

An Introduction To European Chemicals Legislation

REACH - Registration, Evaluation and Authorisation of Chemicals

CHCS Members can read a more detailed "[Introduction To The REACH Regulation](#)" and may be interested in "[Tracking Substances Through Regulatory Processes](#)"

The EU's Council of Ministers and European Parliament adopted Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) on 18th December 2006.

The [European Chemicals Agency \(ECHA\)](#), set up by REACH, was established in Helsinki, Finland in June 2008. REACH has since been subject to a number of amendments and adaptations to technical progress.

The registration provisions of REACH were applied in a phased approach, commencing from 1 June 2008. The transitional arrangements for registration of substances ended on 31 May 2018, from which time all substances manufactured or imported into the EU/EEA in quantities of 1 tonne per year or more must be registered.

For further information on REACH:

www.hse.gov.uk/reach/index.htm

www.echa.europa.eu/regulations/reach/legislation

The CLP Regulation

CHCS Members can read a more detailed "[Introduction To The CLP Regulation](#)" and may be interested in "[Tracking Substances Through Regulatory Processes](#)"

In December 2008, Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures, was adopted.

This directly acting Regulation aligns previous EU Directive driven legislation on classification, labelling and packaging of chemicals to the [Globally Harmonised System of Classification and Labelling of Chemicals \(GHS\)](#). The main objectives of the legislation are to facilitate international trade in chemicals, whilst maintaining a high level of protection of human health and environment. GHS is the United Nations system for the classification of hazardous chemicals, and communication to users of these hazards, through standard pictograms, hazard statements and precautionary standards on labels and through safety data sheets (SDS).

For further information on REACH:

www.hse.gov.uk/chemical-classification/legal/clp-regulation.htm

www.echa.europa.eu/regulations/clp/legislation



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The Seveso Directive

Directive, 2012/18/EU on the control of major-accident hazards (COMAH) involving dangerous substances

CHCS Members can read more on "[The Seveso III Directive](#)".

The Control of Major Accident Hazards (COMAH) Directive and UK Regulation transposing the Directive, impose duties on establishments storing or processing quantities of hazardous materials above defined thresholds.

The first Seveso Directive (82/501/EEC) was introduced in 1982, following a chemical accident at an industrial plant in Seveso, Italy in 1976. It was enacted to prevent major-accident hazards involving dangerous substances.

Subsequent amendments to the Directive followed in 1987 (87/216/EEC) and in 1988 (88/610/EEC). Seveso II (Directive 96/82/EC) was eventually adopted following lessons learned from further chemical incidents, the most tragic of which led to the loss of thousands of human lives, when methyl isocyanate gas was leaked from a pesticide plant in Bhopal.

The 2012 revision (Seveso III) was necessary to align the hazard classification criteria to the CLP Regulation. The latest revision to the Directive is transposed into UK legislation, as the Control of Major Accident Hazards Regulations 2015.

To determine whether in scope, organisations must examine their chemical inventories against the qualifying criteria, consisting of volume thresholds of named substances and generic hazard categories. The maximum quantities present, or likely to be present at any one time, including the potential for chemicals to be produced during chemical reaction, whether planned or otherwise must be established.

Mixtures must also be counted when classified in one of the generic categories. In the case of substances or mixtures falling within more than one hazard category, the lowest threshold hazard category must be used.

An establishment may still be in scope even if the threshold is not reached for any named substance or individual generic category, due to the requirement to aggregate similar hazard categories.

There are two volume thresholds for the quantities of hazardous materials, resulting in two categories of scope, lower tier and upper tier. The duties for upper tier sites are more extensive to reflect larger volumes on site, or greater potential for chemical incident. Upper tier sites are subject to more rigorous and frequent inspection regimes.

For further information on the Seveso Directive and UK Regulation:

www.hse.gov.uk/comah

www.ec.europa.eu/environment/seveso

The Cosmetic Regulation, Regulation (EC) No. 1223/2009

CHCS Members can read more at "[Cosmetics Product Regulation](#)"

The Cosmetics Regulation introduced a number of changes from the preceding legislation, Directive 76/768/EC.

Cosmetic products cannot be placed on the EU market, without a designated 'responsible person' located within the EU. The responsible person has a number of duties, including notification of the cosmetic product to the EU cosmetic products notification portal (CPNP) and maintaining a safety report covering the cosmetic product.

Colourants, preservatives and UV-filters, including those that are nanomaterials, must now be explicitly authorised. Products containing other nanomaterials may be subject to a full safety assessment at EU level, if there are safety concerns regarding use in cosmetic products. A number of other important changes were introduced with enactment of the regulation.

For further information on the Cosmetic Products Regulation:

www.ec.europa.eu/growth/sectors/cosmetics/legislation_en

Prior Informed Consent (PIC) Regulation

CHCS Members can read more at "[Prior Informed Consent Regulation](#)".

The import and export of chemicals from the UK is subject to a number of regulations, including the [Prior Informed Consent \(PIC\) Regulation \(EU\) 649/2012](#). This regulation implements the Rotterdam and Stockholm Conventions and controls the import and export of certain dangerous chemicals. In addition, Article 17 imposes more general duties on exporters to provide information to their non-EU customers, including EU compliant labels and safety data sheets, providing these meet the requirements of the importing country.

Additional requirements apply to chemicals that may be used in the manufacture of drugs and chemical weapons. Further information on the import and export of drug precursors can be found on the [Home Office website](#), whilst information on the chemical weapons convention can be found [here](#).

Suspicious enquiries for chemicals that might be used as precursors for drugs and/or chemical weapons should be reported, as soon as possible to the Anti-Terrorist Hotline on 0800 789321. See [National Counter Terrorism Security Office website](#) and [leaflet](#).



CHCS Training

CHCS offers Modular Training Courses on the writing of Safety Data Sheets (SDSs), and related issues such as classification, labelling and other documentation.

For more information see [CHCS Training](#).

If you have any queries about our training, please [Contact CHCS](#).

Chemicals Legislation Support From CHCS

We provide a range of pages on this website that provide you with an introduction to different aspects of chemicals legislation / regulation:

[Legislation \(Introduction\)](#)

[Brexit](#)

[Transport: Modal Regulations](#)

[International Legislation](#)

[GHS Pictograms](#)

[Transport: Model Regulations](#)

[European Legislation](#)

[EU Law Making Process](#)

[Transport: UK Requirements](#)

[UK Legislation](#)

[EH40](#)

For CHCS members only:

[REACH Regulation](#)

[Prior Informed Consent \(PIC\)](#)

[Seveso III Directive](#)

[CLP Regulation](#)

[The Cosmetics Regulation](#)

[Tracking Substances](#)

[EH40](#)