

European Union's REACH Program – Companies Face Shifting Global Regulatory Environment

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Companies doing business in international markets face a bewildering array of local regulatory requirements governing their business and marketing activities. These can range from local environmental, safety and health restrictions to protect workers in foreign manufacturing operations, to standards governing the use of hazardous materials in products and product packaging.

In the past, many companies tried to meet these requirements by gearing their multinational compliance programs to US regulatory standards. The assumption was that US standards were considered the most stringent in the world, so that compliance with US standards as a general matter would almost certainly ensure compliance with other, less stringent standards in effect elsewhere. Increasingly, this assumption is no longer correct. Regulatory programs in jurisdictions outside the United States are becoming increasingly sophisticated and complex. In some cases, they also are taking approaches to risk and hazard management that differ in significant ways from what has been accepted in the United States. The result is that existing corporate compliance programs based on US standards alone may be inadequate to assure regulatory compliance in global markets going forward.

Perhaps the most ambitious regulatory program currently under development outside the United States is the so-called REACH (Registration, Evaluation and Authorisation of Chemicals) proposal currently being considered in the European Union. Under this proposal, substances manufactured or imported (on their own or in preparations) in the European Union in volumes greater than one tonne per year would have to be registered in a central database managed by a new European Chemicals Agency. Unlike regulations in the United States, the EU registration requirement would apply to “articles” (objects composed of substances and/or preparations, with a specific shape, surface or design), where substances could be released during normal and foreseeable use. The proposal also contemplates pre-market authorization of the use of chemicals of “very high concern,” placing a high burden of proof on businesses seeking to put these chemicals to new use not previously approved. Finally, downstream users must consider the safety of their uses of substances, take appropriate risk management measures and report required information.

Despite assurances to enhance the workability of REACH, the proposal has raised a number of concerns with industry groups. REACH would shift the burden of assessing the risks of chemical substances from regulatory authorities to enterprises, and it would increase the level

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of testing that would have to be carried out by companies that manufacture, import or use chemical substances on their own or in preparations or finished articles. REACH could also result in a significant barrier to international trade, especially if testing methods and results obtained outside the Community are not readily recognized. Finally, there are concerns over new disclosure obligations that could seriously compromise the protection of confidential business information.

CEFIC, the European Chemical Industry Council, as well as the American Chemistry Council, have strongly opposed drafts of the proposal, warning of the “de-industrialisation” of Europe if certain elements are carried forward, as well as the erection of significant trade barriers “in violation of the European Union’s WTO obligations.” The European Commission itself estimates that the program will cost between €2.8 and 5.2 billion over 11 years. Other studies predict that the program will result in losses in gross domestic product of between 0.4 percent and 6.4 percent in Germany and France, with corresponding increases in job losses. Since chemicals are used in some manner in the manufacture or use of most products, the US government has predicted that REACH could affect the majority of US goods exported to the European Union.

The REACH proposal in the European Union is not the only new international regulatory regime confronting US businesses operating in global markets. Japan recently amended its Law Concerning Examination and Control of Manufacture and Handling of Chemical Substances (or CSL), which has its own requirements for pre-authorization, notification and reporting in the use of designated chemicals and substances. In 2003, China also adopted new rules on the administration of new chemical substances, with detailed declaration procedures, exemptions and restrictions on importation and manufacture. On top of these and other national and regional programs, the United Nations Environment Programme (UNEP) has approved a new Globally Harmonized System of Classification and Labelling of Chemicals (GHS), which provides a common framework for characterizing and managing information about chemicals and chemical risks. The GHS is part of a broader effort to harmonize chemicals and materials management programs in the context of global initiatives on sustainable development.

The time for US businesses to adjust their global compliance programs to accommodate these new regulatory developments is now. This means taking a systematic look at the products they make or sell in global markets and evaluating what chemicals and substances are manufactured, used or imported in connection with those activities; reviewing the information companies already have regarding the substances they handle; determining whether necessary classifications and registrations have been undertaken in accordance with EU and other laws; assessing whether there are potential substitutes for the substances used, manufactured or distributed; and evaluating what information needs to be kept confidential and whether adequate legal instruments have been developed to preserve confidentiality.

For many smaller and medium-sized businesses, the scope of the compliance challenge may exceed the capacity of internal resources to effectively manage it. In such cases, firms should consider bringing in external help in the form of regulatory monitoring services and competent international counsel. While increased costs will be associated with reliance on external support, the costs of mishandling international compliance will undoubtedly be greater.