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REACH: Part 2 of a 2-Part Feature
Do you know your RIPs from your SIEFs?

The new European law on chemicals, REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) entered into force on 1 June 2007.

Availability of Guidance Documents

The European Chemicals Agency (ECHA) website lists all the Guidance Documents, which are currently available, or will be become available. These documents have been developed with the participation of many stakeholders (Industry, Member States and NGOs) within projects managed by the Commission. The objective of these documents is to facilitate the implementation of REACH by describing good practice on how to fulfil the obligations.

Some parts of these documents have been or will be translated in all the European Community languages. Guidance is (or will be) available under the following headings.

Guidance on the different processes under REACH

- Guidance mainly for Industry use
- Guidance mainly for Authorities use

Guidance on the different methods under REACH

Manufacturers and Importers

Pre-registration *(to gain the correct phase-in registration periods)*

- Collect available information
- Locate other relevant information holders and consider consortium
- Share data

Registration *(normally together with the other substance suppliers)*

Carry out the Chemical Safety Assessment and write the Chemical Safety Report {≥10 tonne}

- Compile and submit Registration Dossier
- Communicate up and down the supply chain

Don't forget to pre-register in time!

The vast majority of obligations under REACH apply to **manufacturers and importers** of substances in the EU. The REACH processes relevant for manufactures and importers are: -

Substance registration

Manufacturers and importers of substances must submit a registration to the Agency for each substance manufactured or imported in quantities of 1 tonne or above per year. Failure to register means that the substance cannot be manufactured or imported. Producers and importers of articles need to pre-register and register substances which are present in their articles in quantities over one tonne a year and if those substances are intended to be released (e.g. printing cartridges). For these cases, the same registration obligations as for manufacturers and importers of substances apply in analogy.

Registrants wishing to use the phase-in provisions will be required to pre-register to the Agency to permit sharing of available information (data sharing). Registrants will be required to share data gained by vertebrate animal testing.

Registrants are required to update their registrations on their own initiative as soon as the quantity of a substance reaches the next tonnage threshold and/or when relevant new information becomes available.

Notification obligations for articles

If an article contains a substance of very high concern (≥ 0.1% w/w) which has been placed on the candidate list for authorisation there is an obligation to notify the Agency. This requirement applies if the substance is present in the article produced or placed on the EU market in quantities of 1 tonne or more a year and exposure to humans or the environment cannot be excluded. The obligation will apply from 1 June 2011 at the earliest (or six months from the date the substance has been placed on the candidate list, in case the substance has not been on the list before 1 December 2010).

Classification and labelling inventory

Manufacturers and importers must notify to the Agency the classification and labelling of all substances subject to registration or classified as dangerous (Art. 1 of Directive 67/548/EEC) and placed on the EU market. The Agency will include the notified substances in the Classification and Labelling Inventory.

Information in the supply chain

REACH will replace the current Safety Data Sheets Directive. The SDS requirements and responsibilities for manufacturers and importers will remain and be extended by the requirement to convey information from any relevant chemical safety assessment.

When a chemical safety assessment is performed (substances placed on the market in quantities ≥ 10 tonnes per year by a manufacturer or importer), exposure scenarios must be developed for dangerous substances and PBT/vPvB substances. These exposure scenarios shall be placed in an annex to the Safety Data Sheet. The exposure scenarios contain a description of the risk management measures which the manufacturer or importer has implemented and recommends downstream users to implement. For this purpose, manufacturers or importers must assess all uses that are identified to them by their downstream users. If they decide not to support a particular use, they must justify this and notify the Agency and their downstream user.

Producers or importers of articles containing a substance of very high concern (≥ 0.1% w/w) which has been placed on the candidate list for authorisation must supply sufficient information to allow safe use of those articles to industrial and professional users. To consumers this information must be provided on request. In addition, the same information obligations as for manufacturers and importers of substances apply in analogy for substances in articles intended to be released.

Substances subject to authorisation

An authorisation is required for uses and placement on the market of substances included in Annex XIV of the REACH Regulation. An authorisation can be requested by manufacturers, importers or downstream users on their own or in collaboration with other actors in the supply chain. Importers of articles are not required to apply for authorisation even if the article contains a substance included in Annex XIV.