

*William (Bill) Tarantino  
Associate, Morrison & Foerster, San Francisco  
December 2007*

## **THE EU'S REACH REGULATION AND CHEMICAL MANAGEMENT SERVICE PROVIDER**

The European Union's Registration, Evaluation, and Authorization of Chemicals (REACH) regulation has been looming over companies that manufacture, import or use chemicals for nearly three years. Now, with its final enactment in July 2007, the massively complicated REACH regulation has finally arrived. As a comprehensive replacement for over 40 different directives, REACH requires registration of chemicals made in or imported to the EU, assessment of the risks arising from chemical use, and multi-party implementation of measures to manage those risks.

Under REACH, each chemical producer will be required to provide authorities, the public, and customers along the supply chain with basic toxicity and exposure information for any chemical it produces or uses in quantities of over one metric ton per year. Absent such information, the chemical will not be allowed on the EU market. Companies seeking to use the most hazardous chemicals (carcinogenic, mutagenic, toxic to reproduction, persistent, or bioaccumulative) will be required to seek permission for their continued use, and they will have to demonstrate that there are no alternatives, that they can be used safely, or that there is a compelling need for their use.

Although the legislation is technically limited to the EU, REACH will result in new standards among chemical producers and users not only in Europe, but also in the United States and other countries. It is the most far-reaching piece of environmental legislation in Europe in the past 30 years, addressing perceived limitations in current regulatory programs for chemicals management that presume most chemicals on the market are safe until proven harmful. REACH will have a significant impact on the \$20 billion chemical industry in the U.S. and other manufacturers exporting their products to Europe.

For Chemical Management Services (CMS) providers, REACH presents a new opportunity for increasing the value of existing life cycle management services. Ultimately, REACH will drive more efficient and effective use of chemicals, in line with CMS providers' and their customers' business goals. However, as with most new regulatory regimes, there will be a significant adjustment period as the regulated community adapts to these standards. CMS providers can add value by not only understanding the basic requirements, but also helping customers anticipate some of the legal and business conflicts that are likely to arise as the requirements come into effect.

### **HIGHLIGHTS OF REACH'S IMPACT ON DOWNSTREAM USERS**

Without question, REACH places the most burdensome requirements on manufacturers and EU importers of chemicals. However, there are also significant requirements for downstream industrial users of chemicals. Chemical users will have to ensure that appropriate chemical safety assessment data are obtained from the registrant manufacturer

or importer, and that the chemicals they use are properly registered for particular uses. If the downstream user intends to use the chemical outside the conditions described in the exposure scenario used for registration, that user must develop its own appropriate risk management measures through a chemical safety assessment conducted in accordance with Annex I of REACH. This issue could arise if the downstream user wants to use a substance in a manner unforeseen by its suppliers, and the downstream user prefers to keep chemical use confidential. In such a case, the downstream user would have to supplement the registration information in order to continue the intended use of the chemical.

REACH imposes other unconventional obligations on industrial chemical users. A downstream user must apply the risk management measures communicated to it through the chemical safety assessment. If it does not agree that the identified risk management measures are appropriate, the downstream user will need to inform its supplier of the perceived deficiency, or carry out an independent chemical safety assessment. REACH does not specify when manufacturers and importers must follow those recommendations or what the consequences are if they chose to decline the users' suggestions. Legally, the result is potentially increased liability to all entities involved. Both government action and product liability actions may apply the user's heightened standard of care if the manufacturer or importer does not follow the recommendations and an injury or harmful exposure occurs. At a minimum, all regulated parties under REACH will need to re-examine their existing supply contracts for appropriate risk-allocation provisions with respect to chemical risk management measures. These informational provisions come with both recordkeeping and compliance burdens, and with an undefined new standard imposed upon the transactions involving regulated substances.

In addition to these unique liability issues, REACH also poses the risk of inconsistent obligations with existing toxic chemical regulations, including the Toxic Substances Control Act (TSCA). While many U.S. companies have experience with addressing varying TSCA-like statutes in different countries, the sweep of REACH is much broader, covering "existing" chemicals and an extensive geographic region with many diverse economies. While the proponents of REACH assert that the standardization of toxic chemical regulation is intended to avoid conflicting standards, there is no provision in REACH specifically designed to incorporate or provide comity for existing external standards (such as TSCA). Depending on how the EU agencies restrict chemical use under REACH, the EU's controls could be far stricter than existing US standards.

## **PREPARING FOR REACH**

Despite the uncertainty about its implementation, companies that will be subject to REACH should begin to prepare for the first phase, "pre-registration," which takes place from June to December 2008. By acting during the pre-registration phase, companies can avoid market disruption and can take advantage of extended deadlines for full compliance. Companies will likely look to their CMS providers to assist them in determining whether their current chemical portfolio is appropriately registered for the business's current or proposed use. In addition, if a company uses chemicals as an intrinsic part of its products, that company will need to determine which products are considered "articles" under REACH and whether releases of those chemicals to the environment are likely. In essence, companies can be best prepared by reviewing their own current chemical use and evaluating whether alternative,

lower impact chemicals are feasible replacements. In many cases, CMS providers are well-situated to assist their customers with these reviews.

While large, multinational companies have significant experience in managing inconsistent regulations from various countries, smaller and more localized companies may lack this experience. In any event, both types of companies will likely seek out CMS providers to help manage their REACH-related obligations. REACH has the potential to affect how downstream users will choose suppliers. Because of the stringent requirements for registration and testing, REACH may cause downstream users to prefer EU suppliers or large multinational suppliers to ensure maximum compliance, especially in light of recent laws passed by states such as California that have adopted EU environmental standards verbatim.

## **CONCLUSION**

In the next year, the implementation of REACH will shift the landscape of chemical regulation in the EU and around the world. It is sure to present complex challenges for those dealing with hazardous chemicals, and will likely require many companies to develop customized compliance programs. CMS providers have the opportunity to help their clients approach REACH and provide the chemical management information they will need to ensure cost-effective compliance.

---

### **About the Author**

William (Bill) Tarantino is an associate in at Morrison & Foerster's San Francisco office, where he is a member of the Land Use and Environmental Law Practice Group. Mr. Tarantino's practice includes environmental law and regulation with an emphasis on toxics and hazardous materials, waste management, water quality, toxic torts, and environmental remediation.

Mr. Tarantino received his J.D. from the Georgetown University Law Center with honors, Masters in Public Health from the Johns Hopkins Risk Sciences and Public Policy Institute, and a bachelor's degree from the University of California, Berkeley.