

REACH

A Summary Guide

REACH

(Registration, Evaluation & Authorisation of Chemicals)

- New EU regulation on chemicals and other substances (including metals)
- Agreed by Council and European Parliament on 18 December 2006
- Enters into force on 1 June 2007
- Good balance between improving protection of human health and the environment, and maintaining industry competitiveness
- Rationalises the current EU regulatory system for chemicals (will replace over 40 pieces of existing legislation)
- Carries forward existing EU restrictions regime and safety data sheets system
- Introduces new registration requirement covering all substances supplied above 1 tonne per year, and new authorisation requirement covering substances of very high concern (e.g. carcinogens)
- Transfers responsibility for gathering data and carrying out initial risk assessments from the authorities to industry

Why the need for REACH?

- Over 30,000 substances on the EU market above 1 tonne per year
- Very limited information available on hazards and risks to human health and the environment
- Current regulatory system has been very slow to produce results – less than 200 substances assessed properly over past 30 years
- Increasing public concern over risks of chemicals
- Need for better evidence base to address this concern
- Current system confusing for industry to understand and for authorities to administer

REACH – key elements

- REGISTRATION - a manufacturer or importer will need to register any substance they supply to the EU market above 1 tonne per year
- EVALUATION – the authorities will carry out annual in-depth evaluations (i.e. assessments) of substances flagged as being of potential high risk (e.g. on the basis of information provided at registration)
- AUTHORISATION – the uses of substances of very high concern, e.g. CMRs (carcinogens, mutagens, and toxic to reproduction), PBTs (persistent, bioaccumulative, and toxic), and vPvBs (very persistent, very bioaccumulative) will require authorisation
- AGENCY - a new EU Chemicals Agency based in Helsinki will administer REACH, in co-operation with Member States' competent authorities

Registration

- Substances manufactured or imported above 1 tonne per company per year must be registered – covers around 30,000 substances
- Registration dossier prepared by industry to provide core hazard data, plus risk assessments for substances supplied above 10 tonnes per year
- Registration phased over 11 years (2007-2018), starting with high tonnage substances
- Most kinds of substances covered: organic & inorganic; consumer & industrial applications
- Though certain exemptions from registration, e.g. substances covered by equivalent sectoral legislation, and certain low risk naturally occurring substances.

Evaluation

Two types - Dossier evaluation & Substance evaluation

Dossier evaluation

- Agency scrutinises all testing proposals submitted with a registration dossier (primarily to ensure no unnecessary animal testing is carried out)
- 5% of all registration dossiers subject to full compliance check by Agency

Substance evaluation

- Member States and Commission agree on an annual list of substances to be assessed in-depth
- Competent authorities carry out substance evaluation – may lead to new control measures or to no further action

Authorisation

- All uses of substances of very high concern (e.g. CMRs & PBT/vPvBs) must be authorised – covers around 1,500 substances
- Authorisation will be granted if the risks of a substance are under ‘adequate control’
- ‘Adequate control’ allows authorities to prioritise action on hazardous substances that cannot be so controlled
- If adequate control not possible, authorisation may be granted on socio-economic grounds if there is no suitable safer alternative
- Companies will be required to make efforts to find safer substitutes as part of the authorisation process
- But any substitute must deliver lower overall risks and be technically and economically feasible

REACH and Downstream Users

- Most of REACH provisions cover manufacturers and importers of chemicals, not downstream users
- But downstream users have rights and obligations too
- Downstream users have the right to join a Substance Information Exchange Forum during the registration process
- Downstream users have the right to request that their supplier's chemical safety assessment covers their use(s)
- Downstream users are obliged to implement risk reduction measures recommended by their suppliers
- And under certain circumstances a downstream user may be obliged to carry out a risk assessment covering their particular use(s) of a chemical

REACH and SMEs

- 20,000 of the 30,000 substances subject to REACH registration are supplied between 1-10 tonnes per year, mainly by SMEs
- Special provisions in REACH to help SME low tonnage suppliers
- Greatly reduced information requirements for substances supplied between 1-10 tonnes
- 1-10 tonne substances have 11 years to register (by June 2018)
- Reduced fees to be set for SMEs in all areas of REACH
- New EU Chemicals Agency to take particular account of SME needs in preparing technical guidance and enforcement strategies

REACH implementation timeline (key dates)

- 1 June 2007: REACH entry into force
- 1 December 2008: Deadline for all companies intending to register a substance to notify their intention to the EU chemicals Agency (pre-registration)
- 1 December 2010: Registration deadline for manufacturers/importers supplying a substance above 1,000 tonnes per year, or a CMR cat.1 or 2 substance above 1 tonne per year, or an R50-53 substance above 100 tonnes per year
- 1 June 2013: Registration deadline for manufacturers/importers supplying a substance above 100 tonnes per year
- 1 June 2018: Registration deadline for manufacturers/importers supplying a substance above 1 tonne per year

UK competent authority

- HSE has been asked to provide the UK competent authority for REACH
- The competent authority will work closely with Defra (lead Govt Department for REACH), the Environment Agency, the devolved administrations and other Govt Departments including DTI, and liaise with the new European Chemicals Agency in Helsinki
- HSE REACH helpdesk launched in Nov 2006 – it can be contacted on 0845 408 9575 or via email at ukreachca@hse.gsi.gov.uk

Implementation and enforcement

- Member States are responsible for enforcement of the REACH Regulation in their own country.
- The Government published a consultation document on 13 March, prepared with the Devolved Administrations, to gather stakeholder views on proposals for the UK implementation. The deadline for replies is 4 June.
- The Government is proposing to use a best practice approach which encourages compliance, supported by more formal procedures where necessary.

The REACH activities where UK enforcement is needed are:

- The manufacture, import, sale, supply or use of substances without the appropriate registration
- Using a hazardous substance outside the terms of an authorisation or contrary to a restriction
- Failure to provide required information up and down the supply chain
- Failure to comply with other duties regarding information, e.g. workers' or consumers' rights of access to information
- Failure to comply with the duty to apply recommendations, e.g. in safety assessments
- Failure to comply with the duties to co-operate and supply information (in a timely manner)