

The European Union's REACH regulation: A review of its history and requirements.

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**Abstract** In 2006, the European Union (EU) promulgated a monumental regulatory initiative for the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH). To date, several thousand pages of text have been needed to describe the expectations of this regulation. There were numerous reasons for the promulgation of REACH, but, by and large, it is an extension of the global desire to produce fewer industrial chemicals, to understand the possible human and ecological hazards of those that are produced, and to insure that any major threat is anticipated, as well as prevented. Most industry-related groups consider it the most wide-ranging and costly regulatory initiatives related to health risk assessment ever to be promulgated. This review presents a description of REACH that should inform scientists, managers, and others about its objectives and the means to satisfy them. Registration is required for all chemicals manufactured or imported into the EU, unless specifically exempted. Registration is expected to be a collaborative process among companies, which will generate a dossier containing data on physicochemical characteristics, as well as toxicological and ecotoxicological properties. Though the magnitude of the gaps in the data required for registration is uncertain at this point, it is clear that basic toxicology testing will have to be conducted for many chemical substances that have not undergone formal review up to this point. For many chemicals, an examination of hazards and risks arising from the use of these substances will also be required in the form of a chemical safety report (CSR). Beginning with the dual processes of dossier and substance evaluation, the European Chemicals Agency (ECHA), the Member States of the EU, and the European Commission will identify chemicals that may pose unacceptable hazards to human health and/or the environment, and will curtail or restrict their usage. The implementation of REACH will expand and deepen the fields of applied toxicology and exposure assessment by spurring activity and innovation in sampling and analysis, toxicology testing, exposure modeling, alternative toxicity testing, and risk assessment practices.

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