Client Alert

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EU Court Advisor's Opinion on the Concept of "Articles" Under REACH May Significantly Increase Burden for Industry

The 2006 REACH Regulation imposes information and notification requirements for substances of very high concern listed on the Candidate List (SVHCs) above a 0.1 percent threshold in "articles." Member state interpretations of the term "article," however, diverge, in particular on how the threshold should be applied to complex articles, such as laptops. The European Commission and most Member State authorities concluded that the threshold applies at the level of the whole article, but seven countries, including France and Germany, decided to apply the threshold at the level of each individual component, in the case of a laptop, the screen, plastic case, capacitor, integrated circuit, etc.

Needless to say, application of the 0.1 percent limit to each component increases the burden of complying with the pertinent REACH obligations. Specifically, the application of the limit value at the level of each individual component requires that companies collect data on all components, which must be more granular. If supply chains extend around the world, this exercise becomes onerous.

In April 2014, the Court of Justice of the European Union was asked to rule on whether the 0.1 percent limit applies to the article as a whole or to each component separately. On February 12, 2015, the Advocate-General, an advisor to the court, issued an opinion on this issue.[1] This opinion is important, since the Court, more often than not, follows the substance of such opinions. Below, the key elements of the Advocate-General's opinion are reviewed.

Is a Component an Article?

According to the Advocate-General, a component is an "article" if, once integrated, it retains a shape, surface or design of its own. 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." The Advocate-General reasoned that this definition does not distinguish between stand-alone articles and articles integrated in a bigger article and an article does not lose its function once it is integrated in a bigger one, though that function might change. The only criteria to be taken into account is whether the product has a shape, surface or design which is more relevant than its chemical composition.

Should the 0.1 Percent Threshold Apply at the Level of the Whole Article or Each Component Separately to Determine Whether the SVHC Notification Requirement is Triggered?

The Advocate-General opined that the 0.1 percent limit applies at the level of the article as a whole for EU producers and at the level of each component for importers. Under the REACH Regulation, "producers" and "importers" of articles must notify ECHA if there is a substance of very high concern (SVHC) present

[1] Available at: http://curia.europa.eu/juris/document/document_print.jsf?doclang=EN&text=&pageIndex=0&part=1&mode=lst&docid=162239&occ=first&dir=&cid=22499

in the article in a concentration exceeding 0.1 percent and the total volume is equal to or more than one ton per year.

As the Advocate-General notes, a producer of a complex article typically assembles components supplied by third parties. In accordance with common usage of the term "producer," the producer of the complex article is not also the producer of all components supplied by third parties; it can be viewed only as the producer of the components it made and of the assembled complex article. Therefore, a producer must notify ECHA if a substance on the Candidate List is present in concentration higher than 0.1 percent by weight of the whole article or of any component that it made and that retains a shape, surface or design of its own.

An importer, on the other hand, imports both the whole article and all its components. It therefore must notify ECHA if a substance on the Candidate List is present in concentration higher than 0.1 percent by weight of any "article" that it imports, including any component that retains a shape, surface or design of its own.

The Advocate-General believes that this interpretation is consistent with REACH's objective of ensuring that ECHA collects sufficient information to determine whether any regulatory action is required. Further, she opines that this interpretation is not disproportional or discriminatory, as it would impose a lighter burden than the current ECHA interpretation. According to the Advocate-General, the ECHA interpretation would require that the concentration of any listed SVHC be determined in each component as well in the article as a whole.

Does the SVHC Information Requirement Apply to the Article as a Whole or to Each Component Separately?

Based on the reasoning set out above, the Advocate-General opines that the 0.1 percent threshold also applies to each component for purposes of REACH's "safe use" information requirement, provided that relevant information is available. Under the REACH Regulation, "suppliers" of articles containing a listed SVHC must provide information on "safe use" to customers and, upon request, to consumers, if the SVHC's concentration exceeds 0.1 percent by weight (w/w).

If the supplier is an importer, the Advocate-General continues, it is deemed to be the supplier of the whole article and all its components. The 0.1 percent threshold therefore must be applied at the level of each component separately. In the Advocate-General's opinion, this would also be necessary to achieve the purpose of the REACH Regulation to fully inform customers and consumers.

Further, the Advocate-General reasons that EU producers of components must pass on SVHC-related information to their customers and this information thus is available in the EU, but it might not be the case for importers, in particular importers of small quantities of articles. To avoid an undue burden, it would thus be reasonable to limit this obligation to situations in which the information is available.

Conclusion

The Advocate-General's opinion raises a series of issues for both EU producers and importers. As the Advocate-General does not seem to understand the risk-based compliance approach adopted by many companies, her recommendations are not necessarily practical and would further complicate REACH compliance in relation to SVHCs in articles. The limitation of the concept of "article" to things that have "a shape, surface or design which is more relevant than its chemical composition" does not appear to exclude many non-liquid components.

The Court of Justice of the European Union is expected to release its judgment in the next several months. If it endorses the Advocate-General's advice, the REACH compliance burden imposed on companies selling products on the EU market would increase, and it would increase in different ways for EU producers and importers. With respect to SVHC notification, EU producers would have to notify listed SVHCs above the threshold in each component (possibly including sub-assemblies) they produce and in

the article as a whole. On the other hand, EU importers would have to notify if the threshold is exceeded at the level of each component. In practice, this might mean that producers and importers would more frequently invoke the exemptions available under REACH, including if the use in article has already been registered or if no exposure can be expected during reasonable conditions of use, further reducing the low level of notifications to ECHA so far.

Interestingly, if the court endorses the Advocate-General's recommendations, with respect to the provision of SVHC information, suppliers would have to inform their customers and consumers if the 0.1 percent threshold is exceeded at the level of each component, provided that relevant information is available. Suppliers of products made in the EU would likely be deemed to possess such information and therefore will have to integrate this information into their own communication to their customers and consumers. It is unclear, however, how importers should determine whether the information "is available" and what level of effort would be required before it could be concluded that no information is available. Or would it mean that not knowing could be a viable strategy?

How Hunton & Williams LLP Can Help

The regulatory team of Hunton & Williams has extensive experience in assisting clients with REACH and regulation of plant protection product, biocide and industrial facilities. They advise clients on all regulatory matters, including compliance management, liability assessment, product stewardship audits, product defense, specific compliance issues, consortium and SIEF management, data rights, contracts, inspections and enforcement, and legal remedies. We work closely with our clients and with regulatory and technical experts so that clients' interests are protected effectively by professionals best placed to assist.

Hunton & Williams is a global law firm with a strong focus in regulatory law and with qualified and experienced lawyers on both sides of the Atlantic, in its offices in Brussels, Raleigh and Washington, DC, and also in its Asian offices, including Beijing.

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