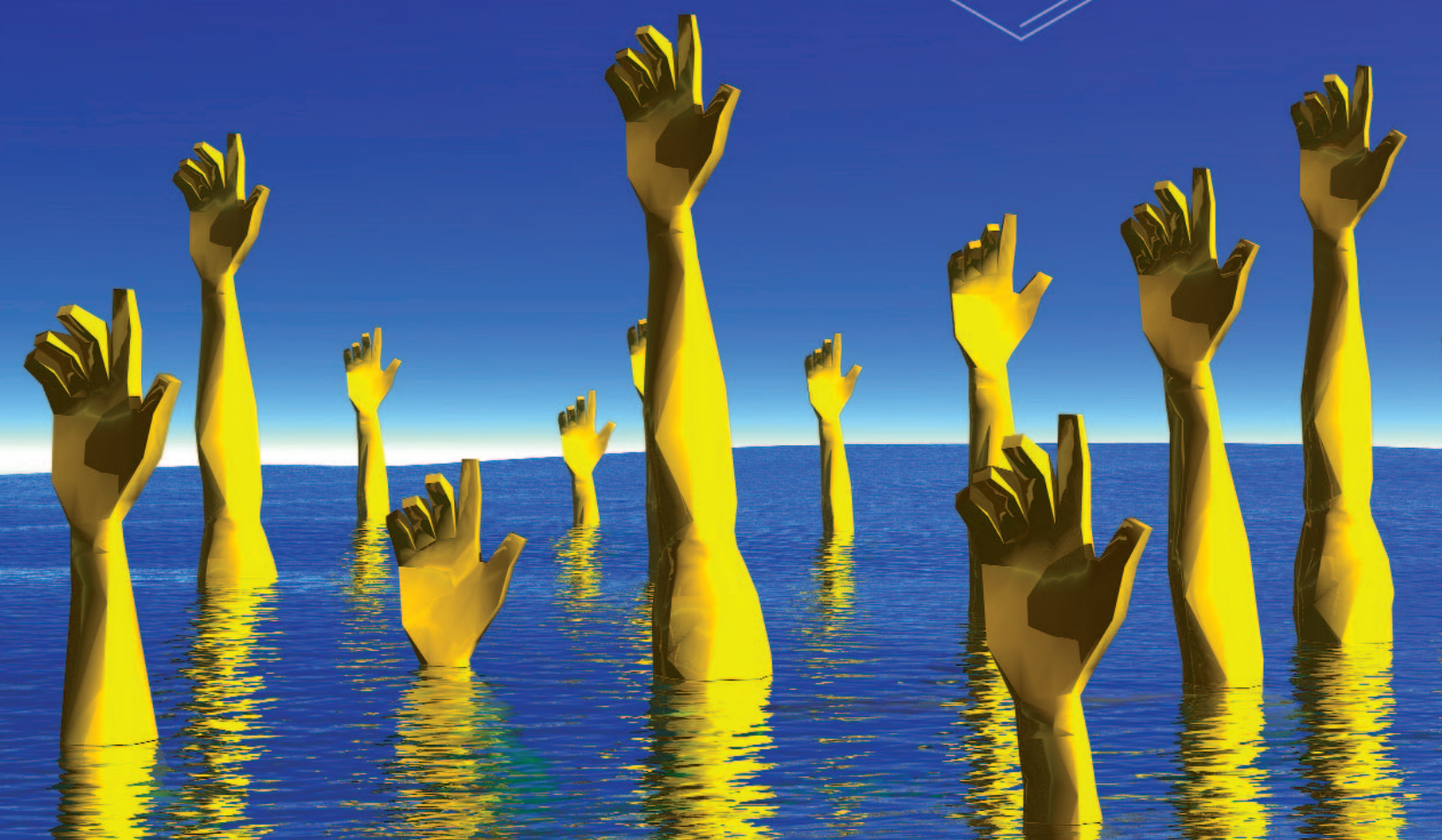
REACHing for Chemical Safety



A new chemical policy under consideration by the European Union (EU) will, if implemented, initiate a significant change in the way industrial chemicals are regulated in the world's second largest economy. It will be the most comprehensive such policy in the world, and it will not only affect all the countries and industries that do business in the EU, but may also prompt changes in other nations' chemical policies. The proposal—Registration, Evaluation, and Authorisation of Chemicals (REACH)—will be introduced in the European Parliament late this year. If it passes in its current form, the new REACH requirements will be phased in over about a decade, first handling the most dangerous chemicals and so-called high production volume (HPV) chemicals, those produced or imported at volumes above 1,000 metric tons annually.

The European Commission (EC), which is the executive branch of the EU, began developing REACH in 1998. In February 2001 the EC adopted a white paper, "Strategy for a Future Chemicals Policy," detailing the proposed system. Since then, interested parties, including the global chemical industry, environmental nongovernmental organizations (NGOs), and other governments (particularly the U.S. government) have been weighing in on REACH's pros and cons. Nearly every provision of REACH is the subject of intense debate and lobbying.

Much is at stake. The chemical industry is among the biggest of big businesses worldwide. According to the white paper, world production of chemicals has mushroomed from 1 million metric tons in 1930 to 400 million metric tons today. The European Chemical Industry Council states that in 1999 world sales of chemicals totaled US$1.6 trillion, with the EU accounting for 29%, or US$474 billion. Another 2% is generated by non-EU European countries, making Western Europe the world's leading producer of industrial chemicals. About 3 million jobs in the EU depend on chemical manufacturing and related businesses. The U.S. chemical industry ranks second, producing 27%, or US$484 billion, of world output in 1999. According to the U.S. Chamber of Commerce, American companies export upwards of US$20 billion in chemicals to Europe every year, along with US$400 billion in downstream products.

Historic Precedent

In the EU, as in the United States, chemical regulation has been based on historic precedent. Chemicals on the market in the EU before 1981 were "grandfathered"—that is, they could continue to be used without testing to prove that they were safe for humans and the environment. Since 1981, only about 2,700 new substances have entered the market, according to the white paper. However, of the approximately 100,000 substances listed in the European Inventory of Existing Commercial Chemical Substances, a database maintained by the EC, some 80,000 are thought to be currently in use in the EU. Thus, the vast majority of chemicals now in use have undergone no risk or hazard assessments. Further, according to the white paper, 70% of the 2,700 new chemicals introduced in the EU since 1981 have been found to be "dangerous" as defined by EU Directive 67/548, under which chemicals are considered dangerous if they are corrosive, flammable, mutagenic, carcinogenic, developmentally or otherwise toxic, irritating, or sensitizing.

The United States is in a similar state of ignorance. The April 1998 Environmental Protection Agency (EPA) Chemical Hazard Data Availability Study revealed that although nearly 3,000 chemicals have HPV status in the United States (defined by the EPA as imported or produced at 1 million pounds per year), complete basic toxicity profiles (covering acute, subchronic, chronic, developmental, and reproductive toxicity, as well as mutagenicity) were available for only 7% of these.

This problem has been recognized for years, and efforts to gather and organize chemical hazard and risk information are under way at many levels, says Lesley Onyon, a scientist with the World Health Organization's International Programme on Chemical Safety (IPCS). Because of widespread concern about the amount of animal testing that might be necessary to fill all the gaps in chemical hazard and risk information, Onyon says, the IPCS is working to gather "existing information about the hazards of chemicals that is currently not being used"—such as the "observational human data generated through routine clinical and occupational health and safety practice"—and to improve access to that information.

The Organisation for Economic Co-operation and Development (OECD), a group of 30 industrialized nations including all EU member countries and the United States, is the foremost player in efforts to deal internationally with the limited data on chemicals. The OECD has developed extensive chemical testing guidelines and is assessing 1,500 HPV chemicals (with HPV defined here as over 1,000 metric tons per year) with the voluntary participation of the chemical industry. And the U.S. EPA is developing a Screening Information Data Set that includes acute toxicity, chronic toxicity, developmental and reproductive toxicity, mutagenicity, ecotoxicity, and environmental fate information for the 3,000 HPV chemicals in use in the United States. The EPA is also conducting the Voluntary Children's Chemical Evaluation Program, in which manufacturers of 23 chemicals (including benzene, trichloroethylene, and ethylene dichloride) are evaluating the health risks to children of exposure to these chemicals.

REACH's Provisions

REACH will replace 40 different EU-level regulations and will apply to both domestically manufactured and imported chemicals, and, to a lesser extent, to those products made from them that expose humans or the environment to chemicals of concern. Prior to REACH, governments have been responsible for determining chemicals' toxicity, mutagenicity, potential for endocrine disruption, carcinogenicity, persistence, and bioaccumulation, as well as the degree and likelihood of exposure to humans and the environment. Under REACH, the burden of proof of a chemical's safety is transferred primarily to manufacturers. If a chemical is used in a way unanticipated by the manufacturer, downstream users such as computer makers, paint formulators, and textile importers will have to show proof of safety.

REACH requires registration of all chemicals marketed at annual volumes above 1 metric ton per manufacturer or importer; this is estimated to be 30,000 substances. Because of their low production volume, about 80% of these would require no further action. Chemicals produced in volumes above 100 metric tons per year require evaluation, including review of animal testing data, by member state experts and a new EU chemicals agency, which will be enabled by the passage of REACH. Chemicals termed "substances of very high concern"—carcinogens, mutagens, reproductive toxicants, and those that are persistent or bioaccumulative (including endocrine disruptors and persistent organic pollutants)—will require authorization for each contemplated use. The EU white paper estimates there are about 1,400 of these chemicals. Some chemicals may be banned altogether.

REACH explicitly invokes the precautionary principle—that when scientific evidence suggests a substance may harm human health or the environment but the type or magnitude of harm is not yet known, it is preferable not to use the substance until the scientific questions are resolved. It also encourages, but does not require, the substitution of less hazardous chemicals if available,

Rubberball, Matt Ray/EHP

and aims to reduce the number of animals used in testing whenever possible by applying quantitative modeling techniques and accepting *in vitro* data and certain existing test results rather than requiring entirely new tests. Data sharing along the supply chain is encouraged. Its framers also intend REACH to support and be consistent with other international chemical agreements, such as the Stockholm Convention on Persistent Organic Pollutants, World Trade Organization policies, and OECD chemical testing protocols.

Testy about Testing

Testing is one of the REACH provisions that provokes the most debate. Registration documentation must include information on a chemical's intrinsic properties, risks for human health and the environment, anticipated uses, probable exposure scenarios, risk management procedures, and a safety data sheet. Industry balks at having to provide this complete profile on every chemical, saying that chemicals' hazards should be weighed against their benefits, and that if the risk of exposure to the chemical is low, testing standards need not be as thorough.

Wolf-Rüdiger Bias, vice president for regulatory affairs and product safety at BASF, one of the world's largest chemical companies, estimates that it costs US$448,000 to test a new chemical about which nothing is known and that is manufactured at 10–100 metric tons a year. "This would be much more than almost any substance in this volume range could earn in the course of ten years," Bias says, "and would thus have a dramatic impact on a company's portfolio."

Industry is particularly concerned about the status of intermediates (chemicals that are used to produce other chemicals and thus are not present per se in the final products) and polymers (large, stable molecules used in plastics and other compounds) because inclusion of these classes of chemicals would vastly increase the number of chemicals to be tested. In its present form, REACH exempts most intermediates and polymers from most testing requirements, but will require simplified registration for some.

Despite the dearth of information about chemicals' biological effects, the chemical industry insists that its products are safe. "It's not in the interest of any company in the world, including the U.S. companies, to come out with chemicals that are known to be hazardous to the public," says Scévole de Cazotte, senior director for European trade policy at the U.S. Chamber of Commerce. "In reality, companies already take precautionary measures, including extensive testing of their products, before they market them." He adds, "Now companies at their own cost will bear alone the responsibility to prove to the new European authorities that their products are risk-free, rather than manage the risks that are scientifically proven or likely. Certification by bureaucrats does not make any substance safer. It is the application of sound principles of risk management that does."

The current extent of undisclosed test data held by chemical companies is unknown, because most chemical companies object to revealing their own data. "We would not like to share proprietary information with competitors, and it is not easy to establish a system that ensures that this information will be kept behind closed doors," says Bias.

But, counters Jim Willis, director of the United Nations Environment Programme's Chemicals Programme, "Nobody considers health and safety data to be confidential information. If [industry] has done the safety testing, they ought to make it publicly available." The REACH proposal provides that nonproprietary hazard and risk information from registration documentation will be published in a database maintained by the newly established EU chemicals agency.

The chemical industry is concerned about duplicative and incompatible testing, but the REACH proposal states that OECD standards will be applied. The OECD developed a system known as Mutual Acceptance of Data that Robert Visser, director of the OECD's Environmental Health and Safety Division, says avoids duplication of testing and nontariff barriers to trade. One standard test per end point, such as carcinogenicity or biodegradation, is accepted among all OECD members. Countries can ask for more tests for other end points, but any requested tests outside the standard OECD battery will not be accepted by other OECD countries.

Costs: How High the Moon?

A 7 May 2003 EC memo released with the draft proposal, "Questions and Answers on the New Chemicals Policy REACH," projected US$4.2 billion as the "most likely" total direct cost to industry of registration and testing, with indirect costs to industry and "society as a whole" of US$16–18 billion from inception to 2020. According to a January 2003 Worldwide Fund for Nature (WWF) analysis of REACH, "A New Chemicals Policy in Europe—New Opportunities for Industry," over REACH's extended phase-in period, industry's worst-case estimate of US$8.2 billion in costs would represent about 0.1% of the European chemical industry's annual sales revenues.

Chemical control measures such as REACH would also decrease chemical-related health care costs. There have been a few educated guesses as to the potential savings. According to the EC white paper, in 1999 the German Advisory Council on the Environment estimated the annual cost of allergies in Europe at US$34 billion. A recent study by Philip Landrigan, director of the Center for Children's Health and the Environment at the Mount Sinai School of Medicine in New York City, and others, published in the July 2002 *EHP*, calculated an annual price tag of US$54.9 billion for pediatric lead poisoning, asthma, childhood cancer, and neurobehavioral disorders in the United States. The researchers attribute significant fractions of these diseases to environmental toxicants. "Questions and Answers on the New Chemicals Policy REACH" estimates "likely occupational health benefits" of US$21–63 billion over a 30-year period.

The chemical industry itself may find that an ounce of prevention is worth a pound of cure. Notes Mary Taylor, senior research officer with the NGO Friends of the Earth in the United Kingdom, "In the long term we expect advances in science to permit more precise identification of cause and effect with respect to specific chemicals and specific diseases, opening up the prospect of increased litigation by affected individuals and groups." And the WWF report suggests that the phrase "assessed according to EU standards" could provide a sort of seal of approval that might encourage chemical users around the world to buy EU chemicals.

Critics say the combination of the increased financial burden of testing, the bureaucracy of registration and authorization, and the requirement of applying the precautionary principle will discourage innovation and could ruin many small and medium-sized enterprises, which are often the most innovative companies. But in its analysis of REACH, the WWF argues that small and medium-sized enterprises will survive because, whereas the old system requires no testing of grandfathered chemicals and thus discourages innovation, REACH will level the playing field by subjecting all chemicals to the same standards for registration and testing based on production volume. Therefore, there is no longer an incentive

to keep using older chemicals and a disincentive to produce new, and possibly greener, chemicals. REACH also provides up to a 10-year period for research and development before a substance must be registered, and raises the threshold for registration of new substances from the current 10 kilograms per year to 1 metric ton per year. Chemicals used in basic scientific research and medical applications are exempt altogether.

Chemical Politics

The chemical industry supports the idea of replacing the current arbitrary and cumbersome system, but some industry representatives think REACH goes too far. "Initially the legislation was a very good idea because it was rationalizing the [regulation] process," says de Cazotte. "The idea was to simplify and market it better based on available science." But, adds de Cazotte, environmental lobbyists "hijacked" the concept by inserting language requiring what industry views as burdensome and expensive actions.

Industry groups such as the European Chemical Industry Council and the American Chemistry Council (ACC), as well as the U.S. Chamber of Commerce, have mounted major lobbying campaigns to ease REACH's impact on business, asserting that REACH would cause widespread unemployment, deal a body blow to the U.S. economy, and "deindustrialize" Europe by forcing manufacturers into the developing world. The ACC submitted a formal critique of REACH during the May–July online comment period, which is posted on its website at **http://www.accnewsmedia.com/**. The ACC calls REACH "burdensome, costly, and impractical." The ACC did not respond to repeated requests for an interview for this article.

NGOs including the WWF, Friends of the Earth, and Greenpeace, both individually and through the umbrella European Environmental Bureau—which is accredited to have input into EU deliberations—argue that REACH, although a major step forward in protecting human and ecosystem health, has been diluted by industry pressure. In this, they say, industry has had a powerful friend in the U.S. government.

The Bush administration has "tried quite hard to slow REACH down," says Daryl Ditz, senior program officer for toxics at the WWF. An 18 May 2003 article in *The New York Times* reported that John Graham, administrator of the Office of Information and Regulatory Affairs, said in a speech to EU regulators that the Bush administration considers the precautionary principle "to be a mythical concept [that demands no serious consideration], perhaps like a unicorn." And a paper, "US Intervention in EU Chemical Policy," issued in September by the Jamaica Plain, New York–based NGO Environmental Health Fund (EHF), charges that the Bush administration has sought to weaken REACH by inappropriate means. The report calls for "a full congressional investigation into corporate influence over government actions."

The EHF report states that in March 2002,s Secretary of State Colin Powell circulated the curiously titled "United States Nonpaper on EU Chemicals Policy" to U.S. embassies in EU member states, urging the embassies to distribute the document to member states' environment and trade ministries. The "nonpaper" was unsigned and printed on plain paper without any U.S. government letterhead. It said REACH could distort global markets and violate World Trade Organization principles, and that the precautionary principle would result in "politically motivated bans" of U.S. chemical products. The EHF report found that parts of the text closely resembled statements by the ACC, and an article nearly identical to the "nonpaper" appeared under the byline of the U.S. Trade Representative in the June 2002 issue of the ACC magazine *Chemistry Business*.

According to an EPA official in the Office of Pollution Prevention and Toxics, who declined to speak for attribution, the EPA has "shared our experience and approaches" with the U.S. Trade Representative, the Department of State, and the Department of Commerce, and has met directly with REACH developers, but the administration position has been advanced mostly by those other agencies. The EPA official says, "REACH, as proposed, presents a potentially costly, burdensome, and pretty complex approach. We have concerns about how workable it will be in its implementation." The Department of Commerce did not respond to requests for an interview about the U.S. government's position on REACH.

In late September it appeared that industry and government pressure had succeeded in changing the May 2003 draft policy, to the dismay of green NGOs. A revised draft was leaked to NGOs and journalists, and although the EU would not comment on it, an EU spokesperson confirmed that an *Environment Daily* report of 24 September 2003 was "factually correct." That report said that under the revised draft, downstream users of chemicals will not be required to register their products at all, and importers will have to register their articles only if a chemical is both classified as dangerous and intended to be released in the product; that the transparency of the registry database has been obscured by a provision of automatic anonymity for the registering company; that polymers are almost entirely exempt; and that below a production level of 10 metric tons per year, no chemical safety reports will be required. The only change favorable to environmentalists is a slightly stronger emphasis on encouraging—but not requiring—substitution of a "greener" alternative for a chemical that is required to undergo the authorization process.

Despite these changes, the ACC found the revised draft to still be unacceptable and issued a press release on 9 October 2003 saying REACH would "create a confusing, wasteful, and inefficient bureaucracy."

Reaching into the Future

Because of chemical reform's momentum, most stakeholders believe REACH will be enacted in some form. A vote is not expected before mid-2004, but before then, elections will result in significant changes in the makeup of both the EC and the European Parliament. Moreover, in May 2004, the EU's membership will jump from 15 to 25 nations with the accession of Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, and Slovenia. However, these changes are not expected to radically affect REACH's chances of passage. Even so, it is impossible to predict exactly how REACH will emerge from the political process.

In a 16 May 2003 speech at the New European Chemicals Policy Conference to solicit comments on the REACH proposal, EU Environment Commissioner Margot Wallström said, "A newborn baby may have her father's eyes and her mother's toes. But the child will also have a cocktail of synthetic chemicals in his or her bloodstream that have been 'inherited' from our modern way of life." Given what is already known about the few chemicals whose biological harm has been identified, it would be helpful to know what effect that cocktail has on human health. Whether the EU chooses to maintain the status quo or build a new regulatory edifice from the ground up, its decision will reverberate around the world.

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