



Helpdesk

EU NEWS ON IMPLEMENTATION OF “ACQUIS COMMUNAUTAIRE”

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Six-month window for REACH pre-registrations



Chemical substances already on the market must be pre-registered by 1 December 2008 with the European Chemicals Agency if they are to continue being sold after 1 June this year. The requirement comes from the new REACH Regulation designed to assess and manage the hazards to health and the environment posed by all new and existing chemicals.

The REACH [Regulation](#) (Registration, Evaluation, Authorisation and Restriction of Chemicals) came fully into effect on 1 June 2008. A single Regulation replaces about 40 pieces of existing legislation regulating the use of chemicals, and places the onus on industry to demonstrate that products are safe.

[REACH](#) applies to all chemicals in a very broad sense, not just chemicals handled in an industrial environment but all the chemicals that surround us. However, it excludes chemicals controlled by other legislation, such as those used in medicinal products or foods.

The old regulatory structure had failed to assess the estimated 100 000 chemicals already on the market. Over a period of 20-25 years about 140 have been identified as needing a full risk assessment and of those only 40 have been studied.

The new Regulation aims to make the management of chemicals safer. To achieve this, it requires industry to gather data on chemicals, find out about the risks they pose to the environment and to human health and determine how to manage those risks. All existing chemicals should be assessed over the next ten years, with priority given to those which are most hazardous and used in the largest quantities.

Registration process

All manufacturers of chemicals in the EU and all companies which import chemicals from outside the EU must register their products with the new European Chemicals Agency ([ECHA](#)) if volumes exceed one tonne a year. An external supplier can nominate a company within the EU as its only representative, to fulfil the obligations of an importer.

Chemicals new to the market must be registered immediately, accompanied by a full registration dossier. Chemicals already on the market, known as 'phase-in' substances, can be pre-registered free of charge in a simple on-line process between 1 June and 1 December 2008. It is estimated that about 30 000 substances will need to be pre-registered.

Pre-registration allows companies to benefit from extended deadlines for registration. If they pre-register, manufacturers and importers then have a longer period to prepare a full registration dossier, depending on the degree of risk and the annual production volumes. The most hazardous and largest volume chemicals must be fully registered by 1 December 2010, while safer and lower-volume substances can wait until 1 June 2013 or 1 June 2018.

Each registration dossier will contain data about the properties and classification of the substance, its effects on health and guidance for using it safely. The more of the chemical is produced, the more detailed the dossier needs to be.

ECHA may require further evaluation of certain substances and, in the case of particularly hazardous materials, they can be referred to the Commission for authorisation. In addition, substances posing a risk to human health or the environment that is not adequately controlled can be made subject to restriction.

Pooling data

Manufacturers or importers who fail to pre-register existing chemicals by 1 December 2008 should withdraw them from the market until the full registration process is completed. ECHA will publish a list of pre-registered substances in January 2009.

Once the pre-registration period has closed, manufacturers and importers will be grouped into a 'substance information exchange forum' (SIEF) for each chemical. The forums will be used to pool information that can be used to draw up the dossiers and avoid unnecessary duplication of tests, thereby saving costs, and animal lives where applicable.

Extensive guidance on REACH and the pre-registration process is available from the ECHA website and from national helpdesks run by Member States. ECHA's online Navigator tool can also help clarify obligations under REACH.

It should be stressed that manufacturers and importers should not miss this pre-registration period. There is a concern that there are a lot of companies, in particular SMEs, which are not aware of REACH. And even among those which have heard of it, there are some companies outside the chemicals sector which still believe they are not affected.

New agency will oversee REACH

The European Chemicals Agency ([ECHA](#)), which became operational on 1 June, will manage the technical, scientific and administrative aspects of REACH. Initially, its main tasks are to handle the pre-registration and registration of chemicals, carry out the evaluation of dossiers and oversee the substance evaluation process.

ECHA provides guidance to industry, and information to the public regarding chemicals. It runs its own helpdesk and coordinates the network of national helpdesks.

The executive director of ECHA, Geert Dancet, was appointed to a five-year term from 1 January 2008. The agency expects to have more than 400 staff working in its Helsinki office by 2010.

Contact

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