



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 governing chemicals in EU commerce: Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH). 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 that existed under the former law. 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. Some U.S. chemical industry representatives believe that REACH is “impractical,” in part due to the large number of chemicals and difficulties of identifying end uses of chemicals in many products. In contrast, some public-interest groups are urging U.S. legislators to adopt a similar legislative approach.

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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 an EU law for Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) in EU commerce, which went into force June 1, 2007.¹ This report summarizes REACH and progress in its implementation. For information about U.S. chemical law, see CRS Report RL34118, *The Toxic Substances Control Act (TSCA): Implementation and New Challenges*, by Linda-Jo Schierow.

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 are being 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.

Registration

REACH requires all chemical producers and importers of more than one metric ton (t) per year of any chemical² 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 (ECHA).³ 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. Since June 1, 2008, when the ECHA began to function, registration has been required for new chemicals before they enter commerce. Companies had between one year and 18 months to pre-register existing

¹ REACH is a "Regulation" (Regulation No. 1907/2006) which is "binding in its entirety on" and "directly applicable in all Member States" of the European Union (i.e., the nations that are members of the European Union) (Isabelle Laborde, "Sources of European Environmental Law," *Natural Resources & Environment*, v. 25, n. 4 (Spring) 2011).

² All polymers and some intermediate chemicals are exempted from at least some provisions. Chemicals sold for specific regulated purposes (e.g., to control agricultural pests or to treat medical conditions) also are not affected by the new law.

³ 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. Pre-registration ended November 30, 2008. The first registration deadline for existing chemicals was in November 2010, and applied only to “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. About 4,725 substances reportedly were registered in this category.⁴ The second registration deadline for existing chemicals is May 31, 2012, and applies to substances produced in the 100 to 1,000 t range annually. The final deadline is June 1, 2018, by which point all substances produced or imported in small quantities, between one and 100 t annually, must be registered.

Evaluation

Member states (i.e., the nations of the EU) *evaluate* the dossiers based on guidelines provided by the ECHA, 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.

On October 21, 2011, ECHA announced that it had used the information submitted in the first round of data collection for substances produced in high volumes to identify 91 high-priority substances for risk evaluation by Member States. These will be the first chemicals subject to the evaluation stage of REACH, because ECHA suspects that use of these substances might pose a risk to human health or the environment. The evaluations will aim to clarify such risks to determine whether additional data should be collected and whether authorizations or restrictions may be necessary.⁵

Authorization

Producers of “substances of very high concern” may be required to apply for *authorization* of each particular use, demonstrate that the risks can be adequately controlled (e.g., 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.

As of February 27, 2012, 14 substances⁶ have been identified as *substances of very high concern* (SVHC) that are effectively banned from use in the EU unless such use is authorized under the law. In all, ECHA has identified 73 chemicals or chemical groups as SVHC candidates for

⁴ Stephen Gardner, “EU Chemicals Agency Says 4,725 Substances Now Registered Under REACH Legislation,” *Daily Environment Report*, March 14, 2011, Bureau of National Affairs, Inc.

⁵ ECHA, “Draft Community Rolling Action Plan (CoRAP),” October 25, 2011, December 15, 2011, <http://www.element14.com/community/docs/DOC-38813/1/draft-community-rolling-action-plan-corap>.

⁶ European Chemicals Agency, “Authorisation List,” February 27, 2012, <http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list>. The chemicals are hexabromocyclododecane, tris(2-chloroethyl)phosphate, 2,4-dinitrotoluene, lead chromate, diarsenic pentoxide, diarsenic trioxide, lead sulfochromate yellow, lead chromate molybdate sulphate red, bis(2-ethylhexyl) phthalate, benzyl butyl phthalate, diisobutyl phthalate, dibutyl phthalate, 5-tert-butyl-2,4,6-trinitro-m-xylene, and 4,4'-diaminodiphenylmethane.

authorization,⁷ with many more chemicals being evaluated for this designation, including approximately 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). According to the law, no use of PBTs or vPvBs is to 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. 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.⁸ 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).

Some 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 (i.e., no longer producing or selling products in 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 addressed some of what they saw as flaws in older EU laws covering

⁷ European Chemicals Agency, “Candidate List table,” February 27, 2012, http://echa.europa.eu/chem_data/candidate_list_table_en.asp.

⁸ Prescott, Jennifer Yoder, “U.S. Government Responds to the E.U. Chemicals Policy,” *Chemistry Business*, June 2002.

chemicals.⁹ 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 encouraging 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.¹⁰ For more discussion of the perceived flaws of U.S. law, see CRS Report RL34118, *The Toxic Substances Control Act (TSCA): Implementation and New Challenges*, by Linda-Jo Schierow.

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⁹ See, for example, the presentation by Daryl Ditz of the Center for International Environmental Law at http://www.chemicalstrategies.org/pdf/workshop_events/DDitz_Emerging%20Int%271%20Issues.pdf.

¹⁰ *Ibid.*