

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.

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.

Are there registration fees?

Yes, there are fees to complete the registration process. The fees will be set in a separate Fee Regulation, which will be published by 1 June 2008.

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.

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.

What is not covered by REACH?

Several uses are exempted from all or some parts of REACH. This includes substances in food and medicinal products as they are covered by other specific legislation. Waste is also exempted from REACH. Member States may exempt substances used for defence purposes.

Do polymers need to be registered?

Polymers are exempted from registration and evaluation, but its basic ingredients, monomers and other components, must be registered. The Commission may propose legislation for the registration of polymers once a practicable and cost-effective way of managing polymers on the basis of sound technical and valid scientific criteria can be established.

Do intermediates need to be registered?

Chemical substances used to manufacture other chemical substances are called intermediates. If manufactured and used inside a closed system they are fully exempt from REACH (non-isolated intermediates). Intermediates that are separated during the production process (isolated intermediates: on-site & transported) will need to be registered. Simplified information requirements apply in this case since they pose lower risks for human health and the environment.

What manufactured products are covered by REACH?

Products such as construction material, electronic components, toys or vehicles are covered by REACH if they contain substances intentionally released. These substances need to be registered.

Products with substances on the candidate list of substances of very high concern will need to be notified to the Agency. A first candidate list with these substances is likely to be published by the Agency in autumn 2008.

What are the main benefits of the new REACH Regulation?

The main benefit of REACH is that it more systematically identifies hazards and risks of chemicals. This allows companies to identify and communicate appropriate risk management measures through the supply chain. Better knowledge on chemicals and more efficient communication on risk management measures will contribute to the prevention of health problems caused by exposure to chemicals. This is expected to lead to a lower occurrence of occupational diseases and preventable deaths, thus lowering costs to national health systems. The benefits will come gradually as more and more substances are assessed under REACH. The European chemicals industry will also benefit from a single EU regulation covering all chemicals. REACH provides clear deadlines for decision-making and may enhance consumer confidence in chemical products. Downstream users of chemicals will get relevant information on the safe use of the chemicals substances they use thus helping them to better protect their workers. Everyday

products are expected to become safer for consumers and the environment, facilitating the implementation of companies' corporate and social responsibility policies.

Help for companies and further information

Will industry receive help to comply with its obligations?

The European Commission, in close cooperation with industry, Member States and NGOs, has developed a number of technical guidance documents, and IT tools for industry and national authorities to facilitate the implementation of REACH. All necessary information can be obtained via the website of the European Chemicals Agency in Helsinki. A navigator tool on this website will help companies to identify their obligations under REACH. The IT tool for entering and storing information on chemicals and preparing and submitting registration dossiers to ECHA will be IUCLID 5. REACH requires EU Member States to set-up helpdesks to provide companies with the necessary information to fulfil their obligations under the new chemicals legislation.

What should companies do to prepare for REACH?

To prepare for the implementation of REACH companies should carry out the following three steps:

STEP 1. Nominate a REACH manager

- Identify a person within the company who will be accountable for preparatory activities and compliance
- Ensure appropriate skill-set and management support

STEP 2. Be aware of information sources

- Regulation (1907/2006/EC)
- Guidance documents (will be available for all main topics on the ECHA website)
- The ECHA website is a single point of entry for information on REACH helpdesks in Member States

STEP 3. Identify the company's obligations under REACH

- Create an inventory of substances (on their own, in preparations and those intentionally released from products)
- Consider exemptions for substances and uses in the inventory
- Compile data based on volumes (≥ 1 tonne ≥ 10 tonnes, ≥ 100 tonnes & ≥ 1000 tonnes)
- Understand the sources of the substances (EU or non-EU supplier)
- Determine the obligation with regard to each substance (manufacturer, importer or downstream user)

Is there more information available?

Further information can be found on the following websites:

HSE UK: www.hse.gov.uk/reach/

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

European Commission:http://ec.europa.eu/enterprise/reach/index_en.htm

http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm

<http://ecb.jrc.it/REACH/>