Scope of the REACH regulation

REACH applies to the manufacture, placing on the market or use of substances on their own, in preparations or in articles. REACH follows a substance based approach: the obligations do not directly apply to preparations and articles (with the exemption of the requirements for Safety Data Sheets which also apply to preparations).

General exemptions

REACH applies to all substances with a few exemptions: radioactive substances (Directive 96/29/Euratom), substances under customs supervision, non-isolated intermediates and the transport of substances are not covered under REACH. Waste (as defined in Directive 2006/12/EC) is also specifically exempted as it is not a substance, preparation or article within the meaning of REACH. Member States may allow for exemptions from REACH in specific cases for certain substances, on their own, in a preparation or in an article, where necessary in the interests of defence.

Exemptions from parts of the provisions of REACH

- **Medicinal products for human or veterinary use**
  Substances used in these products are not subject to registration, downstream user obligations, evaluation and authorisation.
  The provisions concerning the information in the supply chain do not apply to these products in the finished state, intended for the final user.
- **Food or feeding stuffs**
  Substances used in these products (including uses as additive or flavouring) are not subject to registration, downstream user obligations, evaluation and authorisation. The provisions concerning the information in the supply chain do not apply to these products in the finished state, intended for the final user.
- **Cosmetic products**
  The provisions concerning the information in the supply chain do not apply to these products in the finished state, intended for the final user.
  The chemical safety report need not include consideration of the risks to human health for the end uses in cosmetic products.
  In case of substances subject to authorisation only because of hazards to human health, the provisions of authorisation do not apply to their uses in cosmetic products.
  Restrictions do not apply to the use of substances in cosmetic products, with regard to restrictions addressing the risks to human health within the scope of the Cosmetic Directive (76/768/EEC).
- **Invasive medical devices or medical devices used in direct physical contact with the human body**
  The provisions concerning information in the supply chain do not apply to these preparations in the finished state, intended for the final user, in so far as Community measures lay down provisions for their classification and labelling which ensure the same level of information requirement and protection as the legislation on dangerous preparations/mixtures.
- **Food contact materials**
  The chemical safety report need not include consideration of the risks to human health for the end uses in food contact materials. In case of substances subject to authorisation only because of hazards to human health, the provisions of authorisation do not apply to their uses in food contact materials.
- **Plant protection products and biocidal products**
  The registration is regarded as completed for manufacture or import for the use of active substances and co-formulants as a plant protection product. The registration is regarded as completed for manufacture or import for the use of active substances in a biocidal product.
  The authorisation process does not apply to the uses of substances in plant protection products and biocidal products.
- **Fuels**
  The provisions of authorisation do not apply to the uses of substances as motor fuels, as fuel in mobile or fixed combustion plants of mineral oil products and as fuels in closed systems.
- **Polymers**
  They are for the time being exempted from registration and from evaluation.
- **Substances included in REACH annexe IV**
  They are exempted from registration, downstream user obligations and evaluation as sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties.
- **Substances covered by annexe V**
  They are exempted from registration, downstream user obligations and evaluation as registration is deemed inappropriate or unnecessary for these substances and their exemption from these processes does not prejudice the objectives of REACH.
- **Scientific research and development**
  Substances manufactured, imported or used for the purpose of scientific research and development, carried out under controlled conditions, in a volume below 1 tonne per year, are exempted from registration, authorisation and restriction obligations.
- **Product and process orientated research and development (PPORD)**
  Whenever research and development is related to product development or the further development of a substance, in the course of which pilot plant or production trials are used, this falls under the definition of PPORD. Substances used for PPORD will receive exemption from registration if they are notified to the European Chemicals Agency.
  The exemption can be up to 5 years and may be extended upon request for up to a further 5 years (or 10 years in case of medicinal products or substances not put on the market). When identifying substances subject to authorisation and restrictions, it will be specified if the requirement does not apply to PPORD and the maximum quantity exempted.
- **Substances registered, exported and re-imported into the Community** (by the same or another actor in the same supply chain)
  They are exempted from registration, downstream users obligations and evaluation, under certain conditions.
- **Recycled or recovered substances already registered**
  Provided a number of conditions are met, these substances are exempted from registration, downstream user obligations and evaluation.
- **On-site and transported isolated intermediates**
  They have to be registered. However, reduced information requirements apply if they are used (and transported) under strictly controlled conditions. They are not subject to authorisation.
- **Substances present in preparations** below certain concentration limits defined in article 56(6) of REACH are exempted from authorisation.
  A chemical safety assessment need not be performed for a substance which is present in a preparation below certain concentration limits defined in article 14(2).