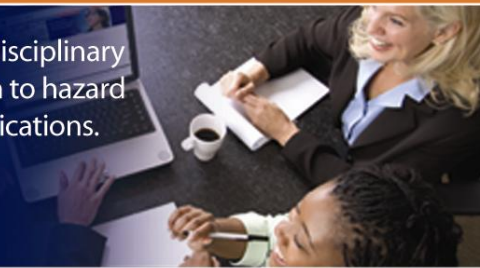




A multi-disciplinary approach to hazard communications.



ARE YOUR PRODUCTS READY FOR REACH?

On June 1, 2008, the first provisions of the European Union's new sweeping regulation of chemical substances will take effect. REACH, short for "Registration, Evaluation, Authorisation, and Restriction of Chemicals," will cover approximately 30,000 chemical substances. From June 1 through November 30, 2008, REACH implementation of a detailed chemical pre-registration scheme begins for these chemical substances and a new framework for hazards communications using revised safety data sheets. Thereafter, REACH will require private industry to undertake detailed risk and safety assessments for the chemicals they produce and use. These chemical safety assessments will be reported to the newly created European Chemicals Agency ("ECHA") in Helsinki, Finland and will also be incorporated into REACH's hazard communications requirements. Eventually, ECHA will evaluate and is expected to restrict usage of several thousand higher-risk and more dangerous chemicals. An underlying REACH principle is that chemical manufacturers, importers, and downstream users will now bear the burden to ensure that the substances they manufacture, place on the market, and use do not adversely affect human health and the environment.



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has defended manufacturers in product liability lawsuits in state and federal courts across the country. He previously worked as a litigator for the Department of Justice in Washington, D.C. Here, he discusses the impact of REACH on manufacturers of which the first provisions will take effect on June 1, 2008.

U.S. Manufacturers Will Be Impacted

REACH will impact virtually all sizeable manufacturers, importers, and downstream users of chemicals within the European Union. REACH will also inevitably "reach" beyond EU borders and also impact any non-EU manufacturers and producers who want access to the EU market. REACH makes importation in the EU one of its gateway points for regulation, with importers responsible for all chemical substances, including those in "articles" (items such as textiles, apparel, consumer products, commercial products) and preparations, that they bring into the EU. In practice, EU importers will look up the stream of commerce to non-EU companies for information about the chemical composition of their prospective imports. To ensure uninterrupted EU market access, non-EU companies will need to verify that their products are REACH compliant.

Although REACH might first appear to be a new regulatory burden, it is intended to create a more efficient, streamlined EU-wide system. Through innovative regulations, it permits joint collaboration within industry to pool resources and costs to assess the risks and health effects of their chemicals. Moreover, REACH will replace approximately 40 existing pieces of legislation and will create a single regulatory system for most substances. Thus, with pro-active planning and best practices, companies can not only meet REACH's regulatory challenges, but also potentially use their REACH preparedness to gain competitive advantage in and outside the EU.



Products Or “Articles” That Contain Or Release Chemical Substances

Because REACH aims to ensure a high level of protection of human health and the environment, its coverage extends beyond the manufacture and import of chemical substances, and reaches, in certain instances, “articles.” Articles are defined to include manufactured products such as textiles, apparel, consumer products, and commercial goods. There are two situations where REACH will impact both EU and non-EU producers of articles.

First, where a product contains chemical substances or preparations that are “intended to be released during normal and reasonable foreseeable conditions of use” of the article, the released substance must be registered with ECHA. The preliminary technical guidance gives several examples of “intentional releases” of substances from articles: A pen releases ink for its writing function. A cleaning wipe releases detergent and perfume scent for its essential cleaning function. A burning candle releases scents for its function of fragrance. With respect to textiles, the initial guidance suggests even that fade-out styles of denim jeans may intend to release dyes as part of their function. The exact parameters for whether a product intentionally releases substances and triggers registration requirements may be refined or revised by final forthcoming technical guidance from ECHA. For most consumer products, registration may be the exception.

Products Containing Substances Of Very High Concern

The second area of REACH concern is where a product or article contains any “substances of very high concern” or “SVHCs.” If the concentration levels of an SVHC in an article exceed 0.1%, the producer or importer may be required to notify ECHA with certain information regarding the article and the SVHC it contains. Notification is separate from REACH registration. REACH also requires that the supplier of the article containing the SVHC communicate sufficient information down the supply chain to the recipient of the article to allow safe use of the article, including, at a minimum, the name of the SVHC.

Under REACH, ECHA will create a candidate list of SVHCs. These will include substances that are carcinogenic, mutagenic, and toxic for reproduction; substances that have persistent, bioaccumulative and toxic qualities; substances that have endocrine disrupting properties; and other substances of equivalent health and environmental concern.

The Subsequent Registration, Evaluation, And Authorization Process

Once pre-registration is completed, REACH envisions a process of communication, and collaboration between all manufacturers, importers, users, and interested third parties, working towards satisfying their obligations to timely complete full registrations of each chemical substance. REACH requires all potential registrants, downstream users, and third parties who have submitted pre-registration information to the ECHA to be participants in a “SIEF”—a “substance information exchange forum.” Through SIEFs, these parties will work together, share costs, and, with limited exceptions, eventually have one “lead registrant” submit one “technical dossier” to ECHA to complete registration of the substance. The SIEFs will work to prepare the technical dossiers which will contain scientific studies regarding chemical safety assessments and chemical safety reports.



After registration, ECHA will conduct its work of evaluating the registration dossier information and the hazards and risks of the chemical substances. ECHA will also undertake to create lists of SVHCs and determine whether to issue restrictions, authorizations, or bans of these substances.

New Safety Data Sheet Formats

New REACH safety data sheet ("SDS") requirements take effect on June 1, 2008, as well. For shipments of covered chemical substances and preparations as of that date, an SDS is required in accordance with the requirements of REACH Article 31. The new SDS will need to follow the specified content and format as set forth in Annex II of REACH.

As the registration and chemical safety assessment process is completed, an extended SDS must be developed. An extended SDS will require the inclusion of an annex with "relevant exposure scenarios," which will be developed from chemical safety assessments. Relevant exposure scenarios will address operational conditions and risk management measures for the substance and will recommend to downstream users how to control exposures to humans and the environment.

Eventually, however, REACH envisions that safety data sheets will need to be adapted to be in accord with the Global Harmonized System of Classification and Labeling of Dangerous Chemicals.

Downstream Users And Distributors In The EU

As REACH aims to limit human and environmental exposures to harmful chemical substances, it implements, as part of its risk management measures, a scheme for communication of information both up and down the supply chain. Downstream users and other actors in the supply chain have various obligations under REACH, some of which involve the SDS communication process and substance registration processes. Voluntary and required communications will vary depending upon an entity's position and activities within the supply chain of a substance or preparation.

A downstream user may be obligated to communicate up the supply chain any new information on hazardous properties or information that might call into question the appropriateness of the risk management measures contained in the supplier's SDS. Downstream users must provide certain chemical safety and use information to their employees.

With respect to the registration process, downstream users have the right to communicate up the supply chain their particular uses of the supplied substance or preparation. The aim of this communication is to provide manufacturers and importers information on how their substances and chemicals are used, so that these uses are considered in the process of completing chemical safety and risk assessments, safety data sheets, exposure scenarios, and registration dossiers. The manufacturer or importer may decide that the downstream user's use of the substance is unacceptable or inappropriate. In such a situation, the downstream user would then be obligated to conduct its own chemical safety assessment and safety data sheets for such unapproved uses.



Thus, downstream users are encouraged to follow and, where appropriate, provide input into the REACH registration process, as activities up the supply chain may have an impact upon their actions.

Getting Prepared For REACH

REACH is a large piece of legislation, with many highly technical legal and scientific concepts, definitions, and provisions. Only the first impending compliance issues are summarized here. REACH is still in its initial pre-implementation stages and much of the voluminous technical guidance for industry compliance is still being prepared.

All manufacturers and importers of chemical substances, preparations, and articles headed towards the EU marketplace will want to consider whether their operations and products are ready for REACH. Through a properly targeted audit and inquiry, REACH obligations and requirements can be effectively addressed. Many compliance determinations may be clear and of limited burden. Others may be more complex and require more strategic preparations and planning. Ultimately, if properly addressed, ensuring REACH compliance may add quality and competitive advantage.

For more information about REACH issues as they may relate to your operations and products, contact us about these regulatory compliance issues.

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