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NEW EUROPEAN CHEMICALS POLICY IMPERILS U.S. ECONOMIC GROWTH

by

Jane C. Luxton, Philip A. Moffat, and Khouane Ditthavong

In May 2003, The European Union ("EU") released details of its New Chemicals Policy, which will require registration, evaluation, and authorization of all chemicals manufactured in or imported into the European market. The new regime is radical: it reverses the traditional burden of proof for environmental regulation. No longer will regulators have to show a chemical's risk outweighs its benefits in order to ban or restrict it. Instead, manufacturers of tens of thousands of existing chemicals — and products containing chemicals — will now have to prove each use is safe, or else cease selling the product in the EU.

The new program, known by the acronym "REACH" (for **r**egistration, **e**valuation, and **a**uthorization of **ch**emicals), has been under development for several years, and Europeans view it as unstoppable, despite scalding opposition from the U.S. Government and others. *See, e.g.*, Comments of the United States on the European Commission's Draft Chemicals Regulation, July 10, 2003 (describing the REACH proposal as "costly, burdensome, and complex" and likely to "adversely impact innovation and disrupt global trade.") Available at http://europa.eu.int/comm/enterprise/chemicals/chempol/whitepaper/reach.htm.

Critics object to the enormous financial burden and onerous testing and registration requirements the new approach will impose on manufacturers who ship to this critical market, which accounts for more than twenty percent of all U.S. exports. U.S. Department of Commerce, Int'l Trade Admin., Office of Trade and Economic Analysis, Export Statistics, available at http://ese.export.gov/ITA2002/Intro_new.htm (last visited July 3, 2003). Even beyond these effects, there are grave concerns about the legislation's consistency with the EU's international legal obligations under World Trade Organization ("WTO") rules. Nor does international anxiety stop there: aware of the economic havoc this proposal will wreak upon European markets, the EU Commission has acknowledged that the plan's negative competitive impact can be justified only to the extent the "REACH regime is successful in establishing itself as a new international standard." Chemicals-Orientation Paper, Communication by Mr. Liikanen and Ms. Wallstrom, at 16 (Apr. 1, 2003), available at www.europa.eu.int/comm/enterprise/chemicals/chempol/whitepaper/reach.htm. U.S. observers have already witnessed one European attempt to transplant REACH ideology into an international environmental undertaking — the United Nations Environmental Programme's ("UNEP") Governing Council principles on mercury, adopted in February 2003 in Nairobi. Although the United States and other countries blocked the EU's gambit there, these efforts will continue. Without question, the REACH program is

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Jane C. Luxton is a partner, and **Philip Moffat** and **Khouane Ditthavong** are associates, in the Washington, D.C. office of the law firm King & Spalding LLP. King & Spalding represents the Ad Hoc Metals Coalition, which filed comments on the REACH program. The firm is active on this and other domestic and international environmental issues.

awakening a far-reaching sense of alarm in the United States and elsewhere.

Origins in the Precautionary Principle. In recent years, the EU has assigned to itself responsibility for pushing the envelope on environmental regulation. Spurred on by the Nordic countries, national Green Parties, and others with extreme agendas, the EU has enacted aggressive measures on global warming, take back requirements on autos and electronics, and bans or stringent restrictions on an array of substances. *See, e.g.*, Council Directive 2002/96/EC on Waste Electrical and Electronic Equipment, O.J. (L37) 24; Council Directive 2002/95/EC on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment, O.J. (L37) 19. Many of these initiatives, like the REACH proposal, find their justification in the EU's "precautionary principle," based on but substantially modified from the precautionary approach announced in Principle 15 of the 1992 Rio Declaration on Environment and Development.[1] Principle 15 presented a precautionary approach that balances scientific uncertainty with "cost-effective measures" for deciding how best to respond to serious or irreversible threats to the environment and human health. The EU, however, has calibrated its precautionary stance to such a high degree of risk aversion that it has essentially written factors other than caution out of the equation. What is left is the philosophy that lack of scientific data that corroborate the need for or consequences of stringent environmental measures should not stand in the way of their adoption. In contrast, U.S. law proceeds from the premise that chemicals should be banned or restricted only if credible scientific data show an "unreasonable risk," after undergoing a cost-benefit analysis. *See*, *e.g.*, section 6 of the Toxic Substances Control Act, 15 U.S.C. § 2605. The ideological clash between the two approaches is irreconcilable.

Fear of the Unknown. The REACH program represents the EU's response to the belief that it cannot effectively regulate chemicals by traditional risk-based methods. In explaining why the European Commission had taken this new path, EU environment commissioner Margot Wallstrom told *The New York Times*: "There is no control whatsoever of the 400 million tons of chemicals sold in the European Union each year." Elizabeth Becker and Jennifer Lee, *Europe Plan on Chemicals Seen as Threat to U.S. Exports*, N.Y. TIMES, May 8, 2003, at C7. Doubtless, a gross exaggeration, but this sentiment echoes deep-seated European fears that trace back to studies such as the 1984 publication, *Toxicity Testing*, which estimated that basic toxicity information was unavailable for seventy-eight percent of chemicals in U.S. commerce at production volumes greater than one million pounds. TOXICITY TESTING 84 (National Academy Press 1984). Ten years later, a second report, the Environmental Defense Fund's landmark *Toxic Ignorance*, confirmed that more than seventy percent of chemicals sold in the United States at high production levels lacked sufficient data to allow regulators to conduct basic hazard assessments.[2] Despite the institution since then of massive data generation and collection efforts intended to reduce these information gaps, the EU has clearly decided to go a different way, relying on its liberal interpretation of the precautionary principle to effectively ban all chemicals unless and until their safety is proven.

Even with billions of dollars and more than a million jobs at stake, the EU appears determined to proceed with REACH. The EU insists that economic arguments will not sway it, in spite of studies showing that the national economies of France and Germany will suffer noticeable hits — a loss of 1.7 to 3.2 percent of France's gross domestic product over the next ten years, for instance.[3] Notwithstanding these impacts, the

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[1] *Rio Declaration on Environment and Development*, 31 I.L.M. 874 (1992). For an analysis of problems created by the EU's insertion of the precautionary principle into international food safety regulation, *see* Mark Mansour, *Excessive "Precaution" Threatens Food Consumers and Foreign Trade*, WLF LEGAL BACKGROUNDER, vol. 16, no. 44 (Oct. 19, 2001).

[2] DAVID ROE ET AL., TOXIC IGNORANCE: THE CONTINUING ABSENCE OF BASIC HEALTH TESTING FOR TOP-SELLING CHEMICALS IN THE UNITED STATES 15 (Envt'l Defense Fund 1997). Follow-up studies conducted by U.S. EPA and the Chemical Manufacturers Association [now American Chemistry Council] found that more than ninety percent of 3,000 high production volume chemicals had insufficient available human health and environmental hazard screening data to permit useful assessments. CHEMICAL HAZARD AND DATA AVAILABILITY STUDY: WHAT DO WE REALLY KNOW ABOUT THE SAFETY OF HIGH PRODUCTION VOLUME CHEMICALS? (EPA OFFICE OF POLLUTION PREVENTION AND TOXICS 1998); PUBLIC AVAILABILITY OF SIDS RELATED TESTING DATA FOR U.S. HIGH PRODUCTION VOLUME CHEMICALS (Chemical Manufacturers Ass'n 1998).

[3] *Threat of Recession may Argue Against European Chemical Policy Bill*, EPA Risk Policy Report, vol. 10, n. 6 (June 24, 2003), (citing a study by Mercer Management Consulting commissioned by the French government and French industry groups. The study also estimates 360,000 - 670,000 lost jobs in France; a German study attributes 900,000 lost jobs in Germany

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EU contends that health benefits balance the costs associated with REACH. Moreover, the EU fears that if it does not act to implement a stringent chemicals control regime, it may eventually face the same nightmare of toxic tort litigation that plagues the United States.

How the REACH Program Would Work. Through REACH, the EU intends to create a new chemical management system that shifts the burden for registering and proving the safety of chemicals to chemical manufacturers, importers, and users. REACH also would impose a "duty of care" on all companies that manufacture, import, and use chemicals to manage them in such a way that they do not adversely affect human health and the environment. The REACH program's main components are registration, evaluation, and authorization of chemicals.

Registration. Unlike previous chemical regimes, REACH requires registration and testing prior to market entry for all chemicals manufactured or imported in volumes greater than one metric ton per year. Registration will be a Herculean undertaking; more than 30,000 chemicals currently on the market meet the minimum production volume threshold and would require registration. Some polymers and chemical intermediates are exempt from registration or will have reduced registration requirements, but all chemicals (including metals) regardless of actual threat to the environment will fall within the program's scope. Each company must file its own registration, even if sister corporations or subsidiaries have also submitted information. Each registration must have an accompanying Chemical Safety Report that at a minimum contains: human health hazard assessment; analysis of physicochemical properties; environmental hazard evaluation; exposure assessment; and risk characterization information. Furthermore, the Chemical Safety Report must identify and assess at least 90% of all intended uses of the subject chemical. Data requirements and deadlines for registration vary with the volume of the chemical produced or imported, with higher volume chemicals having more extensive data requirements and earlier deadlines for registration. Chemicals that are carcinogenic, mutagenic, or toxic to reproduction ("CMR"); persistent, bioaccumulative, and toxic ("PBT"); very persistent, very bioaccumulative ("vPvB"); or otherwise of concern (*e.g.*, endocrine disruptors) must be registered irrespective of production or importation volume.

Evaluation. Under REACH, chemicals produced in volumes greater than 100 metric tons per year are subject to further evaluation by public authorities in the EU Member States. During the evaluation process, regulators will evaluate registration applications and determine the sufficiency of testing information included in support of the chemical. The public authority may ask for additional information or testing if the submitted materials are of questionable quality or, more nebulously, "if there is reason for concern."

Authorization. Specific uses for the most hazardous chemicals must undergo the authorization process. Authorization is a permitting-type system under which the European Commission must approve each intended use of a chemical. More than 1,000 chemicals may have to satisfy this more intensive and costly authorization requirement. Under REACH, registration and authorization are independent processes, and it is possible that a chemical will have to go through both at the same time. To obtain an authorization, a manufacturer, importer, or user must demonstrate that the risk from the use of a substance can be adequately controlled or that the socio-economic benefits outweigh the risk. If the risks cannot be controlled, REACH requires an assessment of available alternatives before the Commission can grant an authorization.

In an attempt to help reduce costs associated with registration, the EU is encouraging companies to form consortia to share registration information. REACH would require manufacturers and importers of existing chemicals to pre-register their chemicals at least eighteen months before the registration deadline. Companies that pre-register the same chemicals can participate in a Substance Information Exchange Forum where they can share testing information, identify data gaps, and pool resources to fill those gaps. Testing costs are estimated to range from $75,000 to $125,000 per chemical, but can be much higher depending on the nature of the chemical. Consortia may submit testing information together, but each member must nonetheless submit its company-specific information under separate cover. The REACH proposal includes provisions designed to discourage "free riding" by penalizing those who do not want to pay their fair share of testing costs. Companies participating in research consortia must exercise care to ensure compliance with

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U.S. and European antitrust laws.

Opportunity for Comment and Beyond. Although there are growing signs of possible delays resulting from slowing European economies and addition of new Member States, the EU has targeted enactment of final REACH legislation by the end of 2005. Strong views abound on all sides of the issue. The Bush Administration and industry groups have spoken out vigorously against the REACH program's potentially severe competitive effects, while environmental and consumer groups profess disappointment that REACH does not go far enough and seek to close perceived loopholes in the legislation. Some groups, for example, hope to reinstitute a requirement in earlier drafts that obligates manufacturers to stop using hazardous chemicals if safer alternatives are available. Public comments have been posted at http://europa.eu.int/comm/enterprise/chemicals/chempol/whitepaper/reach.htm.

Issues for U.S. Commenters. Since the release of the draft REACH legislation, several major areas of concern for U.S. companies have emerged. The first and most obvious is the potentially enormous economic impact on the U.S. chemicals industry. The U.S. chemicals industry is responsible for 22% of all U.S. exports to the EU, with totals reaching $37 billion per year. Office of Trade and Economic Analysis (OTEA), Trade Development, International Trade Administration, U.S. Department of Commerce, http://export.gov/tradestatistics.html (last visited July 3, 2003). Critics of the REACH proposal estimate that the chemicals industry would lose as much as $17 billion of these exports per year if the new program is implemented as written. Eileen Ciesla, editorial, *European Union Chemicals Policy Threatens to Unfairly Hinder U.S. Industry*, ORLANDO SENT., June 9, 2002, at G1. For small businesses with narrow profit margins, the consequences could well be fatal. U.S. losses are staggering even when compared against the monumental costs the European economies will face. Further, as the EU economies falter under the REACH program's weight, all U.S. exporters will begin to feel the economic effects through decreased EU demand for their goods and services.

Another compelling issue is the trade discrimination that non-EU companies would face in selling chemicals and chemical intermediates to EU downstream users, an inconsistency with the EU's WTO and other international obligations. Downstream users of EU-manufactured chemicals will benefit from streamlined requirements if they can rely on registrations and authorizations obtained by an EU supplier. In contrast, purchasers of chemical intermediates from non-EU manufacturers will have to bear the full responsibility for registering and obtaining any required authorizations themselves. This overwhelming disincentive for any EU downstream user to buy from a non-EU source likely violates WTO rules that require no less favorable treatment for imported products than for domestic "like" products. Moreover, EU requirements that are more trade restrictive than necessary to achieve legitimate, health-related regulatory objectives will run afoul of Article 2.2 of the Agreement on Technical Barriers to Trade and the Agreement on the Application of Sanitary and Phytosanitary Measures. Interestingly, even European authorities are raising these points. German Chancellor Gerhard Schröder noted in a June 29 speech that the REACH legislation "would be attacked — probably successfully — by our overseas allies" because of conflicts with EU WTO obligations. *EU Regulatory Scheme Panned*, CHEMICAL AND ENGINEERING NEWS, July 7, 2003, vol. 81, no. 27, at 4.

While these issues represent some of the major concerns with REACH, many more problems are coming to light, including inadequate protection of trade secrets,[4] the lack of procedural rights, inconsistencies between REACH and ongoing global chemical harmonization efforts, impacts on developing countries, and others buried in the complex 1,200-page draft legislation. William Lash, Assistant Secretary of Commerce for Market Access and Compliance, has repeatedly emphasized the importance of U.S. business's involvement, noting "this is a big game; it will dwarf the G.M.O. [Genetically Modified Organisms] dispute." Elizabeth Becker and Jennifer Lee, *Europe Plan on Chemicals Seen as Threat to U.S. Exports*, N.Y. TIMES, May 8, 2003, at C7. The comment period closed July 10, 2003, but there will be continuing opportunities for participation as REACH moves through the European Parliament and the Council of the European Union.

[4]This may also give rise to international trade objections, as Article 39.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPs") requires the EU to protect registrants' trade secrets, a particularly important issue for high tech industries.

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