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REACH Update

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What is REACH?

The REACH Regulation is an environmental legislation passed by the European Union that attempts to regulate the large number of chemicals on the market that were in use before the most environmental and health legislation was enacted. The framework of REACH is Registration, Evaluation, Authorization, Restrictions, and Enforcement. The identification and characterization of SVHC is covered under the Authorization framework.

The purpose of Authorization is to ensure that risks of substances of very high concern (SVHC) are properly controlled and mitigated and that these substances are eventually replaced.

What is SVHC?

A substance of very high concern (SVHC) is a material for which it has been proposed that the use within the European Union be subject to authorization under the REACH Regulation. The rationale for the authorization is that the current restrictions on the use and disposal of these SVHCs is insufficient. The listing of a chemical on the SVHC Candidate List is a first step in the Authorization Process. European Union members can petition the European Chemicals Agency (ECHA) to add materials to SVHC Candidate List. The current candidate list is provided at http://echa.europa.eu/web/guest/candidate-list-table.

Some substances from the candidate list will be prioritized for authorization and be included in Annex XIV ("SVHC authorization list"). Those substances on the authorization list will not be allowed to be used, placed on the market or imported into the EU after a date to be set unless the company is granted an Authorization. As of April 2013, there are 151 substances on the SVHC candidate list and 22 substance on the SVHC authorization list.

Once a material is identified as a SVHC and placed on the candidate list, suppliers of articles with more than 0.1% by weight of any SVHC must provide their customers with a safety data sheet on request[1]. Manufacturers or importers of articles containing more than 0.1% by weight of any SVHC must provide their customers, and consumers on request, with adequate information on the safe use and disposal of the article, including the name of the SVHC(s) concerned[2]. From 1 June 2011, manufacturers and importers of articles also have to notify the European Chemicals Agency of the quantities of SVHCs used in their articles[2].

If you produce or import an article you will be required to 'notify' the ECHA if the article contains an SVHC on the candidate list if both the following conditions are met:

(a) the substance is present in those articles in quantities totaling over 1 ton per producer or importer per year; and
(b) the substance is present in those articles above a concentration of 0.1 % weight by weight (w/w).

[1] Article 31.3, REACH Regulation, at p. 108.
[2] Article 7, REACH Regulation, at pp. 63–66.

What is an Article under REACH?

REACH defines an article as:

> *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 [Article 3 Definitions, Section 3, page 20]*

Unfortunately, that definition is relatively vague and provides limited clarity. As a result, a number of organizations have tried to provide a more specific definition or some well-defined examples. The European Chemicals Agency (ECHA) states[3]

> *An article is generally understood to be an object composed of one or more substances or mixtures given a specific shape, surface or design. It may be produced from natural materials <sic> or from synthetic ones <sic>. It may be very simple <sic>, but can also be very complex, like a laptop computer, consisting of many parts. Most of the commonly used objects in private households and industries are articles, e.g. furniture, clothes, vehicles, books, toys, kitchen equipment and electronic equipment [Guidance on Requirements for Substances in Articles]*

The United Kingdom Health and Safety Executive provides additional guidance in their Information Leaflet #9[4]:

> *An article is usually considered a finished product. Examples that have been used include a telephone, a chair and a car. However, a car is an article made up of other articles, such as wheels, seats, etc.*

However, REACH authorities[5] in Belgium, Denmark, France, Germany, Norway, and Sweden reject the interpretation by ECHA.

> *Once an object during production has become an article of its own, it will remain an article until it eventually becomes waste after end use. This means that when two articles are joined to form an assembled article, they both maintain their status as articles and the 0.1% trigger limit thus apply to each object – within an assembled article – that fulfils the definition of an article in REACH, and that was an article already before the assembly.*

[3] Guidance on requirements for substances in articles, Version 2, ECHA, April 2011 (ECHA-11-G-05-EN)
[4] UK Competent Authority Information Leaflet Number 9 – Articles – Nov 2012 – Version 3.0
[5] Guidance for Suppliers of Articles, The Reach Duties To Inform About Candidate List Substances, July 2013

Who Decides What is an Article?

While the manufacturer makes the decision on what is an article, industry associations can have an important role to play in ensuring the consistency of decisions made by different companies. Regardless of the process on how an article is identified, it is recommended that the justification for any decision be documented.

How an article is identified is critical when determining if the level of SVHC's exceeds 0.1 wt%, as the 0.1 wt% relates to the whole article as imported. This is true even in the case of a complex article that is made up of smaller articles. For example, a car is an article. Therefore, the 0.1 wt% limit for SVHC's applies to the entire car, even if the seats inside the car are above 0.1 wt% SVH.

However, if individual components of the car are imported separately and assembled in the EU, then it is the weight of each individual component that must be considered[6].

Why do I care about the Definition of an Article?

Due to this confusion in Article Definition, companies have found that different test labs will take different approaches in regards to assessing REACH compliance. Some labs will recommend digestion of your entire product. This is will tend to be lowest cost approach and the one to least likely to measure substances of concern about the 0.1 wt% limit. However, it also brings some risk as there may be some European agencies that will reject the results of the assessment. The alternate approach, which separates the product into different articles, can result in wildly different costs and approach depending interpretation (especially for very complex systems).

In one case study, a manufacturer sent its system to two different test labs for an initial REACH assessment. The first lab broke down the product into three (3) articles: the main system, all the accessories, and the packaging. The second lab broke down the product into almost 25 different articles, resulting in a significant increase in cost and very different results for substances of very high concern.

How are Substances of Very High Concern Identified?

Depends if the substances are inorganic or organic. Inorganic substances tend to be digested followed by Inductively Coupled Plasma (ICP). Organic substances are subjected to solvent extraction and analysis using some combination of gas chromatography mass spectroscopy (GC/MS), liquid chromatography mass spectroscopy (LC/MS), and gas chromatography with electron capture detector and flame ionization detector (GC-ECD-FID).

The limitation of the approaches used for inorganic substances can immediately be seen, as the substances detected are simply elements and not the actual substance itself. Therefore, depending on the weight percent of certain elements, additional test and measurement may be necessary.

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[6] UK Competent Authority Information Leaflet Number 9 – Articles – Nov 2012 – Version 3.0

Detection of organic substances can be more straightforward in terms of reporting, since the techniques can report the actual chemical formulation. However, regardless of whether organic or inorganic, OEMs can save themselves from substantial cost and delay if they apply some common sense and skepticism to any chemical measurement results.

As one example, a test lab reported the detection of lead (Pb) in a BNC cable. They claimed that the Pb could be lead(II) bis(methanesulfonate), lead oxide, or lead tetroxide and therefore additional, more expensive testing would be required. However, Pb in a BNC cable is limited to a number of sources, including SnPb solder used to attach the connector to the cable or an alloying element in brass or phosphor bronze.

In another case study, a test lab reported detecting approximately 0.3 wt.% of DEHP in a PVC hose. As stated by ECHA, '*DEHP has been the main "general purpose" phthalate used over the last 50 years*'[7]. And phthalates are the most common type of plasticizers, especially for polyvinyl chloride (PVC). However, the concentration of DEHP is far lower than expected for a plasticizer, which would be between 10 to 40% for a PVC application[8]. This strongly suggests an error in the analysis results.

Conclusion

In conclusion, OEMs must play an active role in the analysis and interpretation of any REACH compliance activity. A little due diligence, and common sense, upfront can save a significant amount of time and resources later on in the process. For more information or for assistance in the REACH process, feel free to contact DfR Solutions.

[7] European Chemicals Agency, Evaluation of New Scientific Evidence Concerning the Restrictions Contained in Annex Xvii to Regulation (Ec) No 1907/2006 (Reach), Review of New Available Information fo bis (2-ethylhexyl) phthalate (DEHP), Review Report, July 2010

[8] R. Stringer et. al., Concentrations of phthalate esters and identification of other additives in PVC children's toys, J Environmental Science and Pollution Research, V 7, N 1, pp. 27-36