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2: Pre-registration, Data Submission to ECHA and REACH

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The European Chemicals Agency (ECHA) in Helsinki hosts its formal inauguration today. This coincides with the start of the key processes of pre-registration and registration under REACH. ECHA and the European Commission therefore remind companies to pre-register their chemicals before 1 December 2008. Research and development related notifications (PPORD), inquiries on substances and mandatory registration of non phase-in substances started also on 1 June 2008.

Implementing REACH in practice

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. On 1 June 2008, companies started to submit data to ECHA. Companies who pre-register their phase-in substances will benefit from extended registration dead lines. These depend on the quantities of the substance involved and its hazard classification. The staggered deadlines 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. Data Submission to ECHA

1.1 How can companies submit data to ECHA?

The REACH-IT portal on the ECHA website will be the main channel for companies to submit data to ECHA. It will be initially used for:

- Company sign up (Account creation), and
- Online pre-registration of phase-in substances.

During the initial period after 1 June 2008 temporary submission procedures are used for:

- PPORD notifications,
- Inquiries, and
- Registrations.

1.2 Where can companies find practical information on data submission to ECHA?

The "REACH-IT" web pages on the ECHA website provide the information, templates and guidance on how to submit pre-registrations, PPORD notifications, inquiries and registrations.

The web pages provided the latest information and ECHA News Alerts are sent to registered subscribers when ever the submission procedures change.

2. Pre-registration

2.1 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.

2.2 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

¹ Substances fulfilling at least one of the following criteria are phase-in substances:

- Substances listed in the **E**uropean **I**nventory of **E**xisting **C**ommercial **C**hemical **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";

information needs to be sent to the European Chemicals Agency and there is no pre-registration fee.

2.3 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 dossier² for the substance to the European Chemicals Agency.

2.4 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.

2.5 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 **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.

2.6 When can companies pre-register?

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

2.7 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:

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.

- 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.

2.8 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.

2.9 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.

2.10 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.

2.11 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.

3. REACH Regulation

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 1 June 2008.

3.1 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.

3.2 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.

3.4 How important REACH is for the EU?

The objectives of REACH are to improve the protection of our citizens and the environment from harmful chemicals while maintaining and enhancing the competitiveness of industry. For the European Community both aspects, health & safety as well functioning of our economy, are very important. It is also important that when we generate new information on chemicals we do it in such a way that testing studies will keep the number of animals used for testing to an absolute minimum.

The active debate during the legislative process clearly indicated that various stakeholders felt that the EU required a new chemicals policy. This process also allowed everybody to participate and influence the final Regulation. As an outcome the new legislation is balanced and realistic in the spirit of the Commission Better Regulation initiative.

Therefore, REACH is not only important in what it must achieve but also in how it was drafted and how the stakeholders participated in the preparatory work.

3.5 What are the main benefits of the new REACH Regulation?

The main benefit of REACH is that the hazards and risks of chemicals will be more systematically identified. This will allow for more effective risk management measures by industry and more speedy regulatory action by the public authorities where required.

This should contribute to the prevention of health problems caused by exposure to chemicals, leading to a lower occurrence of diseases and preventable deaths, and, with that, lower costs for the national health systems. The benefits will come gradually as more and more substances are phased into REACH and the necessary risk reduction measures are taken on the basis of the data gathered. This should also benefit consumers who will have access to more information on the hazards and risks of chemicals.

The European chemicals industry will benefit from a single EU regulatory system, a decision-making system with clear deadlines, and more consumer confidence in their products. A positive impact on innovation is also expected, as industry will have incentives to develop safer substances and technologies.

REACH will also intensify the communication within industrial supply chains, allowing closer relationships between suppliers and customers. Suppliers will better understand the needs of their customers. Downstream users of chemicals will get relevant information on the safe use of the chemical substances they use in their production processes which will help them to ensure better protection of their workers.

As with any major project such as REACH teething problems are unavoidable particularly as we enter into the operational part of the system from 1 June 2008. But such problems will be overcome and we can expect to see real progress as more substances are phased-in to the system.

3.6 What changes will EU consumers?

The benefits of REACH to consumers will rise from improved information on chemicals during their entire life cycle and the more detailed assessments carried out by companies on dangerous chemicals, leading to better safety instructions for users and, ultimately, for consumers. Some uses will also be restricted or banned for safety reasons.

The consumers will also have access to more information on the properties of chemicals, e.g. the public information on the Agency website. Consumers will be better informed, less exposed to and better protected from dangerous chemicals.

In addition, REACH introduces a duty to communicate information on substances in articles, especially with regard to very toxic chemicals. The use of that category of chemicals will also be subject to the authorisation procedure leading ultimately to much more limited risks for consumers or complete substitution of the chemical.

3.7 How does REACH work?

Companies that manufacture or import one tonne or more of a chemical substance annually will be required to register it in a central database at the European Chemicals Agency.

The **registration** procedure involves submitting a technical dossier containing information on the substance and guidance how to handle it safely. For quantities of 10 tonnes and more companies also need to submit a Chemical Safety Report to document a safety assessment of the substance demonstrating safe handling for all identified uses and manufacturing.

Evaluation allows regulatory authorities to determine if further testing is needed and to assess whether information provided by industry complies with the requirements (dossier evaluation). Substances suspected to pose a risk to health or the environment will be selected for substance evaluation. This may lead to the actions under the restrictions or authorisation procedures.

Substances of very high concern are subject to an **authorisation** procedure. Companies who apply for authorisation need to show that the risks posed by those substances are adequately controlled, or that the socio-economic benefits from their use outweigh the risks and there are no suitable alternatives. The aim is to give industry the incentive to progressively substitute these substances with safer alternatives when technically and economically feasible.

Substances of very high concern are:

- carcinogens, mutagens or toxic to the reproductive system, categories 1 and 2
- substances which are persistent, bio-accumulative and toxic
- very persistent and very bio-accumulative
- or substances such as those having endocrine disrupting properties, which give rise to an equivalent level of concerns as the preceding categories Member States and the Agency, on a request from the Commission, can place substances on a candidate list of substances of very high concern. The first list will be available on the Agency's website from late 2008.

Restrictions are the safety net of the system. Any substance on its own, in a preparation or in an article may be subject to Community-wide restrictions if its use poses unacceptable risks to health or the environment. Restrictions can be imposed on the use of a substance in certain circumstances and products, the use by consumers or even on all uses (complete ban of a substance). Restrictions and authorisations can also apply to substances produced or imported in volumes below 1 tonne per year.

3.8 What is the timeframe for the registration of chemical substances?

From 1 June 2008 to 1 December 2008 the **pre-registration** of so-called phase-in substances will take place. Companies are strongly encouraged to pre-register their phase-in substances to benefit from staggered registration timelines. Pre-registration requires companies to send only limited information to the Agency.

Pre-registration will allow companies to get in touch with other companies who are intending to register the same substance and gives them sufficient time to set-up 'Substance Information Exchange Forums' (SIEF). In a SIEF, companies are obliged to share animal testing studies to keep the number of animals used for testing to an absolute minimum. They may also share other data voluntarily.

By **1 December 2010** the following will have to be registered with the European Chemicals Agency: all 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 1 tonne/year and substances classified as very toxic to aquatic organisms (**R50/53**) at and above 100 tonnes/year;

On **1 June 2013** all substances produced or imported in quantities equal to or greater than **100 tonnes/year** will need to be registered as are substances produced or imported in quantities equal to or greater than **1 tonne/year** by 1 June 2018.

Manufacturers and importers not having registered substances in time according to the appropriate volume levels will no longer be able to manufacture in or import that substance to the EU market.

Non-phase-in substances need to be registered before they are manufactured or imported. Their registration will start on 1 June 2008.

Substances in articles which are on the “candidate list of substances of very high concern” will need to be reported to the European Chemicals Agency from 1 June 2011.

3.9 Are there registration fees?

Yes, there are fees to complete the registration process. The fees are set in a separate Fee Regulation, which was adopted on 16 April 2008.

3.10 Is REACH a testing programme?

No, REACH is not intended to be a testing programme. New testing should only be a last resort if available information is not sufficient. Companies registering the same substance need to share the available data. The data owner will get financial compensation from other companies who use this data.

In addition to data sharing, a combination of factors including the use of alternative methods and exposure-based waiving of testing will prevent unnecessary animal testing.

3.11 Will REACH change the rules for classification and labelling?

No, but many REACH provisions refer to and build on classification and labelling like registration, chemical safety assessment, preparation of safety data sheet, authorisation and restriction.

The EU's chemical legislation has for a long time required industry to classify and label dangerous substances and preparations according to standard criteria.

The current EU classification and labelling legislation will be replaced in the coming years. The European Commission is currently finalising a proposal for a new Regulation which is based on the UN Globally Harmonised System for the Classification and Labelling of substances (GHS). Relevant REACH provisions will be updated accordingly.

3.12 Which chemicals are exempted from REACH?

Low-risk substances such as water, oxygen, noble gases and cellulose pulp are excluded from registration. Other substances naturally occurring in nature such as minerals, ores and ore concentrates, and cement clinker do not need to be registered as long as they are not chemically modified. These substances as well as other exempted substances are listed in annexes IV and V of the REACH Regulation.

Further Information

European Chemicals Agency web site at: <http://echa.europa.eu>

Press Memo 1: European Chemicals Agency on the Press Office page of the ECHA website.

Press Memo 3: REACH Case Story Summaries on the Press Office page of the ECHA website.

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