

REACH and suppliers of articles

Introduction

Although REACH is an EU chemicals' management regulation it also affects companies who make, and indeed, supply articles. A small number of articles' producers and importers may have been affected by pre-registration and registration duties where substances were intended to be released during use; reaching much further are the aspects of REACH which regulate chemicals of concern in products. This guide sets out the main features and the obligations of suppliers and has been updated in light of the ECJ Ruling on SVHCs in articles on 10 September 2015.

Registration

The duty to submit a registration to the European Chemicals Agency (ECHA) applies on at a substance level, meaning an article itself does not need to be registered. Where an article is actually a container or carrier of chemicals such as in the case of a marker pen or wet wipe, the article and substance/mixture are to be considered separately. Registration duties may apply to the substance/mixture component, but this guidance focuses on the article itself, i.e. the casing of the pen and the woven fabric of the wipe in the above examples.

When an article is not deemed to be a carrier or container of a substance or mixture, we regard it as an article with integral chemicals. An example would be pipes or guttering made from coloured PVC. In those circumstances, an article producer or importer would only need to register component substances provided **both** the following conditions apply:

- the substance(s) is intended for release under normal or reasonably foreseeable use of the article but is not necessarily the primary function of the item; and
- the total quantity of the substance(s) within all articles from which it is released exceeds one tonne per year.

Where these conditions are met, registration of the substance follows the same process as that for any other registrant. The registration applies only to the substance(s) being released, not to the full chemical composition or to the article in its entirety.

In practice, there are very few situations in which registration is required due to intended release, the most notable examples being fragranced consumer products such as coat-hangers, drawer liners, and moisturising socks and gloves. Unintended releases or those due to wear and tear do not require registration by the article producer or importer (unless they are manufacturing or importing the substances in their own right in chemical form).

ECHA may also require a registration is made in other circumstances, if they feel an unintended release from an article presents a risk to human health or the environment.

Substances of Very High Concern

One of the fundamental principles of the REACH Regulation is to encourage innovation and change to safer alternatives and technologies where substances have the potential to cause significant harm to human health or the environment. The first step in facilitating substitution is for ECHA to identify substances of very high concern (SVHCs). SVHCs are identified through their inclusion in the 'Candidate List', which is usually updated in June and December each year. Presence of a substance on the Candidate List prompts immediate duties for the information disclosure along the supply chain and to ECHA.

Article 7(2)

Within six months of a substance being added to the Candidate List, an EU producer or importer of an article containing the SVHC in concentrations above 0.1% by weight must notify ECHA where the total quantity of that substance in those articles exceeds one tonne per year. There are exemptions if the substance has already been registered for that use, or if the producer or importer can exclude exposure throughout the lifecycle of the article (including disposal).

In the case of complex (multi-component) articles, the European Court of Justice ruled (Case C106/14) on 10 September 2015 that each of the articles incorporated as a component of a complex product is covered by the relevant duty to notify and communicate when they contain an SVHC above 0.1% by weight. The ECJ's judgement is based on a premise of 'once an article, always an article', i.e. that assembly does not mean that component parts cease to be articles in their own right. However, we also note that a complex article producer's notification obligation does not extend to the component articles which were produced by a third party (i.e. upstream supplier) and applies only to those articles it makes or assembles itself.

Article 33

In addition to the duty of importers and producers to notify ECHA, any EU supplier of an article containing more than 0.1% w/w of a substance listed on the Candidate List, must provide, electronically or on paper, relevant safety information (as a minimum the name of the SVHC). This information must be given automatically to business recipients of that article once a substance is added to the Candidate List, and reactively to consumers within 45 days of such a request. In the case of complex articles, in light of the ECJ's judgement, our interpretation is that the disclosure obligation applies at both the component level and to the product as a whole.

Note that the Article 33 duty is linked to supply rather than production or assembly; where relevant, disclosure is still required if the article was produced prior to the inclusion of the substance on the Candidate List.

Although inclusion in the Candidate List does not automatically mean a prohibition on the substance's use or supply, many downstream companies and sectors regard the Candidate List as a "blacklist", seeking to replace SVHCs with less hazardous alternatives. It is therefore important to consider the potential impact on supply, as well as the legal implications, when acknowledging the presence of an SVHC in a substance.

Authorisation

Some Candidate-Listed substances may also be included in Annex XIV, which lists substances subject to authorisation – it's often referred to as the Authorisation List. From the relevant “sunset date”, the EU/EEA use and supply for EU/EEA use of a substance on the Authorisation List requires authorisation from the European Commission, unless an exemption applies or a valid application made before the “latest application date” is still pending. Unlike with registration, there is no tonnage threshold applied to authorisation.

Imported articles containing substances in Annex XIV do not need authorisation: the authorisation process does not cover import or use of articles containing substances on the Authorisation List. When substances are added to Annex XIV however, they remain on the Candidate List, and the duties for notification and communication still exist.

Some substances, or their uses in articles, may also be subject to a restriction under REACH. Restricted substances and categories are listed in Annex XVII to REACH; any producer, importer, supplier and distributor of articles covered by the restriction must comply with its requirements.

Managing compliance

There are some steps that may help you meet your obligations:

- If manufacturing articles in the EU/EEA: consider working towards substitution of SVHCs on a voluntary basis, so that if they are eventually subject to further regulation, your company – and your supply chain – is prepared;
- If importing articles, ask your non-EU/EEA suppliers to help you identify if SVHCs are present.
- Consider substitution as a collaborative project within your supply chain;
- Inform your business customers about any Candidate-Listed substances above 0.1% w/w in the articles you supply and comply with any relevant Annex XIV or XVII conditions;
- Be prepared to answer questions from your customers. All questions, and responses, may be useful records to show you are doing your best in attempting to find out what is in the products you supply and to communicate with your suppliers and customers;
- Commercial software, such as Bill of Substance systems, may help track substance use in the supply chain; REACHReady has Approved Service Providers who can help!

Need further help?

If you need help understanding the impact of REACH on your business, you can get advice by emailing our Helpdesk at enquiries@reachready.co.uk or calling +44 (0) 207 901 1444. Alternatively REACHReady run regular training events specifically aimed at suppliers of articles which you will find details of on the website at www.reachready.co.uk/events.

If your customers or suppliers need help, get them to sign up to REACHReady's Gold service at <http://www.reachready.co.uk/> and let us help them too!

If you need an IT tool to help you track and manage substance information within your supply chain, contact the helpdesk and ask for our Matchmaker service.