

REACH - Exemptions

If you have responsibilities under REACH then you need to know what impact this might have on your business. This leaflet explains the way REACH excludes some chemicals from its provisions.

What is REACH?

REACH (Registration, Evaluation, Authorisation and restriction of Chemicals) is the system for controlling chemicals in Europe. It became law in the UK on 1 June 2007.

One of the biggest changes REACH brings about is to move away from concentrating only on chemicals we already know are dangerous, and instead think about a much wider range of substances – including ones that we don't yet know enough about. This leaflet aims to help you understand which chemicals are covered by REACH, and which are exempt from all or parts of it. It is intended to be a starting point to help you understand the extent to which REACH might impact on the chemicals in your business.

REACH covers most chemical substances that are manufactured in or imported into the EU. This can be:

- Substances on their own
- Substances in a mixture (a preparation or formulation; for example, ink or paint)
- Substances that make up an 'article' (essentially, an object that is produced with a special shape, surface or design)

Substances do not need to be registered under REACH if they are manufactured or imported at less than 1 tonne per year, per manufacturer/importer. Some substances are exempt from all or certain aspects of REACH ("partial" exemptions). The following describes what substances are exempt from which parts of REACH.

Total Exemptions

Substances which fall into any of the categories below are totally exempted from the requirements of REACH [reference: REACH Article 2(1), (2) and (3)];

- Radioactive substances within the scope of Council Directive 96/29/Euratom;
- Substances, on their own, in a mixture or in an article, which are subject to customs supervision, provided that they do not undergo any treatment or processing, and which are in temporary storage, or in a free zone or free warehouse with a view to re-exportation, or in transit;
- [Non-isolated intermediates](#);
- The carriage of dangerous substances and dangerous substances in dangerous mixtures by rail, road, inland waterway, sea or air;
- Waste as defined in Directive 2006/12/EC.

European Union Member States can also create specific exemptions in the interest of defence. In the UK the Ministry of Defence (MoD) will be responsible for issuing these exemptions. They should be contacted directly for advice on using this exemption.

Partial Exemptions

In addition to those substances which are totally exempt from REACH, there are a number of substances which are exempt from only certain aspects of REACH. This is often because they are used in products which fall under the scope of more specific legislation. These are listed below together with the relevant article of the REACH text and the part of REACH from which they are exempt.

1. Substances contained within products falling into scope of the following European Directives and Regulations are exempted from the following parts of REACH: Title II (Registration); Title V (Downstream Users); Title VI (Evaluation); Title VII (Authorisation)

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- Medicinal products [Article 2(5)(a);
 - for human use within the scope of Directive 2001/83/EC;
 - for veterinary use within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC.
 - Food and Feedingstuffs in accordance with Regulation (EC) No 178/2002 [Article 2(5)(b)]; including use
 - as a food additive in foodstuffs within the scope of Directive 89/107/EEC;
 - as a flavouring in foodstuffs within the scope of Directive 88/388/EEC and Directive 1999/217/EC drawn up in application of Regulation (EC) No 2232/96;
 - as an additive in feeding stuffs within scope of Regulation (EC) No 1831/2003;
 - in animal nutrition within the scope of Directive 82/471/EEC.
2. Substances contained within products in the finished state, intended for the end user, falling into scope of the following European Directives and Regulations are exempted from the following Parts of REACH: Title IV (Information in the supply chain) [Article 2(6)]
- Medicinal products (as per the bullet point above);
 - Cosmetic products as defined in Directive 76/768/EEC;
 - Medical devices which are invasive or used in direct physical contact with the human body in so far as Community measures lay down provisions for the classification and labelling of dangerous substances and mixtures which ensure the same level of information provision and protection as Directive 1999/45/EC;
 - Food and Feedingstuffs (as per the bullet point above).
3. As described in Article 2(7), there are further groups of substances exempted from the following Parts of REACH: Title II (Registration); Title V (Downstream Users); Title VI (Evaluation). These groups are:
- i) Substances covered by Annex IV or V:
- Substances specifically named in Annex IV, as sufficient information is known about the intrinsic properties of these substances that they are considered to cause minimum risk;
 - Substances covered by Annex V, as registration is deemed inappropriate or unnecessary for these substances and their exemption from these Titles does not prejudice the objectives of this Regulation.
- Further details of exemptions covered by Annex V are given in the following section;
- ii) Substances on their own or in mixtures, which have been registered, that are exported from the Community by an actor in the supply chain and then re-imported into the Community by the same or another actor in the same supply chain who shows that:
- the substance being re-imported is the same as the exported substance;
 - he has been provided with the information in accordance with Articles 31 or 32 of REACH relating to the exported substance.
- Note: the advice of the European Commission and the European Chemicals Agency is that this exemption applies **only** when a substance has been fully registered. It would not apply to the re-import of pre-registered substances and the re-importing company may need their own pre-registration.*
- iii) Substances, on their own, in mixtures or in articles, which have been registered, which are recovered (i.e. recycled) in the Community if:
- the substance that results from the recovery process is the same as the substance that has been registered; and
 - the information required by Articles 31 or 32 of REACH relating to the substance that has been registered is available to the establishment undertaking the recovery.

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Article 31 relates to the requirements for Safety Data Sheets;

Article 32 relates to the duty to communicate information down the supply chain for substances on their own or in mixtures for which a Safety Data Sheet is not required.

*Note: the advice of the European Commission and the European Chemicals Agency is that this exemption applies **only** when a substance has been fully registered. It would not apply to recovered substances that have only been pre-registered. Many substances that are recovered, e.g., metals, solvents, etc were registered in 2010.*

4. [On-site isolated intermediates](#) and [transported isolated intermediates](#) shall be exempted from Chapter 1 of Title II (Registration), with the exception of Articles 8 and 9; and Title VII - Authorisation. (Article 2 (8))

Chapter 1 of Title II refers to the General Obligation to register and information requirements, Article 8 refers to Only Representatives and Article 9 to Exemptions from the general obligation to register for product and process orientated research and development.

There are special registration provisions for on-site isolated intermediates and transported isolated intermediates in Articles 17 and 18 of REACH. These can be used if the substances are handled under the specified Strictly Controlled Conditions.

5. The provisions of Titles II (Registration) and VI (Evaluation) shall not apply to polymers (Article 2(9)).

However the monomers or other substances within the polymer will require registration if they meet both the following criteria and have not already been registered by somebody higher up your supply chain:

- o the polymer consists of 2 % weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);
- o the total quantity of such monomer substance(s) or other substance(s) makes up 1 tonne or more per year.

*Note: the advice of the European Commission and the European Chemicals Agency is that this exemption applies **only** when a substance has been fully registered and does not exempt the monomers or other substances used to make the polymer from pre-registration.*

6. Substances used in product and process-oriented research and development (PPORD) (Article 9).

A substance which is manufactured in or imported into the EU for the purposes of product and process orientated research and development is exempt from certain aspects of Registration for a period of 5 years, providing the manufacturer applies to the European Chemicals Agency for this exemption. Further details of how to do this and what exemptions apply can be found in Article 9 of REACH.

7. Substances used as active substances in Plant Protection Products and Biocidal Products (Article 15).

Substances manufactured in or imported into the EU which are used as active substances within Plant Protection or Biocidal Products are deemed to be registered under REACH. These substances must appear on Annex I of the Plant Protection Products Directive (91/414/EC) or Annex I, IA or IB or the Biocidal Products Directive (98/8/EC) or be in the review programme of the relevant Directive.

Non active substances and non Plant Protection/Biocidal uses of active substances are subject to the requirements of REACH.

Annex V exemptions

There are several parts of Annex V which give generic exemptions to substances that meet certain criteria. Details of these are given below:

1. The following substances which occur in nature, if they are not chemically modified:

Minerals, ores, ore concentrates, raw and processed natural gas, crude oil, coal. [Annex V, paragraph 7]

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Notes:

*A mineral is defined as a combination of inorganic constituents as found in the earth's crust, with a characteristic set of chemical compositions, crystalline forms (from highly crystalline to amorphous) and physical properties. In general minerals are inorganic and most of them are crystalline. **Synthetic minerals are not covered by this exemption.***

Ores are the minerals used to obtain metals or mineral aggregates whose mining has an economical benefit. Ore concentrates are essentially processed ores in which impurities and other materials that would not produce any metal have been removed.

Natural gas is a gaseous fossil fuel which consists predominantly of saturated hydrocarbons. Natural gas can have different compositions depending on the source. The exemption covers both the raw and processed (purified for supply) gas

Crude oil is a lipophilic mixture of hydrocarbons which is incorporated into the earth's crust. It is a complex mixture of thousands of organic constituents. Substances present in the crude oil that are derived from the extraction process (e.g. those used as additives in the drilling muds, etc) are impurities in the crude oil and are thus part of the oil.

Substance obtained from the processing and separation of crude oil, the constituents or mixtures of constituents arising from these processes are not included under the exemption.

Coal is the solid fossil fuel formed by carbonisation of plants. All types of coal are covered by the exemption

2. Substances which occur in nature other than those listed under paragraph 7, if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC or with properties that would mean it were categorised as a PBT or vPvB or equivalent concern: [Annex V, paragraph 8]

Notes:

This is a generic exemption and to use it a substance must meet the definitions in Article 3 for 'Substances which occur in nature' and 'Not chemically modified substance' (see below) and not be classified as dangerous or be a so called PBT or vPvB or 'a substance of equivalent concern'. It is important to note that a lack of information on a substance's properties cannot be taken as an indication of a lack of hazard. To do so would undermine the aims of REACH.

3. The following substances obtained from natural sources, if they are not chemically modified, unless they meet the criteria for classification as dangerous to Directive 67/548/EEC with the exception of flammable (R10), as an eye irritant (R36), as a skin irritant (R38), or with properties that would mean it were categorised as a PBT or vPvB or equivalent concern:

Vegetable fats, vegetable oils, vegetable waxes; animal fats, animal oils, animal waxes; fatty acids from C6 to C24 and their potassium, sodium, calcium and magnesium salts; glycerol. [Annex V, paragraph 9]

Notes:

This exemption is not limited to naturally occurring substances in the sense of the definition of Article 3(39). Substances falling under this exemption can be obtained through other processes than those described in Article 3(39), including a chemical modification (e.g. ester hydrolysis to obtain fatty acids). The original source must be a natural material (e.g. plants or animals). In this context, 'not chemically modified' means that the substance covered by this exemption is not further chemically modified (e.g. a fatty acid is only covered as the substance itself and not in any chemically modified form)

*Vegetable fats, vegetable oils and vegetable waxes: Vegetable fats and oils are substances derived from plants that are composed of triglycerides. Nominally, oils are liquid at room temperature and fats are solid. A wax is composed of non-glycerolic esters of long chain fatty acids esterified with long chain fatty alcohols, triterpenic alcohols and sterols. An example for a vegetable wax is carnauba wax. In general, vegetable oils originate from the seeds of oilseed plants, although some other parts of plants may also yield oils. **This exemption does not cover essential oils** (e.g., lavender oil, peppermint oil, etc).*

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Animal fats, animal oils, animal waxes. These are normally rendered tissue fats that can be obtained from a variety of animals. Nominally, oils are liquid at room temperature and fats are solid. A wax is composed of non-glycerolic esters of long chain fatty acids esterified with long chain fatty alcohols, triterpenic alcohols and sterols. Examples of edible animal fats are lard (pig fat), fish oil and butter. Examples of animal waxes are bee wax and lanolin.

Fatty acids are carboxylic acids often with a long unbranched aliphatic tail (chain) which is either saturated or unsaturated. The entry in Annex V exempts fatty acids with chains containing between 6 to 24 carbons, and their potassium, sodium, calcium and magnesium salts. Fatty acids covered by this exemption are only partly available in free form in natural sources like fats and oils but must be obtained from them through ester hydrolysis of the parent glyceride (i.e. the fat or oil).

Glycerol (EC No: 200-289-5, CAS No: 56-81-5) is also commonly called glycerine or propane-1,2,3-triol and forms the backbone of triglycerides bound to a number of fatty acids.

4. The following substances, if they are not chemically modified:

Liquefied petroleum gas, natural gas condensate, process gases and components thereof, coke, cement clinker, magnesia. [Annex V, paragraph 10]

Notes:

Liquefied petroleum gas is generally comprised of the hydrocarbons propane, propene, butane, butene and mixtures thereof. It is extracted as a by-product during the distillation and cracking of crude oil in oil refineries as well as during the processing of raw natural gas. For example, commercially supplied butane and propane mixtures would fall under this category.

Natural gas condensate is a low-density mixture of hydrocarbon liquids that are present as gaseous components in the raw natural gas. It is a by-product of the processing of the natural gas.

Process gases are not naturally occurring substances. The expression 'process gas' can be regarded as an umbrella term for all kinds of gases produced during certain technical processes. Examples of process gases are blast furnace gas, welding fumes, wood dust, soldering fumes, etc.

Cement clinker is a component of cement mixtures. Cement clinker is manufactured by high temperature (1400°-1450° C) treatment of the raw materials limestone, clay, bauxite, iron ore and quartz. This process produces a complex mixture of calcium aluminium silicates. Cement clinker does not have an EINECS number but it is very close in composition to "Cement, Portland, chemicals" (EC number 266-043-4) and/or "Cement, alumina, chemicals" (EC number: 266-045-5).

Magnesia is a natural form of magnesium oxide found as a mineral. It is also called periclase.

Coke is the black, combustible residue from the coking (heat treatment with exclusion of air) of coal. It predominantly consists of carbon. Coke can also be formed from petroleum.

5. The following substances unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC and provided that they do not contain constituents meeting the criteria as dangerous in accordance with Directive 67/548/EEC present in concentrations above the lowest of the applicable concentration limits set out in Directive 1999/45/EC or concentration limits set out in Annex I to Directive 67/548/EEC, unless conclusive scientific experimental data show that these constituents are not available throughout the lifecycle of the substance and those data have been ascertained to be adequate and reliable:

Glass, ceramic frits. [Annex V, paragraph 11]

Notes:

For the purposes of this exemption, glass is considered to refer to those materials commonly called glasses. These materials can best be defined through their starting materials and production process. EINECS has several entries for glasses as follows: Glass, nonoxide, chemicals (EC: 295-731-7), Glass, oxide, calcium magnesium potassium sodium phosphosilicate (EC: 305-415-3), Glass, oxide, calcium magnesium sodium phosphosilicate (EC: 305-416-9) and Glass, oxide, chemicals (EC: 266-046-0).

A frit is a ground glass or glaze used in pottery; some materials have to be fritted before they can be used because they are soluble or toxic. EINECS lists frits under the following entry: Frits, chemicals (EC: 266-047-6).

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The glass and frits substances are very similar in composition and manufacturing process. Only those types of glass and ceramic frits are exempted which do not have any hazardous properties themselves or which do not contain hazardous ingredients above the limits set out in Directive 1999/45/EC or in Annex I to Directive 67/548/EEC. However, this would not apply if conclusive scientific experimental data show that these constituents are not available throughout the life-cycle of the substance and those data have been ascertained to be adequate and reliable. It is the responsibility of manufacturers or importers to assess and document the conclusive scientific data to demonstrate their substance(s) fulfil these criteria.

Man Made Vitreous Fibres (MMVF) included in Annex I to Directive 67/548/EEC are not covered by this exemption as they meet the criteria in Annex VI of that Directive. In addition, MMVF, which are not listed in Annex I to Directive 67/548/EEC, but that meet the criteria for classification as dangerous according to Annex VI of Directive 67/548/EEC are also not to be exempted.

6. Compost and biogas. [Annex V, paragraph 12]

Notes:

This exemption covers compost when it is potentially subject to registration, i.e. when it is no longer a waste, and is understood as being applicable to substances consisting of solid particulate material that has been sanitised and stabilised through the action of micro-organisms and that result from the composting of any bio-waste capable of undergoing aerobic decomposition in its entirety.

Biogas is gas produced by the biological breakdown of organic matter in the absence of oxygen and consists of mainly methane.

Definitions:

Substances which occur in nature: means a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means;

Not chemically modified substance: means a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities;

Further information

For advice on the application of REACH obligations, you can contact the UK REACH Competent Authority's national helpdesk:

Email: UKREACHCA@hse.gov.uk

Website: www.hse.gov.uk/reach

