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## The New European Chemicals Law

by Philip E. Karmel\*

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# New York Law Journal

## Toxic Torts

### The New European Chemicals Law

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On June 1, 2007, a new law on chemicals - the [Registration, Evaluation, Authorisation and Restriction of Chemicals \(REACH\) Regulation](#) - entered into force in the 25 nations comprising the European Union.

This column will describe REACH, compare it to the principal chemicals law in effect in the United States and discuss how it may affect toxic tort litigation.

#### REACH

REACH creates a comprehensive, unified framework for chemicals regulation in the European Union (EU). According to the European Commission, the genesis of the law is concern that there is inadequate information as to the human toxicity and ecological effects of most of the chemicals in use in modern society.<sup>1</sup> The scope of the law is impressive. It covers essentially any "substance" in commerce. The term "substance" is defined to include chemical elements and compounds in natural or manufactured forms, including process-related impurities.

REACH requires that the manufacturer of a substance manufactured in the EU register the substance with the European Chemicals Agency in Helsinki. If the substance is manufactured elsewhere but imported into the EU, the importer is subject to the registration requirement. Water, minerals, medications and food stuffs and a few other specifically listed substances are exempt.

Substances manufactured or imported in quantities of less than one metric ton per year (per manufacturer/importer) are also exempt from registration. A substance not specifically exempted is subject to the law. Approximately 30,000 substances are expected to be registered under the law.<sup>2</sup>

To register a substance, the manufacturer or importer must submit a technical dossier. The information required varies according to the classification of the substance and whether it is manufactured in large or small quantities. The data required includes the chemical identity of the substance and its physical-chemical properties. For substances manufactured (or imported) in quantities of 10 metric tons per year or more, toxicological and ecotoxicological data are required, which for many heretofore untested (or inadequately tested) substances may require extensive laboratory data development. The data required to be gathered may include information as to the substance's carcinogenicity, teratogenicity, acute and chronic toxicity to humans, acute and chronic toxicity to benthic, aquatic, terrestrial and avian ecological receptors, and potential for bioaccumulation, biodegradation and persistence.

The aim of this intensive data-gathering exercise is to enable the manufacturer (or importer) to establish that its substance is safe to use. Thus, the testing required turns on the expected uses of the chemical at issue and the potential for each such use to result in human or ecological exposure to the chemical, and the nature of that exposure (e.g., inhalation, ingestion or dermal exposure). This assessment process requires a chemical manufacturer (or importer) to acquire and analyze information from its customers (or their downstream customers) concerning the substance's ultimate end use.

Most environmental laws regulate a manufacturer's production process. REACH regulates the use of substances and requires companies to communicate down the supply chain to understand the variety of uses (and resulting potential exposure scenarios) for the substances that they manufacture or import.

Over the next 15 years, REACH is expected to generate approximately €10 billion of toxicity and exposure data.<sup>3</sup> These data will be available to scientists, regulators, and the public worldwide and are expected to add significantly to the information we have about the safety of chemicals in commerce.

A failure to register the substance by the applicable deadline precludes the manufacture or importation of the substance. This has been called the "no data, no market" principle.

The next step in the process, after registration, is evaluation. The European Chemicals Agency will evaluate the information provided to it through the registration process. It will determine whether the registration submission is complete. In consultation with the environmental agencies of the EU member nations, the agency will evaluate the information submitted and may request additional information to clarify data suggestive of risks to human health or the environment.

### **Substances of Special Concern**

REACH requires authorization for substances of special concern. These include substances that are carcinogenic, mutagenic or reproductive toxicants (CMRs); substances that are persistent, bioaccumulative and toxic (PBTs); substances that are very persistent and very bioaccumulative (vPvBs); and substances with endocrine-disrupting properties. Collectively, these substances are referred to as substances of very high concerns (SVHC). The authorization procedure is expected to apply to approximately 1,500 substances. The procedure is use-specific for each SVHC. Applications for authorization must present information on the availability of substitute chemicals, and the possibility of substitution will be considered in determining the authorization of a SVHC for a specific use.

The necessity of obtaining authorization for SVHCs - and the likelihood that authorization will not be forthcoming for many such substances - is expected to induce companies to avoid the manufacture or use of these substances where feasible substitutes exist. Manufacturers of products with multiple components - for example, automobiles - will face a mind-boggling task to communicate with all of their upstream suppliers (and their suppliers, back to the source) to determine whether any of the components or subcomponents contain a non-authorized SVHC.

The restriction procedure is a backstop that allows the prohibition of any substance (or use) that presents unacceptable risks to health or the environment.

### **Comparison to U.S. Law**

The principal chemical regulation law in the United States is the [Toxic Substances Control Act](#) (TSCA), enacted in 1976.<sup>4</sup> There are significant differences between REACH and TSCA. Under REACH, the technical dossier must be submitted for essentially all chemicals in commerce. This requirement is self-executing under the statute and does not require action by the administering agency. Under TSCA, information must be submitted to the U.S. Environmental Protection Agency prior to the manufacture of a new chemical, but the 62,000 chemicals in commerce at the time the statute became effective are exempt from that requirement. Although the EPA has authority under TSCA to require testing of these "grandfathered" chemicals, it has exercised that authority for fewer than 200 chemicals.<sup>5</sup>

There are also differences between the two statutes with respect to the information required to be submitted to the administering agency. Under REACH, the filing company must develop risk information, assess it to decide whether or not it indicates risk, and decide what risk-management measures to employ and whether they are adequate. These determinations in the technical dossier are subject to agency review, but the requirement that they be performed by the filing company is self-executing.

By contrast, TSCA does not require chemical companies to test a new chemical for toxicity or likely future exposure before a pre-manufacturing notice is submitted to the EPA. Chemical companies submit no health and safety data for approximately 85 percent of the chemicals they register.<sup>6</sup> The EPA has the authority to require the company to conduct health and safety testing, and it has done so for chemicals it deems a potential hazard, but the requirement is not self-executing.

REACH requires the tracking of the use of a chemical to determine potential exposures. TSCA gives the EPA authority to issue a Significant New Use Rule in connection with its review of a pre-manufacturing notice, and it has done so for certain chemicals, but the requirement is not self-executing.

The authorization procedure of REACH appears to give the administering agency broad discretion to determine that the submitting company has not established the safety of a particular use of a chemical, and the absence of feasible substitutes. Although TSCA gives the EPA the authority to ban chemicals, the burden of proof is set so high that the courts overturned the EPA's rule banning asbestos, notwithstanding its notoriety as a serious health risk.

The EPA rulemaking - which spanned 10 years and three presidential administrations - included a docket that cited more than 100 scientific studies on the health risks of asbestos, but the reviewing court determined that the EPA had failed to meet its burden of proving by substantial evidence that all uses of asbestos pose an unreasonable risk of injury to human health or the environment.<sup>7</sup> Under REACH, the burden of proof of establishing the safety of a chemical use lies with the manufacturer.

### **Impact on Tort Litigation**

The impact of REACH on toxic tort litigation in the United States will be indirect, but it could be substantial. Chemicals produced in the United States but exported to Europe - a substantial export market for American industry - will be required to meet the same standards as those manufactured within the European Union.

By requiring the generation of massive amounts of new data on the health risks of chemicals, REACH may provide additional evidence that can be brought to bear by either plaintiffs or defendants in tort litigation. By requiring European manufacturers to track the use of their chemicals to understand potential exposures, REACH will provide ammunition for plaintiffs' attorneys to argue that American manufacturers should follow the same standard of care. A chemical banned in Europe may still be offered for sale in the United States, but it can be expected that plaintiffs' attorneys will seek to use the EU's safety determination in arguments concerning failure to warn (or the adequacy of warnings) and with respect to general causation (the ability of the chemical to cause harm).

At the very least, plaintiffs will argue that American manufacturers should be aware of and consider the determinations of the European Chemical Agency with respect to the substances that they manufacture or use in their products. Defense counsel may seek to use the EU's decision not to ban a chemical as evidence that no warnings were required and that the chemical is reasonably safe for its intended use. Although the American chemical industry actively opposed the enactment of REACH,<sup>8</sup> it also possible that the new law will spur legislative developments in the United States at the federal or state level.<sup>9</sup>

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**Endnotes:**

1. [http://ec.europa.eu/environment/chemicals/reach/fact\\_sheet.pdf](http://ec.europa.eu/environment/chemicals/reach/fact_sheet.pdf).
2. Uwe Lahl, et al., "REACH - The New European Chemicals Law," *Env. Sci. & Tech.*, pp. 7115-21 (Dec. 1, 2006).
3. *Id.*
4. 15 USC 2601-2692.
5. GAO, "Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program," GAO-05-458, p. 4 (June 2005).
6. *Id.*, p. 11.
7. *Corrosion Proof Fittings v. EPA*, 947 F2d 1201 (5th Cir. 1991).
8. "Waxman Criticizes Lobby Efforts Abroad: Report describes White House/industry campaign to change EU chemicals policy," *Chemical & Engineering News* (April 6, 2004).
9. "California eyes green chemistry plan modeled on REACH," *Chemical Week* (March 22, 2006).