

REACH - Substances of Very High Concern

This leaflet aims to help you understand the requirements under REACH for Substances of Very High Concern (SVHC). It is a starting point to help you understand the extent to which the regulation of SVHC under REACH might impact on the chemicals in your business.

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.

What are SVHC?

In general terms, SVHC are substances that have hazards with serious consequences, e.g., they cause cancer, or they have other hazardous properties and/or remain in the environment for a long time with their amounts in animals gradually building up.

The criteria in REACH, Article 57 for these SVHC are:

- Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction (CMR) category 1 or 2 in accordance with Directive 67/548/EEC;
- Substances which are persistent, bio-accumulative and toxic (PBT) in accordance with the criteria set out in Annex XIII of the REACH Regulation;
- Substances which are very persistent and very bio-accumulative (vPvB) in accordance with the criteria set out in Annex XIII of the REACH Regulation;
- Substances giving rise to an equivalent level of concern to substances meeting the above criteria. Such substances may have endocrine disrupting properties or have properties, that although not meeting the criteria for being a CMR, PBT or vPvB, there is scientific evidence of probable serious effects to human health or the environment. Such substances will be identified on a case-by-case basis.

Substances meeting these criteria may be placed on one or both of two lists that are defined in the REACH Regulation: the so called 'Candidate List' and the 'Annex XIV List'. It is possible that some substances that meet the criteria will not appear on either list.

A potential SVHC may be prioritised by national REACH Competent Authorities, or by the European Chemicals Agency (ECHA) at the request of the European Commission (EC), and a dossier prepared for nomination of the substance for inclusion on the Candidate List. The list of proposed substances is then published on the ECHA website and interested parties are invited to submit comments within a set timeframe. If no comments are received, the substance will be automatically included on the Candidate List. However, if comments are received, ECHA will refer the dossier to its Member State Committee where agreement will be sought as to whether the substance meets the Article 57 criteria. If there is failure to reach a unanimous agreement at the Member State Committee then the EC will prepare a draft proposal on the identification of the substance and a final decision subsequently taken in accordance with the comitology procedure laid out in Article 133.

It is only once a substance is placed on the Candidate List that the specific responsibilities highlighted in this leaflet are placed on industry.

What are the consequences of a substance appearing on the Candidate List or Annex XIV?

1) Duty to communicate information on substances in articles

An 'article' is 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 (see [UK REACH Competent Authority Leaflet Number 9 – Articles](#)).

REACH - Substances of Very High Concern

Suppliers of an article containing a substance that appears on the Candidate List in a concentration above 0.1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of the substance (Article 33). This applies when the article is supplied to recipients who are to use it as part of their work.

Equivalent information should be supplied to consumers (the general public) if it is requested. The supplier has the duty to provide this information within 45 days of receipt of this request.

Section 8.9 of the ["ECHA Guidance on requirements for substances in articles"](#) gives more advice on how to communicate this information.

2) Duty to communicate information on substances in preparations

Suppliers of a preparation not classified as dangerous according to Directive 1999/45/EEC ('Dangerous Preparations Directive') have to provide the recipients on request, with a safety data sheet if the preparation contains at least one substance on the Candidate List, present at concentration of at least 0.1% (w/w) for non-gaseous preparations or 0.2% for gaseous preparations.

3) Duty to communicate information on substances

Suppliers of a substance that appears on the Candidate list have to provide a safety data sheet for the substance to their customers.

4) Notification

Suppliers of articles (see above) containing substances that appear on the Candidate List may need to submit a notification to ECHA.

Notification by the producer or importer of the articles is required under Article 7 (2) when the following conditions are met:

- i. The substance has been included on the candidate list as discussed above **and**
- ii. The substance is present in the articles above a concentration of 0.1% weight by weight (w/w) **and**
- iii. The total amount of the substance in the articles exceeds one tonne per producer or importer per year **and**
- iv. The substance has **not** yet been registered for that specific use.

There may be no obligation to notify if the producer or importer can **exclude** exposure to humans or the environment during normal or foreseeable conditions of use and disposal (Article 7(3)). This can often be difficult to demonstrate adequately and effectively.

Notification of SVHC in articles could be unnecessary in many cases. This is because the substances may have been registered for that use further up the supply chain.

The detailed guidance on substances in articles published by ECHA states that in multi-component articles (e.g., a car, a television, etc) the 0.1% w/w limit applies to the average concentration of the entire article as produced or imported and not the individual components. For example, if one were to import a car, it would apply to the car; however, if one were to import an engine, then it would apply to the engine and so on. A more detailed example on calculating the amount of these SVHC in articles is given in the [ECHA guidance](#).

Typically, a notification would include the company's details, the identity of the substance, its classification and labelling, and a brief description of the use of it in the article and the uses of the article (Article 7(4)). ECHA may then choose to review a notification and may require producers or importers to submit a registration (if one has not already been received) subject to all the conditions laid out in Article 7(5).

REACH - Substances of Very High Concern

Notification will need to be made from 1st June 2011 and thereafter at the latest 6 months after the substance has been included on updates of the Candidate List (Article 7(7)). No notifications are due before 1st June 2011

5) Authorisation

Probably the most critical aspect in relation to SVHCs is that some may need to be authorised for specific uses. The first proposed list of priority substances that will be subject to authorisation (known as Annex XIV) will be published at the latest by 1 June 2009 by ECHA. This will be drawn from the [Candidate List published by ECHA](#). The Candidate List will be updated regularly through the procedure described above.

The only way it will be possible to use substances listed on Annex XIV will be to obtain an authorisation from the EC. There will not be any sort of “blanket” authorisation for a substance to be used generally. Instead, companies that register or use the substance will have to apply for authorisation for specific uses. When a substance is placed on Annex XIV a ‘sunset date’ will be set after which its use will be prohibited unless an authorisation has been granted for that use. An application for an authorisation must be made not less than 18 months before its sunset date. There will be a significant charge to apply for authorisation (see the [REACH fees regulation](#)), and application in itself does **not** guarantee that an authorisation will be granted. Authorisations that are granted are ‘time limited’ and will need to be renewed, and in addition they can be reviewed at any time during the authorisation period.

Authorisation decisions will be made by the EC, who will be advised by ECHA and its Risk Assessment and Socio-Economic Analysis Committees. Briefly, an authorisation can be granted in two ways:

1. The use of the substance is considered safe as long as the risks are adequately controlled, and the conditions of the authorisation are met, or
2. The use of the substance can be demonstrated to be so important on socio-economic grounds that its continued use outweighs the risks to human health and the environment.

Either way, those applying for authorisations must provide an assessment of whether other, less hazardous, substances could be used as viable alternatives. If there are suitable alternatives, the authorisation application should include a plan for phasing out the hazardous substance (known as the ‘substitution plan’). Where alternatives are not yet available, evidence of a research plan aimed at developing alternatives should be included.

Further information

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

Email: UKREACHCA@hse.gsi.gov.uk

Website: www.hse.gov.uk/reach

