

EU legislation: EU chemical policy REACH

Introduction

In order to improve the protection of human health and the environment a new EU regulatory framework for the Registration, Evaluation and Authorisation of Chemicals (REACH) has been adopted in **Regulation (EC) No. 1907/2006**. This Regulation harmonises all chemical legislation in the EU Member States.

The new Regulation is seen as one of the most important changes in European law in 20 years and the impact on EU producers and importers of chemical substances and/or preparations will be considerable. Not only will it apply to the placing on the market of chemicals themselves, but also products containing and/or releasing chemicals fall under the legislation.

In order to facilitate a smooth transition, the new legislation will enter into force in different stages, resulting in a stepwise repeal of existing EU-legislation. For an overview of the different stages see the following timetable:

- June 2007: Entry into force of REACH
- June 2008 – November 2008: Pre-registration of so-called phase-in substances
- June 2008: Registration of new and existing substances
- June 2009: Repeal of Directive 76/769/EEC by REACH Regulation
- November 2010: Registration deadline for substances in quantities of 1000 tonnes and above as well as carcinogens, mutagens and substances toxic to reproduction (CMR category 1 and 2) and PBT/vPvB substances
- June 2013: Registration deadline for substances in quantities of 100 tonnes
- June 2018: Registration deadline for substances in quantities of 1 tonne and more

Voluntary registration at earlier date is always possible. Dossiers can be submitted as of 1 June 2008.

➔ [For more information](#) per article of the Regulation please see a link to the detailed timetable in the external links section.

This document discusses the key elements of the new chemical policy and outlines its possible implications for producers of chemicals in developing countries exporting to the EU.

➔ [For more information](#) on the present phase of REACH and what exporters need to know, see the related document.

Impact of REACH

As the new REACH Regulation is shifting the responsibility for safe use of chemicals from the EU governments to the EU private sector, the impact of the implementation of REACH on EU producers and importers of chemical substances and/or preparations is expected to be considerable. Producers and exporters of chemical substances and/or preparations as well as articles containing chemicals substances that are released during use, exporting to the EU, are **not** directly involved.

Indirectly, EU importers might have requests for more information in order to comply with the REACH requirements. Or, when costs will be involved, for instance to create a dossier with information, EU importers might pass on a part of those costs to the suppliers in for instance developing countries. Therefore, it is advised to producers and exporters of chemical substances and/or preparations as well as articles containing chemical substances that are released during use, based in developing countries, to stay up-to-date on the main requirements of REACH and the phases of implementation.

Companies in developing countries may also benefit from the new Regulation as it harmonises legislation throughout all 27 Member States. Moreover, in time more information about hazards

of chemical substances will become available because of the registration by EU companies. If a substance is found to be dangerous and these dangers are communicated properly in the sector, companies all around the world using those substances can either look for alternatives or take the necessary precautions to protect workers.

Outline of the legislation



REACH stands for **Registration, Evaluation, and Authorisation of Chemicals**. The Regulation places great responsibility to the EU industry in obliging it to manage the risks from chemicals and to provide safety information on the substances. This means that **manufacturers, importers and downstream users located in the EU** will be required to gather and provide information on the properties of the substances and/or preparations they work with. The Regulation further introduces a new European Chemical Agency (EChA) established in Helsinki, Finland, which will be managing the registration of substances through a database. The European Chemical Agency will be having an important role in the evaluation and authorisation of substances. The agency is also a helpdesk for questions and has specific capacity to answer questions from developing countries.

➔ [For more information](#) refer to the website of the European Chemicals Agency. You can find a link in the external links section.

1. Scope

REACH will cover all chemical substances and/or preparations traded on the EU market. The following substances are **excluded** from the scope of the legislation:

- radioactive substances (because they are covered by other legislations);
- substances under customs supervision which are in temporary storage, in free zones or free warehouses with a view to re-exportation or in transit;
- non-isolated intermediates – an intermediate that during synthesis is not intentionally removed from the equipment in which the synthesis takes place

The obligation to register will **not** apply to substances used:

- in medicinal products for human or veterinary use
- as a food additive in foodstuffs
- as a food flavouring in foodstuffs
- as an additive in feeding stuffs
- in animal nutrition
- substances included in Annex II and Annex III of the Regulation
- temporary excluded: polymers, however monomers do need to be registered!

➔ [For more information](#) please see the full text of the Regulation in the external links section.

2. Key elements of REACH

Pre-registration

From 1st June – 1st December 2008 all existing substances/preparations need to be pre-registered by EU producers and importers. Pre-registration is the intention to register. There are no costs involved and all information is collected in an EChA database.

It is possible that EU importers will request their suppliers outside the EU to pre-register and consequently register their substances themselves. However, this will not happen on a huge scale. In that case the supplier has to create a so-called only representative in the EU who will represent him and be the responsible party for REACH.

For downstream-users of chemicals including those in developing countries it is important to be sure that important substances used are pre-registered.

SIEF

After pre-registration the EChA will publish substance specific pages and create Substance Information Exchange Fora (SIEFs) that will have access to these pages. So, all pre-registrants

of the same substance meet each other through these internet pages of EChA. Together these groups have to create a dossier on the substance and register it.

In practice, it is the expectation that the biggest company will become the 'lead registrant'. Costs will be divided within the group. Depending on the amount of costs, suppliers in developing countries might get a share of it. But still, it will be cheaper than creating a dossier themselves.

Registration of substances

Registration starts with the most dangerous substances and next with substances traded in big quantities. Quantities are measured in tonnes per year per producer or importer and per application or use. The bigger the quantity, the more test information is needed. Substances traded > 10 tonne/yr per producer/importer need to have a chemical safety report.

- Dangerous substances: registration till 1st December 2010
 - CMRs (carcinogens, mutagens and reproductive toxins) > 1 tonne/yr
 - PBTs (persistent, bioaccumulative and toxic substances) > 100 tonne/yr
 - vPvBs (very persistent and very bioaccumulative substances), same PBTs
- Substances > 1000 tonne/yr: latest 1st December 2010
- Substances > 100 tonne/yr: latest 1st June 2013
- Substances > 1 tonne/yr per producer or importer: latest 1st June 2018
- Substances < 1 tonne/yr: no registration needed
- Substances in preparations: idem
- New substances: from 1st June 2008 onwards

Registration of substances in articles

REACH defines an article as follows: "an object composed of one or more substances or preparations which during production is given a specific shape, surface or design determining its end use function to a greater degree than its chemical composition does".

Substances intentionally released, i.e. fragrance in a scented candle

- articles containing substances that are intentionally released and
 - not registered before regarding the present use and
 - > 1 tonne/yr per producer/importer
- will need to be registered according the scheme above.

Substances incidentally released during use, i.e. ink cartridges in copiers

- notification of dangerous substances (> 1 tonne/yr and concentration of > 0.1% of weight)
- from 1st June 2011 onwards
- A list of dangerous substances will be published before that time.

Information needed for registration

1. Technical information

- The identity and contact details of the producers or importer (section 1 Annex IV)
- The identity of the substance (section 2 of Annex IV)
- Information on the manufacture and uses of the substance (section 3 Annex 4)
- The classification and labelling of the substance
- Guidance on safe use(s) of the substance (section 5 Annex IV)
- Summaries of information derived from the application of Annex V to IX
- Robust study summaries of information derived from the application of Annex V to IX
- A statement as to whether or not information has been generated by testing on vertebrate animals
- Proposals for testing where required by the application of Annexes V to IX
- A declaration stating whether the registrant agrees or disagrees to share the

information derived from the application of Annexes V to VIII with regard to testing against payment with subsequent registrant

2. A chemical safety report

Note that the exact data required will be proportionate to the production volume of, and the risks presented by, the substance concerned.

Evaluation

Evaluation aims to avoid the use of unnecessary testing. Three types of evaluations will be established:

Dossier evaluation

EChA will check whether registration dossiers will be complete and correct

Evaluation of proposals for animal testing

Evaluated by EChA

Substance evaluation

EChA and the Member States will check substances.

Authorisation

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 if that's not the case, that the socio-economic benefits from their use outweigh the risks. The aim is to give industry the incentive to progressively substitute these substances with safer alternatives if possible.

- Authorisation per company and application
- R&D plan and substitution plan required
- Duration each authorisation decided per case
- Restrictions substances valid for each producer

Restrictions

Certain substances listed in Annex XVII of the Regulation shall not be manufactured, placed on the market or used unless they comply with the conditions of that restriction. This Annex will contain the restrictions that are already in force in the EU under Directive 76/769/EEC on the marketing and use of certain dangerous substances and preparations. The REACH Regulation will repeal Directive 76/769/EEC entirely. This repeal will be in effect from 1st June 2009.

Classification and labelling inventory

The provisions for a classification and labelling inventory ensure that classifications of all dangerous substances manufactured in, or imported into, the EU are available to all. Industry will thus be required to include all its classifications in the inventory. Non-confidential information on chemicals will be available and certain information will be kept confidential.

On 27th of June 2007, The European Commission adopted a proposal to on classification, labelling and packaging of substances and mixtures. The proposed act aligns the EU system of classification, labelling and packaging substances and mixtures to the United Nations Globally Harmonised System (GHS). It is expected to facilitate global trade and harmonised communication of hazard information of chemicals and to promote regulatory efficiency. It will complement the new REACH Regulation on the registration, evaluation, authorisation and restriction of chemicals.

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