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Phone: +1 212 537 6331 | Fax: +1 212 537 6371 | customerservice@portfoliomedia.com

Implications Of The New REACH Laws

Law360, New York (November 19, 2008) -- In December 2006, the European Parliament enacted sweeping legislation for the Registration, Evaluation, Authorization and Restriction of Chemicals, Regulation Number 1907/2006 ("REACH").

This legislation became effective on June 1, 2007, and ushered in an eleven-year period, at the end of which approximately 30,000 chemical substances currently in use, as well as new chemicals and compounds, will be required to be registered with the European Chemicals Agency ("ECHA").

The European Union's articulated purpose behind REACH is "[t]o achieve a high level of protection of human health and the environment." Guidance on Information Requirements and Chemical Safety Assessment, at 7.

To achieve this goal, one of the key components of REACH requires companies that manufacture certain chemicals in the European Union, and companies that import those chemicals into the European Union, to disclose information concerning the uses for and risks associated with those chemicals.

The impact of this disclosure requirement undoubtedly will extend beyond the articulated purpose behind REACH. Among others, two basic questions are relevant to companies whose substances are subject to the REACH legislation.

First, are those companies required to perform new testing to obtain the information sought by the legislation if that information is not presently available? Second, what impact will these disclosures have on current and future litigation concerning these substances?

Depth Of Information To Be Disclosed And The Need For New Testing

The REACH legislation itself specifically speaks to the potential need for new testing. In particular, the "Registration" step in the process "requires the submission of relevant

and available information on intrinsic properties of substance." ECHA, Guidance on Data Sharing 11, Sept. 2007.

It will not always be sufficient to rely only on currently available data, because when that currently available data does not adequately respond to the information sought by the disclosure requirement, REACH expressly calls for "the generation of information, including testing." *Id.*

The type and depth of this information depends on the quantity of that substance that the registrant (i.e., manufacturer or importer) manufactures in, or imports into, the European Union. REACH provides for these minimum data requirements at Annexes VI-X of the legislation.

For example, for those substances manufactured or imported in quantities of 10 tons or more, registrants must provide a Chemical Safety Report that "identif[ies] all human and environmental hazards relative to the chemical."

Guidance on Information Requirements and Chemical Safety Assessment; Steven F. Faeth, *Global Chemical Testing & Registration Programs and Their Potential Impact on Toxic Tort Litigation*, at 7 [hereinafter "Faeth"].

The published guidance documents on REACH also make it clear that if the required information does not currently exist, companies that are registering their substances are required to perform additional testing.

To that end, the guidance documents provide that "[w]here available data are not adequate to meet the requirements of the REACH Regulation, additional testing may need to be generated." *Safety Assessment Guidance*, at 7.

Additionally, REACH Annex VI describes a four-part scheme that a registrant is required to perform in order to fulfill its reporting obligations. One of those includes the need to "generate new information or propose a testing strategy." *Chemical Safety Assessment Guidance*.

Thus, both REACH itself as well as its guidance documents clearly and expressly contemplate a requirement in which registrants must perform new testing on substances.

The REACH drafters recognized that the reporting requirements, and the need to perform additional testing, could create a potential burden on those companies whose substances fall within REACH's domain.

In an attempt to alleviate some of the resulting financial burden, REACH recognizes Substance Information Exchange Forums ("SIEFs"). A goal of the SIEFs is to have its members, who share the same interests in the same substances, register the substances together.

This, in part, is intended to avoid the need for duplicate testing. Guidance on Data Sharing [hereinafter "Data Sharing Guidance"]. "Data generated through animal testing must be shared, but the sponsoring party will be entitled to seek reasonable compensation." Faeth, at 8. (Incidentally, the creation of these SIEFs, and the concomitant obligation to share data derived from animal testing, has the result of furthering another REACH objective – protecting animals. Data Sharing Guidance, at 13.)

Thus, while the REACH legislation will increase costs on manufacturers and importers who may now be required to conduct additional testing to fill information gaps about the safety of the substances, REACH also attempts to ease some of that burden by spreading the costs among all companies that have the same reporting requirements.

This too can be a double-edged sword. "As a general rule, there shall be one SIEF for each phase-in substance." Data Sharing Guidance at 13. As a result, it remains unclear how antitrust and competition laws will be applied to companies that share data and information within their SIEFs.

Part of the purpose behind collecting the requested information is to determine whether substances contain "properties of very high concern." These substances of very high concern "must be specifically authorized" by the ECHA. Faeth at 7.

"Applicants will have to demonstrate that risks associated with uses of these substances are adequately controlled or that the socio-economic benefits of their use outweigh the risks." Id.

Indeed, the ECHA has drafted an initial list of sixteen substances that it is proposing to classify as substances of very high concern. See ACC Believes NGO Reports on REACH Impacts Create Unnecessary Confusion and Public Concern, Targeted News Service (Sept. 30, 2008).

This list includes the following substances: Anthracene; 4,4'-Diaminodiphenylmethane; Dibutyl phthalate; Cyclododecane; Cobalt dichloride; Diarsenic pentaoxide; Diarsenic trioxide; Sodium dichromate, dihydrate; 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene); Bis (2-ethyl(hexyl)phthalate) (DEHP); Hexabromocyclododecane (HBCDD); Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins); Bis(tributyltin)oxide; Lead hydrogen arsenate; Triethyl arsenate; and Benzyl butyl phthalate. See Substance of Very High Concern: Annex XV Reports to Be Commented by Interested Parties.

This list was published on Sept. 1, 2008, and interested parties had 45 days from that date to provide the ECHA with scientific comments on the identification of the substance as substances of very high concern, as well as further information related to exposures, alternative substances and risks. Id.

Litigation Concerns

In addition to the inherent additional costs that will result from REACH, many of the basic elements of the legislation also are likely to have an impact on future litigation. REACH's framework itself is likely to enhance this concern. Particularly, information developed through the disclosure requirements is intended to be passed up and down the supply chain and, perhaps more importantly, the general public will have access to the information developed under REACH.

The concern that this legislation could have an adverse impact on companies that manufacture and import chemicals subject to the REACH disclosures has historical roots. Indeed, "[d]ata generated through environmental regulations have been used to support toxic tort suits and data from toxic tort suits have been the impetus for environmental regulations." Faeth, at 1.

Additionally, in light of REACH's requirement that companies perform additional testing, as discussed above, there is a fear that those companies that sponsor these tests could face tort liability if the testing is negligently or improvidently performed and a third-party is eventually injured as a result. See *id.*, at 10 (citing *Dow Chem. Co. v. Malhum*, 970 P.2d 98 (Nev. 1998) (upholding finding of liability against chemical company for negligent performance of chemical testing performed on behalf of one of its subsidiaries)).

Additionally, it remains to be seen whether plaintiffs will attempt to hold companies liable when those companies rely on faulty test data generated by unrelated companies. In this regard, it is important to recognize that even under REACH, although a registrant is required to collect all relevant data, it is still required to assess the "reliability" of that data under the "Evaluation" portion of the REACH framework, which should provide a mechanism for dealing with bad science.

One area where the drafters of REACH have attempted to put in place safeguards to protect registrants is in the area of confidential business information, which would otherwise end up in the public domain under the legislation.

To remedy this problem, REACH attempts to strike a balance between companies' interests in keeping confidential information confidential, and protecting human health and safety and the environment.

First, Regulation No. 1049/2001 regarding public access to European Parliament, Council, and Commission decisions applies to documents held by the ECHA, the newly established body located in Helsinki and charged with carrying out the day-to-day management of the REACH requirements.

Second, REACH anticipates these concerns and protects against the ECHA disclosing certain information that will usually be deemed to undermine the protection of the commercial interests of the concerned person.

This protected information includes details of the full composition of a preparation; the precise use, function, or application of a substance or preparation; the precise tonnage of the substance or preparation manufactured or placed on the market; and links between a manufacturer or importer and its downstream users. Thompson Hine Client Alert, REACH: Adoption Of New Chemicals Legislation, December 2006.

Nonetheless, where disclosure of such information is necessary to protect human health, safety or the environment, the ECHA still is permitted to disclose this information. *Id.*

While the legislative intent behind REACH is "[t]o achieve a high level of protection of human health and the environment," that necessarily comes at a cost – a substantial part of which will be shouldered by the chemical industry. By one calculation, the estimated cost on the chemical industry will be more than 2 billion Euro during the first 11 years of REACH's applicability. European Commission Environment Directorate General, REACH in Brief.

This same study found that costs on downstream suppliers as a result of REACH may reach as much as an additional 5.2 billion Euro. *Id.* It remains to be seen, however, how much of an economic impact REACH will have on these companies through litigation.

--By Joshua A. Klarfeld, Thompson Hine LLP

Joshua Klarfeld is an associate in Thompson Hine's product liability litigation practice group.