

Comment on Using Competition-Based Regulation to Bridge the Toxics Data Gap

by Mark Greenwood

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In her Article, Prof. Wendy Wagner takes on one of the core challenges of U.S. chemical management policy: how to assure that useful toxicity data is generated about chemicals in commerce. She offers a creative proposal for harnessing competitive instincts in companies to assure that such data are developed. As described below, there are important questions about whether this proposal will actually work in practice. At the same time, the history of chemical regulation in the United States has taught us that our assumptions about how the market will respond to specific regulatory policies are often wrong. In that context, this proposal and other experimentation with competition-based regulatory initiatives deserve serious attention.

At the outset of the article, Professor Wagner presents a fairly pessimistic assessment of the current state of information about chemical risk in our society. She presents her perspective on the failures of the Toxic Substances Control Act (TSCA) to generate necessary toxicity information about chemicals, arguing that the U.S. Environmental Protection Agency (EPA) is stuck in a “cops and robbers” legal framework that stymies its ability to force testing by regulation. She also indicates that the marketplace and the tort liability system provide additional disincentives for chemical producers to generate and disseminate information about their products. Her conclusion is that “multiple, entrenched incentives for ignorance help explain the substantial lack of toxicity testing for most chemicals in the United States.”¹

Certainly there is some reality to the disincentives she describes. At the same time, it is not the case that these existing mechanisms have been a complete failure. If one focuses on the set of chemicals that are actually in commerce, it is a misnomer to suggest that there are no toxicity data available on these chemicals. Particularly in the last several years, government programs around the world, both regulatory and voluntary, have stimulated more toxicity testing.² In addition,

chemical producers have faced increasing demand for product safety information from their downstream customers. In some cases, these efforts have evolved into collaborations with a broader community of academic and non-governmental institutions.³

One of the problems that have undermined policy debates on U.S. chemical regulation for several decades has been a lack of common understanding about the relevant universe of chemicals. Many commenters, including Professor Wagner, indicate that there are 75,000 chemicals in commerce in the United States. This number, however, is an estimate of the number of chemicals on the TSCA Chemical Substances Inventory, a list of chemicals that may have been in commerce since 1978. EPA has recognized, however, that this list is unlikely to represent the universe of chemicals that are actually in commerce.⁴ Most recently, in the context of its Chemical Assessment and Management Program (ChAMP), EPA has estimated that the universe of organic chemical substances produced in a significant volume (above 25,000 pound per year), is approximately 6,750 substances.⁵ When measured against that universe, the state of available chemical toxicity testing does not appear as bleak.

The better way to frame the problem is that policymakers face a mixed picture of chemical testing. Some chemicals in commerce are well characterized, reflecting mandates and

ufacturers to provide a base set of testing information on chemicals produced at volumes of over one million pounds per year, has made publicly available over 8,000 previously unpublished studies. See U.S. EPA, Basic Information—High Production Volume (HPV) Challenge Program, <http://www.epa.gov/hpv/pubs/general/basicinfo.htm> (last visited June 1, 2009). In conjunction with this voluntary program, EPA has required testing under the authorities of TSCA for HPV chemicals that were not sponsored in the voluntary program. For the most recent rule of this nature, see *Testing of Certain High Production Volume Chemicals; Second Group of Chemicals*, 73 Fed. Reg. 43314 (July 24, 2008) (to be codified at 40 C.F.R. pt. 799).

3. An example of such collaborations is the Green Chemistry and Commerce Council. See <http://www.greenchemistryandcommerce.org/home.php> (last visited June 1, 2009).

4. See U.S. EPA, Chemical Assessment and Management Program (ChAMP): TSCA Inventory Reset, <http://www.epa.gov/champ/pubs/hpv/tsc.html> (last visited June 1, 2009).

5. U.S. EPA, Chemical Assessment and Management Program (ChAMP): Basic Information, <http://www.epa.gov/champ/pubs/basic.html> (last visited June 1, 2009).

1. Wendy Wagner, *Using Competition-Based Regulation to Bridge the Toxics Data Gap*, 39 ELR (ENVTL. L. & POL'Y ANN. REV.) 10789 (Aug. 2009) (a longer version of this Article was originally published at 83 IND. L.J. 629 (2008)).

2. As an example, EPA has reported that its High Production Volume (HPV) Challenge program, which seeks voluntary commitments from chemical man-

incentives that emanate from regulatory agencies and various marketplace actors. For other chemicals, however, those systems are not working effectively, and we have information gaps that should be filled. In many ways, this situation presents the most difficult of challenges for policymakers. What is the best set of policy actions to address important data needs that will not also discourage current incentives that seem to be working? Since nobody seems to have developed a comprehensive field theory that adequately guides those choices, pragmatic experimentation is the order of the day.

Professor Wagner puts forward a proposal under which a regulatory agency (presumably EPA) makes determinations about the environmental superiority of particular chemicals through an adjudicatory process. In this proceeding, competitors for an economic niche (a chemical use) would present the best case for their products and challenge the claims of competitors. After reviewing the evidence underlying the competitive claims, EPA would make a determination about whether a particular chemical substance is superior for its intended use, after considering its environmental benefits as well as its technical and economic performance. While it was not entirely clear what further actions would necessarily follow from this determination, the range of options could include product labeling changes and possibly bans on the “losing” substance.

This proposal presents significant challenges for the agency administering the program, many of which Professor Wagner has accurately characterized. The most difficult problems to overcome include the following:

- After decades of work on federal environmental policy, we do not have established methodologies for making tradeoffs among differing environmental values. What are the metrics for determining how many British thermal units (BTUs) of increased energy demand are worth reducing a pound of pollutant emissions? When should we prefer a chemical that is less toxic to humans but presents a serious threat to wildlife?
- Replacing chemicals in complex technological settings is a difficult task. In most modern industrial settings, it is rare that we find drop-in substitutes for existing chemicals. The series of assessments necessary for switching to new chemical ingredients and process aids, often referred to as the qualification process, typically involves multiple analyses of end-product performance characteristics, compatibilities among reactants and necessary equipment modifications that can take several years and substantial cost to complete. It is not always easy to determine that a safer chemical can easily be substituted for another chemical.
- Adjudications take time. Adversarial processes typically include multiple procedural steps, rules for presenting evidence and opportunities to be heard. To do

justice to the extensive record developed in such proceedings, the finders of fact must review large bodies of information and formulate well-reasoned conclusions. It is worth noting that the modern day emphasis on informal rulemaking under the Administrative Procedure Act as the primary mechanism for establishing regulations was, in many ways, motivated by the desire to move away from slow-moving adjudicatory processes for the formulation of policy.

The adjudicatory process suggested by Professor Wagner would also present many challenges to those who might participate in such proceedings, including the following:

- As a threshold matter, it is not clear that companies will initiate these proceedings to challenge their competitors. This is less a question of industry loyalties than a matter of uncertain results in an intimidating process. Companies will reasonably assume that they will face high transaction costs in challenging a competitor in an EPA proceeding. Of the three potential outcomes—win, lose or draw—two represent a waste of money and one of those is a disaster. If a company has strong data showing the comparative advantage of its product for the environment, most companies would prefer to turn that information over to their sales staff and tell them to do their job, rather than take on the high cost and uncertainty of an EPA proceeding.
- Some of the better arguments about the comparative advantage of particular chemical products may be based on information about material sourcing and cost profiles that constitute trade secrets, information that companies would be disinclined to offer as evidence in a proceeding that shares such information with competitors.
- The challenges of an adjudicatory process will be most difficult for medium and small businesses, many of which operate on the cutting edge of new technology. There is some risk that a competition-based adjudicatory process would favor larger companies with older, entrenched products who could afford to muster the resources necessary to wage effective challenges in such a process and thereby intimidate newer technologies under development by small companies.

Despite these limitations, Professor Wagner’s proposal warrants further consideration and refinement as part of a package of policy reforms that could encourage development of better risk-related information. There will be situations where a combination of factors, including the available environmental data, the market position of differing companies, customer sensitivity to health or environmental considerations, and differences in corporate culture, could produce effective results through adjudications about the environ-

mental superiority of competing chemicals. It is worth experimenting with this model and learning from the experience.

In the end, it is only through the willingness to experiment that the United States will develop a stronger national chemical management program. At times the most direct way to improve the availability of risk-related information is to mandate further testing through regulation. The European Union's Registration, Evaluation and Authorization of Chemicals (REACH) program is certainly the current grand experiment on the world stage with this approach. We do not yet know, however, whether this highly ambitious program will be efficient in generating the right data in a timely way.

Other strategies worth considering, which share Professor Wagner's valid emphasis on the power of market forces, are ones that emphasize the obligations of chemical manufacturers to disclose all that is known and not known about the toxicity of the materials they are offering to their customers. For example, it could make sense to enhance current hazard communication programs, including the Material Safety Data Sheets that routinely accompany chemicals in commerce.

Perhaps an even more fundamental set of policy changes could focus on reforming the basic scientific tests we use to assess human health effects, potentially reducing the cost of such testing. The world of chemical hazard assessment is undergoing substantial change as scientists develop new methods for screening chemicals, often through high-throughput mechanisms, that will allow us to obtain valuable insights on the potential toxicity of chemicals more cheaply, much faster and with a greater sensitivity to the animal welfare concerns associated with wide-scale use of existing test methodologies.

In this field of environmental policy, where the political and economic dynamics guiding behavior are difficult to characterize, it seems that a pragmatic willingness to try multiple approaches is the only sensible strategy.