

Client Alert

April 2015

European Court Expands Commission and ECHA Powers to Subject Substances to Regulation Pursuant to REACH

On 30 April 2015, the European Union's General Court issued two rulings on the concept of "substances of very high concern" (SVHCs) in the REACH Regulation. Such SVHCs may be listed on the REACH Candidate List and subjected to authorization pursuant to REACH. This was the first time the European courts opined on the scope of the SVHC concept.

The concept of SVHCs is loosely defined under REACH. Although REACH's definition of SVHCs does not refer to respiratory sensitizers, the General Court upheld the listing of these substances on the REACH Candidate List. These rulings open the door for the listing of other classes of hazardous substances in addition to those classified as CMR, PBT and vPvB. For industry, it will become harder to predict which categories of substances will be eligible for listing on the Candidate List and possibly subjected to authorization.

This alert first summarizes the pertinent REACH provisions and the Court's judgment. It then discusses some of the consequences of the judgment for businesses, i.e. producers, importers or users.

1. Candidate List and Substances of Equivalent Concern

Under the REACH Regulation, "substances of very high concern" ("SVHC") may be listed on the Candidate List. Such listing triggers information requirements, including an obligation for article suppliers to communicate safe use information to customers and consumers if the substance concerned is present in a concentration above 0,1% w/w. Listed substances may subsequently be subjected to phase out pursuant to REACH's authorization regime.

SVHCs are defined to include well-known categories of very hazardous substances, i.e. CMRs (categories 1A and 1B), PBTs and vPvBs, and an open-ended category of substances "of equivalent concern." This last group is defined as "*those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria [for PBT or vPvB] — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of [CMR, PBT or vPvB] and which are identified on a case-by-case basis (...).*"

This REACH provision has not been further interpreted in Commission and ECHA guidance, and, thus far, the Member States, the European Commission and the European Chemicals Agency ("ECHA") have not been overly ambitious in interpreting it broadly. There are currently 161 substances on the Candidate List, of which only 14 are listed because they are substances of "equivalent concern." These 14 include five environmental endocrine disrupters¹ including two substances that degrade into environmental endocrine disrupters,² and six substances with adverse effects on kidney and bone tissues after

¹ 4-(1,1,3,3-tetramethylbutyl)phenol; 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated; 4-nonylphenol, branched and linear; 4-nonylphenol, branched and linear, ethoxylated; and DEHP.

² 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated and 4-nonylphenol, branched and linear, ethoxylated.

prolonged exposure.³ The list includes also three respiratory sensitizers⁴; the listing of these substances was challenged before the General Court.

National and European authorities have also been discussing the possible listing of other categories of substances, including skin sensitizers or carcinogenic substances, category 2.

2. Inclusion of Respiratory Sensitizers in the Candidate List

Producers and users of two respiratory sensitizers added to the Candidate List in December 2012 challenged this decision before the General Court. They claimed that the category of substances of equivalent concern does not cover respiratory sensitizers. They did not challenge the vagueness or proportionality of the category of substances of equivalent concern as such, however.

On 30 April 2015, the General Court ruled that the ECHA was entitled to include the two respiratory sensitizers on the Candidate List. It concluded that this interpretation was consistent with the wording of the relevant REACH provision and with the REACH Regulation's objective of a high level of protection of human health and the environment.

The General Court further noted that the two respiratory sensitizers did not have a safety threshold and that sensitization induction was irreversible, which justified their listing. In so ruling, the Court disregarded the fact that there are no actual safety concerns for these substances, because they are mainly used as intermediate or monomer in industrial settings.

3. Business Implications

These two rulings leave open the question as to whether the category of substances of equivalent level of concern as such meets general principles of EU law, such as legal certainty and proportionality. Nevertheless, the General Court leaves no doubt that respiratory sensitizers and, possibly, other categories of substances, such as skin sensitizers, may be included on the REACH Candidate List based on an "ad hoc" assessment of aspects such as the absence of safety threshold, irreversibility of adverse effects and societal consequences of these adverse effects. And such substances may be listed regardless of whether there is any exposure or safety concern.

Following these two rulings, the national and European authorities may well seek to increase the number of substances on the Candidate List by expanding the categories of substances of equivalent concern. This is likely to increase the uncertainty for industry. Companies will face additional information requirements, once their substances are included on the Candidate List. Candidate listing also raises the spectre of phase out through the REACH authorization program.

How Hunton & Williams Can Help

Hunton & Williams has extensive experience in assisting clients with chemical law issues, including REACH listing. Our motto is: "in the space where science, regulation, liability and politics interface, special acumen and skills are required to devise pragmatic and cost-efficient solutions to business challenges." We advise clients on a wide range of regulatory and liability matters, including evaluation, authorization, classification and labeling, liability assessment, enforcement and legal remedies. Working closely with our clients and with technical experts, we ensure that our clients' interests are effectively protected.

³ Cadmium; cadmium oxide; cadmium sulphate; cadmium chloride; cadmium fluoride; and cadmium sulphate.

⁴ Cyclohexane-1,2-dicarboxylic anhydride; hexahydromethylphthalic anhydride; and diazene-1,2-dicarboxamide.

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

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