to you for your convenience. The preferred way of working is to obtain a UUID from the IUCLID 5 website allowing preparation of your files in advance. If you use IUCLID 5 but not the pre-registration plug-in (see also question 2.3), you should still upload your UUID in REACH-IT.

It is essential that the third party representative signs up to REACH-IT first. If you submit a pre-registration with a UUID of a third party representative that has not signed up yet, the file will be rejected (in the case of bulk pre-registration through

## REACH Pre-registration Questions & Answers

IUCLID 5) or you will not be able to select your third party representative (in the case of on-line pre-registration within REACH-IT). You can refer either in your IUCLID 5 pre-registration list or in the REACH-IT application to the UUID of your third party representative. The contact details of your third party representative will then be made visible in the pre-SIEF for other pre-registrants to be contacted.

### **2.8. *What will happen if I will try to pre-register the same substance several times?***

It is crucial for pre-registration to define each substance correctly for each pre-registering legal entity. As a main rule, one mono-constituent substance or multi-constituent substance (defined by one EC- and CAS-number or other identifiers) can be pre-registered only once by the same legal entity. Otherwise the previous information may be overwritten. For a bulk pre-registration, the information will be overwritten whereas for an on-line pre-registration you will be warned that you have already pre-registered that substance. In the case of a multi-constituent substance, a same constituent can be pre-registered as a constituent of another multi-constituent substance.

### 3. Questions on IUCLID 5

#### 3.1. *How do I establish pre-registration lists per legal entity in the IUCLID 5 pre-registration tool?*

The first step is to clarify in the IUCLID 5 database which substances are manufactured or imported per legal entity. When adding substances into your own pre-registration list, you can make a query of substances per legal entity. Sorting the substances, deciding which to pre-register and creating the pre-registration lists per legal entity in advance are recommended due to the need to pre-register per legal entity.

#### 3.2. *Will information on the legal entity be stored in the pre-registration XML files?*

No, the legal entity information will not be in the pre-registration XML export file that will be uploaded into the REACH-IT application. The association between the legal entity and the pre-registration will be based on the legal entity of the uploading user inside the REACH-IT application. However you may optionally specify contact information for each pre-registered substance.

#### 3.3. *Can a pre-defined CAS number coming from the EC inventory be modified in the IUCLID 5 pre-registration tool?*

The standard workflow starts by searching from the EC inventory to identify the EC number – CAS number combination. If you for some reason have another CAS number identifying your phase-in substance, you should not try to link that to the EC number. Since the EC inventory is not updateable, choosing an EC number for pre-registration implies that you approve the EC number – CAS number combination in the inventory and only the EC number will be communicated into the export file.

Phase-in substances for which an EC number is not known, or that is not listed in the EC inventory, should be pre-registered individually, either by creating a single IUCLID 5 pre-registration file and uploading it into REACH-IT, or by pre-registering online directly into REACH-IT. Such pre-registrations are not only supported for substances identified by EC-number, but also for those identified solely by CAS-number or chemical name. Assistance is provided by allowing the dynamic searching of chemical inventories.

#### 3.4. *Will it be possible to carry out a bulk pre-registration of substances having no EC number?*

No, all bulk pre-registrations of substances must be identified by an EC number, and will be rejected by the IT system if this is not the case.

**REACH Pre-registration**  
Questions & Answers

**3.5. *Will a multi-constituent substance, where some of the constituents have no EC-number, be allowed into a bulk pre-registration?***

No, all bulk pre-registered substances must be identified by an EC number. If the substance is a multi-constituent substance, all constituents must be identified by an EC number.

**3.6. *Will there be a compliance check in the IUCLID 5 pre-registration tool?***

No, the IUCLID 5 pre-registration tool will only accommodate you in the creation of the files that you can use for pre-registration in the REACH-IT application.

## 4. Questions on REACH-IT

### 4.1. *Is it possible to modify the data entered during pre-registration?*

With the exception the substance identity information, all entered data can be modified at a later stage. This means that contact information (both internal contact and third party representative), similar substances, envisaged tonnage band, envisaged registration deadline and the information field for the pre-SIEF may be updated if needed.

A pre-registration cannot be deleted, but during the pre-SIEF phase you can deactivate yourself from the pre-SIEF to indicate that you will not be interested in registering the substance e.g. in a situation where you decided to cease the manufacture or import. Note, however, that even as a non-active participant you still may be required to share your data.

### 4.2. *Will the 'Super User' functionality as mentioned in the Guidance on Data Sharing be available in REACH-IT?*

The REACH-IT concept of 'Affiliation' is being considered as a means of facilitating the management of submissions (including registrations and consultation of dossier status) from different legal entities belonging to the same company group. It would allow a user to have some form of view across all of the affiliated companies.

This affiliation concept will not be available at entry into operation (1 June 2008), and it has not yet been determined if this concept will be used by REACH-IT because potentially there are legal and security issues linked to this solution.

### 4.3. *Will there be a pre-registration number distributed to the pre-registrant?*

Yes, every successfully pre-registered phase-in substance will receive a pre-registration number. This number will be unique for every company and pre-registered substance.

The structure of the pre-registration number will be:

<TYPE>-<BASE-NUMBER>-<CHECKSUM>-<INDEX-NUMBER>

Example: 05 - 1234567890 - 49 - 0000

Where:

- 05 is the pre-registration type
- 1234567890 is the random unique 10-digit number
- 49 is the calculated checksum (changeable 2-digit number)
- 0000 is the index number

This structure is of the same basic format as the other registration and notification numbers that REACH-IT will provide.

**4.4. *Can I, as a downstream user, check on-line the pre-registration number and see if my supplier did pre-register?***

No, there is no functionality planned into REACH-IT that would accommodate and distribute such information as this information could be considered as confidential business information. Downstream users may wish to make appropriate contractual arrangements with their suppliers to ensure that they comply with REACH and that pre-registration takes place within the pre-registration period.

If you are in doubt and need verification, please contact your local enforcement authority in the Member State for more information.

**REACH Pre-registration**  
Questions & Answers

**REACH Pre-registration**  
Questions & Answers