

REACH: an overview

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What will REACH do?

- Places responsibility on the industry for: ensuring safety of chemicals to generate data; assessing of risks; developing appropriate risk management measures
- Registration will provide a record to the authorities and monitor compliance by manufacturers and importers
- Evaluation of registered substances may eventually lead to restrictions

Who could be affected?

- EU manufacturers and importers of substances
- EU manufacturers and importers of preparations and
- EU manufacturers and importers of certain types of articles that contain substances
- Non-EU manufacturers have no obligations under REACH but will normally need to provide necessary information to importers
- All separate legal entities must register (including companies within the same group)

Only Representative (1)

- A non-EU manufacturer may appoint an **only representative** to carry out the obligations that an importer would have under REACH
- The only representative would be legally responsible for such obligations
- The only representative replaces the importer's obligations
- It can be a subsidiary company or a professional service representing several non-EU manufacturers

Only Representative (2)

The only representative:

- can be a natural or legal person
- must be located within the EU
- must have a sufficient background in the practical handling of substances and the information related to them
- must keep up-to-date information on quantities of substances imported and customers sold to
- The only representative can be changed
- Separate registrations have to be filed for each non-EU manufacturer

Registration - Scope

- Substances manufactured or imported in quantities of one tonne or more per year per manufacturer or importer must be registered
- Even “harmless” substances have to be registered

Exemptions:

- REACH does not apply to substances under customs supervision, radioactive substances, non-isolated intermediaries, wastes (but not recovered wastes), substances for defence
- Substances causing minimum risk (e.g., water, oxygen, corn oil) and non-chemically modified “natural” substances (e.g., minerals, crude oil, gas, coal, ores) are exempted from registration

Registration – Timing

- The substance must be registered by the applicable deadlines, prior to manufacturing in or import into the EU
- Failure to register will mean the substance cannot be manufactured or imported
- Substances already existing on the EU market will benefit from a phase-in period provided they are pre-registered
- Such existing substances (>100,000) are referred to as phase-in substances
- The pre-registration period began on 1 June 2008 and ends on 1 December 2008 (only “first time” manufacturers or importers may pre-register later)

Pre-registration

For pre-registration, each potential registrant of a phase-in substance must provide certain information to ECHA:

- Name of the substance
- Name, contact information of the relevant manufacturer/importer and its only representative (if any)
- Envisaged deadline for the registration and the tonnage band (1, 100, 1000 tonnes or more)
- Names of other similar substances (read-across approach)

Consequences of failure to pre-register: immediate suspension or penalties

Non-phase-in substances: no transitional regime

Registration – Deadlines

If pre-registered:

- first registration by: 30 November 2010 (for certain hazardous substances and those of 1000 tonnes or more p/a, per manufacturer or importer)
- second registration by: 31 May 2013 (100 tonnes or more p/a, per manufacturer or importer)
- third registration by: 31 May 2018 (1 tonne or more p/a, per manufacturer or importer)

Registration and pre-registration to be submitted on-line

Registration – Required Information

- Registration will require submission of technical dossier with extensive information on the substance including:
 - intrinsic properties
 - manufacture and usage
 - guidance on safe use
- The higher the tonnage, the higher the information requirement
- Chemical safety report is also required for substances manufactured or imported in quantities of 10 tonnes or more per year

Registration – SIEF (1)

- All potential registrants of the same substance must submit certain information together (e.g., on hazardous properties, classification and labelling, any proposals for testing) for registration
- The exchange of information between potential registrants will be carried out through the **Substance Information Exchange Forum** (SIEF)

Registration – SIEF (2)

- Data on tests involving vertebrate animals must be shared among SIEF participants
- Activities include gathering data, considering information needs, identifying the gaps, generating new information, sharing of costs, and joint submission
- Data for other tests must be shared upon request
- Also note:
 - Antitrust concerns (sharing of information)
 - Property rights (confidentiality issues)
 - Compensation issues (no free-riding)

Registration – SIEF (3)

- Optional but recommended: setting up of consortia for substances (pre-SIEF)
- By 1 January 2009 ECHA will publish a list of all pre-registered substances
- The general rule will be “one substance, one SIEF”
- SIEF participants can appoint a third party representative (agent only)

Preparations - Registration

- **Registration** must be made for the substances contained in a preparation if:
 - any such substance is present in the preparation in quantities of 1 tonne or more per manufacturer or importer per year
 - traditional concepts of *article* may not apply under REACH: an object may in fact be a *preparation* contained in a container or on a carrier, e.g. toner cartridges, pens, wet wipes, fire crackers

Articles – Registration

- **Registration** must be made for a substance contained in an article if:
 - the substance is present in the article in quantities above 1 tonne per manufacturer or importer per year; and
 - the substance is intended to be released under normal or reasonably foreseeable conditions of use
- The registration requirement for articles does not apply to substances that have already been registered for that use

Monomers – Registration (1)

- Polymers are exempt from registration.
- Monomers or other substances in polymers must be registered if:
 - the polymer consists of 2% weight by weight or more of such monomer substance(s) or other substance(s), in the form of monomeric units and chemically bound substance(s); and
 - the total quantity of such monomer substance(s) or other substance(s) makes up at least 1 tonne per year.

Monomers – Registration (2)

- No obligation to register if already registered by an actor in the supply chain
- Additives such as heat or light stabilisers or antioxidants, if necessary to preserve stability, do not have to be registered