

Registration Requirements & Exemptions for Substances Under REACH

REACH was adopted at second reading on 18 December 2006, and took effect 1 June 2007. An estimated 140,000 dossiers for 30,000 phase-in substances are expected to be received in the first 11 years of REACH implementation. REACH establishes the European Chemicals Agency (ECHA) in Helsinki, Finland as the EU agency responsible for much of the data management aspects of REACH registration. Each Member State (MS) will establish a Competent Authority to support the ECHA and perform the MS's obligations under REACH (<http://ecb.jrc.it/links/>).

Registrations are required by each legal entity that manufactures or imports a substance, including substances in preparations (e.g., mixtures) and in articles. [See over for a description of exemptions and exclusions from the REACH requirement for registration.] Different legal entities that are part of a holding company or group company will be required to separately register and pay registry fees for the same substance. Joint submission of the hazard information is required by all manufacturers and importers of that substance, unless the legal entity opts out of the joint submission, due to concerns of confidentiality or other reasons.

Identifying the substances being registered under REACH is essential for knowing both the registration requirements and the deadlines that apply. Certain chemicals that were notified under prior regulations are considered to already be registered, while the so-called "phase-in substances" have staggered registration deadlines based on the annual average quantity of the substance manufactured or imported during the past three calendar years, but the staggered deadlines only apply for manufacturers and importers that provide a pre-registration under REACH. Pre-registration applies to substances, including those in articles and preparations, and will be available from 1 June to 30 November 2008. The final legislation also allows some substances that have unknown or variable composition, such as complex reaction products or are biological materials, to be registered as a single substance – a complexity to be addressed in future guidance documents under REACH Implementation Project (RIP) 3.10.

To begin a registration, manufacturers and importers submit specific documents:

- **Technical dossier** for substances in quantities of 1 tonne or more per year. The technical dossier contains information on the properties, uses, and classification of a substance, as well as guidance on safe use. The level of detail required in the dossiers depends on the tonnage of substance manufactured or imported per calendar year.
- **Chemical safety report (CSR)** for substances in quantities of 10 tonnes or more per year. A CSR identifies the hazards and classification of a substance and the substance' status as a persistent bioaccumulative toxic (PBT) or a very persistent very bioaccumulative (vPvB) chemical. Exposure scenarios covering all identified uses of the substance over its life-cycle must be included with the CSR for substances classified as dangerous, PBT, or vPvB substances. Exposure scenarios must include risk management measures and operational conditions for uses.

Reference:

- Guidance on Registration http://ecb.jrc.it/DOCUMENTS/REACH/RIP_FINAL_REPORTS/RIP_3.1_REGISTRATION_GUIDANCE/RIP_3.1_registration_en.pdf

Exemptions from REACH Registration Requirements

Substances exempted from all REACH requirements: non-isolated intermediates; wastes; radioactive substances; substances under customs supervision; in transit by rail, road, inland waterway, sea or air; & substances Member States exempt in interest of defence (Article 2(1-3)).

Exemptions from registration (many to be reviewed by 1 June 2008) apply to:

- REACH Annex IV lists 68 substances exempt from registration under Existing Substances Regulation (793/93/EEC); cellulose pulp was added at Second Reading of REACH.
- REACH Annex V identifies 9 criteria that exempt substances from registration, as taken from experience with New Substances Directive (67/548/EEC) (Article 2(7b)), including:
 - Substances resulting from chemical reactions incidental to: storage, exposure to env. factors, end uses, additives, physiochemical function, byproducts, & by adding water.
 - Not chemically modified: minerals, ores & concentrates, cement clinker, natural gas & condensate, liquefied petroleum gas, process gas & components, crude oil, coal & coke.
 - Basic elemental substances with well known hazards and risks: hydrogen, oxygen, argon, helium, neon, xenon, and nitrogen.
- Substances registered, then exported, and re-imported as the same substance (Article 2(7)).
- Substances registered, and then recovered as the same substance (Article 2(7)).
- On-site and transported isolated intermediates (Article 2(8)).
- Polymers are exempt, but residual monomers >2% are not exempt (Articles 2(9) & 6(3)).
- Uses regulated by other legislation: medicinal products for human (726/204/EC & 2001/83/EC) or veterinary use (2001/82/EC); food or feedingstuffs (178/2002/EC) including additives or flavorings (Article 2(5)). EC to review overlap of laws by 1 June 2012.
- Substances manufactured or imported at <1 tonne do not require registration, but no cut-off applies to authorisation, restriction, or classification and labeling inventory (Article 17).

Some substances regarded as already being registered:

- Substances notified under Directive 67/548/EEC and in the European List of New Chemical Substances (ELINCS), but when the quantity of a notified substance reaches the next tonnage threshold, the importer or manufacturer must submit additional information corresponding to that tonnage threshold and all lower tonnage thresholds.
- Biocides & plant protection products are regarded as being registered, and require no other registration (Article 15).

Certain activities exempt substances from requiring registration for a period of time:

- Substances involved in “product and process orientated research and development” (PPORD) are exempt from registration and testing requirements, including those for isolated intermediates, for five years (Article 9), but must provide notification to the ECHA. PPORD includes any scientific effort related to product development or further development of a substance, including in preparations or in articles, during which pilot plant or production trials that are used to develop the production process or to field test applications. The PPORD exemption for a particular substance may be extended.