Product Makers Everywhere May Find Themselves Within the Grasp of EU's REACH

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In-house counsel around the globe increasingly understand that they must remain aware of the broad scope of European Union (EU) chemicals legislation, and in particular relevant aspects of the REACH Regulation that can apply to manufacturers, importers, and distributors of products sold in the EU.

Companies often rely on trade associations, consultants, and external testing organisations to keep them up-to-date with the latest requirements of EU legislation, guidance, and standards. To better understand what providers are telling them and to make sure they can ask the right questions, product manufacturers and distributors need to have some familiarity with REACH.

REACH and associated legislation and guidance is so voluminous that no short advisory can claim to be comprehensive. Here we highlight some aspects of the REACH regime that really must be understood by anyone advising companies selling products into the EU. We also include an update on some newly-identified Substances of Very High Concern (SVHC) and recent case law.

Finally, we provide some examples of the ways in which concerns about chemicals in products in the EU often are shared globally, and can adversely affect entry and survival in other major markets, including the US.

Restrictions and Registration

In addition to requiring all substances entering the market to be registered with the European Chemicals Agency (ECHA) and supported by a technical dossier, REACH imposes specific restrictions on the use of certain substances in products. Although these aspects are generally beyond the scope of this article, restrictions can be checked by referring to the ECHA website. While testing will ensure that products do not contain any restricted substances, it is critical to know what should be tested for, which may require an understanding of the substances typically used in manufacturing of specific products and whether there are any risks associated with those substances (e.g. inadvertent contamination of articles, recent changes in source of supplies or production processes).

SVHC

Substances identified as SVHC under REACH require specific authorization once they are included in Annex XIV of the legislation. However, it may be prudent to take certain actions with respect to such substances even before they require authorization (see below).

SVHC Candidate List

The Candidate List for substances to be included in Annex XIV of REACH is published on the ECHA's website.

Article 57 of REACH provides the criteria for substances to be deemed SVHC which includes (among others) that a substance is a carcinogen, mutagen, reproductive toxin, persistent bioaccumulative toxin, or an endocrine disruptor. (Full details on the SVHC criteria appear in Articles 57-59 and Annex XIII of REACH; and sections 3.5-3.7 of Annex I to the EU's Classification, Labelling and Packaging (CLP) Regulation (EC) No 1272/2008.)

New Substances Added to SVHC Candidate List

On 15 June 2015, two substances were added to the SVHC Candidate List.

1. 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5)
    - This is a substance used in adhesives, lubricants, coatings, building material, cable compounding, polymer foils, PVC compounds and artist supply. Sweden proposed its inclusion and this was confirmed on the grounds that it is a reproductive toxin (Article 57 (c)).
2. 5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof]
    - These are substances used in fragrances, soaps, and detergents. Inclusion was proposed by the Netherlands and this was confirmed on the grounds that they are very persistent and very bioaccumulative (vPvB) (Article 57 (e)).

There are now a total of 163 substances on the List.

Inclusion on the Candidate List already carries with it regulatory obligations relating to the use of the substance in articles. Compliance with those requirements must be achieved within six months of inclusion on the Candidate List. The more important elements of these requirements are noted here. The failure to comply with these requirements can result in administrative or criminal sanctions. Enforcement is carried out by EU Member State national authorities under local legislation, so the exact penalties vary. In the case of the UK, for example, contravention of a REACH provision may result in a fine of up to GBP5,000 fine and/or up to three months imprisonment following summary conviction; and an unlimited fine and/or up to two years imprisonment following conviction on indictment.

Notification to ECHA

The ECHA must be notified of substances in articles (essentially finished goods) where: (i) the substance appears on the SVHC Candidate List; (ii) the substance is present in articles in a concentration equal to or greater than 0.1%; *and* (iii) the total quantity of the substance present in the articles in a concentration of 0.1% or more is over 1 tonne per year. Notification to the ECHA is not necessary if: (i) exposure of the substance to humans or the environment can be excluded; (ii) the use of the substance in the article has already been registered by another company; *or* (iii) the articles were only produced/imported before the substance was included in the Candidate List.

Multiple components

ECHA guidance suggests that a product is made up of multiple components (a laptop is one of the examples given) the SVHC content of each component is first assessed separately. If none of the components has more than 0.1% of a SVHC, then the assessment stops there, and no notification is necessary. If one or more component does have more than 0.1% of a SVHC, then a further calculation is done to assess whether the total for the whole product is greater than 0.1% or not. If the 0.1% threshold exceeded for the entire product then the presence of the SVHC must be notified.

Curiously, differing standards might apply to domestic manufacturers of articles versus importers. In a recent case before the European Court of Justice (C-106/14 FCD and FMB) the Advocate General's Opinion of 12 February 2015 suggested, among other things, that notification rules might apply differently to EU producers who could notify if the amount of SVHC in the whole product was over 0.1%, as opposed to importers, who would need to notify if any individual component contained a SVHC exceeding the threshold level. It remains to be seen if the Court will follow this opinion.

Notification Within the "Value Chain" (Distributors and Consumers)

In addition to ECHA, the presence of SVHCs over 0.1% must be notified to distributors and, upon request, to consumers.

Implications Abroad and Expanding

Increasingly, there is considerable collaboration among regulatory bodies not only within the EU and elsewhere on the Continent, but also inter-continentally. Thus, the US Environmental Protection Agency (EPA) is extremely mindful of efforts in the EU to assess and restrict chemical substances, and vice-versa. Makers of commercial chemical products and consumer use products must therefore remain aware of similar regulatory requirements for substances of concern in different countries. In the US for example, notifications are required to be submitted to the US EPA pursuant to the US Toxic Substances Control Act (TSCA) 90 days prior to commencing any significant new use of certain categories of substances that also have been the subject of long-standing concerns in the EU. This includes TSCA notification rules concerning certain polybrominated diphenyl ethers (PBDEs) flame retardants, and similar regulations for certain long-chain perfluoroalkyl carboxylate (LCPFAC) chemical substances and for perfluoroalkyl sulfonate (PFAS) chemical substances that had been used in the manufacture of coatings and additives used in both consumer and commercial products. At the time of writing, the US, EPA is actively considering amendments that would considerably expand both regulations. *See* http://www.epa.gov/oppt/exlstingchemicals/pubs/qanda.html; and http://www.epa.gov/oppt/pfoa/pubs/pfasdocket.html

If you have any questions about any of the topics discussed in this advisory, please contact your Arnold & Porter attorney or any of the following attorneys:

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