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REACH Pre-registration & Registration - Questions and Answers

The EU's new chemicals legislation REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) entered into force on 1 June 2007. It covers all chemical substances, manufactured or imported into the EU, in quantities of one tonne or more per year. Mandatory registration of new substances begins on 1 June 2008. Later deadlines exist for 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.

What is the purpose of REACH pre-registration and registration?

REACH requires manufacturers and importers of chemical substances (≥ 1 tonne/year) to obtain information on the physicochemical, health and environmental properties of their substances and use it to determine how these can be used safely. Each manufacturer and importer must submit to the Agency a registration dossier documenting the data and assessments.

All users of dangerous chemicals will be obliged to ensure the safe use of those chemicals through risk management measures identified in the registration dossiers and communicated to the users of chemicals through extended Safety Data Sheets.

Tens of thousands of companies across the EU are expected to be affected by the pre-registration and registration obligations. It has been estimated that over 180,000 pre-registration files will be submitted. They are expected to cover some 30,000 substances and 40,000 intermediates.

In the following guidance is given on the **pre-registration obligations** which apply to **substances** for which the REACH requirements will be progressively phased-in.

In the case of **non phase-in substances,** registration starts on **1 June 2008**.

1. Pre-registration

What is pre-registration?

Pre-registration of **phase-in substances**[1] allows companies to benefit from the extended registration deadlines (2010, 2013 or 2018). **Otherwise, they would have to register their substances immediately** if they wish to continue manufacturing or importing.

Why should companies pre-register?

The objective of pre-registration is to facilitate sharing of data between registrants, where possible, in order **to reduce unnecessary testing**, especially on vertebrate animals, and **to decrease costs for the industry**.

Companies are strongly encouraged to pre-register to benefit from the extended registration deadlines (2010, 2013 or 2018, see below). Pre-registration ensures that there will be no interruption in manufacturing, importing or supplying substances to users. Only limited information needs to be sent to the European Chemicals Agency and there is no pre-registration fee.

What will happen to companies that do not pre-register a substance?

A company that has not pre-registered a phase-in substance must suspend manufacturing or importing it after 1 December 2008 until it has submitted a full registration dossier[2] for the substance to the European Chemicals Agency.

What are the duties linked to pre-registration?

All companies that pre-register the same substance will become a member of a **Substance Information Exchange Forum** (SIEF) the aim of which is to avoid duplication on the testing of substances. 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.

Who should pre-register?

All EU-based companies that manufacture in, or import chemical substances into, the EU should pre-register if the quantities of the substance are one tonne or more per year.

EU-based producers or importers of articles should also pre-register those phase-in substances which are intentionally released from their articles, unless the substances were already registered for use in those articles.

Companies that manufacture substances, formulate preparations or produce articles outside the EU cannot (pre-)register substances. However, they can nominate an

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[1] Substances fulfilling at least one of the following criteria are phase-in substances:
- 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) but have not been placed on the EU market after 1 June 1992;
- Substances that qualify as a so-called "no-longer polymer";

[2] A registration of a substance will comprise:
1) Compilation and assessment of the hazard properties of the substance and its conditions for safe use;
2) Submission of this information to the European Chemicals Agency (ECHA); and
3) Payment of the relevant registration fee.

Only Representative established within the EU to carry out the required (pre-)registration of their substances that are imported into the EU. Their EU-based importers are then relieved from the duty to (pre-)register.

When can companies pre-register?

Pre-registration starts on 1 June and closes on 1 December 2008.

What does a company need to do for pre-registration?

A company needs to submit limited information on each substance to the European Chemicals Agency. The information consists of the substance name/identifiers, company information, envisaged registration deadline, tonnage band and potentially an indication of related substances that can help assessment of the substance. If a company does not want to disclose its identity to other SIEF participants, it can inform the Agency that it has appointed a **so-called third party** representative that will act as its agent in the SIEF.

Pre-registration must be carried out **electronically** via the REACH-IT portal on the ECHA website (see below).

There are two possible ways to submit a pre-registration file:

- On-line pre-registration - Enter the required information directly on the REACH-IT website
- Computer file pre-registration - Import a pre-registration prepared separately (via IUCLID 5 provided by the ECHA or industry's own IT-tools) in an XML file for submission to REACH-IT. The format is specified by the ECHA.

How can one find out what has been pre-registered?

The European Chemicals Agency will publish a list of pre-registered substances on its website by 1 January 2009. The published list will contain the names of substances, related identity codes and the first envisaged registration deadline. It will also include the names and other identifiers of related substances that pre-registrants have, but no information on the companies which have communicated them.

Can a company benefit from the extended registration deadlines, if a substance is not pre-registered by 1 December 2008?

Only if the company is a so called first-time manufacturer or importer of that substance in quantities of one tonne or more per year after the pre-registration deadline (1 December 2008) has passed. Manufacture or import for the first time, refers to the first time after the entry into force of REACH (1 June 2007).

First-time manufacturers or importers must pre-register within six months after the first manufacture or import reaches the one tonne threshold, and not later than 12 months before the relevant deadline for registration.

The same applies for imported articles that contain a phase-in substance for which registration is required.

What is the timeframe for the registration of pre-registered chemical substances?

The following extended registration deadlines apply to phase-in substances that have been pre-registered:

Until **30 November 2010** - substances produced or imported in quantities equal to or greater than 1000 tonnes/year; carcinogens, mutagens and substances toxic to reproduction (CMR category 1 and 2) equal to or greater than one tonne/year and substances classified as very toxic to aquatic organisms (R50/53) at and above 100 tonnes/year;

Until **31 May 2013** - substances produced or imported in quantities equal to or greater than 100 tonnes/year;

Until **31 May 2018** - substances produced or imported in quantities equal to or greater than one tonne/year.

What is the ECHA's role in pre-registration?

The ECHA has prepared easily understandable guidance and tools on its multilingual website and its helpdesk is assisting companies in pre-registering on-line.

The Agency is responsible for the management of the REACH-IT portal – the sole channel for submitting pre-registrations to ECHA. The portal will be launched by 1 June.

The ECHA will publish the list of pre-registered substances on its website by 1 January 2009. It may also help users of chemicals to find potential registrants after the pre-registration period is over.

2. REACH = Registration, Evaluation, Authorisation and Restriction of Chemicals

The EU's new chemicals legislation REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) entered into force on 1 June 2007. The registration requirements will apply from 1June 2008.

Which countries will implement REACH?

REACH applies in the 27 EU member states. Iceland, Lichtenstein and Norway are in the process of implementing it through the European Economic Area agreement.

What is the scope of REACH?

REACH covers all chemical substances manufactured in, or imported into, the EU in quantities of one tonne or more per year. Registration under REACH is for substances only. However, the provisions of the Regulation apply to the manufacture, placing on the market or use of substances on their own, in preparations or in articles.

There are some exemptions from certain parts of the legislation. For example, substances in food and medicine are covered by separate EU legislation. Natural substances are also exempt from registration under REACH, if they are not dangerous and have not been chemically modified.

Further information can be found on the following websites:

European Chemicals Agency: http://echa.europa.eu