

REACH pre-registration requirements

June 2008



REACH is the new EU chemicals legislation that will manage the safe use of chemicals throughout their entire life cycle. The system consists of four pillars: Registration, Evaluation, Authorisation and Restriction of Chemicals.

It will apply to all substances, on their own, in preparations and in articles, that are manufactured in or imported into the European Economic Area (EEA) market in quantities of 1 tonne or more per year.

In the first instance, REACH will require most chemicals within the scope of the Regulation to be registered in order to have the right to manufacture and access the EEA market. Pre-registration and registration apply directly to metals, metal compounds and metals in alloys manufactured in and imported into the EEA. They do not apply to minerals, ores and ore concentrates provided that they are not chemically modified¹.

For non phase-in substances, i.e. substances that have not been manufactured or imported in the EEA over the last 15 years, registration will be required before manufacture or import of the substance in the EEA. The phase-in (or existing) substances however can benefit from extended registration deadlines if they are pre-registered.

The REACH Regulation entered into operation on 1 June 2008, with the pre-registration of phase-in substances and the registration of non phase-in substances.

The scope of this leaflet is to outline how companies producing metals, metal compounds and alloys can meet their pre-registration obligations with the aim of retaining access to the EEA market during the transition period between the pre-registration and registration deadlines.

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1. What is a pre-registration?

Pre-registration is a purely administrative procedure. All companies producing and importing the relevant substances on their own, in preparations or in articles with an intended release, in quantities of 1 tonne or more per year, will have to pre-register by submitting a limited set of information to the European Chemicals Agency (ECHA). This will enable companies to benefit from an extended registration deadline, depending on the tonnage band (see Figure 1).

Companies will retain the right to manufacture and to have access to the EEA market during the transition period.

Pre-registration should be seen only as a declaration of the intention to register a substance, it does not oblige a manufacturer or importer to actually proceed to register the substance.

The only obligation triggered by pre-registration is the duty to participate in the Substance Information Exchange Forum (SIEF) of the pre-registered substance and the substances that the pre-registrant has indicated as being similar to the pre-registered substance for the purpose of





read-across and application of (Q)SAR (Quantitative Structure-Activity Relationships).

This will, however, generate a certain workload due to the duties of SIEF members, which are:

- responding to requests for information of other SIEF members
- requesting missing information from other SIEF participants
- providing other SIEF participants with existing studies at their request
- collectively identifying the need for further studies to meet the registration requirements
- making arrangements to perform the identified studies
- agreeing on classification and labelling where there is a disagreement between potential registrants.

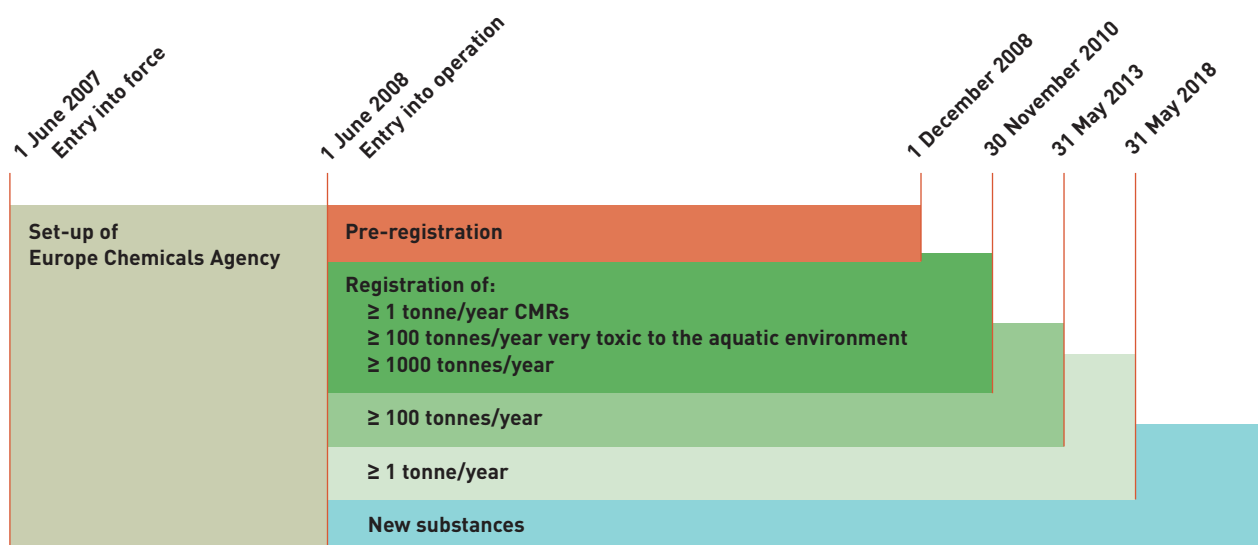
It is important therefore to consider carefully the workload that the participation to SIEF will generate, especially if intending to pre-register a substance for strategic reasons or when identifying substances considered to be similar for the purpose of read-across.

2. When to pre-register?

The period for pre-registration began on 1 June 2008 and will end on 1 December 2008. Failure to meet the deadline for pre-registration will mean that a company loses the benefit of the extended registration deadline and will have to register the substance before it can continue manufacturing or importing of that substance.

An exemption to the general rule exists for substances that are manufactured or used in the EEA or imported within the EEA market (in quantities exceeding 1 tonne per year) for the first time after 1 December 2008. In this case, a company will still be able to benefit from the transition measures on condition that the requested information for pre-registration is submitted within six months of the first manufacture, use or import of the substance, and at least twelve months before the relevant registration deadline (e.g. 30 November 2009 for substance in the first tonnage band).

Figure 1: Overview of registration and pre-registration timelines



3. Who can pre-register a substance?

Each natural and legal person who is required to register a phase-in substance after 1 June 2008 may pre-register that substance. These persons include:

- EEA manufacturers or importers of substances, either on their own or in preparations in quantities totalling 1 tonne or more per year², including intermediates.
- EEA importers of articles containing substances which are released under normal and reasonable conditions of use and are present in quantities totalling 1 tonne or more per year.
- An 'Only Representative': As non-EEA manufacturers cannot directly pre-register or register substances, substances in a preparation or substances in articles, they may appoint an 'Only Representative (OR)' to take over the duties of their customers (importers)³.

It is important to note that for EEA manufacturers, both the pre-registration and the registration under REACH must be prepared and performed on the basis of one pre-registration per legal entity.

EEA manufacturers and importers (or an OR of a non-EU manufacturer) of substances, preparations or articles including substances with an intended release, may opt to pre-register a substance for practical and/or strategic reasons if they are:

- currently manufacturing or importing in volumes of less than 1 tonne per year, but intend to increase this volume in the future; or
- currently not manufacturing or importing in the EEA, but intend to start doing so after 1 December 2008.

Alternatively in these cases, providing the correct conditions are met, one may still fall back on the exemption to the general rule on pre-registration of phase-in substances as outlined in section 2.

4. What can be pre-registered?

The following substances can be (pre-)registered:

- Substances on their own (e.g. zinc or zinc oxide) or in preparations (e.g. nickel in ferronickel), including chemically modified intermediates (e.g. copper matte), which are imported or manufactured in quantities of 1 tonne or more per year.
- Substances in articles which are intended to be released from the articles and are present in quantities of 1 tonne or more per year.

Manufacturers or importers of substances in quantities of less than 1 tonne per year who foresee increasing their manufacturing/import capacities to quantities exceeding the 1 tonne per year threshold may opt to pre-register and hence to be involved in the SIEF discussion for strategic reasons.

Only substances on their own or contained in preparations or in articles (that are intended to be released under reasonable foreseeable conditions of use) manufactured from primary sources are required to be pre-registered and registered under REACH, except if an exemption applies.

Substances resulting from a recovery process might be able to benefit from the exemption from registration in Article 2.7(d). However, due to the current lack of clarity on the practical application of this Article, the application of this exemption is uncertain. Therefore, manufacturers and importers of substances and alloys from recovered materials are advised to pre-register these substances and substances in alloys in order to ensure their access to the EEA market during the transition period (comprised between the pre-registration and the registration deadlines).





5. What should not be pre-registered?

The following are out of the scope of REACH or exempted from registration and hence, from pre-registration:

- Minerals, ores and ore concentrates: REACH only recognises as 'minerals, ores and ore concentrates' those materials that have not been chemically modified. Manual, mechanical or gravitational processes, dissolution in water, flotation, extraction with water, steam distillation, drying, or extraction from air are not considered to constitute chemical modifications. Processes to remove impurities, but that leave the chemical structure of the remaining constituents unchanged, are also not considered to constitute chemical modification⁴.
- Substances resulting from a recovery process might benefit from exemption from registration under Article 2.7(d). However, due to the current lack of clarity on the practical application of this Article, the application of this exemption is uncertain. Manufacturers and importers of substances and alloys from recovered materials are therefore advised to pre-register these substances and substances in alloys in order to ensure their access to the EEA market during the transition period (between the pre-registration and the registration deadlines).
- Waste as defined in Directive 2006/12/EC
- preparations themselves
- articles themselves
- non-isolated intermediates⁵
- by-products, unless they are imported or placed on the market
- re-imported substances, are exempted (as outlined in article 2.7(c)), if:
 - the re-importer substance is the same; and
 - the EU origin can be demonstrated via the availability of article 31 or 32 information
- substances used in medical products for medical or veterinary use
- substances used in food or feeding stuff
- substances under Customs supervision.

For an exhaustive list of full and partial exemptions from the scope of the legislation we invite you to consult Article 2 of the Regulation text.

6. What information needs to be provided?

As already indicated, the set of information required for pre-registration is reasonably restricted:

- Contact information of the company;
 - company name
 - contact information (address, contact person, representative for the dossier)
 - third party representative (name, address) (optional).
- Substance ID;
 - EC (EINECS or ELINCS) number
 - CAS number
 - IUPAC name
 - other names (common names, trade names, abbreviations, others).
- Envisaged tonnage band and deadline for registration.
- Names of similar substances (read-across, (Q)SARs, grouping).
- Interest in acting as SIEF facilitator (optional).



7. How to proceed with pre-registration?

Pre-registration can be done in two ways:

1. On-line pre-registration

The information is submitted directly on the REACH-IT Internet space. This online tool is mainly designed for individual submissions for pre-registration and notification dossiers.

2. Offline pre-registration

The information is compiled in a IUCLID 5 pre-registration file (IZ5 file format, through a plug-in software) or other offline tools (using the pre-defined XML format). Each file needs to be uploaded via the REACH-IT tool, 'one-by-one' or via a 'bulk submission' of several files. The latter is however only possible for substances that have an EC number.

This second solution could be the most appropriate as it allows the pre-registration file to later be used as a starting point for the compilation of the final registration dossier.

8. What are the consequences of failing to pre-register?

No access to the market

Missing the pre-registration deadline for the substance, means loss of access to the EEA market: *'no data, no market'*, i.e. no registration dossier, no manufacturing or import.

Should a non-EEA manufacturer intend to legitimately market a substance in the EEA after the pre-registration deadline without having pre-registered, they need to consider that:

- Registration requirements apply from 1 June 2008 (even though the pre-registration deadline is 1 December 2008).
- Non-EEA Manufacturers or EEA importers will have to perform the registration before the import of the substance can be continued beyond 1 June 2008.
- One may have to interrupt manufacture, marketing and use of the substance from 1 June 2008 up until 3 weeks after completion of registration, subject to:
 - the inquiry process to check if there are producers that want to register the same substance. The required data are outlined in Article 26 § 1
 - submission of testing proposals for vertebrate animal studies
 - submission of Registration dossier
 - completeness of the Registration being checked by the Agency.

If pre-registration is not completed and the marketing or use of the substance continues, this puts the producer/importer and clients at risk, as the marketing of the substance will be considered illegal and subject to measures under development at Member State level.

Even if not pre-registering, entities are still bound to data sharing and joint submission of the core data set for the substance.





9. Recommendations

In order to ensure timely and successful pre-registration and registration, and in order to correctly identify obligations under REACH, companies should:

- Prepare an inventory of all the substances they manufacture, use or import, including substances on their own, in preparations or in articles, and substances that are considered intermediates under REACH. By-products (such as, slags and drosses) and recovered materials should also be included in the inventory as they may in the future no longer be considered as waste and therefore fall within the scope of REACH.
- Calculate the tonnage bands that are currently manufactured or imported per legal entity. The calculation of this annual average volume, may be based either on the three last consecutive years of manufacturing and/or import, or if one expects to increase production the future annual volume can also be taken into account to calculate the average.
- For non-EEA-manufacturers it will be critical to decide as soon as possible on the strategy to follow, i.e. to identify and appoint a suitable 'Only Representative' or to leave it to the importers to register the substance.
- How one prepares the pre-registration data ahead of the actual pre-registration largely depends on how one intends to perform the pre-registration. There are two major options:
 - on-line: in this case one needs to have the required information at hand in whatever form so that it can be entered manually and substance by substance; or
 - off-line: Here, one can prepare the electronic file in XML format, either via the use of the IUCLID 5 pre-registration plug-in or with any other tool that uses the available XML template. This method has the advantage that one can prepare the file in advance and that one can submit the pre-registration for single or multiple substances in one go.
- Contact and join a Consortium to facilitate pre-registration and ensure structured formation of a SIEF.
- Consult the REACH Metals Gateway (www.reach-metals.eu) for further information on consortia as well as the latest information in respect of the implementation of REACH.

End Notes

¹ Some materials that companies have traditionally referred to as 'ores' or 'concentrates' may not be legally recognised as such under REACH.

² Or those intending to manufacture/market a substance above 1 tonne per year in the future.

³ An OR can be any natural or legal person located in the EEA and shall have a sufficient background in the practical handling of substances.

⁴ The definition of 'not chemically modified' is critical and poses some interpretation challenges. See www.reach-metals.eu for more details.

⁵ 'Non-Isolated' means not intentionally removed from the process equipment.

Eurometaux

Eurometaux constitutes the interface between the European non-ferrous metals industry and the European authorities and international or intergovernmental bodies. It is committed to establishing dialogue with the latter in order to ensure early consultation in all fields of policy and legislation that may affect industry and to asserting the sector's views and positions in this respect. It asserts the contribution of the European industry and its products to sustainable development, as well as this industry's views and positions, whenever the opportunity to do so arises across all sectors of society.

www.eurometaux.org

ICMM

The International Council on Mining and Metals (ICMM) is a CEO-led industry group that addresses key priorities and emerging issues within the industry. It seeks to play a leading role within the industry in promoting good practice and improved performance, and encourages greater consistency of approach nationally and across different commodities through its association members and member companies. ICMM's vision is for a respected mining and metals industry that is widely recognized as essential for society and as a key contributor to sustainable development.

For further information on industry initiatives on hazard and risk assessment, including MERAG and HERAG, visit: www.metalsriskassessment.org

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