



Still OverREACHing

The European Union's Proposed Chemicals Policy Has Not Been Fixed

A Update to Europe's Global REACH, published in November 2005

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The European Union's (EU) proposed chemicals policy—called REACH, which stands for registration, evaluation, and authorization of chemicals—has undergone several rounds of revisions, as politicians attempt to address concerns about its high costs—particularly to small and mid-sized (SME) businesses. Last June, the European Commission released a new version of REACH that supposedly as fixed the program, making it affordable and fair. This paper addresses some of REACH's irreparable flaws as well as some analysis of why specific “fixes” to the program are little more than window dressing.

Background. The stated purpose of REACH is to improve public health by increasing knowledge about chemical risks, which will be used to eliminate dangerous products and replace them with safer ones. As its name implies, REACH attempts to meet this goal via a multi-stage regulatory program.

- The first stage is registration, during which firms will have to submit data to register chemicals that they produce or import into the European Union in amounts of one ton or more.
- Next comes evaluation, during which a newly created European Chemicals Agency determines if it will demand additional data for a substance.
- Authorization applies to substances found to be of “special concern”—substances deemed either carcinogenic, toxic in reproduction, persistent in the environment, or that accumulate in the human body. After demanding further study and review of such chemicals, regulators then decide which substances to ban or regulate and which to provide final approval.

A newly created European Chemicals Agency will administer REACH, registering substances on a phased schedule. When a firm registers depends on the volume of substances it uses: “High volume” users/producers (1,000 tons or more annually) register three years after REACH becomes law; mid-level users/producers (100-1000 tons annually) register in year six; and “low volume” users/producers (1-100 tons annually) register in year 11.

The European Commission proposed REACH in 2003, and the European Parliament and Council of Ministers considered and amended it last year. In June 2006, the Commission produced what is called the Common Position, which attempts to reconcile the Parliament and Council versions of REACH. This version is currently being considered by the Parliament, which will amend it further and then either approve or reject it this fall. The Parliament and the Council are expected to agree on a final version by 2007, which would make REACH law.

Fundamentally Flawed. REACH has been criticized for being expensive and bureaucratic. These problems cannot be fixed because REACH’s underlying assumptions are fundamentally flawed.

First, REACH does not focus on high-priority risks, but instead arbitrarily applies the precautionary principle to low-level chemical exposures and risks. As a result, REACH is unlikely to produce any substantial public health benefits because the public exposures it addresses are so low that the risks are insignificant and undetectable. Moreover, workplace exposure has already been controlled under various other programs and directives. In fact, health trends do not indicate problems associated with these exposures in Europe or in other developed nations, as documented in an earlier study on REACH.¹ Not surprisingly, REACH advocates have been unable to produce a convincing study documenting REACH benefits.²

Application of the precautionary principle compounds this problem by setting an impossible standard. It essentially demands that companies prove that their products are safe before their introduction into commerce. Since manufacturers cannot prove that anything is 100 percent safe, this policy will likely produce arbitrary bans of many relatively safe substances and discourage innovation in return for no public health benefits.

The other fundamental problem with REACH is that it depends on a misguided faith in centralized, bureaucratic management. History has demonstrated the failure of such systems, and REACH is no different. As a result, REACH is destined to become little more than an expensive exercise in bureaucratic futility.

The costs of the REACH bureaucracy have never been fully documented—but we do know that they are likely to be substantial, with cost estimates of just the first stage ranging up to €5.2 billion.³ In addition, there will likely be very high indirect costs resulting from more expensive alternative products, reformulations, trade impediments, and other issues.⁴

Exemption Politics. The European Commission has attempted to reduce opposition to REACH by providing exemptions to some industries. It used this strategy early on by exempting polymers. In addition, some industry categories are exempt because they are regulated under other programs, such as pesticides, pharmaceuticals, and cosmetics. Most recently, the Common Position provides an exemption to ores, ore concentrates, minerals and, cement clinker.

However, exemptions are no guarantee that an industry won't be affected or be hit from another direction. Polymers, for example, may be exempt, but their component monomers are not. In addition, once the REACH regulatory apparatus is in place, the Commission will likely expand its scope by arguing that it must apply to all substances to ensure consistency, fairness, and public health. In fact, the Commission has already indicated that it will reconsider the exemption for polymers in the future.⁵

Exempt industries will also pay indirectly. For example, REACH may impact availability of key ingredients of exempt products, some of which may disappear from the marketplace. In that case, a cosmetic or pesticide might be exempt as a finished product, but companies producing those products may face high reformulation costs as key ingredients disappear. In addition, products used in their industrial processes may be subject to REACH regulations, and exempt industries may find that other products are more expensive as their suppliers face REACH-related costs.

Substituting Markets. A key focus of REACH is to force companies to substitute so-called “dangerous products” with safer alternatives. According to a Commission question-and-answer paper on REACH, such substitution remains a key goal of REACH and is embodied in the Common Position.⁶

Ultimately, the concept of substitution is seriously flawed. It is based on the faulty idea that regulation can prompt industry to find products that are superior to products that have been legally designated as “dangerous.” If the substitutes were really superior, they would prevail in the marketplace without government mandates. The allegedly safer substitutes are usually not commonly used because they carry trade-offs, including higher prices, reduced product quality, and increased incidence of product failures. In some cases, substitutes selected or pushed by regulators are actually *more* dangerous than the products they replace or less understood in terms of risk. **For example, mandating less**

effective disinfectants for water supplies to substitute chlorine could increase waterborne illnesses and diseases.

Other unexpected problems can arise with government-mandated substitution. In Washington, D.C., a regulatory measure designed to advance substitution of chlorine gas for water disinfection increased corrosion in the pipes. The corrosion caused increased levels of lead in the drinking water supply. While public health was not compromised, the increased lead levels created a public health scare that cost the city tens of thousands of dollars to address.⁷

Market selection of products is driven by such concerns as price, utility, and quality. Government-forced substitutions, in contrast, are the result of politics that favor the politically organized. Inferior substitutes are often advocated by environmental activists with limited understanding of industrial processes. Other times, substitutes are advanced by the firms that produce them, who have an obvious financial interest in getting government to advocate their products.

Substitution advocates simply ignore the fact that it makes more sense to manage risks rather than seek to eliminate them. Consider chlorine. Its disinfecting qualities are caustic when misused, but those qualities can be managed to produce important benefits. Chlorine's "dangerous" qualities ensure safe and clean water for millions of people around the world, while areas that lack adequate chlorination often suffer from dangerous water supplies.

The Common Position does move in the direction of management by granting the European Chemicals Agency more leeway to manage risks. It changes language from the Parliament bill that would have fully applied the "substitution principle" by demanding that firms not produce "dangerous" chemicals if substitute products are available. The current draft would allow "dangerous substances" if a firm could show that "the risks are adequately controlled," the "social and economic benefits outweigh the risks," or that "suitable alternative substances do not exist."

In the end, how many products are banned or restricted in the name of the substitution principle will depend on European Chemicals Agency. Firms will still need to assess potential substitutes and then convince the Agency why existing products are better. The Agency will also decide what "adequately controlled" means. Moreover, the Common Position does not apply all the new flexibilities to substances deemed persistent, bioaccumulative and toxic (PBT) or very persistent, very bioaccumulative (vPvB). Anyone marketing or using these products could not defend their use because risks are "adequately controlled."

"One Registration" Advantages for Early Registrants. The Common Position replaces the provisions that would have required that each firm register

a substance either separately or through membership in a consortium of businesses. It replaces that approach with one called “one substance-one registration.” In that case, once a firm registers a product other firms will have free access to the first firm’s data for their own registration starting 10 years after the original registration.

If a firm registers before the 10 years are up, it must financially compensate the original registrant for the data. In that case, potential registrants and existing registrants must negotiate compensation in a way that is “fair, transparent, and nondiscriminatory”⁸ a standard that may be interpreted differently by each party.⁹ Unfortunately, firms that register within 10 years of the original registration may find themselves caught up in a battle with the first registrants to access data, or paying a high price for the data.

It appears that REACH drafters expect such conflicts to emerge, and it has set up a process for conflict resolution that promises yet more costs and delays for new registrants. According to the REACH text, if parties fail to come to an agreement on compensation, several things could happen. First, the issue could be brought before an arbitration board, which might cost small and medium enterprises (SMEs) precious time and money.

Second, the potential registrant could inform the European Chemicals Agency, which, within a month, could allow the registration to proceed using the original registrant’s data. However, the original registrant can appeal that action and force the Chemicals Agency to reconsider and place a four month “waiting” period on the new registration. Once the data is finally released, the original registrant would then be entitled to collect compensation of 50 percent of its costs of producing the data from the new registrant as long as it provides copies of the complete research to the new registrant. Thus, original registrants could collect up to 50 percent of their costs from all new registrants who requested the underlying data. That would place them at a competitive advantage, since they could delay new entrants and eventually collect more than 100 percent their original costs.

The Common Position also allows some parties to opt out of data-sharing mandates under the “one substance-one registration” provisions. Firm may withhold their data (with the exception of animal data) or refuse to use existing data of another firm when it disagrees with the other firm’s data selection or when a firm fears that “joint” registration would expose “commercially sensitive information.” Firms are right to be concerned about confidentiality. But these opt-out terms undermine any potential benefits of “one-substance-one registration.”

Unfortunately, there aren’t many good answers to these problems—alternatives will simply mean trading off one interest to meet another. Given the nature of

such centralized, bureaucratic schemes, all approaches are likely to be expensive, time consuming, and riddled with conflicts.

Abandoning Science to Save Rats. The one substance-one registration approach is also supposed to reduce the number of animal tests needed to comply with REACH. REACH’s provision on data sharing states: “Studies involving vertebrate animals shall not be repeated,”¹⁰ indicating that new registrants must use only the animal data from the original registrant rather than conduct additional tests. The issue of animal tests gets to the heart of REACH’s alleged value. REACH is supposed to increase scientific understanding of chemicals and their risks.

There are reasons to reconsider how rodent tests are used for regulatory purposes. Some types of rodent tests are of highly questionable value because they dose rodents with massive amounts of chemicals to make assumptions about the health impacts of trace-level exposures to humans. Such extrapolations from rodents to humans and from high exposures to trace level exposures may not be appropriate.¹¹ If policymakers want better scientific understanding, they need to allow maximum scientific freedom to explore better testing methods and validation of those methods through replication.

REACH does the opposite. Rather than address the flaws with these studies, REACH would mandate that regulatory policy be governed by a single set of faulty rodent tests. Yet to ensure that any scientific study is meaningful, it must be reproduced—*over and over again without limit* until results are so consistent that they lead researchers to a reasonably solid conclusion. Such repetition can take decades of research and often involves considerable testing of rodents. Halting that process—rather than improving it—flies in the face of good science and undermines the stated purpose of REACH.

“Low-Volume Registrations” and High Volume Futility. Another provision to save costs for SMEs reduces data submission requirements for “low volume” chemical users and producers. Supposedly, these users will simply have to gather existing information and submit it to the Chemicals Agency—preempting the need for additional research. Yet additional study will be required for such low-volume substances if they are identified as meeting simple criteria highlighting them as of potential concern. In any case, the costs of even basic submissions are certain to remain considerable even though the submissions reveal nothing new about the regulated substances.

This provision goes to show one thing: REACH promises to amount to little more than a multinational exercise in paperwork. The bulk of REACH activity will require thousands of firms to devote thousands of hours to filing thousands

of pages of paperwork that promises to reveal nothing new and provide no verifiable benefits.

Centralized Red Tape. The Common Position also changes the jurisdiction for the evaluation process, removing it from member states and centralizing it the European Chemicals Agency. This change may lead to a more rational process with more consistent standards, but it places much more power and responsibility with the EU centralized bureaucracy.

In addition, it is highly questionable whether this agency will be able to handle the workload any better than the old system, which REACH is supposed to fix. Under existing directives, government agencies request information from manufacturers about “new chemicals” (about 3,000 chemicals developed after 1981) and conduct risk assessments, while no such requirements apply to the older “existing” chemicals. This process has proven slow and not particularly effective, according to the Commission. It notes that since 1993, agencies had only identified 141 high-volume substances as priorities for risk assessment studies that would hopefully lead to risk reduction policies. Of these, only 27 chemicals have completed the process.¹²

The Commission’s contention that REACH will solve inefficiencies in the current process is highly questionable as it creates a vast new workload for just one agency. REACH covers an estimated 30,000 chemicals developed before 1981, about 3,000 chemicals developed after 1981, any new products that might be developed, and an estimated 40,000 intermediaries. To expect industry to work through this maze of regulations and complete the tests in a reasonable timeframe is simply unrealistic.

The Chemicals Blacklist. The Common Position also includes a provision to set up a process to list chemicals that could potentially undergo authorization in the future.¹³ Listing would result from a political process—rather than a scientific one—whereby the Chemicals Agency would consult with “stakeholders” from industry and non-governmental organizations. Businesses have taken issue with this listing process as it would essentially condemn products without scientific justification. Indeed, listing chemicals will signal to manufacturers that these may become subject to restrictions or bans in the future. Firms will not want to invest in such products, even if they are superior to alternatives. Again, politics will supersede science—leading firms to stop using valuable products, switch to more expensive and potentially inferior products, and engage in needless and expensive product reformulations.

Conclusion. Ultimately, REACH is about further empowering and growing the EU bureaucracy and granting it control over a substantial portion of Europe’s economy. With the promise that it will fill research gaps and improve public health, REACH is much more likely to become a massive paperwork

processing program through which regulators will collect and sort a massive amount of existing information and have arbitrary power regulate and eliminate politically unpopular chemical products based on limited research under the program. Ironically, none of this is necessary to protect health since REACH doesn't address risks that warrant such a massive response.

Notes

¹ For details see: Angela Logomasini, *Europe's Global REACH: Costly for the World, Suicidal for Europe* (Brussels: Hayek Institute, 2005), http://www.fahayek.org/index.php?option=com_content&task=view&id=387&Itemid=40

² Ibid.

³ Joan Canton and Ch. Allen, *A Microeconomic Model to Assess the Economic Impacts of the EU's New Chemicals Policy*, (Brussels: European Commission/DG Enterprise, November 2003), http://europa.eu.int/comm/enterprise/reach/docs/reach/effects_new_chem_policy-2003_11_17.pdf

⁴ For details see: Logomasini, *Europe's Global REACH*.

⁵ European Commission, *REACH in Brief* (Brussels: EU Commission, September 15, 2004), p. 4, http://europa.eu.int/comm/enterprise/reach/docs/reach/reach_in_brief-2004_09_15.pdf

⁶ European Commission, *Questions and Answers on REACH*, updated March 23, 2006, <http://ec.europa.eu/environment/chemicals/pdf/qa.pdf>

⁷ D'Vera Cohn "Lead in D.C. Water Slashed Decline Comes After WASA Resumes Using Chlorine as Disinfectant," *Washington Post*, May 21, 2004, B01.

⁸ REACH Common Position, Title III, Article 27 (3), p. 90.

⁹ REACH Common Position, Title III, Article 27 (3), p. 90.

¹⁰ REACH Common Position, Title III, Article 26 (3), p. 89.

¹¹ For more information on this topic, see: *America's War on "Carcinogens": Reassessing The Use of Animal Tests to Predict Human Cancer Risk*, Elizabeth Whelan, Ed. (New York: American Council on Science and Health, 2005).

¹² Andreas Ahrens et al., *Sport Report, Final Report* (Hamburg: Institute for Environmental Strategies, July 2005); See also: European Commission, European Commission, *Q and A on the New Chemicals Policy* (Brussels: European Commission, October 29, 2003), <http://europa.eu.int/rapid/pressReleasesAction.do?reference=MEMO/03/213&format=HTML&aged=1&language=EN&guiLanguage=en>

¹³ See "Whereas" number 67 in the Common Position, p. 22 and Title VII, Article 58 (1) p. 133, <http://register.consilium.europa.eu/pdf/en/06/st07/st07524.en06.pdf>

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