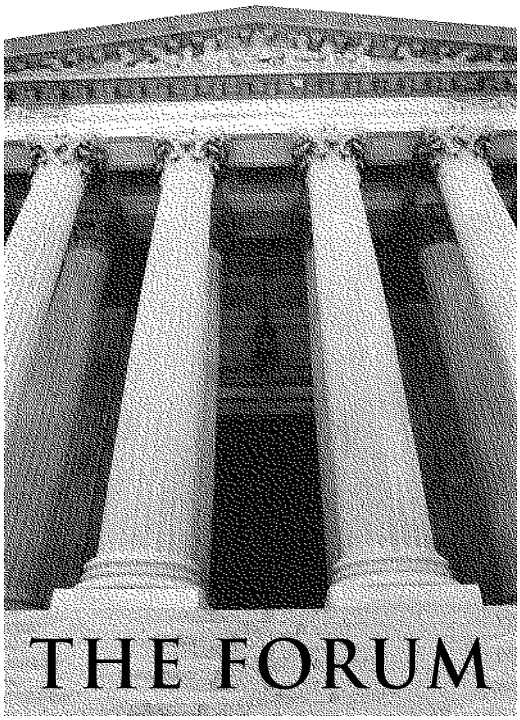

The Long Arm Of REACH: A Bold Proposal From The EU On Chemical Safety

While the United States was busy in Iraq, "Old Europe" was busy at work on what many observers are calling a radical new approach to chemical regulation.

It's called REACH, for *R*egistration, *A*uthorization, and *E*valuation of *Ch*emicals. It began as a White Paper floated by the European Commission in 2001, which was followed by a proposed regulation issued last May that weighs in at 1,200 pages. Thus far, all EU member countries have supported the proposal, which would not take effect until 2005 at the earliest.

REACH would make several important changes in the way chemicals are assessed, and therefore handled and used. To call its potential impact on the industry — both U.S. and global — huge would be an understatement. It would shift the burden of proof from the government (to prove that a substance is harmful) to the manufacturer, importer, and user (to prove that it is not). It would thus mark one of the first times that the precautionary principle would have a significant impact on American industry. And, perhaps most significantly, whereas existing toxics legislation such as the Toxic Substances Control Act primarily affects chemicals coming onto market, or being applied to significant new uses, REACH would reach back and affect all chemicals *on* the market.

Needless to say, calculations of economic, and environmental, impacts have only begun.

Lynn L. Bergeson
Partner
Bergeson & Campbell, P.C.

"The proverbial train has left the station. Too much time and energy has gone into the program, and it is highly unlikely the European Union will simply say 'never mind' and move on to Plan B. The real question is how are U.S. chemical exporters, domestic companies with EU affiliates, and others preparing for REACH."

Daryl Ditz
Senior Program Officer
World Wildlife Fund
Toxics Program

"The Bush administration has ignored three tangible benefits to the United States: Safer chemicals for consumers; access to a newly harmonized EU market for industry; and fresh information on chemical hazards and safer alternatives.

Uwe Lahl
Director General
Pollution Control, Transportation, and Health Division
German Federal Ministry of Environment, Nature Conservation, and Nuclear Safety

"Germany has the largest chemical industry in Europe, and the federal government feels it is very important to be active in and committed to this reform. This commitment is also highlighted by the fact that we were able to gain a constructive basic position from our industry."

William H. Lash III
Assistant Secretary for Market Access and Compliance
U.S. Department of Commerce

"We fully support the EU's interest in a protective chemicals policy, but REACH appears prohibitively costly, overly burdensome, unworkable in its implementation, and will negatively affect global trade, while preventing the EU from accomplishing its goals of protecting health and the environment."

Michael P. Walls
Senior Counsel
American Chemistry Council

"In the end, REACH isn't really geared toward managing or reducing risks — it's aimed squarely at eliminating hazard. The European Commission's White Paper named the specific objective of 'encouraging the substitution of dangerous by less dangerous substances' — an objective that can only be read as a focus on hazard characteristics."

Preparation May Be Best And Only Response

LYNN L. BERGESON

REACH should not be implemented. Fundamentally the very premise of a "one size fits all" regulatory program that seeks to harmonize the approval of new and existing chemicals is flawed. The much-discussed problems with implementing REACH are not Chicken Little hype; they are the inevitable consequences of this flawed premise. REACH is not the "model for reform" that will cure the perceived failures of existing global chemical programs. REACH is a train wreck in the making, and the European Commission should heed the thousands of adverse comments it received during the consultation process this past July, scrap the program, and begin anew.

REACH has commanded considerable comment since it was floated five years ago. The White Paper the European Commission published in 2001 focused the issues, and helped brace the global chemical community for the sticker shock of the 1,200 pages of complicated, turgid regulation proposed by the European Commission on May 7, 2003. The length and complexity of the proposal is matched only by the intensity of the adverse comment received on it.

The draft regulation's core problems are well documented. At bottom, REACH shifts the burden of proof that a chemical substance is safe to use from the government (to prove that it is not) to the manufacturer, importer, and user (to prove that it is). The "duty of care" that REACH imposes, without qualification, could be (and will be) interpreted to impose an "absolutely safe" standard, making REACH the first widespread application of the precautionary principle. The regulation is expected to result in the imposition of restrictions on many chemicals, and in a ban on more than a few, with no proof that the chemical is actually causing harm.

The impacts on downstream users of chemicals are expected to be especially challenging. Downstream users of chemicals are required to prepare Chemical Safety Reports — CSRs — regardless of whether the chemical is registered, and are required to register chemicals (and possibly obtain authorization) if their uses are not addressed by the manufacturer's or importer's registration. The implications of this, given the thousands of chemicals covered by REACH and the thousands of uses by downstream users of these chemicals, are nothing short of staggering and portend a transactional nightmare.

Complicating the downstream user impact is the lack of adequate protection for confidential information. REACH's implementation will necessarily require the development, submission, and distribution of large amounts of data. The newly created European Chemical Agency that will manage REACH will publish these data. CSRs may well identify chemical suppliers, which, in turn, may breach business confidences that have long been protected, and properly so. The regulation invites the loss of confidentiality in many other places.

The American Chemistry Council has thoroughly documented the trade distortions that will arise if REACH is enacted. That REACH discriminates against imported chemicals is clear. As such, and for the other reasons that the ACC and others have carefully outlined, REACH is inconsistent with the European Union's World Trade Organization obligations and thus imposes illegal trade barriers the global economy can ill-afford to endure.

Finally, that REACH is out of step with the global trend toward harmonizing chemical regulation is beyond question. Some might contend that global harmonization is more fiction than fact, and with considerable merit. That said, however, it is difficult to rationalize a program that departs in so many key respects from current OECD testing protocols as do the technical guidelines in the proposed regulation. These departures invite confusion and inconsistency in interpreting the results of chemical testing, increase significantly the cost of meeting mandatory testing requirements, and, in some cases, require the unnecessary sacrifice of more test animals than their counterpart OECD testing protocols.

Many believe, this writer among them, that notwithstanding the legion of problems with REACH, the proverbial train has left the station. Too much time and energy has gone into the program, and it is highly unlikely the European Union, in response to comment, will simply say "never mind" and move on to Plan B.

The real question is how are U.S. chemical exporters, domestic companies with European Union affiliates, and others preparing for REACH. It is more likely than not the European Parliament and Council will enact REACH. Given the imminent expansion in the composition of the European Union, timing is unclear. Global chemical stakeholders should use the time available wisely, take a hard look at how REACH will influence their business operations, and plan for the worst. The information gleaned from this exercise will help prioritize business goals and prepare for managing chemical products and finished goods made from targeted chemical components expected to be at the greatest risk under REACH for enhanced restriction or elimination. Preparation may be the best and only response to the new world order REACH is likely to impose.

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Still Much To Learn From 'Old Europe'

DARYL DITZ

Last July 10,000 Americans and over 60 organizations signed a U.S. Declaration of Independence from Hazardous Chemicals, speaking out for safer chemicals in consumer products, in the workplace, and in their communities. Why? In large part, they were inspired by European efforts to overhaul their regulatory strategy. In the eyes of many environmental, health, and labor advocates, REACH is the most promising international initiative on the horizon for eliminating hazardous chemicals.

Bold action is long overdue. Both U.S. and European laws ignore the risks of most chemicals. The industry acknowledges that roughly 90 percent of the top chemicals on the market lack adequate information on their environmental behavior and on the potential health hazards to people and animals. Scientific evidence is accumulating of chemical contamination. Chemicals that are not yet household names — bisphenol A, polybrominated diphenyl ethers — are routinely found in the fat of polar bears and in mothers' milk. Margot Wallström, European commissioner for the environment, notes that under the current system, in the past 10 years only 11 of 140 high-risk, high-volume chemicals have been fully reviewed. The situation is not too different in the United States.

REACH is the result of a deliberate process in Europe to bring chemicals under a coherent system of management. With the basic notion of "no data, no market," REACH represents a fundamental change. Chemicals of high concern would be subject to authorization and, where warranted by the data, to restrictions or bans. REACH places new responsibilities on manufacturers, importers, and users of chemicals in the EU, including the burden of proof regarding the safety of the chemicals they use. By influencing the mix of chemicals manufactured, imported, or used in the EU it is clear that REACH could have implications for downstream "chemical choosers" outside Europe's borders.

The proposed legislation could be better. The U.S. Declaration of Independence called for three improvements: to enforce substitution of safer alternatives for dangerous chemicals; to expand access to information about the presence and effects of chemicals in products, in the workplace, and in communities; and, to remove the double standard that favors imports of chemicals into the EU as "substances in articles."

Even so, European progress on chemical reform contrasts starkly with U.S. policy stagnation. The bulk of our economy still relies on chemicals that where exempted from scrutiny in the 1970s. Hence the prevailing cloud of what Environmental Defense rightly named "toxic ignorance." Since new chemicals receive at least a perfunctory screening for persistence, bioaccumulation, and toxicity, the current regulatory framework offers a powerful incentive to stick with old, untested chemicals. "No data, no problem," quipped a senior Dutch official.

The Bush administration has ignored three tangible benefits to the United States from REACH. First, U.S. consumers would be on the receiving end of safer chemicals in household, commercial, and industrial products from Europe. There's no way to know how REACH's information-forcing mechanism will contribute to reduced health costs. But a report by noted economists David Pearce and Phoebe Koundouri estimated the potential social benefits from lower incidence of chemical-related disease and productivity savings could range from 33 billion euros to as high as 260 billion euros by 2020, exceeding even the darkest industry cost predictions.

Second, U.S. businesses that offer quality goods — free from hazardous chemicals — stand to gain from ready access to a newly harmonized EU market of over 500 million consumers. Surprisingly, the U.S. government has produced no analyses of the potential trade benefits or costs of the proposed legislation, though Rockwell Schnabel, U.S. ambassador to the EU, has claimed that $8.8 billion of U.S. trade was put at risk by Europe's proposed chemical reforms. (Let's come back to that in a minute.)

Third, U.S. scientists, managers, regulators, and citizens will benefit from fresh information on chemical hazards and safer alternatives. This new knowledge constitutes a valuable resource in R&D, product design, procurement, investment, and regulatory decisions. All this at an estimated cost on the order of 4 billion euros (in direct costs) spread over the next 11 years. That amounts to roughly 0.1 percent of annual chemical sales, hardly the costly burden predicted by its strongest critics.

So what should the United States do? For starters, the federal government could turn down the rhetoric and open its eyes to the potential benefits of REACH: to U.S. consumers and workers, to U.S. companies, and to U.S. policy.

The Bush administration and its chemical industry allies have been shopping around a dodgy dossier of anti-REACH hyperbole, predicting trade barriers, huge regulatory costs, and dire threats to small business, innovation, animal welfare, and even European competitiveness. They have been enthusiastic messengers of the dangers of REACH, expressing official U.S. anxieties throughout Europe and countries from Chile to China.

In April, Secretary of State Colin Powell directed U.S. embassies across Europe to convey the U.S. government's misgivings about REACH to Commission offices in Brussels and to appropriate "environment, trade, industry, and foreign ministry officials" in their host countries. The following week the Commission released the draft legislation for public comment. While the EU encouraged participation from all corners of the political land-

scape, the Bush administration developed the official U.S. position on REACH on the basis of unsubstantiated industry speculation, and without meaningful public input.

Would REACH impede U.S. trade with Europe? The U.S. government has repeatedly warned that REACH may discriminate against U.S. manufacturers, in potential violation of WTO rules. This was based on a report by the American Chemistry Council, the chief lobbyist for U.S. chemical manufacturers. Prepared over a year before the draft legislation was released, the ACC paper assumed that without chemicals like acrylonitrile (a carcinogen that would be subject to authorization under REACH), U.S. industry would no longer make the hard plastic casing on personal computers. No acrylonitrile, therefore no plastic, therefore no U.S. computer sales to Europe. That's $7.5 billion of the mythical $8.8 billion figure Ambassador Schnabel has been touting. In fact, plastics mostly escape scrutiny in the draft legislation.

Instead of lobbing grenades at REACH, the U.S. could draw important lessons from the European experience, as some states and local governments are beginning to do. San Francisco's newly enacted precautionary principle will guide its entire environmental code. Seattle is implementing a 2002 ordinance designed to reduce persistent, bioaccumulative, and toxic chemicals from its procurement. These innovators are also likely beneficiaries of the new information that REACH promises. Perhaps they will also lay the foundation for the eventual reform of U.S. chemicals policy.

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Green Light From Government And Industry

UWE LAHL

The main problem with the current regulation of chemicals under European law is that there is insufficient information available on approximately 100,000 substances that are over 20 years old — and that constitute 97 percent of all chemicals on the market. Up until 1993, in fact, these substances did not have to be either reviewed nor evaluated. That year, the EC Existing Substances Regulation, which applies to quantities over 10 tonnes, entered into force, but it requires only that available data have to be submitted — no new tests were required.

In many cases, therefore, very little is known about the effects of the production and the products on human health and the environment of the vast majority of hazardous chemicals in commerce. Up to now, basic data have been required to be submitted for just the 140 substances that are on the EC priority list — and in only about 30 cases has there been a conclusive evaluation. The situation is exacerbated by the fact that the state must prove that a substance represents a risk requiring regulation and has to rely on the manufacturer to make the necessary data available. The result is incomplete and unsystematic risk management.

New chemical substances are subject to a registration procedure, but about 3,700 have been registered since EU requirements went into effect in 1981. Manufacturers or importers wishing to market more than 10 kilograms per year of a substance must first register it with the competent authority and for quantities of 1 annual tonne must provide basic data allowing an initial evaluation of the environmental and health hazards. This is mainly a question of identifying acute impacts for humans and the environment. For a marketing volume of over 100 annual tonnes, there must be studies which also permit the long-term harmful effects to be evaluated such as carcinogenicity or mutagenicity.

This unbalanced treatment of existing and new substances has led to massive criticism within the EU and was the reason for the Environment Ministers Council Decision of June 1999, during the German Presidency, which called on the EC Commission to submit a strategy paper on a comprehensive restructuring of the EU chemicals policy. In 2003, the EC Commission submitted the preliminary draft of REACH — a "Regulation (EC) of the European Parliament and the Council concerning the *R*egistration, *E*valuation, *A*uthorization and Restriction of *Ch*emicals."

The REACH system contains the following essential elements:

The *registration* of all substances which are produced/imported in quantities above 1 annual tonne per producer/importer, with specific basic information on the substance to be provided by the companies.

Systematic government *evaluation* of all substances which are produced in quantities of more than 100 annual tonnes, as well as those produced in smaller quantities if they are of concern.

Authorization for high risk substances (especially carcinogenic, mutagenic or reprotoxic, etc.); the authorization covers substance applications for which the producer has previously verified the safety. This requirement reverses the burden of proof.

REACH also places an obligation on the downstream user to notify the authorities of other applications of a substance which have not been intended by the producer and, where necessary, to perform supplementary tests.

In Germany, events have proceeded further. The federal government along with the German Chemical Industry Association (VCI) and the Mining, Chemical and Energy industrial union (IG BCE) met to discuss several proposals and issued joint statements in March 2002 and August 2003.

After the second meeting, the group issued a Joint Evaluation, commenting on the consultation draft of REACH. This consensus document says that the final chemicals policy must, on the one hand, guarantee a high level of protection for human health and the environment and, on the other, guarantee the ability of the chemical industry to be competitive and innovative.

The Joint Evaluation seeks simple and workable procedures as a prerequisite both for achieving environmental and health related protection objectives and for the economic sustainability of future regulations. In addition, the evaluation calls for a comprehensive assessment of the effects of the regulations of chemicals law on the economy as a whole. This study should, however, take into account the anticipated benefits of the future REACH system as well as the probable burdens for trade and industry.

The special significance of the Joint Evaluation is that all in all — disregarding the basic criticisms voiced by the industry to some extent with regard to the consultation draft — it again succeeded in producing a constructive joint position with the directly affected industry and those representing its employees in a manner supportive of the reform process.

There are arguments for and against, but we believe on balance they favor a REACH policy, implemented in a way that addresses our concerns:

Costs for the testing of existing substances too high? But if no data are available, that is not responsible care. If the data are available, which up to now the industry has always maintained to its critics, the costs cannot be so high.

Competitive disadvantages on foreign markets? In the long term, "Made in Europe" will mean a safer product to the American consumer and in other markets.

Innovation and economic strength? Precisely the experiences on the foreign markets show how important it is to have tested environmental and health protection with sound science, in order to keep liability risks low.

Industrial secrets, bureaucracy? As our Joint Evaluation declared, there must be balance between environmental concerns and legitimate business needs.

Germany has the largest chemical industry in Europe, and the federal government feels it is very important to be active in and committed to this reform. This commitment is also highlighted by the fact that we were able to gain a constructive basic position from our industry — the Joint Evaluation. This has set the signal to green and the legislative procedure in the Council and Parliament can begin.

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Useful Proposal — But Needs To Be Re-Worked

WILLIAM H. LASH III

The chemical industry is one of the most significant sectors in the U.S., EU, and global economies, directly or indirectly involved in almost every manufactured product. This is why the U.S. Department of Commerce, as part of a larger U.S. government effort, has focused considerable time and energy on the European Commission's proposed chemical legislation. We believe REACH — *R*egistration, *E*valuation, and *A*uthorization of *Ch*emicals — could have a significant impact on global trade, not just of chemicals themselves, but all products containing chemicals.

We fully support the European Union's interest in developing a new chemicals policy that ensures robust protection of the environment and human health. However, we remain concerned that the proposed REACH approach appears prohibitively costly, overly burdensome, unworkable in its implementation, and will negatively affect global trade, while preventing the EU from accomplishing its stated goals of protecting human health and the environment.

With $450 billion in annual revenues, the U.S. chemical industry employs over a million Americans. The United States exported over $25 billion in chemicals to the EU in 2002, accounting for 18 percent of U.S.-EU trade. As it could be read to cover all products containing chemicals, the REACH proposal could affect the majority of U.S. manufactured exports to the EU — $143 billion in 2002. More broadly, we believe that the proposal likely will have a negative impact on the global economy — loss of jobs, significant costs, and severe disruptions in supply chains and the manufacturing process — as it could take years to register the 30,000+ chemicals it covers.

The U.S. government, and many of the other 6,400 stakeholders who submitted written statements during the European Commission's public comment period, expressed concerns that REACH is overly burdensome and costly in its efforts to legislate a risk-free environment for European citizens. The European Commission based REACH on the "precautionary principle," a regulatory scheme that focuses not on the scientific basis for the management of risk, but rather on the perception of hazard: that all chemicals are presumed to be hazardous until proven they are not. We believe that sound science must be the basis and foundation for the development of any chemicals policy.

Through the Transatlantic Business Dialogue and other forums, the U.S. government has a number of high-level discussions with the European Commission on REACH. In addition, U.S. and Commission regulators have engaged in a constructive regulatory dialogue to discuss this proposal and other technical issues involv-

ing global chemicals management. These efforts have helped facilitate an exchange of views on this globally important issue.

Even with these constructive dialogues, the U.S. government continues to have concerns about the REACH proposal. In our formal comments to the Commission on this proposal, we identified nine key concerns with the draft legislation, which are summarized below:

Unworkable regulatory approach: Implementation of this regulation as proposed is complex, bureaucratic, and lacks transparency. We are concerned that the Commission's proposal could prove difficult, if not impossible, to implement in an efficient and effective manner. An unworkable regulation will not achieve the EU's stated regulatory objectives.

Departs from ongoing international regulatory cooperation: The proposal does not take into account ongoing international efforts in the Organization for Economic Cooperation and Development and other forums to establish international guidelines for addressing human and environmental risks associated with exposure to chemicals. The Commission's approach should complement, not supplant, these and other ongoing efforts.

Imposes substantial costs/uncertain benefit: REACH likely will have a detrimental effect on the global economy by reducing innovation and dramatically increasing costs. According to the European Chemical industry, REACH will cause a significant loss of GDP (between .4 and 6.4 percent), jobs (up to 670,000), and investment (the total cumulative loss of investments could be up to $103 billion).

Adverse impact on small and medium sized enterprises: The registration, authorization, and restrictions sections of the proposal are extremely complicated and difficult for SMEs, in particular, to follow. The administrative burdens, as well as costly registration fees, may force many SMEs to simply discontinue doing business in, or with, the EU.

Disrupts global trade: The proposed approach could adversely impact production and transatlantic trade in tens of billions of dollars in chemicals and downstream products — from autos to textiles. We are concerned that disruption to the global supply chains will result if this proposal is implemented.

Adversely impacts innovation: The proposal will inhibit innovation and hinder the development and introduction of safer, more innovative chemicals and downstream products, as companies shift resources to cover high compliance costs.

Creates market uncertainty: The lack of clarity in the proposal on how the regulation will operate and what products will be covered creates tremendous market uncertainty, not just for the chemical industry, but also for all potential downstream users of chemicals.

Unclear administrative coordination and consistency: Under the proposal, several agencies have overlapping responsibilities for the management and regulation of chemicals policy in the Member States and the European government. It is unclear from the current proposal how these various agencies will work together to effectively manage and coordinate throughout the process.

Confidentiality of data sharing: Protection of confidential business information and trade secrets is poorly defined in the proposed regulation. The proposed regulations could allow protected information from innovative companies to be released publicly, creating disincentives for companies to register their products for sale in the EU.

In conclusion, for all the above reasons (lack of a scientific basis, cost, efficacy, and feasibility), we have strongly urged the EU not to adopt REACH as currently drafted. If the EU hopes to ensure the protection of human health and the environment, while avoiding overly burdensome and bureaucratic regulation of the production and use of chemicals in Europe, it needs to rethink this proposal. Certainly, the comment period for REACH has been an important step in this process, and we commend the EU for soliciting interested stakeholders' comments. We look forward to working with the EU to address our concerns, while still meeting the EU's stated goals of protection of human health and the environment.

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A Proposal For Regulatory Over-REACH

MICHAEL P. WALLS

The European Commission's proposal for the *R*egistration, *E*valuation, and *A*uthorization of *Ch*emicals needs fundamental restructuring if the Commission is serious about achieving the twin objectives outlined in its February 2001 White Paper on a future chemicals policy — protecting health and the environment and promoting economic and technological development. As drafted, the proposal is little more than regulatory over-reaching.

The REACH proposal flows from the concept that the necessary predicate to effective chemical regulation is a uniform set of data on all chemical hazards, uses, and exposures. It's not hard to see how the Commission arrived at that concept.

The European Community's current regulations on *new* chemicals (those not previously entered on the European inventory) essentially require each new chemical application to be accompanied by a uniform "base-set" of data. The Commission's White Paper criticized the new chemical regulations for their high cost and burden to industry, and their negative impact on innovation and the technological competitiveness of European industry.

Yet in their effort to grapple with the body of *existing* chemicals (those chemicals already in commerce when the inventory was created, and the particular target of the REACH system) the Commission is turning back to a model already demonstrated to have handicapped European industry and Europe's competitiveness.

What's wrong with the "all information on all chemicals" philosophy that underpins REACH and the implementation mechanism suggested in the proposal?

Plenty.

First, the approach tends to assume that all chemicals have similar exposure and use patterns, and require the same information in order to assure safe manufacture and use. Although the Commission has recognized the need for a few "practical" exemptions, the exemptions are woefully inadequate. Even the Commission recognizes that 30,000 chemicals, and some 20,000 additional polymers, will be subject to the new system.

Second, REACH has significant economic and administrative implications. The Commission itself has estimated that the direct testing and registration costs of REACH could go as high as 7 billion euros, and indirect costs as high as 26 billion euros, for total costs of 32 billion euros. Other estimates range higher. Studies by Mercer Management and AD Little on the economic impact of REACH in France and Germany, respectively, estimated that REACH could have a negative impact on the order of 2 to 3 percent of GDP, with consequent job losses and negative impacts on the industries that use chemicals and the consumer who rely on those products.

The administrative impacts are also notable. According to the Commission, Europe is only capable of undertaking 25 to 30 percent of the testing required under REACH, while the rules by which testing conducted elsewhere will be accepted are not part of the package. The UK's Institute for Environment and Health estimates that REACH-mandated testing will require 12 million vertebrates; animal rights advocates have been sharply critical of the requirements. A significant new central European bureaucracy will have to be created to deal with the flood of registration dossiers, and because REACH assumes that EU member governments will analyze those dossiers, the governments will also have to expand their administrative capabilities. Downstream users have important obligations under REACH, notably to develop Chemical Safety Reports. Ford Motor Company estimated that the Commission would receive 55,000 to 85,000 CSRs (and periodic updates) on just the 7,000 chemicals and mixtures used in automobile manufacture!

Third, REACH has significant implications for existing international trade and chemical regulatory disciplines. The proposal raises concerns about Europe's commitment to World Trade Organization agreements, and clearly discriminates against imports of some chemicals contrary to WTO obligations. Moreover, the downstream user requirements apply to importers of articles made with or containing chemicals — basically, every non-agricultural export to Europe.

The fourth major problem is that it misses the point. The focus of any chemical regulatory system should be to assure that the right measures are being applied at the right time to manage risks appropriately. It is hard to imagine how 30,000 registration dossiers, and hundreds of thousands of CSRs, even if they are managed efficiently, will enhance health and environmental protection. Even if the information is all made publicly available (another objective in the Commission's White Paper), how will the public plow through that mass of information?

In the end, REACH isn't really geared toward managing or reducing risks — it's aimed squarely at eliminating hazard. The Commission's White Paper named the specific objective of "encouraging the substitution of dangerous by less dangerous substances" — an objective that can only be read as a focus on hazard characteristics.

The focus on hazard plays out in other aspects of the proposal. The "authorization" phase of REACH is in fact a regulatory track that will operate parallel to the registration and evaluation phases. The proposal envisions use-specific licensing for a set of chemicals identified not by the risks they pose but simply by their hazard characteristic, leading to the possibility of regulatory bans and forced substitution.

There is a better approach.

A more resource-efficient REACH would look first to available hazard, use, and exposure information, and information on existing risk management measures. This would eliminate a substantial amount of testing in the first instance, reduce the need for animal testing, and permit the authorities to evaluate whether the risk management decisions are appropriate given the information. The evaluation phase would help identify any data gaps and consider whether any additional testing is required. Authorization should rely on the data and conclusions of registration and evaluation, rather than create a separate regulatory track focused on hazard. Finally, the Commission needs to provide more comprehensive exemptions for those substances whose chemical structures or uses pose low health and environmental risks, largely by harmonizing the scope and application of the system with other regulatory systems and intergovernmental agreements.

The Commission is assessing the 6,400 comments it received on REACH, and may revise its proposal once more. But the prospects of the Commission taking a more step-wise approach that addresses chemical risks in the context of use and exposure are not encouraging, given its single-minded drive toward implementing the White Paper concepts. REACH is simply a bad idea whose time has not come.

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