Client Advisory

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ENVIRONMENTAL LAW PRACTICE GROUP OCTOBER 20, 2008

THE LONG ARM OF 'REACH': THE NEW AGE OF CHEMICAL AND PRODUCT REGULATION IN EUROPE

Major new chemical legislation enacted by the European Union ("EU") will have significant ramifications for thousands of U.S. companies exporting chemicals and products containing chemicals to the EU, starting with a key December 1, 2008 compliance deadline.

Known as "REACH" – the Registration, Evaluation, and Authorization of Chemicals – the legislation imposes substantial requirements on companies to register and provide health risk information on chemicals manufactured in or imported into the EU in excess of one metric ton per year. The legislation applies, with limited exceptions, to every chemical substance (new and existing) and products containing those substances. Failure to follow the mandates of REACH, including the failure to pre-register certain substances by December 1, 2008, will result in potentially significant disruptions to the marketing of chemicals and products in the EU market.

BACKGROUND

In December 2006, the REACH legislation was adopted by the EU after several years of negotiation. The law replaces over 60 existing EU directives and regulations related to the marketing and use of chemicals. The perception in Europe is that the "old" system was too cumbersome and slow to assess and manage adequately the potential risks posed by over 100,000 chemicals currently on the market. Whereas only about 80 chemical risk assessments have been conducted by the EU over the last decade, under REACH, it is believed that over 40,000 chemicals (those manufactured in excess of one metric ton per year) will be subject to registration.

The scope of REACH extends well beyond the typical view of "chemical manufacture." REACH imposes obligations on companies that manufacture or import into the EU chemicals, mixtures of chemicals (known as "preparations"), and certain articles (finished or semi-finished products). For importers, the extent of REACH obligations depends largely on the form (pure chemical, preparation, or article) in which a substance is imported and the quantity (at least one metric ton per year for registration; though other obligations have no tonnage threshold).

The most immediate REACH issue for companies to assess is whether they manufacture or import chemical substances that require registration (and therefore may warrant pre-registration). However, as discussed below, REACH also imposes a series of communication, notification, and authorization requirements that will affect a wide variety of products.

PRE-REGISTRATION

The importance of timely pre-registration cannot be overstated. Significantly, pre-registration enables a company to take advantage of an extended, "phased-in" registration process, which imposes a series of registration deadlines depending on the type and quantity of the substance. Under this system, the first registration deadline is December 1, 2010, for pre-registered substances manufactured or imported (by a single company) in excess of 1,000 metric tons per year, as well as lesser quantities of "CMR" (carcinogenic, mutagenic or reproductively toxic) and other hazardous substances*.

The pre-registration window opened June 1, 2008, and ends December 1, 2008. Pre-registration involves the submission (to the European Chemicals Agency –

*Registration of substances produced or imported in excess of 100 to 999 metric tons per year is not required until June 1, 2013. Substances produced or imported in quantities equal to or greater than one metric ton per year must be registered by May 31, 2018.

"ECHA") of relatively basic information concerning the identity of the substance and registrant, as well as an estimate of the tonnage manufactured or imported. The importance of pre-registration is that it delays full registration (up to 11 years) for manufacturers and importers. If a company fails to pre-register a substance that is subject to registration, then full registration is due as of June 1, 2008, and products with such substances will not be allowed to be placed on the EU market after December 1, 2008 unless and until they are fully registered.

There is no fee for pre-registration, but this process does trigger other obligations, such as the requirement to participate in and respond to requests for information from substance information exchange for a ("SIEFs") (see below).

REGISTRATION

The fundamental obligation under REACH is the registration of substances. Registration is company-specific and chemical-specific, and only "chemical substances" are registered. Thus, a product or mixture containing chemical substances is not itself registered, but the chemical substances contained in the product or mixture may need to be registered (e.g., if the substance is imported into the EU in excess of one metric ton per year, after accounting for amounts in all products or mixtures from a single company). As noted, failure to register a required substance means the product cannot be placed on the EU market.

Registration involves the submission to ECHA of detailed information concerning a chemical's identity and physical, chemical, and toxicological properties. The extent of the information required to register depends on the quantity of the substance manufactured or imported. The basic submission document is the "Technical Dossier," and includes information on the substance (identity and physical/chemical properties), its potential human health and environmental effects, and appropriate guidance on safe use. Additional toxicological data are required for substances identified as CMR, Persistent, Bioaccumulative, and Toxic ("PBT"), or very Persistent and very Bioaccumulative ("vPvB"), as well as those produced or imported over 10 metric tons. The extent of the requirements increase with the quantity of the substance.

In addition, for substances that exceed the 10 metric ton threshold per year, registrants are required to develop and submit a Chemical Safety Report ("CSR"). The CSR is essentially a risk assessment and management report for each identified use of the substance, assessing the hazards, exposures, and risks over the entire life cycle. Further, the CSR is to be provided to downstream users of a substance as an addendum to the traditional safety data sheet ("SDS") for the product.

To determine if a substance imported into the EU exceeds the registration threshold, a company should determine if the quantity of that substance in all products imported into the EU by that company in a given year exceed one metric ton. A company also should consider whether it may exceed, at some point in the future, the registration threshold for a substance**.

SUBSTANCES IN ARTICLES

The extent of REACH obligations depends, in many cases, on how certain ambiguous provisions of the legislation are interpreted. One of the most significant areas of regulatory uncertainty concerns what products qualify as "articles" and how REACH obligations apply to articles versus "preparations." An article is defined as "an object which during production is given a special shape, surface, or design which determines its function to a greater degree than its chemical composition." In contrast, a preparation is a "mixture . . . of two or more substances."

Determining whether a product is an article or a preparation is critical as the designation affects, in particular, whether substances in the product may be subject to registration. Whereas substances in preparations are

** In the case where a company does not currently manufacture or import a substance into the EU in excess of one metric ton, upon exceeding that threshold after December 1, 2008, the company may "pre-register" the substance within 6 months (and at least one year before the applicable registration deadline) to take advantage of the phased in registration process.

treated under REACH as any other substance (e.g., required to be registered if quantity exceeds the one metric ton annual threshold), substances in articles are only subject to registration requirements if present in excess of the registration threshold and "intended to be released." Unfortunately, current ECHA guidance provides only general instructions on where to draw the line between articles and preparations, and does little to clarify how those guidelines should be applied in individual industry sectors, especially where multiple processing stages are involved.

The guidance provides somewhat more clarity in determining when a substance is "intended to be released" and how REACH obligations (registration and otherwise) apply to such substances. However, this issue also presents interpretive challenges.

Proper resolution of these issues is critical, particularly in light of the December 1, 2008 pre-registration deadline. Given that definitive answers to such questions are not likely to be provided in the next few weeks, companies should consider pre-registering as a precaution.

Substance Information Exchange Fora and Consortia

As a means of streamlining the process and reducing burdens on individual registrants, REACH provides for the establishment of "Substance Information Exchange Fora" ("SIEF") through which "potential registrants" for a common substance pool data and potentially share costs to develop the information needed to complete the Technical Dossier and CSR. SIEF participation is mandatory for all pre-registrants. Non-registrant third parties (such as some downstream users of a substance) that have data relevant to registration also may participate voluntarily in SIEFs as "Data Holders."

The aims of the SIEF are to (1) facilitate data sharing for the purposes of registration, thereby avoiding the duplication of studies (particularly those studies involving animals), and (2) agree on the classification and labeling of the substances concerned. A SIEF is not a legal entity or a consortium, but a forum to share data and other information on a given substance. While participation is mandatory, SIEF members are free to organize as they see fit to carry out their REACH obligations. These SIEF-related obligations raise questions about a variety of data sharing issues, such as what data must be shared and how to maintain confidentiality.

While SIEFs are focused on data sharing and minimizing animal testing, "consortia" are envisaged as the dominant legal mechanism for potential registrants to cooperate in developing the information needed for registration. Beyond the SIEF, REACH does not require or prescribe any particular form of cooperation or consortia agreement. However, a multitude of substance-specific consortia are forming among companies and industry groups with shared interests in a particular substance. Generally, consortia agreements will address elements such as the gathering of information, identification of information needs, generation of missing information, cost sharing, and confidentiality concerns.

Registration by Importer or Only Representative

Of particular significance for U.S. companies is the fact that only an EU-based legal entity can register (or pre-register) under REACH. Technically, REACH obligations only apply to an EU manufacturer or the EU-based importer (often the customer of a non-EU company). Not surprisingly, EU customers may not want to assume registration obligations and may compel the non-EU company to do so. Further, for business reasons (such as protecting sensitive information and exercising control over customer imports), a non-EU company may want to take on the burdens of REACH. Accordingly, REACH provides for a mechanism known as the "Only Representative" ("OR"), which is an EU-based person that serves essentially as the REACH agent for the non-EU company.

Hence, a non-EU manufacturer has two basic registration options. First, it may seek to have the EU

importer of the product perform the registration functions. Depending on the products imported into the EU and the number of customers, this option may be impractical, as each importer separately must register each substance imported from each non-EU manufacturer (in excess of the one metric ton threshold). For some importers this could involve dozens of substances from dozens of non-EU manufacturers, placing a heavy burden on the importer.

The second and often more practical option is to appoint an OR. The OR would register according to the aggregate volume of a given substance imported by the customers of the non-EU company. Through the OR, the non-EU company becomes the registrant for the substance, a status that has significance when EU customers are seeking suppliers. (Absent such a registration, a potential EU customer would have to obtain their own registration in order to be able to import from a non-EU company). The OR also must keep available up-to-date information on quantities imported and customers sold to (including their uses), as well as information required to meet the obligation to communicate information down the supply chain.

Importantly, the OR becomes the legally liable party under REACH, technically responsible for satisfying all relevant REACH requirements, such as responding to SIEF information requests, communicating risk information to downstream customers, and providing appropriate notifications to ECHA. Therefore, in entering into an OR relationship both the OR and the non-EU company must carefully spell out their respective rights and duties, such as "ownership" of the registration (or pre-registration) and how liability for REACH violations will be assigned.

Substances of Very High Concern and the Proliferation of Lists

There are several substance lists to be aware of under and as a result of REACH. First, the EU authorities are developing the "Candidate List" of substances that may be subject to the authorization requirements of REACH. Candidate List substances are those that qualify as "Substances of Very High Concern" ("SVHC"), which include CMR, PBT, vPvB, and similarly toxic substances. In September, ECHA announced the nomination of 16 substances for inclusion on the Candidate List. Earlier this month, 15 of the nominated substances were determined to meet the listing criteria and placed on the first Candidate List. Substances that appear on the Candidate List will be considered for inclusion on yet another list – the list of substances subject to authorization under REACH (the first recommendations for the Authorization List are to be made by ECHA by June 1, 2009).

The initial draft Candidate List was surprisingly short; preliminary speculation was that from several hundred to several thousand chemicals would be listed. In response to criticism from the environmental community, ECHA announced recently that it will publish a "registry of intent," identifying substances that are under consideration for the Candidate List. Meanwhile, the environmental community is publishing its own lists, most notably the cleverly named "Substitute It Now!" (or "SIN") list issued by the International Chemical Secretariat ("ChemSec"), a non-governmental organization. The SIN list includes 267 substances that ChemSec would like to see on the REACH Candidate and/or Authorization Lists.

Regardless of the formal REACH obligations triggered by these lists, perhaps the most significant effect is their market impact and the resulting "black-listing" of substances. Numerous product manufacturers already have lists of prohibited or otherwise undesirable substances that are used to drive substance deselection and serve as de facto specification requirements for material suppliers.

Risk Communication and Notification of SVHC in Articles

Upon inclusion on the Candidate List, manufacturers and importers of SVHC substances – including SVHC in articles (whether or not required to be registered) – become subject to various communication and notification requirements, and potentially will be required to seek authorization for each use of the substance (see below). In particular, article suppliers are required to provide "safe use" and other risk information to direct downstream customers if a Candidate List substance is present in the article at a concentration greater than 0.1 percent. Such communications must be made immediately upon listing. Others may request such information and a response must be provided within 45 days.

Further, starting June 1, 2011, companies must notify ECHA of a substance contained in an article if (1) the substance is on the Candidate List; (2) is present in the article in quantities greater than one metric ton per year; and (3) is present at a concentration of greater than 0.1% by weight. Notification is not necessary if there is no possible exposure to the substance, or if the substance already has been registered for that particular use. In practice, many substances on the Candidate List will be among those chemicals that will be in the first wave of registrations (due December 2010), and therefore, in many cases, article manufacturers will not be obligated to provide ECHA with a separate notification.

Authorization and Substitution

Authorization is reserved for SVHC and substances of "equivalent" concern that are listed on the "Authorization List (under Annex XIV of REACH). For such substances, application must be made to obtain authorization for each intended use. The application must include an analysis of possible substitutes for the substance in particular uses. Authorization will be granted if the applicant shows that the risks may be adequately controlled. If the risks can not be controlled adequately, authorization still may be granted if it is determined that the use is justified by its socio-economic benefits and no suitable substitutes are available.

As part of this process, restrictions may be imposed on the manufacture, marketing, or use of a substance. In addition, a Member State or the EU Commission can propose restrictions on any substance, including banning its sale.

Safety Data Sheets (SDS)

It is important to know that REACH legislation alters the format for compiling SDS, prescribing a 16 category model based largely on accepted international standards. Further, information in the SDS must be consistent with information in the CSR (where a CSR is required). If a CSR has been performed for a registered substance, the relevant exposure scenarios are to be included in an annex of the SDS. Further, Section 8 (Exposure Control/Personal Protection) of the SDS must include Derived No Effect Levels ("DNELs") and Predicted No Effect Concentrations ("PNECs") that are to be developed as part of the CSR process.

The new SDS format requirements became applicable on June 1, 2007. However, obligations linked to the registration of substances only apply after June 1, 2008. Accordingly, requirements such as the exposure scenario annex and DNEL/PNEC information is not required – given that it will not even be available – until the information is prepared through a registration for the appropriate substance.

Conclusion

REACH is a substantial piece of legislation with broad impacts that will affect thousands of U.S. businesses that operate in the EU. Many U.S. companies have been tracking REACH and are well-versed in its provisions, but many are just realizing the full extent of its implications. Right now, the most important and looming deadline under REACH is the obligation to pre-register by December 1, 2008. Companies who think

they may be affected by REACH because they export to the EU substances (including substances contained in preparations or articles) above threshold amounts must give serious consideration to pre-registration. While pre-registration raises some concerns, namely that companies may be subject to data sharing obligations and associated confidentiality issues under mandatory SIEF participation, the risks of failing to pre-register, are potentially devastating.

Companies that have not already begun to prepare for REACH pre-registration should inventory all substances contained in various products shipped to the EU to determine if they meet, or could conceivably meet, REACH thresholds for each substance. Each company should also determine the "article" status of their products, and determine if any articles exported contain substances intended to be released.

It is imperative for each non-EU manufacturer or importer to arrange for pre-registration via a EU-based legal entity (either an EU affiliate, or an Only Representative). In addition, companies should carefully review REACH SDS requirements and compare existing SDS and downstream risk communication mechanisms for compliance. Finally, each company should identify any substances that are, or are likely to be, considered SVHC, as they may be subject to notification and authorization requirements.

Kelley Drye & Warren, LLP ("KDW"), has a team of professionals in our Washington, D.C. and Brussels offices deeply involved in all aspects of REACH. In addition to providing REACH counsel to numerous industry sectors, we can arrange to provide Only Representative services and help develop specific compliance strategies for your company.

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