Reach Information Responsibilities

Safety Data Sheets and Beyond

Best Practice Solutions - After the enforcement of the Regulation (EC) No. 1907/2006 (Reach) in 2007, and now after the end of the first registration deadline in 2010, the industries have gathered lots of experience how to deal with the legislation. But there are left some tasks in the process where best practice solutions are still needed. One of those issues is how to provide supply information up and down the supply chain fully compliant to Reach.

Since Reach expects the exchange of substance information up- and downstream, companies have to face the challenging task of providing and requesting Reach-compliant information to their customers and suppliers. That information relates to the registration status; the substances properties and hazards; the safety and handling information; and the presence of substances of very high concern (SVHC) placed on the European Chemical Agency's (ECHA) candidate list or already listed in Reach Annex XIV as substances subjected to authorization.

Different Roles, Different Obligations

An EC resident legal entity may face very different information obligations. This is dependent on their individual Reach role as manufacturer or importer; downstream user or distributor of chemicals; only representative (OR); and/or producer or importer of article. It is also dependent on the Reach status of their products as substances or isolated intermediates, mixtures or articles.

These obligations for information in the supply chain specified by the Reach title IV with the Articles 31 to 36. The need for information is not only due to the individual obligations, but also for securing the future availability of substances. Thus the correct style to provide the required information also is very important. A graphic overview on the information obligations can be found on www.fit4reach.eu/files/sdb.pdf.
Manufacturers and importers of chemicals (substances, intermediates or mixtures) with residence in the EC have to pre-register and register all manufactured or imported substances - or cease their production or import.

If manufacturers and importers are placing a hazardous substance or preparation on the EC market as suppliers, according to Reach Article 31 they shall provide the recipients of the chemicals with a safety data sheet (SDS), and this SDS shall be worked-out by a competent person.

The SDS must meet the structure required by Reach Annex II and should cover all information on the substance's properties and hazards; risk descriptions and measures sufficient for safe handling; the registration status and registration number; and also possible restrictions and administrations of the substance. The SDS can be submitted to the recipient on paper or electronically. The Annex II meanwhile was amended by the Regulation (EC) No. 453/2010.

After the executed registration of a hazardous substance, the SDS information must correspond to the information submitted in the registration process, especially to the information of the chemical safety report (CSR). At a market level of 10 tons or more per year, the SDS has to be supplemented with an annex containing the exposure scenarios (ES) covering all identified uses of the substance.

Downstream users and distributors of chemicals are also obliged to provide their recipients with SDS according to Reach Article 31 and Annex II, but they usually depend on information from their upstream suppliers. If these upstream suppliers are not resident inside the EU, and the chemicals are subject of imports and thus the distributors become importers, then a double-burden of registration and information obligations may occur.

**Only Representatives**

Since Reach does not apply outside the EU, entities located abroad have no obligations. But according to Reach Article 8, a manufacturer of chemicals outside the EU may appoint an natural or legal person resident in the EU to act as only representative (OR). In place of the manufacturer outside the EU, the OR is enabled to perform registrations and other obligations of the title II of Reach, e.g. to submit information and notifications to the ECHA. The previous importers must be informed about this appointment, since within this appointment they are exempted from the registration obligations and become downstream users again.

The OR is not a supplier, distributor or importer of chemicals, and it does not place
chemicals on the EC market. It is supposed to be a pure service provider and data manager, and it also has no trade relations with the EC importer. Thus, the obligation to provide the recipients of the chemicals with SDS according to Article 31 and Annex II still remains with the former importers who place the chemicals on the market. The OR may provide relevant information and may support or work-out a SDS, but it is not the responsible editor and supplier.

If the chemicals - substances and mixtures - placed on the market are not hazardous, and the mixtures are not hazardous and do not contain hazardous ingredients above specified concentrations, then neither safety data sheets (SDS) nor exposure scenarios (ES) on all identified uses are required. But according to Reach Article 32, the supplier shall provide the recipients with information on the registration, including the registration number; on the restriction or authorization status; use conditions; and risks and risk-management measures. This information can also be submitted to the recipient on paper or electronically.

SVHC

Moreover if articles, e.g. paper products or textiles, household plastics or toys, technical hardware or devices, contain substances of very high concern (SVHC) above 0.1% which are referred to the ECHA candidate list, according to Reach Article 33 the professional recipients (immediately) and the private consumers (on demand within 45 days) of the article must be provided with information on the identity of the SVHC, and also on the conditions of safe use.

In both the cases of non-hazardous chemicals and articles of course no legal obligation exists to submit a safety data sheet (SDS) according to Reach Article 31 and Reach Annex II. But it may be a very attractive option to fulfil the information obligation from Reach Article 32 for non-hazardous chemicals and from Reach Article 33 for SVHC-containing articles by issuing and submitting a product safety data sheet (PSDS) following the structure and content of the Reach Annex II, joining legal compliance with practise oriented design and marketing functionality.

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