

Practical steps for **REACH pre-registration**



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

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This document provides a short summary of the key aspects of the pre-registration process and provides links to the relevant REACH Guidance Documents.

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.

Who should read this document?

If your company manufactures substances¹ in the EU or imports substances from non EU countries to the EU, you may find this document useful. It may help you to find out how to identify your obligations under REACH and to minimise the business risks related to the new EU chemicals regulation.

REACH establishes a new system for registration, evaluation, authorisation and restriction of chemicals. Pre-registration is the first step in an 11-year process to phase in the substances currently on the EU market² into this new system. The pre-registration of substances under REACH will start on 1 June and end on 1 December 2008.

About 30,000 substances are estimated to be impacted by the REACH registration requirement. A registration of a substance will comprise of:

1. Compilation and assessment of the hazard properties of the substance and its conditions of safe use;
2. Submission of this information to the European Chemicals Agency (ECHA); and
3. Payment of the relevant registration fee.

If your company carries out one of the following activities this document is important for you:

- Manufacturing substances (including isolated intermediates) in the EU in amounts of 1 tonne or more per year;
- Importing substances (e.g. dye stuffs, polymers) as such or in preparations (e.g. coatings, lubricants) in amounts of 1 tonne or more per year from non EU countries;
- Importing articles containing substances intended to be released and present in those articles in quantities of 1 tonne or more per year;

Companies that manufacture substances, formulate preparations or produce articles outside the EU cannot (pre-)register substances. However, they can nominate an Only Representative³ established within the EU to carry out the required (pre-) registration of their substances that are imported into the EU.

This document provides you with basic information on pre-registration and links to the most important guidance documents and tools to complete your pre-registration.

1 Further explanation on the terms *substances, preparations and articles* is given in the section "Key Facts/Definitions" at the end of this document.

2 From late 2008, the EEA countries Norway, Iceland and Liechtenstein will also apply REACH with all consequences this has for manufacturers and importers.

3 Further explanation on the term *Only Representative* is given in the section "Key Facts/Definitions" at the end of this document.

What Information has to be provided for pre-registration?

For each substance, pre-registration includes the following information:

- The name of the substance identified by the IUPAC-name, EINECS, CAS or other identity codes. Note:
 - For imported preparations, the single substances in the mixture are to be pre-registered not the imported preparation as a whole;
 - Substances intentionally released from articles⁴ need to be pre-registered and registered, not the articles;
 - Polymers are exempted from (pre-)registration. However the monomer(s) and any other substance(s) used to build the polymer need to be (pre-) registered;
- The name of your company and address and the name of the contact person. Note:
 - 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 Representative⁵.
- The envisaged registration deadline described below and the tonnage band (1 – 10, 10 – 100, 100 – 1000 or 1000 tonnes or more per year);
- The IUPAC-name of other substance(s) which may have relevant substance information to the one 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.

4 Further explanation on the term *articles* is given in the section “Key Facts/Definitions” at the end of this document.

5 Further explanation on the term *Third Party Representative* is given in the section “Key Facts/Definitions” at the end of this document.

What are the advantages of pre-registration?

Pre-registration allows you to benefit from extended registration deadlines. For so-called 'phase-in substances'⁶, REACH provides for a phase-in scheme with staggered registration deadlines depending on the tonnage band and hazards of the substance:

- 30 November 2010; or
- 31 May 2013; or
- 31 May 2018;

This phase-in approach is to allow 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 of downstream users using your substances.

Pre-registration is free of charge and does not establish any obligation to maintain production or import of substances. You should however note that a company who has pre-registered will be part of a Substance Information Exchange Forum (SIEF) until 1 June 2018 and may need to actively participate to the SIEF activities. In addition you may have financial obligations in relation to your substance. Parties sharing data must make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way. In general, it is recommended that an agreement on cost sharing is reached prior to the disclosure of available information by participants⁷.

⁶ Further explanation on the terms *Existing substances, phase-in substances and non phase-in substances* is given in the section "Key Facts/Definitions" at the end of this document.

⁷ See *Guidance on Data Sharing* (EN)

What if you forgot to pre-register?

If your company misses pre-registration for a substance you will not be able to benefit from these transitional periods. In this case you will have to submit a registration dossier for that substance before you can continue manufacturing or importing it in 1 tonne or more per year after 2008.

This may imply that you have to discontinue manufacturing or import of the substance until you have received a registration number from ECHA.

To receive a registration number you have to:

- File an inquiry to ECHA to determine whether a registration or an inquiry was previously submitted for the same substance;
- Obtain⁸ and assess relevant physico-chemical, health and environmental data and use information in order to compile your registration dossier;
- Submit the dossier and pay the related fee to ECHA.

Do not miss the narrow pre-registration time window of 1 June to 1 December 2008. It will allow your company to have a gradual transition to the REACH era.

⁸ Own or have right to use

How will the pre-registration data be used?

By 1 January 2009, a list of all pre-registered substances will be published on the ECHA website. This list will specify 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 will not show the identity of the pre-registrants. This information will only be visible by those who have pre-registered the same substance and those who have pre-registered related substances for read-across.

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.

Be aware the entire SIEF process is the responsibility of Industry.

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'⁹. 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 process¹⁰:

1. Companies need to establish the names and/or identity codes under which they pre-register or register the substance;
2. 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;
3. 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;
4. Companies participating to the three previous steps will then establish a SIEF. Each SIEF will be operational until 1 June 2018.

9 Further explanation on the term *Joint Submission of data by multiple registrants* is given in the section "Key Facts/Definitions" at the end of this document

10 See *Guidance for identification and naming of substances under REACH* (EN) and *Guidance on Data Sharing* (EN)

How to identify substances to be (pre-)registered?

Before you pre-register the following preparatory steps need to be completed:

1. Make an inventory of the products you manufacture in the EU and the products you import from non EU countries;
2. Identify whether these products are single substances or preparations (consisting of various substances to be registered) or contain substances released from articles;
3. Identify whether these substances are monomers, polymers, intermediates, substances for the purpose of Product and Process Oriented Research and Development, substances listed in the exemption annexes of REACH (Annexes IV or V) or substances with any other particular status under REACH¹¹;
4. Collect the available information on the name of the substances identified by the IUPAC-name, EINECS number, CAS number or other identity codes and the analytical data from the laboratory (qualitative and quantitative composition of your substances);
5. Name the substances in line with the guidance for identification and naming of substances under REACH¹²;
6. Check the phase-in status of your substances. Substances fulfilling at least one of the following criteria are phase-in substances¹³:
 - 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 before 2004) but have not been placed on the EU market after 1 June 1992;
 - Substances that qualify as a so-called “no-longer polymer”;
7. Identify the envisaged registration deadline corresponding to volume of the substance in tonnes per year and its classification and labelling.

Do not forget: If you are obliged to register a phase-in substance, you are entitled to pre-register and may benefit from the extended REACH registration deadlines!

11 Details can be found in the *Guidance on registration* (EN).

12 See *Guidance for identification and naming of substances under REACH* (EN).

13 Further explanation on the terms *Existing substances, phase-in substances and non phase-in substances* is given in the section “Key Facts/Definitions” at the end of this document. Details can be found in the *Guidance on registration* (EN).

How is pre-registration carried out in practice?

Pre-registration must be carried out electronically via the REACH-IT portal on the ECHA website. But please note that you need to create your company account in REACH-IT before you start to pre-register your substances. You will find the pre-registration application access point in the REACH-IT section of the website. 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:

1. **On-line pre-registration** (starting from 1 June 2008) by entering the required information directly substance by substance into the REACH-IT system for submission¹⁴;
2. **Submission of a pre-registration as an XML file** prepared separately in a specified electronic file format and uploaded at the moment of the on-line pre-registration. It allows you to submit one or more file(s) with the required pre-registration information for one or multiple substances, respectively.

You can already start to prepare your files for:

- Online pre-registration – manually compile the required data;
- IUCLID pre-registration – using the pre-registration functionality of IUCLID 5 to generate an XML file for submission¹⁵;
- XML pre-registration – using any other IT tool to create and submit your pre-registration files via REACH-IT. The XML file specifications are available on the ECHA website in the IUCLID 5 section.

If you need to register only a few substances and you are not currently using IUCLID 5, an on-line pre-registration via REACH-IT could be your preferred option. Pre-registration using IUCLID 5 or the XML option may be more practical for companies who will pre-register many chemical substances since it allows a submission of pre-registration for several substances in a single file. Prerequisite for that is that an EINECS number is available for the substances of the XML file.

Is it possible to pre-register after 1 December 2008?

If you are manufacturing or importing phase-in substances in quantities of 1 tonne or more for the first time, after 1 December 2008 you can still benefit from the extended registration deadlines if you pre-register:

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

Manufacture or import for the first time, refers to the first time after the entry into force of REACH (1 June 2007).

14 See *User guide on REACH-IT* (EN).

15 See *IUCLID 5 tutorial* (EN)

Where to find further information?

The ECHA website provides a single point of access to information on REACH:

- General information about the Regulation in the [About REACH](#) section;
- A [Navigator tool](#) and glossary which helps you to learn more about your obligations under REACH;
- A specific **pre-registration website** with supporting practical key information on pre-registration and links to relevant pages on the ECHA website containing:
 - Questions and Answers on pre-registration (REACH, IUCLID 5 and REACH-IT);
 - Guidance documents relevant to pre-registration with a keyword search;
 - User manuals (IUCLID 5 plug-in and REACH-IT);
 - Video tutorials on how to pre-register using IUCLID 5 and REACH-IT;
 - Training presentations how to use the pre-registration plug-in and how to prepare your files using REACH-IT.

If you have questions on pre-registration:

- The [REACH helpdesk](#) in your country provides advice about your roles, responsibilities and about guidance and should be your first point of contact. The contact information of the National Helpdesks can be found on the ECHA website;
- The [ECHA Helpdesk](#) will assist you with REACH-IT, IUCLID and registration- related questions. You can submit your questions by filling in an information request form on the ECHA website;
- Your industry association can be a good source of information for sector-specific questions.

Key facts & definitions

Existing substances, phase-in substances, non phase-in substances

Phase-in substances (for which the transitional regime applies) are substances which:

- Are listed in EINECS: The full and exhaustive list of **E**uropean **I**nventory of **E**xisting **C**ommercial chemical **S**ubstances (EINECS) is available in the **E**uropean chemical **S**ubstances **I**nformation **S**ystem (ESIS). Please note that there are also cases where one EINECS entry covers several substances or where several EINECS entries correspond to one substance.
- Have been manufactured in the EU (including accession countries before 2004) but have not been placed on the EU market after 1 June 1992. You will need to prove this on the basis of order sheets, stock lists, or any other documents which can be traced back to a date after 31 May 1992;
- Qualify as a so-called "no-longer polymer". The list of "no-longer polymer" substances is available in ESIS. You must have documentary evidence (order sheets, stock lists, labels, safety data sheets, or any other documents which can be traced back to a date between 18 September 1981 and 31 October 1993) that you placed the substances on the market in the relevant territory and that it was considered as a "no-longer polymer" in order to prove that your substances are phase-in substances.

Substances not meeting any of these three criteria and falling within the scope of REACH are non phase-in substances and do not benefit from the transitional regime.

Substances, preparations, articles

The concept of REACH is based on substances. Most obligations refer to substances, whether on their own, in preparations or in articles.

A substance is defined as a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

If two or more substances are blended together, the term 'preparation' is used. Please note that in the Globally Harmonised System (GHS) for classification, labelling and packaging of substances and mixtures the term 'mixture' is used instead of 'preparation'.

For substances in articles, a special regime applies for registration under REACH. An article is the legal term under REACH for any object that has been given a specific shape, surface or design so that it can be used for a specific purpose (e.g. manufactured goods such as cars, textiles, electronic chips).

REACH requires all substances that are intended to be released from articles during normal and reasonably foreseeable conditions of use to be registered according to the normal rules, if they are produced or imported in quantities of 1 tonne or more per year per producer or importer¹⁶.

16 See *Guidance on requirements for substances in articles* (EN).

Substance identification essentials

The substance definition in REACH is identical to the definition of a substance that is currently used under the 7th Amendment of the Dangerous Substances Directive (Directive 92/32/EEC amending Directive 67/548/EEC). In both cases, the definition goes beyond a pure chemical compound defined by a single molecule¹⁷.

The approach to identify a substance depends on the substance type. Substances can be divided into two main groups:

1. 'Well defined substances': Substances with a defined qualitative and quantitative composition that can be sufficiently identified based on the identification parameters of REACH Annex VI section 2. Rules for identification and naming differ for 'well defined substances' with one main constituent (in principle $\geq 80\%$) and for substances with more than one main constituent (in principle each constituent $\geq 10\%$ and $< 80\%$): the so-called 'mono-constituent' versus 'multi-constituent' substances.
2. 'UVCB substances': Substances of Unknown or Variable composition, Complex reaction products or Biological materials. These substances cannot be sufficiently clearly identified based on their composition alone. Further identifiers have to be considered such as sources or production processes.

Third Party Representative

Any manufacturer or importer may appoint a *Third Party Representative* for certain tasks relating to data and cost sharing. This is typically the case when a company wishes not to disclose their interest in a particular substance as this may give indications to competitors about production or commercial secrets. Companies should be aware that contact details indicated at pre-registration will be made available to all potential registrants of the substance(s) pre-registered under the same identity code as well as to potential registrants of all other substances for which read-across possibilities have been indicated. Whenever they consider such information to be sensitive, a Third Party Representative may be used.

Only Representative

A natural or legal person established outside the Community who manufactures a substance on its own, in preparations or in articles, or formulates a preparation or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfil as his only representative, the obligations of importers. Only Representatives are natural or legal persons:

- Established in the EU; and
- Having sufficient background in the practical handling of substances and the information related to them.

For advice on the Only Representative see the registration guidance¹⁸.

17 See *Guidance for identification and naming of substances under REACH* (EN).

18 See *Guidance on registration* (EN)

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 use¹⁹.

19 See *Guidance on data sharing* (EN)

Links to related material

REACH Regulation EC No 1907/2006

<http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2007:136:SOM:EN:HTML>

REACH Guidance Documents

http://reach.jrc.it/guidance_en.htm

Guidance on registration

http://reach.jrc.it/docs/guidance_document/registration_en.htm

Guidance on data sharing

http://reach.jrc.it/docs/guidance_document/data_sharing_en.htm

Guidance for substance identification and naming of substances under REACH

http://reach.jrc.it/docs/guidance_document/substance_id_en.htm

Guidance on requirements for substances in articles (published by 1 June 2008)

User guide on REACH-IT (published by 1 June 2008)

User guide on IUCLID 5 <http://ecbwbiu5.jrc.it/>

ECHA website: <http://echa.europa.eu>

ECHA Helpdesk: http://echa.europa.eu/reach/helpdesk_en.html

ESIS: <http://ecb.jrc.it/esis/>

IUCLID 5: <http://echa.europa.eu/iuclid>

REACH-IT: <http://echa.europa.eu/reachit>

Pre-registration: <http://echa.europa.eu/pre-registration> (published in mid April)

REACH Guidance Fact Sheets (will be published shortly)

