



Maintain critical control of your business while complying with REACH

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When it comes to selling chemicals in Europe, the EU has a long REACH. Last summer the European Union began requiring all exporters of chemicals, chemical components, and finished products containing chemicals to begin registering those substances. The regulation is called REACH, which stands for the Registration, Evaluation, Authorization, and Restriction of Chemicals.

With REACH the EU aims to minimize the potential health and environmental impact of those substances by sharing information about them among its member states. That means registering some 30,000 chemicals over the next 11 years. It also means additional reporting requirements for a broad spectrum of industry sectors, such as pharmaceuticals, industrial chemicals, cosmetics, and cleaning products. The new policy covers a number of businesses, including producers of substances and end-products, exporters, importers, distributors, and downstream users.

REACH is far-reaching. It applies to all chemicals, from substances used in industrial processes to those used in everyday life, including paints, clothes, furniture, electrical appliances, and others too numerous to list. The regulations require that chemical substances in and of themselves, in preparations, and intentionally released from products be registered with the European Chemicals Agency (ECHA). The regulations went into force June 1, 2007.

What is REACH?

REACH is the world's most ambitious law on public health and environmental protection, replacing some 40 individual pieces of legislation with what the EU hopes will be a more streamlined system. It is designed to consolidate prior laws and regulations to create a single system for chemicals manufactured in and imported into the EU.

REACH places the onus on manufacturers and importers to collect data and share information about the chemicals used in their respective products and any risks they may pose. These regulations present a significant challenge to exporters who must now master the intricacies of the new law or lose the ability to do business in this important market.

Consequences of noncompliance

For exporters to Europe, REACH is a game-changer. If a company cannot comply, it won't be able to sell products in one of the world's largest markets. With nearly 500 million citizens, the 27 member countries that comprise the EU generate about a fifth of global exports and imports, making their combined GDP of nearly 11 trillion greater than that of the United States.

Yet compliance holds considerable risk as producers and importers face the possibility of having to share often proprietary information and even testing of their chemicals if the data is deemed incomplete. The potential for divulgence of trade secrets is very real, so it is critical that REACH compliance be handled extremely carefully. European chemical companies must cease producing and importers must stop importing listed chemicals until they have complied with the mandates.

Even the deadlines pose a challenge. According to REACH, any company that does not pre-register by December 1, 2008, will have to stop producing or importing immediately. And restarting the process requires going through the full-registration procedure. (In some cases, it is possible for a company to pre-register after this date, but the rules are complex.)

Registering chemicals

There are two broad categories of chemicals that must be registered: those already being manufactured or imported into

EU countries (called phase-in substances) and substances new to the EU (called non-phase-in substances). REACH requires manufacturers and importers of chemical substances in quantities of 1 tonne (1 metric ton, or 1,000 kilograms) per year to register. They must obtain information on the physico-chemical, health, and environmental properties of their substances to determine how they can be used safely. Each manufacturer and importer must submit to the ECHA a registration dossier documenting the data and assessments.

Both phase-in and non-phase-in substances that have not been pre-registered must be registered before they can be produced, sold, or used in the EU. However, the two types of substances have different schedules for registration. Manufacturers and importers must pre-register their phase-in substances by December 1, 2008, if they want to benefit from extended deadlines registration. Otherwise, they are obligated to fully register by that date. The penalty for failing to register is that the chemicals / articles will not be permitted into EU commerce. Depending on tonnage band and the hazardous properties of the substance, the staggered deadlines are November 30, 2010; May 31, 2013, and May 31, 2018.

Creating solutions

Under REACH, only a natural or legal person established in the EU can be a registrant. Foreign nationals cannot self-register their chemicals. Exporters that do not have a subsidiary in the EU have three basic routes to compliance. They can establish a subsidiary in the EU; allow the importer to register their products; or they can outsource the process to a legal representative familiar with the chemical industry, REACH, and the EU regulatory climate.

Establishing a subsidiary can be costly and onerous in terms of maintenance and management. Abdicating the process to an importer runs the risk that confidential information could be compromised by disclosure or reverse engineering.

If the registrant is an importer or distributor, that entity technically owns the registration and is responsible for communicating with ECHA, which will require detailed disclosure of the composition of chemicals and other products. In addition, working through an importer or distributor may make it difficult to alter future distribution channels in the EU.

In fact, changing partners in Europe may cost an exporter access to the EU market.

The process of establishing an internal team to gather data, test substances, file reports, and interface with the EU can tax the resources of even the largest companies. The REACH deadlines point up the need to act quickly to ensure uninterrupted access to the EU market. Within this context, outsourcing REACH compliance may prove to be a viable alternative.

Protecting your business

Under REACH, an exporter has the option of working through an *Only Representative*, an agent that can register the substances of non-EU members.

An Only Representative must be both a legal entity established in the EU and have “sufficient background in the practical handling of substances and the information related to them to be able to fulfill the obligations of importers.” As such, it can serve as a valuable adviser for developing a global REACH strategy to complement internal compliance programs through transaction auditing, training, and formulation of appropriate policies for present and future filings.

An Only Representative can provide an exporter greater control over the entire registration process including critical aspects of its substances, thereby minimizing the potential for disclosure of proprietary information. In addition, experts on REACH can help meet and maintain the rigorous and ongoing compliance schedule, allowing exporters to focus on their core business.

A final word

The key challenge to compliance with REACH is remaining competitive while protecting trade secrets and your place in the market. Outsourcing this process can provide a logical solution for exporters looking to maintain their competitive edge by retaining ownership of the registration data and control over the entire process.

GOOD CHEMISTRY

Here are several steps to take when deciding whether to use an Only Representative:

- **Hire an expert** with extensive experience in EU regulations for chemical safety, chemistry and toxicology, environmental risk management, legal issues, and information technology for seamless REACH implementation.
- **Know the data** compiled for REACH compliance and insist it be transparent so you are aware of all status filings, information requests, decisions, and actions.
- **Find an advocate** who possesses excellent communication skills to advocate on your behalf.
- **Consider the total cost** of satisfying the logistics requirements of REACH and ensure your internal team is up to the task. The cost of outsourcing may be competitive in light of the complexity of compliance.
- **Ensure confidentiality and control** through an Only Representative that can fulfill the REACH registration requirements and safeguard proprietary information.
- **Get it in writing** by naming your Only Representative in a letter to protect against an importer changing its position concerning its role.
- **Plan for transition** by building an internal project management team and empower it with oversight and decision-making authority.
- **Negotiate the contract**, spelling out expectations, terms, and responsibilities including scope of work, pricing, milestones, incentives, and penalties. Mandate that your Only Representative maintain the information in the strictest of confidence and use it for the sole purpose of REACH compliance.
- **Keep an open channel** by passing information down the supply chain and responding to information on substances passed from further down the supply chain (for example, requests for new identified uses of substances from downstream users).
- **Retain documents.**

REGISTRATION DEADLINES

For more detailed information on practical pre-registration issues, use of IT tools, IUCLID 5 pre-registration tool, and REACH IT, visit

http://echa.europa.eu/doc/pre-registration/pre_reg_qa_en.pdf.

Nov. 30, 2010 Phase-in substances that were manufactured or imported into the EU at least once after June 1, 2007, in quantities of 1,000 tonnes (metric tons) or more per year per manufacturer or importer.

May 31, 2013 Phase-in substances that were manufactured or imported into the EU at least once after June 1, 2007 in quantities of 100 tonnes or more per year per manufacturer or importer.

May 31, 2018 Phase-in substances that were manufactured or imported into the EU at least once after June 1, 2007 in quantities of 1 tonne or more per year per manufacturer or importer.

Substances not pre-registered but which are imported for the first time into the EU after December 1, 2008, may benefit from the staggered deadlines if the information requested for pre-registration is provided within six months of the first import into the EU and no later than 12 months before the relevant registration deadline.



About the Author:

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Catherine Muldoon joined BDP International, Inc. in 2002 as General Counsel, US and was named Chief Global Counsel in January of 2004. In this role, Catherine is head of BDP's legal department with direct responsibility for all legal and contractual considerations associated with all mergers and acquisitions, joint ventures and business partners, tax planning, corporate structuring and strategy, business services, personnel, banking relations, and real estate. She is also responsible for managing litigation. Catherine takes a lead role in corporate governance and risk management programs within BDP, ensuring that best practices are identified to the Board of Directors and implemented by the business units.

Catherine earned a Bachelor of Arts from The Johns Hopkins University and a J.D. from Seton Hall University School of Law. She is Vice Chair of Corporate Counsel Forum of the International Bar Association and a member of the Association of Corporate Counsel.

About BDP

BDP International is one of the leading privately held freight logistics/transportation management firms based in the U.S. It operates freight logistics centers in more than 20 cities throughout North America and a network of subsidiaries, joint ventures and strategic partnerships in more than 120 countries. The company serves more than 4,000 customers worldwide. Clients include Bayer, Cargill, Conoco Phillips, Heineken USA, Honeywell, Johnson & Johnson, Marks & Spencer, Revlon, Rohm & Haas, Trek Bicycle, Wacker and others.

BDP provides a range of services, including sea, air and ground transportation; lead logistics process analysis, design and management; export freight forwarding; import customs brokerage and regulatory compliance; project and energy logistics; warehousing/consolidation/distribution; and Internet shipping transaction/tracking management systems.

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