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Chemical Regulation in the European Union: Registration, Evaluation, and Authorization of Chemicals

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Summary

On June 1, 2007, the European Union (EU) began to implement a new law, Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH), in EU commerce. It is intended to protect human health and the environment from hazardous chemicals while at the same time protecting the competitiveness of European industry. REACH evolved over eight years and reflects compromises reached among EU stakeholders. The final regulation reduces and coordinates EU regulatory requirements for chemicals *new* to the EU market and increases collection of such information for chemicals *already* in the EU market, thus potentially removing disincentives to innovation. It also shifts responsibility for safety assessments from government to industry and encourages substitution of less toxic for more toxic chemicals in various chemical applications. The Bush Administration expressed concerns about its trade implications for U.S.-produced chemicals. U.S. chemical industry representatives believe that REACH is "impractical." In contrast, some public-interest groups are urging U.S. legislators to adopt a similar legislative approach.

Depending on one's point of view, new chemicals legislation in the European Union (EU) is likely to vastly improve environmental and public health protections and serve as a model for future U.S. law, or it might unnecessarily burden commercial enterprises with regulations and interfere with international trade. The subject of such conjecture is a new EU law for Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) in EU commerce, which went into force June 1, 2007.

Background

On June 1, 2007, the EU began to implement a new approach to the management of chemicals in EU commerce. The REACH directive simplifies and consolidates more than 40 former regulations in an effort to balance two EU goals: to protect public health and the environment from hazardous chemicals and to ensure the continuing competitiveness

of European industry. Although certain chemicals are exempt entirely, and requirements for the other chemicals will be phased in over 11 years, the law generally will apply to nearly all chemicals in EU commerce, including imported chemicals, chemical mixtures, and certain articles that release chemicals to the environment.

The REACH legislation is based on a proposal developed by the EU General Directorates for Enterprise and Environment, which was adopted by the European Commission in February 2001. The draft law was revised several times in response to public comments and amendments adopted by the European Parliament and Council of Ministers (which is comprised of the executive officers of EU member states). The final regulation is binding on all member states.

REACH requires all chemical producers and importers of more than one metric ton (t) per year of any chemical[1] to *register* the product by submitting a technical dossier of information about the properties of that chemical and its uses to a new agency created by the law, the European Chemicals Agency (ECA).[2] The dossier also must contain information about how any risks associated with use of that chemical should be managed. Downstream users of chemicals are required to manage their risks in the manner indicated by producers. Information requirements for the dossier increase as production volume increases beyond 10 t, 100 t, and 1,000 t. Companies have between one year and 18 months to pre-register. The first registration deadline for existing chemicals is in November 2010, and applies only to selected substances of "very high concern," or substances produced in volumes greater than 1,000 t annually or greater than 100 t annually if they are very toxic to aquatic life. New chemicals must be registered before they enter commerce, beginning June 1, 2008, when the ECA begins to function.

Member states (that is, the nations of the EU) will *evaluate* the dossiers based on guidelines provided by the ECA, and may require additional data, if such data are needed to assess health and environmental effects of potential chemical exposure. Member states also may determine that action should be taken to authorize or restrict particular chemical uses.

Producers of chemicals of "very high concern" may be required to apply for *authorization* of each particular use, demonstrate that the risks can be adequately controlled (for example, through labeling or worker training), and justify such uses by submitting additional information to authorities. Companies will not be allowed to manufacture, import, or use a chemical after a specified date unless they have obtained an authorization for a use. In addition, producers will be required to submit an analysis of possible substitutes, a "substitution plan" if substitutes are available, or a research and development plan if no suitable substitute exists.

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[1] All polymers and some intermediate chemicals are exempted. Chemicals sold for specific regulated purposes (for example, to control agricultural pests or to treat medical conditions) also are not affected by the new law.

[2] A metric ton is 1,000 kilograms, or about 2,200 pounds. The current EU requirement for registration applies to chemicals produced or imported in amounts equal to or greater than 10 kilograms, but only if they have not been produced or imported into the EU previously — so-called "new" chemicals.

Chemicals of "very high concern" include about 1,350 chemicals known or likely to be carcinogens, mutagens, or chemicals toxic to reproductive systems; persistent, bioaccumulative, and toxic chemicals (PBTs); or very persistent and very bioaccumulative chemicals (vPvBs). No use of PBTs or vPvBs will be authorized unless there is no suitable alternative and the socio-economic benefits of the use outweigh the risks. If a chemical use presents unacceptable risks, that chemical use may be restricted. The EU Commission will decide within six years whether endocrine disruptors also are of very high concern and should be subject to similar requirements.[3] High-production-volume chemicals routinely will be subject to the authorization process. The authorization and restriction processes also may be applied to chemicals produced or imported in volumes less than 1 t.

Views

The U.S. Government was actively engaged throughout the development of REACH. The Bush Administration expressed concerns about its trade implications for U.S.-produced chemicals.[4] Specific concerns included increased costs of and time lines for testing chemicals exported to the EU; placement of responsibility on businesses (as opposed to governments or consumers) to generate data, assess risks, and demonstrate the safety of chemicals; possible inconsistency with international rules for trade adopted by the World Trade Organization (WTO); and the effect of the legislation on efforts to improve the coherence of chemical regulatory approaches among countries in the Organization for Economic Cooperation and Development (OECD).

U.S. chemical industry representatives believe that REACH is "impractical." Industry has expressed objections to the proposed list of "high concern" chemicals, some of which are essential building blocks for the manufacture of other chemicals. The EU chemical industry is concerned about the cost of compliance, and what it might mean to innovation and international competitiveness. Some national governments of the EU also are concerned about the impact of REACH on their economies and employment, especially if REACH leads to companies relocating outside the EU. The EU has estimated that about 12% of chemicals in commerce will be withdrawn by chemical producers, because continued production under REACH will be costly and distribution not sufficiently profitable to recoup costs. In cases where no substitute is available, loss of a production source might leave some end users without the chemicals they need.

Many environmental, health, and U.S. and EU labor organizations strongly supported the original proposal for REACH, but some are less enthusiastic about the final regulation, which retains its basic purpose and shape but exempts some chemicals from requirements. Nevertheless, these groups agree that REACH addresses what they see as

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[3] Endocrine disruptors are chemicals that interfere with the normal functioning of glands or the hormones they produce. For more on endocrine disruptors in the environment, see CRS Report RL31267, *Environmental Exposure to Endocrine Disruptors: What Are the Human Health Risks?* by Linda-Jo Schierow and Eugene H. Buck

[4] Prescott, Jennifer Yoder, "U.S. Government Responds to the E.U. Chemicals Policy," *Chemistry Business*, June 2002.

flaws in U.S. and EU laws covering chemicals.[5] (For more information about U.S. chemical law, see CRS Report RL31905, *The Toxic Substances Control Act: A Summary of the Act and Its Major Requirements*, by Linda-Jo Schierow.) For example, REACH reduces and coordinates EU regulatory requirements for providing health and safety information about chemicals *new* to the EU market (as well as the number of new chemicals subject to such requirements), while at the same time increasing collection of such information for chemicals *already* in the EU market, thus potentially removing disincentives to innovation and substitution of less toxic for more toxic chemicals in various chemical applications. In addition, to address concerns about the slow pace of chemical risk assessment and management by the EU government, REACH shifts responsibility for assessing and managing the safety of chemicals away from the government and onto chemical manufacturers, importers, and users. Some public interest groups are urging U.S. legislators to adopt a similar legislative approach.[6]

[5] See for example the statement on the website of the Trans Atlantic Consumer Dialog, a group which claims "to promote the consumer interest in EU and US policy making," at [http://www.tacd.org/docs/?id=253].

[6] Ibid.