

REACH: Glossary of Terminology

Actors in the supply chain: All manufacturers, importers, and downstream users in a supply chain.

Agency: The European Chemicals Agency (ECHA), as established by REACH.

Article: An object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.

CMR: Carcinogenic, mutagenic, or reproductive toxics. CMRs are classified in three categories, and only category 1 and 2 substances for which there is a high level of evidence of health damage to humans are substance of very high concern subject to authorisation under REACH.

Competent authority: Authority established by Member States to carry out REACH obligations.

Downstream user: Any natural or legal person established within the European Community (EC), other than the manufacturer or importer, who uses a substance, either on its own or in a preparation, in the course of industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2.7(c) is regarded as a downstream user.

Distributor: Any natural or legal person established within the EC, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties.

Existing chemicals: Chemicals reported to be on the market in 1981, prior to the EC requirement to notify on “new chemicals.” About 100,106 existing chemicals are on the European Inventory of Existing Commercial Chemical Substances (EINECS), and are considered phase-in substances for REACH.

Exposure scenario: Set of conditions, including operational conditions and risk management measures, to describe how a substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends that downstream users control, exposures to humans and the environment. An exposure scenario may cover one or many, processes or uses.

Identified use: Use of a substance or preparation that is intended by an actor in the supply chain. Identified uses include an actors’ own use, & uses identified in writing by an immediate downstream user.

Importer: Any natural or legal person established within the EC who is responsible for the physical introduction into the customs territory of the EC. Importers are deemed to be placing on the market.

Manufacturing: Production or extraction of substances in the natural state.

Manufacturer: Any natural or legal person established within the EC who produces or extracts a substance in the natural state within the EC.

Not chemically modified substance: A substance whose chemical structure remains unchanged, even after a chemical process, treatment, or physical mineralogical change, such as removing **impurities**.

Notified substance: A “new chemical” substance which has been placed on the market since 1981, and for which a notification has been submitted under pre-REACH EU chemical legislation in accordance with Directive 67/548/EEC. These substances are contained in the European List of New Chemical Substances (ELINCS) and are considered registered for REACH, and are to be assigned registration numbers by 1 December 2008. There are about 4000 such substances.

PBTs: Substances of very high concern that are persistent, bio-accumulative, and toxic. Those substances may become subject to authorisation as a priority.

Placing on the market: Supplying or making available, whether in return for payment or free of charge, to a third party. Import is deemed to be placing on the market.

Preparation: A mixture or solution composed of two or more substances.

Producer of an article: Any natural or legal person who makes or assembles an article within the EC.

Product and process orientated research and development (PPORD): Any scientific research effort related to product development or further development of a substance, including in preparations or articles, during which, either pilot plant or production trials are used to develop the production process or to test the potential fields of application. Substances in PPORD are exempt from registration and testing requirements, including for isolated intermediates, for five years, and that may be extended.

Polymer: A substance consisting of molecules characterised by a sequence of one or more types of monomer units, and a range of molecular weights based on the number of monomer units. "Monomer unit" is a reacted form of a monomer in a polymer. Polymers were excluded from EINECS, and those requiring notification are on a "no longer polymers" list and are considered phase-in substances.

Phase-in substance: A substance that was either: (a) an existing chemical, documented as on the market in 1981, and currently listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) (about 100,106 substances); (b) not placed on the market in the 15 years prior to 1 June 2007, even though it was manufactured in the EC (or in countries acceding to the EU on 1 January 1995 and 1 May 2004), and the manufacturer has documented evidence; or (c) a "no-longer polymer" as notified under Directive 67/548/EEC, and placed on the market in the EC (or in countries acceding to the EU on 1 January 1995 and 1 May 2004) before 1 June 2007 by the manufacturer or importer, who has documented evidence. [Note: For phase-in substances imported or manufactured for at least three consecutive years, quantities per year are based on the average volumes for the three preceding calendar years.]

R50/53: very toxic to aquatic organisms: Chemicals that may cause long-term adverse effects in the aquatic environment as specified in Directive 67/548/EEC. R50/53 substances' registrations are due 1 December 2010 if they are phase-in substances and were manufactured or imported in quantities of 100 tonnes or more per year per manufacturer or importer at least once after 1 June 2007.

Scientific research and development: Any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year.

Site: A single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared.

SME: Small and medium-sized enterprises as defined in the Commission Recommendation 2003/361/EC of 6 May 2003 as: "The category of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million."

Substance: A chemical element and its compounds in a natural state or obtained by a manufacturing process, including any additive necessary to preserve stability and any impurity deriving from the process used, but excluding solvent that may be separated without affecting its stability or changing composition.

Substance which occurs in nature: Naturally occurring substance, unprocessed or processed only by manual, mechanical or gravitational means, dissolution in water, flotation, extraction with water, steam distillation, or heating solely to remove water, or that is extracted from air by any means.

Substance of very high concern (SVHC): Substances requiring authorisation, which are defined by REACH to include: CMRs, persistent bioaccumulative toxics (PBTs), and very persistent, very bioaccumulative (vPvB) substances. There are an estimated 1,500 substances of very high concern.

Use: Any processing, formulation, consumption, storage, keeping, treatment, filling containers, transfer between containers, mixing, production of an article, or any other usage.