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REACH—Proactive Planning Is Recommended to Address the EU's New Chemical Policy Initiatives

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Chemical Industry Update

The European Union ("EU") has adopted new requirements for the Registration, Evaluation and Authorization of Chemicals ("REACH") that will become effective on June 1, 2007. REACH is intended to: (a) phase out, or limit the use of, the most dangerous chemicals; (b) promote innovation and development of safer chemicals; and (c) assure that the manufacture and distribution of chemicals in the EU do not adversely affect human health or the environment. REACH shifts the burden of proof from EU Member States to industry to demonstrate that the use of new chemicals and the continued use of existing chemicals will be safe.

REACH establishes a series of deadlines to register existing and new chemicals over the next eleven years. The deadlines vary, depending on the actual or perceived risk posed by the chemicals and the amount of the chemical that is manufactured or imported each year. Firms that fail to register will be denied access to the EU market.

REACH also establishes a special authorization process that will ban uses of substances that are classified as chemicals of very high concern ("CVHCs"). The EU currently estimates that there are approximately 900 CVHCs and that 600 additional substances will be classified as such in the next 11 years while REACH is implemented.

European Chemical Agency

A new agency, the European Chemical Agency ("ECA"), has been established to administer the REACH program, including a public database on the properties of all registered substances. It is the EU's intent to avoid duplicative animal studies and other tests by making all information supplied by registrants available to the public. Manufacturers and importers will need to submit all appropriate information on the substances they use but they may be able to limit their individual research to the extent that information has already been submitted by other businesses. In addition, all manufacturers and importers should closely monitor developments relating to the substances they use. In many cases, product components or chemical constituents may need to be modified to develop alternative products in time to meet future bans or restrictions on the use of many CVHCs.

Registration Requirements

REACH will require all manufacturers and importers to register virtually all new and existing chemical substances that are produced in, or imported to, the EU market in quantities exceeding one ton (1 T) per year. Registration will be required for substances in their pure form, as ingredients in other preparations, and in articles that are expected to release the substance. Registrants must submit registration dossiers that include comprehensive information on the properties of the substance and its safe use.

The registration requirement will be implemented in three phases that correspond to the properties of the various substances and the quantities involved. By November 2010, REACH requires registrations by manufacturers and importers of: (a) 1 T/yr. of category 1 and 2 carcinogens, mutagens, and reproductive toxins; (b) 100 T/yr. of substances classified as very toxic to aquatic organisms; and (c) 1,000 T/yr. of all other substances. All other substances used or imported in quantities greater than 100 T/yr. and 1 T/yr. must be registered by June 2013 and June 2018, respectively.

REACH applies to most substances, but some substances are excluded because they are perceived as presenting little or no risk or are regulated under other programs. The excluded substances include water, oxygen, noble gases, cellulose pulp, minerals, ores, and cement clinker, if they are not chemically modified.

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Food, medicinal products, and wastes are also excluded and Member States are permitted to exclude other substances necessary for defense reasons.

Authorization Process

The CVHCs will be subject to an authorization process. The applicant will have the burden of proving that the risks presented are adequately controlled by ventilation, protective clothing, or other means or that the socio-economic benefits from the use of the substance outweigh the risks.

It is likely that this process will be a lengthy, cumbersome, and high-stakes process that restricts or bans the future use of some, and perhaps many, CVHCs. In the past 13 years, the EU has commenced risk assessments on only 140 chemicals and it has only issued final reports for approximately half (70) of them. The EU plans to expedite the authorization process because REACH requires the applicant to gather all appropriate information, conduct the risk assessment, and submit it to the ECA for review and evaluation. ECA's evaluation of this work product will determine which substances will be banned, which will be subject to future use restrictions, and which may continue to be used without restrictions.

Future Business Implications

The potential impact of REACH on future products is massive. Also, the EU has received numerous inquiries from Canada, Japan, Switzerland, other countries, and several states in the U.S. about REACH and the prospects of developing some requirements in their jurisdictions. Therefore, similar requirements may be developed in other markets.

As mentioned above, the EU currently estimates that approximately 1,500 substances will be classified as CVHCs. Many of these substances are already targeted because they have been classified as class 1 or 2 carcinogens. In the short term, it is likely that industry will be able to establish a need to retain the use of many of these substances.

Instead of merely performing the minimum tasks necessary to comply with REACH, many businesses may well expand research and development to find alternative substances, processes, components, and products to replace those substances that are most likely to be subject to future bans and restricted uses. The first users of CVHCs in each business sector that phase out the use of CVHCs in their products will gain a substantial economic advantage over their competitors. Once a company demonstrates that a substitute exists for a particular CVHC or for a particular use of a CVHC, it is likely that the ECA will ban or restrict the future use of that substance. If the developer of the substitute product has a proprietary substance or process, it may obtain a substantial economic advantage over its competitors. Indeed, some competitors may suffer substantial harm if their use of a CVHC is banned or restricted when a competitor develops a substitute product.

Blank Rome has formed a Chemical Industry Team designed to support manufacturers and distribution and supply companies that are part of the chemical industry with the legal services required for success and expansion. Our team includes lawyers with legal experience in numerous practice areas and business sectors. We are available to assist both existing and potential clients with an understanding as to how REACH will affect your company and your business plans.

For Additional Information

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