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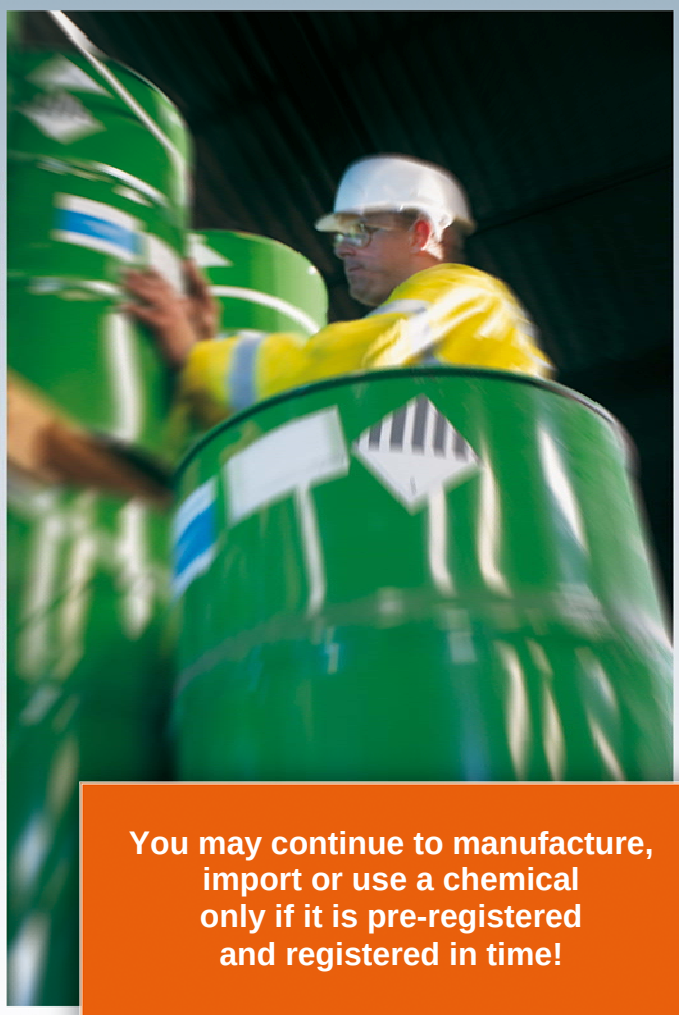
REACH Pre-registration

Questions and Answers

(RELEASE 5)



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

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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 began 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 failed to pre-register a phase-in substance by 1 December 2008 may neither import nor manufacture it 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 **http://echa.europa.eu** and is complementary to the **Frequently Asked Questions on REACH by Industry**, **REACH-IT** 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.

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1.1. What is pre-registration?

Pre-registration is a REACH process that took place between 1 June and 1 December 2008. During this period all manufacturers 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 had the possibility to inform ECHA about which substances they intend to register.

REACH only applies to actors established in the European Community and therefore companies established outside the Community have no obligations under the Regulation. The responsibility for fulfilling the obligations of REACH, such as pre-registration or registration lies with European importers or 'only representatives' established according to Article 8 of the REACH Regulation.

Companies taking the opportunity to pre-register are granted extended registration deadlines for their substances (see also question 1.3). 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.

Companies may use the option of "late pre-registration" provided by Article 28(6) of the REACH Regulation if they manufacture or import chemical substances for the first time in quantities of one tonne or more after 1 December 2008.

Please be aware that pre-registrations cannot be sold as trading objects. They belong to those companies or their legal successors that submitted the pre-registration. It is not lawful to otherwise transfer or sell a pre-registration to another company.

1.2. What are phase-in substances?

Substances fulfilling at least one of the following criteria may be considered as phase-in substances in accordance with Article 3(20) of the REACH Regulation):

- Substances listed in the **E**uropean **IN**ventory 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).

1.3. 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. The respective deadlines to submit the registration dossier to ECHA are as follows:

- 30 November 2010 for CMR[1] ≥ 1 t/y, R 50-53[2] ≥ 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;

1.4. How do I calculate the tonnage in order to determine the respective 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). 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).

1.5. 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 will not contain information on the companies.

Under the ECHA CHEM (**http://echa.europa.eu/chem_data_en.asp**) web section you will find public information and documents from REACH processes as they become available, such as the list of pre-registered substances.

1.6. Was there a pre-registration number distributed to the pre-registrant?

Yes, every successfully pre-registered phase-in substance received a pre-registration number. This number is unique for every company and pre-registered substance**.**

The structure of the pre-registration number:
<TYPE>-<BASE-NUMBER>-<CHECKSUM>-<INDEX-NUMBER>
Example: 05 - 1234567890 - 49 - 0000
Where:

[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.

- 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.

1.7. 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 in REACH-IT that would accommodate and distribute such information as this information could be considered as confidential business information. Downstream users were adviced to make appropriate contractual arrangements with their suppliers to ensure that they comply with REACH and that pre-registration took 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.

1.8. Does a downstream user have pre-registration obligations?

A downstream user who is not manufacturing or importing substances is not required by the REACH Regulation to pre-register a phase-in substance. However, after the publication of the list of pre-registered substances by ECHA (by 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.. ECHA can then provide contact details of the downstream user to a potential registrant.

Under the ECHA CHEM (**http://echa.europa.eu/chem_data_en.asp**) web section you will find public information and documents from REACH processes such as the list of pre-registered substances or Downstream users' notifications as they become available.

More information on the obligations of Downstream users is available in 22 EU languages in the Guidance for Downstream users. Please change the language in the top right corner at **http://guidance.echa.europa.eu**

1.9. How do I as a downstream user, know whether my supplier pre-registered 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. Downstream users established within the EU were 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.

We recommend consulting the **Navigator** that is designed to help companies to learn more about their roles and obligations under REACH.

1.10. I am a downstream user and my supplier did not pre-register, what shall I do?

All manufacturing and placing on the market between the start of the pre-registration deadline and the date of suspension of activities of non- pre-registered substances may be subject to penalties according to national law. Activities involving the substances concerned can then only be restarted after the substance has been successfully registered and the registration number has been received.

By 1 January 2009, the European Chemicals Agency will publish a list of pre-registered substances on its website. There you can find out if and when a substance you use, as such or in preparations, is intended to be registered. If a substance you use is not on the list, you can express your interest in the substance to the European Chemicals Agency (see chapter 3 of Guidance for downstream users - **http://guidance.echa.europa.eu**). The European Chemicals Agency will then publish on its website the name of the substance. On request from a potential registrant, the Agency will provide him with your contact details.

Under the ECHA CHEM (**http://echa.europa.eu/chem_data_en.asp**) web section you will find public information and documents from REACH processes as they become available, such as Downstream users' notifications.

Please note that if your supplier has not pre-registered you cannot place on the market the substances concerned until they will be registered by your supplier. You may also want to seek another supplier that pre-registered the substance. ECHA is however not in a position to provide you any list of potential registrants that pre-registered your substance.

1.11. Do non-EU manufacturers who are appointing an Only Representative need to send information about this appointment directly to ECHA?

No, but non-EU manufacturers need to send information about this appointment to their only representative, who must have it available in case of inspection by the relevant Member State's enforcement authority. In addition, when compiling their registration dossier in IUCLID 5 the only representative must tick the box "Only representative" in IUCLID 5 section 1.1 and is advised to attach this appointment letter to the registration dossier in the field "Official assignment from non EU manufacturer" in IUCLID 5 section 1.7.

More information on the only representative is also provided in the Guidance on Registration (Section 1.5.3.4 – Only representatives of "non-Community manufacturer").

2. After submitting a pre - registration

2.1. Duties following from pre-registration

2.1.1. 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.

2.1.2. 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.

2.1.3. 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.

2.1.4. 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://guidance.echa.europa.eu/docs/guidance_document/registration_en.htm**

The pre-registration of a phase-in substance without an EC number did not require the potential registrant to submit documentary evidence demonstrating the phase-in status of a substance within the meaning of Article 3(20) of the REACH Regulation in his pre-registration (see Art. 28(1) of the REACH Regulation). The pre-registrant had 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.

2.1.5. 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.

2.1.6. 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://guidance.echa.europa.eu/docs/guidance_document/registration_en.htm**

2.1.7. How will the pre-registration data be used?

The list of pre-registered substances specifies for each substance the name of the substance including their EINECS and CAS number if available and other identity codes, and the first envisaged registration deadline. The list will also include the names and other identifiers of related substances that pre-registrants have, i.e. those for which the available information may be relevant for performing adaptation of testing requirements using read across, (Q)SARs and/or grouping of substances. The list as published by ECHA does not show the identity of the pre-registrants. This information is visible to those who have pre-registered the same substance and those who have pre-registered related substances for read-across.

Under the ECHA CHEM (**http://echa.europa.eu/chem_data_en.asp**) web section you will find public information and documents from REACH processes as they become available, such as the list of pre-registered substances.

2.2. Changes to pre-registration after 1st December 2008

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

The owner of a particular pre-registration can modify it with the exception of the *Substance ID* and the *UUID* assigned to that pre-registration. 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 manually if needed.

All the modifications will update the information in the pre-SIEF as well and the user will get a message in his/her REACH-IT Message Box announcing the modifications made to that pre-registration. Users do not need to submit any documentation again to ECHA.

We highly recommend users to take a look at question #19 of the REACH-IT FAQ that is available at **http://echa.europa.eu/reachit/reachit_faq_en.asp** where all the steps in order to delete, deactivate or modify a pre-registration are explained in detail.

2.2.2. 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://guidance.echa.europa.eu**). 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.

3. Situation for potential registrants that did not pre-register by 1st December 2008

3.1. What will happen if a company did not pre-register a phase-in substance?

If a company established in the European Community manufactures or imports a phase-in substance which the company did not pre-register, it will have to suspend its activities involving the substances concerned and register them without delay. All manufacturing and placing on the market of such substances, between the start of the pre-registration deadline and the date of suspension of activities, may be subject to penalties according to national law. Activities involving the substances concerned can then only be restarted after the substance has been successfully registered and the registration number has been received from ECHA.

To receive a registration number, the company has to:
- Submit an inquiry according to Art. 26 of the REACH Regulation to ECHA to determine whether a registration, or an inquiry, was previously submitted for the same substance;
- Share relevant physicochemical, health and environmental data and use information in order to compile a registration dossier
- Submit a complete dossier to ECHA. Please note that the completeness includes also the payment of the fee.

If you want to know what substances have to be registered you may first consult the **Guidance on Registration** (Section 1.6 – What to register).

More information on how to submit an inquiry and registration dossier to ECHA is to be found at: **http://echa.europa.eu/reachit_en.asp**

For further information related to registration dossiers you may visit the ECHA webpage at: **http://echa.europa.eu/pre-registration/registration_en.asp**

For information on the Commission Regulation No 340/2008 on the fees and charges payable to the European Chemicals Agency we kindly advice you to consult the European Commission website:
http://ec.europa.eu/enterprise/reach/reach/fees/index_en.htm

3.2. 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?

Registration of substances in articles is obligatory for article producers or importers only if the substances are intended to be released from the articles and are present in quantities of 1 tonne or more per year. If an article supplier finds out after 1 December 2008 that he has registration obligations for a substance intended to be released from the 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 1 tonne or less per year until:

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

3.3. Is it possible to pre-register a phase-in substance after 1 December 2008?

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

- able to prove that you are established in the European Community and 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 established in the European Community and 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[3] or more per year

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.

Detailed information on the possibility to submit a late pre-registration 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).

3.4. If a phase-in substance has not been pre-registered, can a downstream user benefit from Article 28(6) of the REACH Regulation in case he/she becomes an importer after 1 December 2008?

Downstream users that start importing a substance for the first time after 1 December 2008 may also benefit from the extended pre-registration deadlines in Article 23, provided that all the conditions of Article 28(6) are fulfilled (see section 3.3 for further details).

[3] 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

3.5. 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 fulfill 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://guidance.echa.europa.eu/docs/guidance_document/registration_en.htm**.

4. Data sharing and SIEF

4.1. Pre-SIEF

4.1.1. 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.

4.1.2. 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.

4.2. SIEF

4.2.1. SIEF formation

Pre-registration information provides the basis for the formation of a SIEF to share information among manufacturers and importers of the same 'phase-in' substances and to agree on their classification and labelling. A SIEF may include participation of downstream users and other stakeholders holding information on the substance.

As a general rule, there will be one SIEF for each phase-in substance. The SIEF members may also use the contacts they have made with other potential registrants to organise amongst themselves the mandatory 'joint submission of data[4]'. This includes as an option the exchange of any data needed to perform the Chemical Safety Assessment, drafting the Chemical Safety Report and agreeing on guidance on safe use that may be part of this joint submission.

Deciding whether more than one company manufactures or imports the same substance is a four step process:

- Companies need to establish the names and/or identity codes under which they pre-register or register the substance;
- Companies who have pre-registered their substance(s) under the same names and/or identity code need to establish whether their substances are the same for the purpose of SIEF formation and joint submission;

[4] **Joint submission of data by multiple registrants**

Each manufacturer, importer or only representative is obliged to submit a registration for each of his substances (per legal entity). However in cases where a substance is manufactured or imported by more than one company, they are required to submit certain information together. This is called the joint submission of data. Registrants are required to jointly submit information on the hazardous properties of the substance, its classification and labelling, a testing proposal (if any), and, if they agree, jointly submit a chemical safety report and guidance on safe use

- In addition, they need to verify whether their substance has also been pre-registered or registered under other names and/or identity codes. This step is concluded by an agreement that the substances pre-registered by different companies are the same;
- Companies participating to the three previous steps will then establish a SIEF. Each SIEF will be operational until 1 June 2018.

Please be aware that the entire SIEF process is the responsibility of Industry and ECHA will not participate in the formation of SIEFs.

4.2.2. 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).

4.2.3. How can a non-Community manufacturer help an only representative or an importer in preparing for registration and data sharing?

In most cases it is anticipated that '*non-Community manufacturers*' will provide all necessary data for the 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).

REACH Pre-registration
Questions & Answers

European Chemicals Agency Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland
Tel.: +358 9 6861 80 | Fax +358 9 6861 8210 | http://echa.europa.eu | info@echa.europa.eu