A Practical Guide to REACH—The EU Chemical Classification System

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The European Union's (EU) REACH legislation took effect on June 1, 2007. REACH, which stands for "Registration, Evaluation, and Authorisation of Chemicals," requires parties to register information related to certain chemical substances that are manufactured, imported, or used in the EU. Failure to register will result in prohibition of the substance. The intention of REACH is to evaluate substances that are potentially hazardous to humans and the environment. An authorization system will require companies to gradually switch to safer alternatives whenever possible.

U.S.-based exporters and legal counsel of companies dealing in chemicals need to be aware of what the REACH initiative entails. The legislation could raise several legal issues surrounding registration, including potential sharing and public disclosure of proprietary information, and will create an additional cost of compliance in order to sell products to EU-based buyers.

REACH in Focus

Overview

In general, REACH will impact EU-based companies that deal in the products covered by the legislation. However, the legislation may also affect U.S. exporters of products within the scope of REACH if EU-based partners request technical information regarding the products, some of which may be proprietary, for registration purposes. Another possibility is that EU-based importers could shift the registration burden back to U.S. exporters by refusing to function as registrants, requiring the U.S. exporter to designate a EU-based agent as its registrant or lose the business.

The cost of REACH compliance will impact both exporters and importers. With an added layer of expense, a shift in the marketplace could occur in favor of companies that can afford the extensive testing costs required to support product registration.

Scope

REACH covers about 30,000 substances manufactured, imported, used as intermediates, or marketed as is in preparations or in articles. REACH does not apply to all chemicals. Radioactive substances, for example, are completely excluded from REACH, and food additives, cosmetics, medicinal products, biocides, and pesticides are excluded from the registration and authorization portions of the legislation. The initiative also excludes chemicals produced or imported in volumes less than one ton; chemicals used in research and development; certain chemical substances that are already sufficiently regulated; and low-risk products such as water, polymers, oxygen, certain noble gases, cellulose pulp, minerals, ores, and ore concentrates.

Registration. Registration must be complete before a substance can be manufactured, imported, or placed on the market. For substances that have long been on the EU market, a special transitional period will be instated that will provide time to comply with the legislation. For more on this phased approach, see the Staged Phase-in section below. All other chemicals must be registered by June 1, 2008.

The majority of substances affected by REACH will be subject to only the registration process. This portion of the legislation requires that any producer or importer of chemical substances within the scope of REACH register those chemicals with the European Chemicals Agency (ECHA), based in Helsinki, Finland. Essentially, there are three entities that are obligated to register chemicals: EU-based manufacturers, EU-based importers, and EU-based representatives of non-EU manufacturers. U.S.-based exporters affected by REACH will need to designate a representative in the EU to file registrations if that exporter elects to register directly rather than provide the necessary information to the EU importer.

Information that must be submitted as part of the registration process includes the chemical's properties, identified uses, and safe management guidelines. Registration includes a technical dossier and a Chemical Safety Report (CSR) if more than ten tons of the substance are manufactured or imported per year.

For chemicals that are consumed or transformed into another substance in the manufacturing process and are imported in amounts less than 1,000 tons, light registration is required. Light registration includes the hazard classification, property information that is readily available to the registrant, and risk management measures applied. Only intermediaries transported under strictly controlled conditions qualify for light registration.

In some cases, chemicals may be incorporated as a substance in an article, such as cars, textiles, or electronics chips. If these chemicals meet criteria for classification as dangerous and will be released during reasonably fore-

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seeable use of the article, they must be registered in accordance with the normal tonnage and information requirements. If these incorporated substances are of high concern, as identified by the ECHA, the ECHA must be notified if the substance is produced/imported above one ton (per year per manufacturer/importer), and above a concentration limit of .1 percent weight by weight.

Technical Dossier. The producer/importer must submit a technical dossier as part of the registration process. This document must contain the identification of the manufacturer/importer and information on life-cycle properties, uses, classification of the substance, and the safe use guidelines. The amount of information required depends on the amount of chemicals involved and on the hazard classification of the substance. Hazard classes include persistent, bioaccumulative and toxic (PBT); very persistent, very bioaccumulative (vPvB); and carcinogenic, mutagenic, or toxic for reproduction (CMR).

Chemical Safety Report. If a product is produced or imported in quantities greater than ten tons, a chemical safety report (CSR) must be submitted. The CSR documents the hazard classification of the substance and contains details related to the environmental and health risks of the substance. It also must include various exposure scenarios for the product. These are sets of conditions that describe how substances are manufactured or used during their life cycle, and how the manufacturer or importer controls, or recommends controlling human and environmental exposure. The scenarios must include the appropriate risk management measures and operational conditions that, when properly implemented, ensure that the risk from the uses of the substance are adequately controlled. Exposure scenarios must include the manufacturer's or importer's uses, as well as those made known to them by downstream users. These scenarios will be annexed to the safety data sheets (SDS) that are supplied to all downstream users as part of the registration process.

Staged Phase-in. Several classes of chemicals qualify for staged phase-in. To qualify, chemicals must meet one of the following criteria:

1. The chemical is listed on the European Inventory of Existing Commercial Chemical Substances (EINECS).
2. The substance was manufactured in the EU (except Bulgaria and Romania) at least once after May 31, 1992, without being placed on the EU market by the manufacturer or importer. The manufacturer or importer must have documentation of this.
3. The substance was placed on the market in the EU before June 1, 2007, by the manufacturer or importer and is a "no-longer polymer" (NLP). A NLP is a substance that was placed on the EU market between September 18, 1981, and October 31, 1993, but does not meet the REACH definition of a polymer.

Manufacturers and importers of staged phase-in substances must preregister by December 1, 2008, in order to benefit from the transitional period.

Staged phase-in products imported or produced in quantities greater than 1,000 tons (per year per manufacturer/importer) are CMR or are produced/imported in quantities greater than 100 tons and are PBT or vPvB must be registered by November 30, 2010. The deadline for registering chemicals produced or imported in quantities of 100 to 1,000 tons per year is May 31, 2013. The deadline to register staged phase-in chemicals manufactured or imported in quantities of one ton to 100 tons per year is May 31, 2018.

Data Sharing. Prior to registration, all substances must either be preregistered or an inquiry must be submitted. This is required to prevent unnecessary testing, especially animal testing, which must only be utilized as a last resort. Data collected through animal testing must be shared in exchange for payment. The theory is, if multiple applications are submitted for the same chemical by different companies, only one set of data is needed. The forced sharing of data reduces the need for duplicate testing, but this also presents a new problem in that juridical issues related to unfair competition and sharing of responsibilities may arise.

REACH has several provisions to facilitate the sharing of data between registrants. For staged phase-in substances, a Substance Information Exchange Forum (SIEF) following preregistration will be established. For non-staged phase-in substances, registrants must submit an inquiry to the ECHA regarding whether a registration has been submitted for the same chemical in order to facilitate data sharing. If a registration for the same substance has not been filed, the ECHA will direct the registrant to proceed with registration. If the same chemical has already been registered, the registrant and pre-registered party will be informed to facilitate data sharing.

Downstream Users. Certain downstream users, such as formulators of preparations or users of chemicals in other industrial processes, are also required to consider the safety of their uses. Primarily, the users will be responsible for communicating with their suppliers or importers to advise them of specific uses made by the user so that the producer/importer may include such uses in their exposure scenarios. These additional uses will be incorporated into the SDS. The downstream user is responsible for making sure that its uses are covered in the scenarios.

If the user does not communicate with the producer/importer (to retain confidentiality), then it will be responsible for performing the chemical safety assess-

ment, including developing the exposure scenarios for its uses. The downstream user would then report that information directly to the ECHA.

Evaluation. The evaluation process is a structured means by which the ECHA, in cooperation with member states, examines registration dossiers. There are two steps to this process:

1. Dossier Evaluation: This is used as a check on registration dossiers to prevent unnecessary animal testing and poor quality tests and to ensure compliance with existing requirements.
2. Substance Evaluation: The ECHA may request more information to clarify risks to health or the environment and can delegate the evaluation responsibility to any EU member state.

Authorization. The authorization process will apply to products that pose a high risk of cancer, mutations, problems with reproduction, or accumulation in the body. Authorization will be granted only if risks are adequately controlled, and the producer sustains the burden of proving that the social and economic benefits outweigh the risks where no suitable alternatives exist. After the member states/ECHA have undertaken the evaluation process, in some cases they will require that an authorization be provided before the high-risk products are used or placed on the market. Chemicals falling into any of the categories listed under the Technical Dossier section above, or that cause serious and irreversible effects to humans or the environment must be authorized for use. In some cases, a chemical may be banned altogether.

The ECHA will publish a list identifying all hazardous substances along with those that require authorization for use. Some substances may be exempt if controlled by other legislation. To apply for authorization to use a restricted substance, the applicant must prove adequate control measures are taken that outweigh the risks. The European Commission will prepare decisions surrounding applications for authorization and present them to the public for comment. In some cases, producers may be required to find alternative substances if the risk of their product is deemed of too high a concern.

Classification and Labeling. Producers or importers of chemicals considered dangerous will be required to classify and label such products. Within three years of the REACH legislation's effective date, all producers must submit substance classifications to the ECHA for inclusion in an inventory, which will serve as the central storage bank for use by the industry to harmonize classification and labeling of hazardous and dangerous chemicals.

Penalties for Noncompliance

Proposed Enforcement. Enforcement against violations of the REACH program will be handled by individual EU member states, according to their own internal laws, which will need to be promulgated. No harmonized enforcement body exists, which may result in different penalties from country to country. Failure to register a product will mean that its manufacture in or importation into the EU is in violation of the REACH legislation.

Certain decisions can be appealed to the ECHA's Board of Appeal. Any of the following situations may be appealed:

1. Completeness: Decision to impose a registration and submission deadline for required information or reject registration based on incomplete application or a registrant's failure to meet a deadline.
2. Inquiry: Decision to make preregistered substance data available to a potential registrant.
3. Data Sharing for Staged Phase-in Products: Decision to make data available to SIEF members at the preregistration level.
4. Evaluation: Decision to require further information at the evaluation stage.

The Scope of REACH

U.S. exporters of chemical substances into the EU need to understand the scope of REACH. While REACH should benefit human health and increase environmental safety, it will also create a new cost of compliance, whether the exporter provides the information to its EU-based importer or elects to register on its own. In addition, while a company can request confidentiality of some business sensitive information, REACH's goal is to disseminate information—some of which will be posted on the Internet. Therefore, companies will need to be vigilant to ensure that confidential data is not publicly disclosed. ✦