Lessons from the EU's REACH Program

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In the casual political rhetoric about environmental regulation, it is often claimed that the U.S. government regulates on the basis of risk while the European Union (or EU member states) regulates on the basis of hazard. The implication is that the U.S. government relies on a more rigorous, scientific process of assessment than does the EU, which allegedly helps explain why the EU is more pro-regulation than is the United States.

An alternative view, advanced originally by the late Professor Aaron Wildavsky of the University of California-Berkeley and amplified in a recent book by Professor Jonathan Wiener of Duke University, and colleagues, is that societies engage in a process of "risk selection."[1] What worries some societies does not worry others. As Professor Wiener and colleagues have illustrated through empirical analysis of a wide range of hazards affecting both sides of the Atlantic, the United States is more pro-regulatory than Europe in some arenas (e.g., tobacco and diesel engine exhaust) while Europe is more pro-regulatory in other arenas (e.g., genetically modified foods, chemicals, and global climate change).

Is it true that Europeans are more averse to hazardous industrial chemicals than Americans? Professor Lofstedt seems to think so, and there is considerable evidence to support his view. In addition to the two in-depth case studies (Bisphenol A and Deca BDE) in Professor Lofstedt's article,[2] one can point to the fact that the United States has not changed its basic approach to chemical regulation – the Toxic Substances Control Act – since 1976, while the European Union enacted an ambitious regulatory program for industrial chemicals in 2006 called REACH: Registration, Evaluation, Authorization and Restriction of Chemicals.

At IU-SPEA, we are currently engaged in an assessment of the first five years of REACH implementation, recognizing that REACH will not be fully implemented until 2020 (or later) and that it is far too early to attempt a formal benefit-cost evaluation of the REACH initiative. Our purpose is to determine whether there are any valuable lessons that can be gleaned from the early experience with REACH implementation, as the United States begins to consider modernization of its chemicals regulatory program.

In the course of examining the REACH program, we have considered the design of the legislation as well as some of the initial guidance documents that have been issued to guide the implementation process.[3] Based on this initial inquiry, we have already come to a preliminary conclusion that is quite relevant to Professor Lofstedt's thesis: the REACH program was influenced by a combination of hazard-based and risk-based thinking.

From the hazard perspective, one can point to the fact that REACH requires all chemical manufacturers (in collaboration with processors, distributors, and users) to report standardized information on industrial chemicals to the new European Chemicals Agency (ECHA – Helsinki, Finland). The official registration dossier must include adequate information on the intrinsic properties of each chemical sold in the EU.[4] Those intrinsic properties include a comprehensive toxicological profile of the chemical, such as information about the substance's acute and chronic toxicity, flammability, persistence, and the chemical's potential to bio-accumulate in the environment. For industrial chemicals with certain undesirable properties (e.g., carcinogenicity, reproductive toxicity, and tendency to persist and/or bio-accumulate in the environment), REACH contains an accelerated process of authorization review that includes a regulatory

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1 Jonathan B. Wiener, Michael D. Rogers, James K. Hammitt, and Peter H. Sand (eds), *The Reality of Precaution: Comparing Risk Regulation in the United States and Europe (Washington D.C. and London: RFF Press/Earthscan 2011)*.

2 Ragnar E. Lofstedt, "Risk Versus Hazard: How to Regulate in the 21st Century", in this volume, pp. 149 *et sqq*.

3 The European Chemicals Agency has published twenty-four guidance documents to assist regulated parties on compliance with each of the various aspects of REACH. They are available on the Internet at <http://guidance.echa.europa.eu/guidance_en.htm>.

4 See European Chemicals Agency, "Guidance on Registration", Jan. 2011, available on the Internet at <http://guidance.echa.europa.eu/docs/guidance_document/registration_en.pdf?vers=31_01_11>.

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push for safer substitutes.[5] And, the REACH process of setting priorities for authorization has a strong hazard orientation, since the intrinsic properties of chemicals play a key role in determining whether a chemical makes it on to ECHA's "candidate list" for consideration and the final "priority list" for authorization. The restrictions process under REACH also appears to have a hazard-based orientation; but it is not really new, as REACH simply carried forward restriction authority that was previously authorized under other EU legislation.

It would, however, be a mistake to assume that REACH is based only on hazard-based thinking. Indeed, our review of the legislation and the associated guidance documents reveals that risk-based thinking enters at several critical phases of the program. For starters, the dossier for each chemical also includes information on exposure scenarios for each end use of the chemical, including an assessment of whether the extent of exposure, given information on toxicity, is compatible with established standards of safety. In other words, the dossiers include risk assessments. If REACH had been based solely on hazard-based thinking, there would have been no need for the dossiers to include information on end uses, exposure scenarios, and safety determinations. Moreover, even for chemicals with worrisome intrinsic properties, commercial sale is permitted as long as exposures are "adequately controlled", a socio-economic analysis demonstrates that the benefits of use justify any residual risks,[6] and if effort is underway to invent safer substitutes. All of three of those criteria are risk management constructs. Finally, it should be noted that the EU is an amalgam of nationalities, some more risk averse than others. It therefore makes sense that REACH, which incorporates both hazard and risk-based thinking, is a product of a multi-national governance body like the EU.

What seems to be distinctive about REACH is not a preference for hazard-based thinking over risk-based thinking, but a shift in the technical burden of proving safety from the government to the industry. Since much of the expertise about chemical properties, uses, exposures, and substitutes is in the industry, such a shift in the burden of proof is quite understandable.

We recognize that the actual process of REACH implementation is likely to be quite complex, drawing on participation by the chemical industry, NGOs, ECHA, the European Commission, and the member States of the EU. The European Court of Justice may also be called on to resolve inevitable disputes. Over time, it is possible that the hazard-based aspects of REACH will become more (or less) influential than the risk-based aspects than appears to be the case based on the design of the legislation and the related guidance documents. But as matters stand today, we see REACH as a program that is designed to regulate chemicals based on a combination of intrinsic hazard and assessment of risk.

5 See European Chemicals Agency, "Guidance on the Preparation of an Application for Authorization", Jan. 2011, available on the Internet at <http://guidance.echa.europa.eu/docs/guidance_document/authorisation_application_en.pdf>.

6 See European Chemicals Agency, "Guidance on the Preparation of Socio-Economic Analysis as Part of an Application for Authorization", Jan. 2011, available on the Internet at <http://guidance.echa.europa.eu/docs/guidance_document/sea_authorisation_en.pdf>.

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