Article suppliers and REACH: a challenge

The REACH Regulation involves complex issues, even for those with no direct registration requirements

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One of the main purposes of REACH is to "ensure a high level of protection of human health and the environment" from the hazards of chemical substances. It appears at a first glance that this Regulation only concerns companies that deal with these and their products, but in fact it also covers chemicals in mixtures and articles.

REACH is also not only about the 'R' - registration - but also the 'E' and 'A', evaluation and authorisation. Not covered by the acronym, but of no lesser importance is restriction of the use of substances, which is explicitly mentioned in the full title of the Regulation. Obligations related to the authorisation procedure and use restrictions, in particular, have a potential impact on article suppliers.

Substances classified under the CLP Regulation as carcinogenic and mutagenic classes 1A and 1B or toxic to reproduction class 1A (CMR), or which are persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB), are considered as substances of very high concern (SVHCs) under REACH Article 57. Other substances with properties of similar concern may also be considered as SVHCs.

Such substances may be identified as candidates for authorisation and included in the so-called candidate list, making them subject to special information and notification obligations under Articles 7 and 33 of REACH. The article producer must notify Echa of the use of any candidate substance in an article at above 0.1% w/w.

In September 2015, the European Court of Justice ruled that the 0.1% threshold applies to each article in a complex product. This is one of the most challenging tasks for suppliers, since they need confirmation of every single article in a complex product if there are candidate substances above the threshold concentration.

Supply chain communication

Within the supply chain, the obligation to provide information is mandatory and flows from the top downwards. Consumers also have the right to know about the presence of candidate substances above 0.1%.

However, Article 33 only requires communication if such substances are present above the threshold. Hence, there is always some uncertainty within the supply chain as to whether there are indeed no candidate substances present or whether communication about them was simply overlooked.

Communication can be especially difficult for supply chains with suppliers from outside the European Economic Area (EEA). Non-EEA suppliers may not be aware of REACH duties, since these do not apply directly to them and communication on substances in articles may be incomplete.

If a single company within the supply chain does not communicate, every company further down might potentially be out of compliance with REACH. Therefore, the general recommendation is to be proactive in communicating. An article supplier should obtain the information on candidate substances present above the threshold. Explicit information on their absence is also very helpful in monitoring the composition of a REACH-compliant product.

At Chemical Watch's Enforcement summit in Brussels on 13-14 November, enforcement authorities reported that their target is the presence of candidate substances, not information about them.

Therefore, the article supplier is liable even if no information is available. It was also stated that any efforts undertaken to obtain such information will be taken into account but this will not remove this responsibility.

Beyond the list

Unfortunately, there are other obligations to fulfil, though they may not be as prominent as those described in Articles 7 and 33. The article supplier should not only keep an eye on the list of candidate substances but Annexes XIV and XVII too.

Candidate substances that were included in Annex XIV are subject to authorisation. After the so-called sunset date, it is forbidden to use the substance alone or in a mixture without specific authorisation for it. Furthermore, this is also true for articles.

Therefore, article producers in Europe need to be aware of the presence of substances listed on Annex XIV and to ensure that their use is covered by an authorisation as soon as the sunset date for them has passed. In this case, there is no 0.1% threshold concentration; the substance must not be present in the product at all. Again, this is especially difficult where the raw materials are imported from outside the EEA.

Other substances are already restricted and included in Annex XVII, where the European Commission is convinced that such uses always present a risk to human health and the environment. For example, chromium trioxide in concentrations above 3mg/kg in leather goods and lead or cadmium in jewellery in concentrations above 0.05% and 0.01% respectively, are forbidden. Products in violation of restrictions under REACH may be withdrawn from the market and the reputation of the supplying company may suffer.

Beyond substances

To fulfil their obligations under REACH, companies producing, importing or distributing articles need very specific information from their suppliers about the products they use as raw materials. In the easiest case, where an article producer only obtains raw materials as substances or mixtures from European suppliers, the supply chain has already taken care of all information required and can pass this down.

The most complicated cases are where a distributor or retailer obtains complex products from distributors outside the EEA. In such cases, the company must then not only collect all relevant information needed to be aware of all obligations, it has to be able to explain why it is needed from upstream in the supply chain. Often suppliers outside the EEA do not know or will not state what substances are used in the articles.

According to Article 8 of REACH, a non-EU company that manufactures substances or substances in mixtures or articles, or which formulates a mixture or produces articles, may use an only representative (OR) to fulfil all of its obligations under REACH. Although this is commonly used as a way of removing registration burdens from importing clients, less attention is paid to the possibility for article producers outside the EEA.

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Chromium trioxide is already banned above certain levels in leather goods

Establishing an OR for article obligations enables the producers to share business-critical information without giving this data away to clients. The OR can check the products for REACH compliance in direct discussion with the producer and provide confirmation of this to the clients. However, this only works for article producers, which by definition make or assemble articles. Distributors and retailers generally cannot use an OR.

How to get information?

To obtain the information you need, you first have to know the questions to ask. Hence, you need to make yourself aware of all obligations that may apply to your products. These may not only be REACH obligations; other regulations and directives, such as RoHS, the toy Directive and the cosmetics Regulation, may also require specific knowledge about the products. If you are not certain what questions need to be asked, get help from authority helpdesks, business associations or consultancies.

Compile a compliance statement that addresses all the required questions, to ensure regulatory compliance. You may do this independently or get help from service providers familiar with such questionnaires. Analyse your supply chain and ask the right people. Be prepared to explain why you need the information.

Should the supplier outside the EEA refuse to cooperate, suggest using an OR as intermediary. Collect, evaluate and file the information obtained from upstream in the supply chain. Should there be a reason to doubt its suitability, invite an experienced third party to check the data quality.

The candidate list is updated twice each year. Echa is requested to propose substances for inclusion in Annex XIV at least every two years and restriction processes may be initiated at any time. In that context, it is obvious that REACH compliance is a continuous process and needs to be a fixed part of product stewardship and future product developments.

Avoid from the outset the use of raw materials that contain SVHCs, because it is likely that they will become subject to authorisation or restriction. You may consider implementing a contractual agreement on the general absence of candidate substances with your suppliers. And remember, your clients might well ask you exactly the same questions that are concerning you. They face the same challenges, after all.

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