You may continue to manufacture, import or use a chemical only if it is pre-registered and registered in time!
Reference: ECHA-08-QA-01-EN

Date: 19/11/2008

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 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 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.
TABLE OF CONTENT

Questions & Answers on Pre-registration ............................................................................. 3
Table of Content .................................................................................................................. 4

1. Questions related to practical pre-registration issues.............................................. 7
  1.1. What is pre-registration? .......................................................................................... 7
  1.2. What is meant with extended registration deadlines? ............................................. 7
  1.3. How do I calculate the tonnage for pre-registration in order to determine the envisaged registration deadline? ................................................................. 7
  1.4. Which substances can be pre-registered? ............................................................... 8
  1.5. What are phase-in substances? .............................................................................. 8
  1.6. Can I pre-register non-phase-in substances? ....................................................... 8
  1.7. Must recycled substances be pre-registered? ....................................................... 8
  1.8. What information do I have to submit when pre-registering? ............................. 9
  1.9. What are the advantages of pre-registration? ...................................................... 9
  1.10. Do I have to pay a pre-registration fee? .............................................................. 10
  1.11. Who can pre-register? ........................................................................................ 10
  1.12. May a non-Community manufacturer pre-register? ........................................... 10
  1.13. May a non-Community manufacturer of phase-in substances appoint an only representative for the purpose of pre-registration only? .................................... 10
  1.14. How can a non-Community manufacturer help an only representative or an importer in preparing for pre-registration? ....................................................... 11
  1.15. Does a downstream user have pre-registration obligations? ............................. 11
  1.16. How do I as a downstream user, know whether my supplier will pre-register the substances that he supplies to me? ............................................................... 11
  1.17. How can I find out which substances have been pre-registered? ....................... 12
  1.18. Will the list of pre-registered substances be published only after pre-registration is closed? .............................................................................................................. 12
  1.19. What will happen to companies that do not pre-register a substance? .............. 12
  1.20. Is it possible to pre-register after 1 December 2008? ........................................ 12
  1.21. If I miss pre-registration and I submit a full registration dossier, do I have to wait to continue manufacturing or importing? .................................................. 13
  1.22. Is pre-registration of substances contained in articles required? ........................ 13
  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? ................................................................. 13
  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? ........................................ 14
1.25. Should documentary evidence demonstrating the phase-in status of a substance without an EC number be submitted in parallel with pre-registration? ................................................................. 14
1.26. What are the duties following from pre-registration? .......................................................................................................................... 14
1.27. Can a downstream user participate in a SIEF and share data? ........................................................................................................... 15
1.28. I’m not sure if I need to pre-register. What should I do? .................................................................................................................. 15
1.29. What happens after I submit the pre-registration? .......................................................................................................................... 15
1.30. How can I see what I have pre-registered? ................................................................................................................................. 15
1.31. What is the pre-SIEF forum? .............................................................................................................................................................. 16
1.32. How can I use the pre-registration number? ............................................................................................................................... 16
1.33. Do I need to indicate the pre-registration number on safety data sheets (SDS)? ................................................................. 16
1.34. Is the submission number a proof that my substance has phase-in status? .................................................................................. 17
1.35. If I pre-register do I have to maintain my production/import? ........................................................................................................ 17
1.36. I can not find my substance in EINECS, what shall I do? ................................................................................................................. 17
1.37. How can I pre-register substances without an EINECS number? ................................................................................................. 17
1.38. What if the legal entity is changed during the pre-registration process? ....................................................................................... 18
1.39. Is it possible to transfer the pre-registrations already made by the importers to a newly established only representative? .................................................................................................................. 18
1.40. Am I an importer? / Who is responsible for import? ..................................................................................................................... 18
1.41. If I am an only representative, how do I indicate in the pre-registration which non-Community company I represent? ............................................................................................................. 19
1.42. Can an only representative nominate a third party representative? ........................................................................................... 19

2. Questions related to the use of IT Tools ................................................. 20

2.1. Is it possible to pre-register via e-mail? ................................................................. 20
2.2. How can pre-registrations be submitted to ECHA? ......................................................................................................................... 20
2.3. Which IT tools have to be used to prepare data for pre-registration? .............................................................................................. 20
2.4. When will the IT tools be available for use? ................................................................................................................................. 21
2.5. Will the contact details of my company be shown to other pre-registrants during pre-registration and when forming the pre-SIEF? ........................................................................................................... 21
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? ........................................................................................................... 21
2.7. How can I identify a third party representative when pre-registering? ......................................................................................... 21
2.8. What will happen if I will try to pre-register the same substance several times? ........................................................................ 22

3. Questions on IUCLID 5 .............................................................................. 23

3.1. How do I establish pre-registration lists per legal entity in the IUCLID 5 pre-registration tool? ................................................................................................................................. 23
3.2. Will information on the legal entity be stored in the pre-registration XML files? ..................................................................................... 23
3.3. Can a pre-defined CAS number coming from the EC inventory be modified in the IUCLID 5 pre-registration tool? ........................................................................................................ 23
3.4. Will it be possible to carry out a bulk pre-registration of substances having no EC number? ................................................................. 23

3.5. Will a multi-constituent substance, where some of the constituents have no EC-number, be allowed into a bulk pre-registration? ................................................................. 24

3.6. Will there be a compliance check in the IUCLID 5 pre-registration tool? ......................... 24

4. Questions on REACH-IT .................................................................................. 25

4.1. Is it possible to modify the data entered during pre-registration? ................................. 25

4.2. Will the ‘Super User’ functionality as mentioned in the Guidance on Data Sharing be available in REACH-IT? ................................................................. 25

4.3. Will there be a pre-registration number distributed to the pre-registrant? ................. 25

4.4. Can I, as a downstream user, check on-line the pre-registration number and see if my supplier did pre-register? ................................................................. 26
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 1st 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 CMR1 ≥ 1 t/y, R 50-532 ≥ 100 t/y and other substances ≥ 1000 t/y; or
- 31 May 2013 for other substances ≥ 100 t/y; or
- 31 May 2018 for other substances ≥ 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, PPORD3), only the estimated tonnage band corresponding to the quantities of the normal registration has to be filled in.

---

1 Classified as carcinogenic, mutagenic or toxic to reproduction, categories 1 and 2, in accordance with Directive 67/548/EEC.
2 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.
3 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 European INventory of Existing Commercial chemical Substances (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:

- 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’ (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.

---

4 Guidance on pre-registration is covered by a specific chapter in the ‘Guidance on data sharing’.
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.

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 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\(^5\), 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:

- able to prove that you are manufacturing or importing phase-in substances (on their own or in a preparation) *for the first time* after 1 December 2008 in quantities of 1 tonne or more per year; or
- able to prove that you are producing or importing articles that contain substances intended to be released under normal and reasonably conditions of use *for the first time* after 1 December 2008. In addition, the substance needs to be present in those articles in quantities of 1 tonne\(^6\) or more per year.

If this is the case, the following deadlines apply:

---

\(^5\) 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.

\(^6\) The amounts intended to be released as well as the amounts which are not (intended) to be released need to be taken into account. Furthermore, if more than one type of article with intended release is produced/imported, the quantities of that substance in all articles with intended releases have to be summed up.
• 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 ‘Guidance on 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).

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 under normal and reasonably foreseeable conditions of use and that are present in those articles in quantities of more than 1 tonne per year have to pre-register between 1 June and 1 December 2008. Pre-registration has also the benefit that other registrants in the Substance Information Exchange Forum (SIEF) will be aware of the use of the substance and may include the 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

---

7 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.

8 The amounts intended to be released as well as the amounts which are not (intended) to be released need to be taken into account. Furthermore, if more than one type of article with intended release is produced/imported, the quantities of that substance in all articles with intended releases have to be summed up
been producing or importing already, he cannot submit a pre-registration any more and he has to limit his production/import to 1 tonne or less per year until:
- he has made a registration and received a registration number; or
- someone else registers his use or 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 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).

1.28. I'm not sure if I need to pre-register. What should I do?

In order to avoid unnecessary pre-registrations, companies are advised to coordinate with their suppliers on who in the supply chain shall pre-register. The same holds true for companies importing substances from outside the EU who should contact their non-EU suppliers in this respect. The pre-registrant has to be a natural or legal person established within the European Economic Area (the EEA, comprises the European Union Member States and Iceland, Liechtenstein and Norway) or an only representative established within the EEA.

For certain types of substances, such as re-imported substances (Article 2(7)(c)), recovered substances (Article 2(7)(d)), monomers in polymers (Article 6(3)), and substances intended to be released from articles (Article 7(6)) you might want to pre-register if you are not sure that the substance(s) concerned will be registered by the end of the pre-registration period.

In all cases, the option of late pre-registration (Article 28(6)) should be explored.

1.29. What happens after I submit the pre-registration?

When you have entered all the information into REACH-IT, you are asked to validate it. This is the last step before submission. After validation the user who pre-registered will receive a submission number and a message in his/her internal mailbox. This message contains a link to the submission report (.pdf format) and the pre-registration number for the pre-registered substance. This is the proof of the pre-registration submission. ECHA is not in a position to confirm pre-registrations otherwise.

1.30. How can I see what I have pre-registered?

To see your pre-registrations:

- From the Pre-registration menu, select "View pre-registrations".
- Enter any of the proposed search criteria and click "Search".
- Click the pre-registration number link of one of the returned pre-registrations to view its details.
After submission of the pre-registration the REACH-IT system will automatically put the substance information into the pre-SIEF forum.

1.31. **What is the pre-SIEF forum?**

The Pre-SIEF forum is formed among the pre-registrants of the same identifier (e.g. EINECS entry). The objective of the pre-SIEF discussions is to validate that the pre-registrants are manufacturing, intending to manufacture or importing a substance that is sufficiently similar to allow valid joint submission of data. When agreement on the sameness of substance is reached, a SIEF is formed.

ECHA will not participate in the discussions between the potential registrants and there will be no role for ECHA in confirming or rejecting the creation of a particular SIEF. Moreover, the data holders (i.e. any persons holding information/data relevant to a phase-in substance who has not pre-registered it) will not be involved in pre-SIEF discussions, but will only join SIEFs.

There is a limited possibility to communicate on pre-SIEF/SIEF issues in REACH-IT. One field is reserved for the use of the SIEF Formation Facilitator and for the other all pre-registrants of the substance have writing rights. As both fields will allow only a limited number of characters they should only be used for key messages and referring to further contact details and/or communication tools.

1.32. **How can I use the pre-registration number?**

The pre-registration number is a confirmation that the pre-registration has been received by ECHA. It is up to each pre-registrant to determine how he will use this information.

1.33. **Do I need to indicate the pre-registration number on safety data sheets (SDS)?**

In general, the REACH Regulation does not govern the use of the pre-registration number. As Member States are responsible for enforcement of REACH, individual Member States may have national requirements concerning the communication of the pre-registration number.

However, the registration number (when eventually assigned) shall be indicated on the safety data sheet, as laid down in point 1.1 of Annex II to the REACH Regulation. More information on registration numbers can be found in section 7.4 of the Guidance on registration available on the ECHA website: [http://reach.jrc.it/docs/guidance_document/registration_en.pdf](http://reach.jrc.it/docs/guidance_document/registration_en.pdf)
1.34. **Is the submission number a proof that my substance has phase-in status?**

No, it is not. Neither the receipt of the submission number nor the receipt of the pre-registration number constitutes evidence that your substance has phase-in status. For determining whether your substance is a phase-in or a non phase-in substance, please refer to section 1.7.1 of the registration guidance available at: [http://reach.jrc.it/docs/guidance_document/registration_en.htm](http://reach.jrc.it/docs/guidance_document/registration_en.htm)

1.35. **If I pre-register do I have to maintain my production/import?**

As a consequence of pre-registering a phase-in substance in accordance with Article 28 of the REACH Regulation, a pre-registrant can benefit from the extended registration deadlines specified in Article 23. **Pre-registration does not establish any obligation to maintain production or import of substances.** You should bear in mind, however, that other SIEF members may request from you information required for the purposes of registration and, if you are in possession of such information, you will have to supply it.

1.36. **I can not find my substance in EINECS, what shall I do?**

EINECS is a closed inventory which cannot be amended or changed. Therefore, if your substance is not listed in EINECS, it might be regarded as a non-phase-in substance which has to be registered immediately. Article 3(20) of the REACH Regulation defines the criteria for a phase-in substance. If none of these criteria fits to your substance, it is regarded as a non-phase-in substance.

1.37. **How can I pre-register substances without an EINECS number?**

REACH-IT gives the possibility of pre-registering a phase-in substance without an EINECS number by using the CAS number and CAS name or by only the chemical name. This option is accessible in REACH-IT during pre-registration under the ‘Substance’ tab, when you specify the constituents of your substance.

We advise you to use these identifiers in the following order of preference:
- the EINECS name and EINECS number,
- CAS name and CAS Number,
- IUPAC name.

If the substance has neither an EINECS number nor a CAS number, and you are still able to prove that the substance has phase-in status, you can pre-register it by using the IUPAC name. The ‘any other identity codes’ referred to in Article 28(1)(a) of the REACH Regulation can be for example the EPA number or SDA number. After specifying the IUPAC name, you can click on ‘Add other chemical name’ and insert the other identity codes.
1.38. **What if the legal entity is changed during the pre-registration process?**

In principle, if a new legal entity starts to manufacture or import or is appointed to be an only representative for a phase-in substance between 1 June and 1 December 2008, it is recommended to submit a new pre-registration of that substance to benefit from the extended registration deadlines.

The transfer of registration/pre-registration dossier is possible in case of for instance mergers or acquisitions. Further explanations as to the changes of legal entities can be found in Chapter 1.5.3.2 of the Guidance on Registration available on the ECHA website ([http://reach.jrc.it/docs/guidance_document/registration_en.pdf](http://reach.jrc.it/docs/guidance_document/registration_en.pdf)).

1.39. **Is it possible to transfer the pre-registrations already made by the importers to a newly established only representative?**

As a general principle, chapter 1.5.3.1 of the Guidance of Registration stipulates that each legal entity is required to submit its own registration ([http://reach.jrc.it/guidance_en.htm](http://reach.jrc.it/guidance_en.htm)). As explained in chapter 1.5.3.2 of the Guidance on Registration a transfer of a (pre)registration from one legal entity to another is only possible in cases of mergers, acquisitions, etc. The assessment on whether a link between the legal entities can be made must always be assessed on a case by case basis.

In this respect, the transfer of a (pre)registration from importers to a subsequently established only representative in general cannot be assimilated to the cases of mergers and acquisitions in the guidance. A transfer of a (pre)registration from importers to an only representative is therefore not possible.

1.40. **Am I an importer? / Who is responsible for import?**

“Importer” means any natural or legal person established within the Community who is responsible for import (Article 3(11) of the REACH Regulation). Import means the physical introduction into the customs territory of the Community (Article 3(10)). The scope of the customs territory of the Community is defined in the relevant Community legislation on customs that should be consulted for further information. [Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code]. It is important to note, however, that the REACH Regulation and the Customs legislation are independent from each other.

Please note that according to Article 3(12) of REACH the import of a substance on its own, in preparations or in articles manufactured or produced outside the European Community is considered to fulfil the conditions for placing the substance, preparation or article on the Community market.

As stated in Section 1.5.3.3 of the Guidance on Registration, the responsibility for import depends on many factors such as who orders, who pays, who is dealing with the customs formalities, but this might not be conclusive on its own. This Guidance can be found on the ECHA website on [http://reach.jrc.it/docs/guidance_document/registration_en.htm](http://reach.jrc.it/docs/guidance_document/registration_en.htm).
1.41. If I am an only representative, how do I indicate in the pre-registration which non-Community company I represent?

When making the pre-registration you are not obliged to indicate the non-Community company you have been appointed by, as you have the full responsibility for fulfilling the obligations under REACH.

However, it is possible for the only representative to give additional contact information, such as contact information of the non-Community manufacturer, in the field "Add new contact" in REACH-IT. Different contact details can be given for different substances.

1.42. Can an only representative nominate a third party representative?

Only representatives are not explicitly mentioned in Article 4 of the REACH Regulation concerning the appointment of a third party representative. In general, it is neither necessary nor advisable for an only representative to appoint a third party representative because an only representative is not obliged to disclose to the other participants in the data sharing process the identity of the "non-Community manufacturer" he is representing (for further details see section 4.2.1 the Guidance on data 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 plug-in’. 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](http://iuclid5.eu) 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 plug-in 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 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.
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.