

# Are You Ready For REACH?

**In today's global marketplace, the long arm of REACH will bring about sweeping changes in the use of chemicals not just in the EU, but across the globe**

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This is an important year for any company that makes, uses, buys or sells chemicals or products containing chemicals. On June 1, 2007, the European Union's (EU) Regulation on Registration, Evaluation, Authorization and Restriction of Chemical substances (REACH) came into force. Implementation of REACH begins in earnest in 2008. Widely viewed as one of the most important pieces of EU legislation in 20 years, REACH will bring about sweeping changes in the way products are regulated in the EU and its impact will extend throughout the global supply chain. This article, together with Part 2 (p. 42) of this cover story, gives the reader an introduction to REACH and its implications for business.

Communications about REACH compliance already abound throughout the global supply chain. Companies that prepare carefully now will be well positioned to protect their markets and products in the years ahead.

REACH affects the availability of chemicals and increases the scrutiny of products containing chemicals throughout the world. Further, REACH will significantly increase the amount of environmental and health data about chemicals and products containing chemicals that must be generated, provided to regulators and made available to the public, all of which may have major market and liability repercussions. Lastly, in a global economy demanding "global-products",

REACH product-stewardship-compliance strategies will extend to products and services in non-EU markets.

## Who is covered?

REACH applies to EU chemical manufacturers and importers of chemicals into the EU, covering both suppliers and downstream users. It also applies to downstream users who manufacture or assemble products containing chemicals that may be physically released and that are sold into the EU market. Everything from pens to perfumes to paint and minerals to household cleaning products may be affected. Products that release chemicals during normal use or just from simple wear and tear, such as tires or even clothing that release dyes when cleaned, might also be covered. Industries ranging from textiles to electronics to housing products will come under the scope of the new rules.

There will be exemptions for certain products and chemical substances, particularly in sectors where there is already significant regulation, such as pharmaceuticals, cosmetics and food. However, the scope of each exemption varies and many exempt these sectors from certain, but not all, REACH obligations.

## Shifting the burden

Underlying REACH is a key principle: "No data: No market." This is a major shift from the previous European chemicals regime, under which regulators had



to prove that a chemical was not safe before it could be taken off the market. In contrast, REACH, based on the "precautionary principle", requires companies to produce data to register their chemicals. This applies to chemicals already on the market as well as new chemicals (itself a significant departure from past practice in the EU and U.S.).

If the necessary data are not submitted to support the use of particular chemicals, those chemicals and, in many cases, products containing those chemicals, may not be able to be manufactured in or sold into the EU. Given the significance of the EU market and the influence of EU regulatory requirements, it is possible that chemicals or products that cannot be sold into the EU market might also face barriers in global markets.

## Registration requirements

REACH imposes significant chemical registration requirements on existing and new chemicals. Unless exempt, all substances manufactured or imported (including substances currently manufactured or imported) into the EU will have to be registered with the new European Chemicals Agency in Helsinki, Finland. EU manufacturers or EU importers are subject to the registration requirements. Exporters to the EU cannot register substances themselves (unless they have EU operations acting as the importer). They need to appoint an EU agent with the relevant expertise in chemicals and

their information requirements, or rely on their importer(s) to ensure all registration obligations are met.

The registration dossier must contain extensive information on the identity of the substance, its production and intended uses, as well as risk information on toxicity and the nature and degree of potential exposure. The amount of data required will depend on the volumes imported into or manufactured in the EU (although substances produced or imported in levels below one metric ton generally will not have to be registered). Companies will have to ensure they document what they sell, in what volume,

to whom and for what purposes in order to understand (and possibly limit) their obligations under REACH.

REACH establishes a "pre-registration" procedure for certain substances already on the market. To benefit from extended registration deadlines phased over eleven years depending on the volume and hazard of the chemical, such substances must be pre-registered between June and December 2008. Substances that are not pre-registered will have to be withdrawn unless fully registered by December 1, 2008.

REACH requires that each substance have one registration ("one substance, one registration"). Thus, data generally must be submitted jointly by firms that manufacture and use the same substance. "Substance Information Exchange Fora" (SIEFs) will be formed to facilitate information-sharing among manufacturers, importers, downstream users and other data holders. The SIEF data-sharing process raises a number of issues, including confidentiality of data and the potential violation of antitrust (or competition) laws.

### Authorization rules

Another area where REACH will have a significant impact is on authorization rules. Authorization may apply to around 1,500 substances of "very high concern" that will be placed on a "candidate list" and that may later be added to the authorization list. The substances on the candidate list might

suffer market barriers even if they are not added to the authorization list.

Substances placed on the authorization list may only be used and marketed if each use by a particular company has been specifically authorized. Authorization will only be granted where risks can be sufficiently controlled or are outweighed by socio-economic benefits, and in some cases, only if a less dangerous substitute is not available. These restrictions may also apply to products containing chemicals on the authorization list, unless one can demonstrate no exposure to any authorized chemicals.

This company-by-company and use-by-use review is a major shift from the traditional EU and U.S. presumption that once a chemical is authorized, it can be used by any entity for any use. It will be important for companies to determine, at an early stage, if they manufacture, use in their processes, or put in their products, chemicals that are on the REACH candidate list and potentially subject to the authorization rules.

### Implications to consider

**Extending beyond the EU.** The EU hopes REACH will set the "gold-standard" for chemicals legislation throughout the world. Many of the EU's major trading partners have been monitoring its progress and will be watching closely to see whether REACH's innovations are successful. Countries around the globe may revise their existing chemicals legislation in the next few years using REACH as their guide. Governments might, without creating their own REACH program, adopt the expedient strategy of simply declaring that only chemicals registered under REACH may be used or imported into their markets. For example, California has passed legislation essentially adopting by reference an EU Directive that restricts the presence of certain hazardous substances in electronics (known as "RoHS Directive").

Even if other countries do not adopt REACH, the data generated to meet REACH's requirements may have legal and risk-management implications outside of the EU, including creating reporting requirements. For example, these new data may obligate companies to make new disclosures about

their chemicals under the Toxic Substances Control Act (TSCA) in the U.S. Moreover, the high profile of these data may also influence the views of regulators and other interested parties (such as toxic tort claimants) regarding the risks of particular chemicals and affect potential product-liability exposure.

Further, participants in the global supply chain may, simply as a matter of convenience, demand that all chemicals, components and products supplied to them meet all requirements of REACH, without regard to the ultimate markets at issue. If the global spread of the EU's RoHS Directive into the business-to-business marketplace is any guide, the initial and most visible impact of REACH might be seen in contracts, purchase orders and so-called "supplier declarations" (some of which may not accurately represent the precise legal requirements of REACH).

**Preparing for alternatives.** REACH will impact the availability of chemicals (both process chemicals and product ingredients), as well as components that contain chemicals. For example, a firm that buys a chemical product that is unregistered or becomes subject to an authorization will likely have to seek alternatives. This could entail a range of options, including attempting to get the chemical registered (which may require costly and time-consuming research), working with other suppliers to obtain substitutes, as well as process- or product-design changes, which may require a significant amount of lead time.

**Pooling resources.** It is likely that REACH will create significant resource challenges for small businesses, which may be disproportionately affected by the costs of the data-gathering and registration obligations. In order to face these costs, small businesses may consider pooling resources with other firms (for example by setting up consortia to manage data requirements and joint registrations), while managing the risk that confidential information will be exposed to competitors and ensuring that competition (or antitrust) laws are observed.

**The candidate list for authorization.** Due to resource constraints, only a limited number of high-concern

chemicals on the candidate list for authorization may become formally subject to the company and use-specific restrictions contemplated by the authorization process. However, it is widely anticipated that just being on the much larger candidate list may have a stigmatizing impact that could distort demand for these chemicals or products using them, as customers anywhere in the world might require that products not contain any substances of very high concern on the candidate list. It could also deter companies from trading in the EU market if they believe there is a risk that their right to use a particular substance may at any time be withdrawn.

**Expanded civil liability.** Requiring more evaluation of the environmental, health and safety risks of products may increase potential legal risks. Some of these may arise in a supply-chain context. For example, if a chemical supplier fails to register a substance, its downstream purchaser may lose or be unable to fill existing contracts as a result of not being able to manufacture a finished product without that particular substance. The suppliers may face legal claims from their customers in such situations.

In another scenario, consumers may bring private lawsuits against firms claiming the companies have failed to notify their users about the dangerous properties of the substances. This will become an increasingly important issue, particularly as European countries are beginning to embrace class action suits. REACH could also increase liability concerns in other countries, including the U.S., as more environmental-, health- and safety-risk information becomes available to regulators and the public.

**Evaluating your exposure.** In order to understand your exposure to REACH and its potential impact on your business, you need to know 1) the chemicals you use; 2) how you use them (for example as process chemicals or coatings); 3) the source of the chemicals; 4) where the chemicals end up (for example in products, released from products due to wear and tear or other releases, such as in waste streams and water discharges); 5) what markets you sell into; and 6) how

your chemicals get to those markets and your position in the supply chain. With this baseline set of information, you can begin the process of evaluating how REACH affects your business, ranging from threats to the availability of key chemicals to revising product formulations to anticipating likely customer demands and needs.

*Edited by Dorothy Lozowski*

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