

An Introduction to Reach Regulations

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The Reach Regulation (EC) 1907/2006

Chemicals are indispensable in our society. They play an important role in the economy. There are international rules to assess, control and reduce the risks of chemicals. On June 1, 2007, the ‘new’ European Chemicals Regulation (EC) 1907/2006 commonly referred to by the acronym ‘REACH’ came into force. The REACH Regulation aims to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances. This is done by the four core processes of REACH, namely the Registration, Evaluation, Authorization and Restriction of Chemicals.

It is important to understand how the European REACH legislation on chemicals can affect companies throughout the supply chain.

The regulation fundamentally changed the way that chemicals were regulated in the region

With the launch of REACH, this principle was significantly changed, effectively meaning that chemical manufacturers and importers had to demonstrate to the regulators that the substances they supplied did not pose unacceptable risks to human health or the environment.

It is important for each organization to identify its role within the REACH process in order to determine what actions it would need to take. There are four major categories, and it is possible for any organization to be more than one. Some larger organizations may have responsibilities under all four:

- Chemical manufacturer or importer: Any company manufacturing chemicals in Europe (which are prepared from raw ingredients –

whether mineral or organic), or importing chemicals into Europe, will need to register each chemical it manufactures or imports. For the purposes of REACH, an importer of a chemical has the same obligations as that of a manufacturer.

- Supplier of preparations: A ‘preparation’ is a mixture of chemicals. In the case of a preparation, each individual chemical present should be registered separately. Examples of preparations could include waterproofing sprays, cleaners and leather polishes. Any substance that is supplied in quantities of one tonne per annum or greater by a single company will require registration, if present as an individual chemical or as part of a preparation.
- Downstream users: Chemicals and preparations can be used to make products. During this process, the workers in factories that use these are referred to as ‘downstream users’. REACH requires detailed information on the exposure of downstream users to be available as part of the registration process. Therefore, chemical suppliers need to understand how their products are being used by their industrial customers, in order for them to supply relevant and accurate information.
- Suppliers of articles: This category is for the companies that are producing physical products or materials in the EU, or importing them into the EU. It includes footwear and other consumer goods, as well as tanned leathers, finished textile clothes and components. There is no need to register, but there are two distinct sets of requirements that apply to substances in articles.

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In REACH, these are covered by Annex XVII (mandatory restrictions) and the Candidate List of Substances of Very High Concern (SVHCs).

If anyone needs to identify whether any of the SVHCs (Substances of very high concern, as defined under REACH), are contained in an article or in a chemical mixture, following procedure can be adopted:

Compliance can be demonstrated through a programme of check testing, or by a comprehensive audit of the raw materials and production processes used.

STEP 1

Theoretical assessment, based on information from your supplier:

Does the supplier communicate the presence or not of any SVHC in the product?

If not: Is there any probability that SVHC are present in the product taking into account:

The materials used;

The manufacturing procedures applied;

The suppliers involved.

If the presence of candidate substances is confirmed or has to be suspected:

Will the threshold of 0,1 mass% of each SVHC be exceeded?

Is there a ban or any other restriction of that SVHC in chemical mixtures or for manufacturing process?

In addition, Chemical Assessment to identify potential risk materials due to the likely presence of restricted/hazardous substances in each of the materials listed in your product's bill of materials

STEP 2

If information from step 1 results in an unclear situation, testing may be needed.

This can be the case if no information is available, e.g. if the supplier does not reply, or if there are doubts on reliability of existing information.

A test is performed for identification and quantification of any SVHC in the article or in the chemical mixture. The test program will be different per material (e.g. plastic, glass, wood, metal, etc.), based on general knowledge on which SVHC could be part of which basic material. Similar materials can be grouped together and considered as one testing sample.

This test can deliver the information of whether the threshold of 0.1 % per SVHC in the article is respected, which can help you to identify if you have to fulfill certain legal obligation (communication or notification) according to REACH.

In both case, it is essential to have a clear understanding of the product and good communication and cooperation throughout the supply chain. This is because not all of the 69 entries are applicable to all product types. Some entries are specific to certain types of material, due to the chemical reactions involved in the production process, while others will only be present if certain treatments have been applied. It is therefore crucial to have an understanding of how various materials are used in the construction of a product in order to develop a targeted approach to check testing, or to organize a thorough and efficient audit.

Manufacturers and importers of substances and chemical mixtures have to register all chemicals at the European Chemical Agency (ECHA) if produced or imported in the EU in an amount of >1 tonne per year.

How Reach Annex XVII Applies to the Manufacture of Consumer Products

The main entries in Annex XVII for textiles, leathers and polymers are brief in table 1.

Table 1: Key restricted substances relevant to consumer goods

Material	Applicable restricted substances	Annex XVII entry number	Maximum permitted limit
Textiles	Aromatic amines (azo dyes)	43	30mg/kg
	Organotin compounds	20	1,000mg/kg
	Perfluorooctanoic acid (PFOA) – only applicable if a repellency treatment has been applied	68	25µg/kg
	Formaldehyde	72	75mg/kg
	Nonylphenol ethoxylates	46	100mg/kg
Leather	Aromatic amines (azo dyes)	43	30mg/kg
	Organotin compounds	20	1,000mg/kg
	Perfluorooctanoic acid (PFOA) – only applicable if a repellency treatment has been applied	68	25µg/kg
	Dimethyl fumarate	61	0.1mg/kg
	Pentachlorophenol	22	1,000mg/kg
	Chromium VI	47	3mg/kg
Polymers	Organotin compounds	20	1,000mg/kg
	Cadmium	23	100mg/kg
	PAHs	50	100mg/kg

Restricted Substances in Plastics and Polymers

Polymeric materials such as plastics and rubbers have very different compositions. Therefore different chemicals types are used in the manufacturing process of polymers. The difference is the use of pigments rather than dyes to add colour to polymeric materials. This means that testing for aromatic amines derived from azo dyes is not applicable. The pigments used may contain other restricted chemicals, such as the metallic element cadmium. This is commonly used in certain pigments, and can also be used as a stabilizer in the formulation. Cadmium is toxic to humans and is classified as a carcinogen. Like Pentachlorophenol, it is also a bio accumulator, and so presents environmental concerns. Because of these factors, it is restricted to less than 100mg/kg in plastics and synthetic rubbers.

Another family of restricted substances which may be present in polymeric materials are polycyclic aromatic hydrocarbons (PAHs). These substances are naturally in coal, crude oil and petrol, and they can also be formed during the incomplete combustion of fossil fuels. Therefore they could be present as impurities in carbon black pigment or extender oils. They would not be intentionally introduced during manufacturing, but arise as contaminants. As a result, chemical testing is recommended to show compliance. PAHs are suspected of causing cancer through long-term exposure, and they

are restricted in materials which come into long term contact with the skin, as well as in materials which have repeated, short-term skin contact. There are eight PAHs listed in REACH Annex XVII, all of which are restricted to less than 1mg/kg.

The majority of the substances listed in REACH Annex XVII are incorporated into products as a result of contamination, or from chemical reactions occurring during or after the production process. A select few of the chemicals listed may be, however, purposely added to the product in order to confer desirable characteristics. Examples include the use of dimethyl fumarate (DMFu) as a biocide to prevent mould growth during transportation and the application of perfluorooctanoic acid (PFOA) as a water or stain repellency treatment. In 2009, DMFu was considered to be the cause of a series of very severe allergic skin reactions in upholstered leather furniture, and an immediate ban on the substance was implemented. Following evaluation, DMFu was added to REACH Annex XVII in 2012, with a maximum permitted limit of 0.1mg/kg. PFOA is one of the more recent additions to Annex XVII. This chemical is a carcinogen, and is also highly persistent in the environment and within the human body. As a result, it will be restricted to a maximum of 25µg/kg in final products from July 2020.

Another prominent example is the use of flame retardants to improve flammability performance. The use of these chemicals is often needed to safeguard consumers against the risks of flammable materials in products such as domestic furniture or protective garments for firefighters. However, studies have shown that certain brominated flame retardants have toxic properties and can build up in fatty tissues within the human body. For this reason, two of these flame retardants, octabromodiphenyl ether and decabromodiphenyl ether, are restricted to a maximum of 1,000mg/kg in final products.

Because chemicals present in treatments will only be present in products if they have been deliberately introduced, they do not need to be considered if the supplier can confirm they have not been used. This is a good example of a case where cooperation across the supply chain can help to inform the strategy for demonstrating compliance.

REACH Annex XVII is continuously developing and additional substances are regularly added to the list as ‘substances of very high concern’ (SVHCs) are evaluated and other potentially hazardous chemicals are identified. A significant update to Annex XVII was the addition of entry 72, which was published in October 2018, and will come into force in November 2020. This imposes restrictions on a number of chemicals that are carcinogenic, mutagenic or toxic for reproduction in clothing, footwear and textiles which come into contact with the user’s skin.

One of the most significant additions to Annex XVII included within entry 72 is formaldehyde, as this will be the first European-wide restriction imposed on this substance in articles. Formaldehyde may be used in the textile industry to improve the resistance to creasing, and can also be used as a preservative – particularly for natural textiles. Nevertheless, at high concentrations, formaldehyde is capable of causing severe skin burns or damage to the eyes. Even at low concentrations, formaldehyde presents a risk to human health, as it is a prevalent allergen and some individuals are allergic even at very low concentrations. The maximum permitted amount of formaldehyde in textiles will be 75mg/kg as per the entry number 72.

The purpose of REACH Annex XVII is to protect consumer health and the environment by placing restrictions upon harmful chemicals in consumer products. Manufacturers, importers and distributors have a legal obligation to meet the requirements specified in Annex XVII, and retailers also have a responsibility to make sure that they only place compliant products on the market.

References:

1. <https://echa.europa.eu>
2. Satra Spotlight Articles