

## Department for Environment, Food and Rural Affairs

### What are the main elements of the REACH Regulation, agreed by the European Parliament and the Council of Ministers (EU Member States) in December 2006?

The main elements of the REACH Regulation are as follows:

- A strong emphasis on the need for industry to act responsibly and with care when manufacturing, importing, and marketing substances, and in particular providing the necessary information to ensure effective risk management;
- Significantly more information on substances and their uses available throughout the supply chain, than is presently the case under the existing regulatory regime;
- Strong measures to minimise animal testing, and emphasis on developing alternative test methods to replace it wherever possible;
- Recognition of the particular situation of SMEs, and specific help with the costs of complying with REACH;
- Key role for the European Parliament in scrutinising the work of the new European Chemicals Agency established by the Regulation to oversee the implementation and operation of REACH across the EU, and powers to scrutinise proposed future changes to the secondary elements of the Regulation;
- **Registration:**
  - requires industry to obtain relevant information on chemical substances produced in, or imported into, the EU in quantities above one tonne per year, and to use that data to manage the chemicals safely;
  - staggered registration for existing (“phase-in”) substances over 11-year period, based on tonnage bands (tonnage used as a proxy indicator for exposure), with highest tonnage substances registered first;
  - registrants of the same substance must share core data and work together to submit a joint registration through [‘One Substance, One registration’](#);
  - exemption of certain low-risk substances (such as paper pulp) from registration.

- **Evaluation:**
  - Regulators assess whether the information provided by industry is sufficient, and that they have applied the right risk management measures;
  - Regulators also have the powers to evaluate further substances where they have concerns over potential risks to human health or the environment. An EU-wide rolling action plan of such evaluations will be put in place.
  
- **Authorisation and restriction:**
  - Substances of high concern, i.e. with the most hazardous properties, such as carcinogens, are subject to a ban (i.e. restricted) unless industry can show that the risks are adequately controlled, or that the socio-economic benefits of continued use outweigh the risks;
  - Analysis of possible alternatives form part of the authorisation application, and where this identifies a suitable safer alternative a substitution plan must also be submitted;
  - Enables priority action on those harmful substances that cannot be adequately controlled;
  - Authorisation periods are set on a case-by-case basis, taking account of the substances, control measures, and likelihood of alternatives/substitution;
  - In similar vein to the current regulatory regime, restrictions will be applied to the marketing and use of substances where the risks to human health and the environment are deemed by regulators to be unacceptable.