Pre-Registration Begins for European Union Chemical Safety Regulation (REACH)

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On June 1, 2008, the European Chemicals Agency (ECHA) began accepting pre-registration submissions for all “phase-in” substances under REACH, the European Union’s new chemical safety regulation. Pre-registration allows companies to continue manufacturing or importing chemical substances into the European Union pending the later submission of a full registration dossier. However, following the close of the pre-registration period on December 1, 2008, chemical substances cannot be manufactured or imported into the European Union in quantities exceeding one ton without first undergoing the full registration process, which may be costly and time consuming.

Pre-registration under the REACH regulation is available only to substances that are classified as “phase-in” substances by ECHA. These substances must be one of the following:

- Listed in the European Inventory of Existing Commercial Chemical Substances (EINECS). These chemicals can be found in the European Chemical Substance Information System (ESIS) at http://ecb.jrc.it/esis/
- Manufactured in the European Union but not placed on the market after June 1, 1992, as demonstrated by documents traced to a date prior to May 31, 1992.
- Qualified “no-longer polymers” as identified in the ESIS no-longer polymer list.

Companies that manufacture or import these phase-in substances in the European Union can pre-register up until December 1, 2008. Companies outside the EU can pre-register only by designating a so-called “Only Representative”—a natural or legal person within the EU and with adequate substantive background, who can complete the importer pre-registration process on behalf of non-EU companies.

REACH pre-registration carries no fee and establishes no obligation to continue manufacture or import of a substance. However, pre-registration is essential to allow companies to continue manufacturing or importing chemical substances into the European Union pending the later submission of a full registration dos-
sier. Should a company fail to pre-register their eligible phase-in substances, the company will be required to submit a full registration dossier, including requisite health and safety data, and wait for an ECHA registration number for the substance before the company can resume manufacturing or importing the substance in the EU. This could create considerable delays and supply chain disruptions.

Therefore, it is critical for companies that currently manufacture or import chemical products in the EU to pre-register those products by the December 1, 2008 deadline. It is equally important for downstream users of chemical products (e.g., manufacturers of articles) to confirm that their suppliers intend to pre-register their chemical products, in order to assure supply chain continuity.

The following information is required in order to complete REACH pre-registration:

- The substance name, identified by an EINECS, CAS, IUPAC or other identifying code.
- Company name, address, and contact person information, including any third-party representative for the company (each separate legal entity involved in manufacturing and importing the substance must be pre-registered separately).
- Registration deadline and tonnage band that the company envisions it will fall under (either November 30, 2010; May 31, 2013; or May 31, 2018, depending on output and substance classification; see the ECHA website for more details).

Pre-registration material must be submitted electronically to ECHA. There are three methods of submitting pre-registration information:

- Manually through the REACH-IT website (http://echa.europa.eu/reachit_en.asp), by filling in the required information for each substance to be pre-registered.
- Through an XML file created by a plug-in to the IUCLID 5 software, available without charge at http://ecbwbiu5.jrc.it/. This method is preferred for companies planning to manage large numbers of substances.
- Through XML file created by the company’s own IT tools. This method is also preferable for large numbers of substances, and companies not planning to adopt IUCLID 5 software.

ECHA will publish the list of pre-registered substances by January 1, 2009 on its website, http://echa.europa.eu/home_en.asp.

**Live Links**

ECB, ESIS: European Chemical Substances Information System

European Chemicals Agency, REACH-IT

International Uniform Chemical Information Database, IUCLID 5

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