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HOW LONG IS REACH'S GRASP?— IMPLICATIONS FOR U.S. COMPANIES

Lawrence E. Culleen
Allison Carroll

Non-European producers of chemical substances and even producers of finished goods already are beginning to feel the long arm of REACH, the European Union (EU) requirement addressing the Registration, Evaluation and Authorization of Chemicals. As a result of the new framework, which went into effect June 1 of this year, businesses which manufacture and import chemical substances that are placed on the market within the EU, suppliers of chemical-based raw materials for their downstream users in the EU, and manufacturers and importers of articles all are being forced to reckon with the numerous new requirements REACH will impose. For manufacturers and importers of chemical substances, the requirements imposed by REACH for the registration of substances will be burdensome; but for many entities that heretofore have not considered themselves to be within the scope of traditional chemical-regulatory schemes, the requirements of REACH might seem completely foreign to their way of doing business.

Background

REACH requires that a chemical substance (even one previously on the market in the EU) be registered if the substance is manufactured in or imported to the EU in quantities exceeding 1 metric ton per year. Registration will be directed by the newly-organized European Chemicals Agency (ECA). The registration application must be supported by a dossier of certain data, with more data required for those substances produced at greater volumes or of greatest concern. A chemical safety report must be prepared for substances produced at the greatest volumes. ECA will evaluate the dossiers submitted. Moreover, an authorization is required for any substance which is of very high concern, taking into account the necessity for and benefits of the substance and the availability of substitutes of lesser concern. Restrictions can be placed on the use of certain substances where unmitigated concerns remain. The pre-registration phase for existing substances and the new substance registration process are very much on the horizon, as they will commence next year.

New Information Disclosure Demands

Companies within the traditional industrial chemical sector already have begun preparing by reviewing their inventory of products and determining their registration obligations and data needs. Of course, the extent to which the requirements of REACH apply to the activities of a particular company depends upon: (a) whether the company is a manufacturer or importer of substances into the EU, or simply a downstream user of a substance; (b) the type of substance involved and, in particular, whether it is a substance classified as being of "very high concern" (SVHC); and (c) the tonnage level at which the substance in question is manufactured, imported, or used in the EU. Because it is now the case that downstream users of chemical substances and preparations (e.g., processors of chemical substances and manufacturers of articles) have certain obligations under REACH, these entities are beginning to "push-back" on their up stream suppliers and they are asking tougher questions regarding raw materials and product composition than ever before—and expect responses to those questions as a condition of doing business. This comes as a bit of a shock to those within the chemical manufacturing sector who, until very recently, were able to provide their customers with only the most basic information about their products and formulations, claiming specific product chemistries to be "confidential" and "proprietary." REACH gives users and distributors in the EU considerable new leverage within supplier and customer relationships—at least with respect to information needs.

One of the reasons for customers in the EU to "push back" for information from their suppliers is because registrations under REACH will be "use-specific." Thus, if a customer who is a formulator in the EU

intends to use a substance in a manner which differs from its registered use, that customer/formulator might need to prepare its own dossier. Preparing a dossier under these circumstances would require detailed input from the supplier concerning the product's components.

Manufactured Goods—Articles

To complicate matters further, unlike the chemical notification requirements under the Toxic Substances Control Act (TSCA) in the United States, certain facets of REACH also apply to substances that are contained in articles. Thus, certain packaging materials and the finished products contained therein are not specifically excluded from REACH and could be considered "articles" under REACH; as such, the chemical components therein might be subject to certain provisions of REACH. In particular, manufacturers or importers of articles must notify the ECA if:

- the article contains a substance intended to be released under normal conditions of use, and more than 1 ton of the substance is produced in or imported to the EU (per producer or importer per year)
- the article contains a "substance of very high concern" (a SVHC or "priority substance"), regardless of whether it is intended to be released, and the priority substance is present in a concentration greater than 0.1 percent in the article, or more than 1 ton of the substance (within such articles) is produced or imported per producer or importer per year
- the article or one of its components is governed by a positive decision of the ECA.

For the first time, an entity that imports toys or televisions to the EU might find itself in the awkward position of having to ask its supplier for information that previously they might not have had any desire to know—or could not get because it was, heretofore, considered to be proprietary. There can be important implications which arise when such knowledge is gained.

Collateral Disclosure Obligations

Various requirements exist under REACH for disclosure of test data and other technical information to the ECA, including a registrant's obligation to update its registrations when pertinent new data are obtained. Downstream users must notify the ECA of basic information before they begin using a substance if it have been six months or more since they received the registration number of the substance from the registrant. Downstream users also must submit additional chemical safety reports in certain circumstances. When this occurs, it is very possible that a company which also does business in the United States might come into possession of new test data demonstrating adverse effects not previously reported to the authorities in the United States.

Thus, persons obtaining or generating new data in order to comply with REACH are advised strongly to consider carefully and quickly what obligations, if any, arise for reporting that information in the United States. Such obligations could include notifications, which must be timely filed with the U.S. Environmental Protection Agency (EPA), of adverse health or environmental effects data reportable pursuant to TSCA Section 8(e), the analogous provision under the U.S. pesticides law (FIFRA Section 6(a)(2)), and possibly the U.S. Consumer Product Safety Act (Section 15(b)). Failure to disclose new data to U.S. authorities can lead to very expensive penalties for companies doing business in the United States.

Other Areas of Concern for U.S. Companies

There are several other noteworthy areas in which the REACH framework could be interpreted to impose new requirements on companies that might not themselves directly introduce "bulk" chemical substances into the EU marketplace.

Food Packaging Materials and Containers

For instance, food packaging materials and containers, such as milk bottles, soft drink cans, etc., are not specifically excluded from REACH and could be considered "articles." Although interpretations that are

being worked through in the context of the implementing guidance will generally make clear that a container *per se* is not subject to REACH's requirements, a component chemical within the finished product might be subject to certain provisions of REACH. Because food packaging materials are not explicitly excluded from REACH, this nuance concerning substances in articles could be a concern not only for manufacturers of substances used in packaging materials but also could present an issue for downstream users of such articles, even if they are not themselves the manufacturer of those articles. Even though substances used in food packaging are, of course, already regulated by other EU legislation, it is not yet clear how that existing legislation will interact with REACH. It seems likely that if a substance is considered to be of "very high concern" using the REACH classification scheme, the special legislation pertinent to food packaging materials almost certainly will apply and require limitations on use that may be in addition to any eventually imposed by REACH. If the chemical in question presents a hazard to the environment, REACH requirements are likely to apply as the existing legislation concerning food packaging generally does not address those types of hazards.

Status of Certain Monomers

There is debate also ongoing regarding the interpretation and application of Article 6(3) of REACH which concerns monomers and polymers. On July 11, attorneys representing four chemical companies, at least one of which is based in the United States, announced that they had filed a lawsuit in the Royal Courts of Justice in London to seek clarification regarding the interpretation of REACH Article 6(3). In a departure from the current notification requirements for chemical substances, the litigants claim that Article 6(3) could be interpreted to require registration of all monomers present at greater than 2 percent in any polymer which is imported to the EU. If that were the case, those who import and use polymers in the EU could be forced to cease operations pending registration of the monomers present within those polymers, and there would certainly be major economic and social consequences, both for business within the EU and the polymers industry worldwide. (*Lawsuit in British Court Seeks Clarification of REACH's Requirement for Monomers,* BNA DAILY ENVIRONMENT REPORT, A7 (July 13, 2007). Alternatively, the article could be interpreted to require only "unreacted" monomers, not integrated into a polymer, to be registered under REACH. The lawsuit also seeks clarification of the term "supply chain" as used in Article 6(3) because it could significantly affect the number of companies required to register their products under REACH.)

Possible Legislative and Regulatory Responses in the United States

For more than a decade, criticism has stung officials within EPA concerning that agency's inability to make TSCA more functional and facile—including an omnibus information gathering tool of the kind which REACH seems destined to become. Currently, EPA does not interpret TSCA to require the generation of test data for new chemicals prior to their introduction in commerce, nor to automatically trigger a testing regime at certain production levels for existing substances. In contrast to REACH, TSCA generally requires that EPA sustain the burden of proving there is a need to obtain those data which make it possible to more thoroughly evaluate the potential risks associated with a new or existing chemical substance. In addition, EPA is limited in its ability to share information about chemicals entering the marketplace with the public.

In a report published in June of 2005, the U.S. Government Accountability Office (GAO) outlined the weaknesses of the TSCA framework and commented, "EPA's reviews of new chemicals provide limited assurance that health and environmental risks are identified before the chemicals enter commerce." *Highlights* in OPTIONS EXIST TO IMPROVE EPA'S ABILITY TO ASSESS HEALTH RISKS AND MANAGE ITS CHEMICAL REVIEW PROGRAM, GOVERNMENT ACCOUNTABILITY OFFICE REPORT GAO-05-458, (June 2005). In contrast, REACH has been interpreted as the embodiment of the "precautionary principle," placing a burden on the "sponsor" of a chemical, for purposes of registration, to demonstrate that chemical substance and its intended uses will be "safe," (i.e., not detrimental to human health or the environment),

before the substance may legally be introduced into the European market. Reflecting the validity of some of the criticism hurled at EPA over the years, the U.S. GAO recommended in its 2005 report that Congress consider revising the authorities granted EPA under TSCA, and cited the more expansive laws in place in Canada and the EU, and REACH in particular. Repeated attempts have been made by recent Congresses to amend U.S. law in light of emerging regulation of persistent organic pollutants through the Stockholm Convention, to date without success.

Perhaps with an eye toward their "neighbours across the pond," on Aug. 21, 2007, a statement was released regarding the resolutions of the North American Leaders' Summit pursuant to the Security and Prosperity Partnership, established in 2005. With regard to chemicals regulation, the Leaders' statement emphasized the overwhelming importance of information sharing between North American regulators and policy-makers in the three participant nations. The United States committed to reviewing and initiating needed action on the over 9,000 existing high production volume chemicals by 2012, in addition to enhancing coordination and information sharing between the three nations. *Regulatory Cooperation in the Area of Chemicals*, North American Leaders' Summit at Montebello, Quebec, Canada, (Aug. 21, 2007).

While no new legislation has emerged with would amend TSCA in the United States to make it a "Son-of-REACH," prudence dictates that U.S. manufacturers continue to examine closely the practices in the EU under REACH and prepare for compliance with an inevitably stricter risk assessment regime in the United States.

Mr. Culleen *is an attorney and* **Ms. Carroll** *is a legal assistant in the Washington, D.C. offices of Arnold & Porter LLP*.