

# Client Alert

A report  
for clients  
and friends  
of the Firm     September 2008

## REACH: The European Union's New Chemical Regulation

### New Regulation

Companies that rely on the European Union ("EU") chemical market for selling or buying chemicals need to ensure that they are prepared for the EU's new comprehensive Registration, Evaluation, Authorization and Restriction of Chemicals Regulation ("REACH"). REACH prohibits any chemical from being manufactured, marketed or imported in the EU in quantities in excess of one metric ton per year until it has been registered with the European Chemicals Bureau ("ECHA").

REACH is a very broad regulation that may impact any company, including any company located inside or outside of the EU, that manufactures, markets or imports chemicals into the EU or that depends on chemicals manufactured in the EU for its business.

### Purpose of REACH

REACH was adopted to address the deficiencies of the EU's existing chemical regulatory system under which the burden of ensuring that chemicals do not adversely impact human health or the environment was primarily on the governments of Member States. Its stated aim is to "ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessments of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation."<sup>1</sup>

### Important Deadlines – Pre-Registration & Registration

Companies have until **December 1, 2008** to pre-register with ECHA chemicals that they manufacture, market or import in the EU in quantities in excess of one metric ton per year. Only very basic information is required for pre-registration, including the pre-registrant's contact information and the estimated volume of the chemical manufactured, marketed or imported in the EU per year. Companies that fail to pre-register their chemicals are prohibited from manufacturing, marketing or importing their chemicals in the EU after December 1, 2008 until they have submitted an extensive registration dossier to ECHA. Companies that pre-register their chemicals by the December 1, 2008 deadline may wait to submit the registration dossier until the applicable delayed deadline set forth below:

### Delayed Registration Deadlines:

- December 30, 2010: Registration deadline for chemicals manufactured, marketed or imported in the EU in quantities of over 1,000 metric tons per year and for chemicals with certain dangerous characteristics. The dangerous chemicals consist of those with the characteristics set forth in Annex III of REACH and those that are toxic to aquatic organisms in quantities greater than one hundred metric tons per year.
- May 31, 2013: Registration deadline for chemicals manufactured, marketed or imported in the EU in quantities of over 100 metric tons per year.
- May 31, 2018: Registration deadline for chemicals manufactured, marketed or imported in the EU in quantities of over 1 metric ton per year.

<sup>1</sup> Commission Regulation 1907/2006, Concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), article 1(1), 2006 O.J. (L 396) 1 (EC).

Companies manufacturing, marketing or importing new chemicals (chemicals that have not been manufactured, marketed or imported in the EU before June 1, 2007) cannot take advantage of the delayed registration period and must submit a formal, comprehensive registration dossier (discussed below) to ECHA prior to manufacturing, marketing or importing such new chemicals.

## To What Does REACH Apply?

In addition to chemicals (known as “substances”), REACH applies to chemicals within mixtures (known as “preparations” under REACH) and articles (i.e., manufactured products). Each chemical in a mixture present in quantities over one metric ton must be registered; however, the mixture itself is not required to be registered. REACH also requires that chemicals present in articles in quantities of over one metric ton that are intended to be released during use of the article (i.e., printer cartridge) be registered.

Certain chemicals are exempt or excluded from REACH’s registration requirements, including waste and radioactive substances. In addition certain chemicals are exempt or excluded from REACH based on their usage, including chemicals that used in food and pharmaceuticals and product and process related oriented research and development. However, certain of REACH’s supply chain information distribution and disclosure requirements (discussed below) may still apply to such chemicals.

## Significant Changes under REACH

- *Registration Dossier* – REACH puts the burden on manufacturers, marketers and importers of chemicals to demonstrate that their chemicals do not pose a risk to human health or the environment through a comprehensive registration system of information compilation, testing, risk evaluation and submission of a registration dossier. The information required to be contained in a registration dossier depends on whether the chemical has certain dangerous characteristics<sup>2</sup> and the volume of the chemical that will be manufactured, marketed or imported in the EU per year. REACH provides four volume tiers: (1) 1-10 metric tons, (2) 10-100 metric tons, (3) 100-1,000 metric tons and (4) over 1,000 metric tons. More extensive information, including
- *Appointment of “Only Representative”* – Manufacturers of chemicals located outside of the EU cannot directly pre-register or register chemicals. Either the importer of the chemical or an “only representative” located in the EU is responsible for registration. An “only representative” is a representative located in the EU which is appointed by the non-EU manufacturer to fulfill all of the REACH obligations for a chemical. If non-EU manufacturers do not appoint an “only representative,” they must rely on their importer to comply with REACH.
- *Data Sharing Requirements* – REACH requires that pre-registrants and registrants of the same chemical share and jointly submit to ECHA certain information, including animal studies, chemical classification and labeling information and testing proposals. Owners of shared information are entitled to compensation. However, REACH does not require any specific form of organization for data sharing, mechanism for compensation or means for cost allocation among pre-registrants and registrants.
- *Authorizations* – ECHA expects to publish a list of chemicals of very high concern<sup>4</sup> by the end of 2008. Those chemicals will require an authorization prior to their manufacture, use, placement on the market or import into the EU. Applicants for an authorization have the burden of showing that the risks of such chemicals can be controlled or that there is a compelling socio-economic reason for the authorization and there are no safer substitutes available for the chemical.
- *Downstream User Obligations* – Downstream users<sup>5</sup> of chemicals are not required to register chemicals. However, they are prohibited from placing on the market chemicals that have not been pre-registered or registered pursuant

<sup>2</sup> The dangerous characteristics are set forth in Annex III of REACH.

<sup>3</sup> Potentially harmful chemicals include chemicals that are toxic, flammable, corrosive or explosive, or that meet the criteria for persistent, bioaccumulative and toxic or very persistent and very bioaccumulative chemicals set forth in Annex XIII of REACH.

<sup>4</sup> Chemicals of very high concern are chemicals that are carcinogenic, mutagenic or reprotoxic and that meet the criteria set forth in Annex XIII of REACH, or other chemicals that give rise to concern due to evidence of their serious effects to health and the environment as determined on a case-by-case basis by ECHA and Member States.

<sup>5</sup> REACH defines a downstream user as any person located in the EU, “other than the manufacturer or the importer, who uses a substance, either on its own or in preparations, in the course of his industrial or professional activities.”

to REACH. Downstream users also are prohibited from using chemicals of “very high concern” outside of the uses identified in the exposure scenario provided to the downstream user from the supplier of the chemical. In addition, downstream users must pass certain chemical hazard, risk and risk management information up and down the supply chain.

## Practical Implications of REACH

- *Costs & Timing* – The information and data sharing requirements of REACH may make registration a more costly and time consuming process, especially for chemicals in the higher volume tiers. Companies will need to factor additional costs and time constraints into their business plans and supply contracts.

- *Confidentiality Issues*

**Registration Dossier** – Certain information in registration dossiers will be publicly available on ECHA’s website, including results of toxicological and ecotoxicological studies and guidance on safe use. ECHA will make certain other information publicly available, including a chemical’s trade name and tonnage tier, unless a registrant provides ECHA with an explanation for why that information is commercially sensitive and should remain confidential.

**Data Sharing** – The data sharing requirements of REACH may require companies to share information with competitors. Companies can remain anonymous to competitors by appointing a “third party representative” to fulfill their data sharing requirements.

- *Availability of Chemicals* – Companies will need to check with their suppliers to ensure that chemicals that they need for their businesses will be pre-registered and registered so that they can ensure such chemicals will continue to be available. Due to the costs and time involved in the registration of, or obtaining an authorization for, chemicals of very high concern, suppliers may withdraw such chemicals from the market.

## What You Can Do to Prepare for REACH

- *Prepare an Inventory of Chemicals* – Companies should prepare an inventory of all chemicals that they manufacture, market, use and import in the EU each year, and their respective amounts. That inventory can be used to determine which chemicals a company should pre-register, which chemicals will need to be registered and what roles and obligations a company has in the supply chain.

- *Identify Roles in Supply Chain* – It is important to identify the role or roles your company may have in the supply chain in order to understand your obligations under REACH. Companies may have more than one role in the supply chain with different obligations. A company may be a manufacturer and supplier of a chemical triggering registration and supply chain information distribution and disclosure requirements. That company also may be a downstream user of other chemicals triggering different supply chain information distribution and disclosure requirements, and in the case of chemicals of very high concern, certain use restrictions and risk mitigation requirements.

- *Communicate with Suppliers* – Companies should identify and contact their suppliers of all of the chemicals that they use or market in the EU to confirm that such chemicals will be pre-registered and registered and will continue to be available. Companies should request that all of their uses of any chemical of very high concern be included in the exposure scenario prepared for such chemical.

- *Appoint an “Only Representative” and “Third Party Representative”* – Manufacturers located outside of the EU should determine whether they want to appoint “only representatives” to fulfill their registration obligations or whether they want to rely on their importer to comply with REACH. Companies also should determine whether a “third party representative” should be retained for pre-registration and registration data sharing activities so that the company can remain anonymous to competitors. There are many consulting firms that specialize in providing “only representative” and “third party representative” services.

- *Determine Substitutes for Chemicals Vulnerable to Withdrawal* – Companies should determine whether they manufacture, market, use or import any chemicals of very high concern that may be included on ECHA’s list of chemicals requiring authorization. Due to the potential costs and difficulties in obtaining authorizations, companies should consider whether any viable substitutes exists for such chemicals. Companies that use such chemicals in their businesses should check with suppliers to determine whether such chemicals will continue to be available.

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For a more in depth analysis of REACH, please see “*The Reach of REACH—What Companies Need to Know About the European Union’s New Chemical Regulation*” by Gail S. Port and Kelly Baldwin Corso at [http://www.proskauer.com/news\\_publications/published\\_articles/content/2008\\_09\\_10/res/id=sa\\_File/port%20corso.pdf](http://www.proskauer.com/news_publications/published_articles/content/2008_09_10/res/id=sa_File/port%20corso.pdf)

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