

Written for *Forum Umwelt und Entwicklung*

<http://www.forumue.de/en/publikationen/rundbriefe/admin-rundbrief/rundbrief-iii-2014-reg-ul-ieren-aber-wie-sinn-und-unsinn-der-de-regulierung/>



Ronald White
Director of Regulatory Policy
Center for Effective Government

Industry Control vs. Safety:

The Ineffective United States Chemical Regulation Regime

More than 84,000 chemicals are currently registered for use in the United States, but due to the current, ineffective U.S. chemical regulation regime, the vast majority has not been evaluated for their potential risks to human health and the environment. The high hurdles that the U.S. regulatory process imposes on government for managing chemical risks and the numerous opportunities for industry influence have resulted in minimal controls on public exposure to toxic industrial chemicals. Proposals for regulatory coherence through the Trans-Atlantic Trade and Investment Partnership (TTIP) pose a significant risk of undermining European and U.S. state chemical risk management efforts because of the potential application of components of the ineffective U.S. chemical regulation process.

There is a growing scientific consensus and concern that chemicals have a significant role in the incidence and prevalence of many illnesses, including cancer, reproductive and developmental disorders, neurologic diseases, and asthma. However, weaknesses in the Toxic Substances Control Act (TSCA), the U.S. law governing chemical regulation, have left the U.S. Environmental Protection Agency (EPA) largely unable to act on known health dangers or to require testing on specific chemicals that may be unsafe.

TSCA exempted from any safety review the 62,000 chemicals in commerce at the time the law was passed in 1976. For the last several decades, U.S. chemical regulatory policy has effectively presumed that tens of thousands of industrial chemicals present no substantial risk of harm to health and the environment. In the absence of clear evidence of harm, companies have largely been free to produce and use such chemicals.

These policies contrast sharply with the European Union (EU) approach to industrial chemical regulation under the 2007 Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) policy, as well as the U.S. policy regarding other classes of chemicals such as pharmaceuticals and pesticides, where producers are required to provide the government with information demonstrating their safety, at least when used as intended, before introducing these chemicals into the marketplace. However, for industrial chemicals, the EPA must already have information sufficient to document potential risk, or at the very least, extensive exposure, in order to require even the development of information sufficient to determine whether there is actual risk.

Under the current U.S. approach to regulating industrial chemicals, government bears the burden of proof to demonstrate that chemicals pose an unreasonable public health or environmental risk. Even where the EPA *does* find that a chemical present an “unreasonable risk” of harm and attempts to restrict its use, the agency must consider the benefits of the substance for various uses, the availability of substitute substances for those uses, and the economic consequences of the restriction. These policies place an almost unsurmountable hurdle on the ability of the U.S. EPA to regulate a chemical. As a result of these restrictions, the U.S. government, the public and often the companies that produce and use these chemicals know very little about the potential risks of most of them.

Chemical Industry’s Extensive Influence on U.S. Chemical Regulation

Regulation of industrial chemicals in the U.S. must go through a myriad of procedural hurdles, which include detailed assessments of: 1) toxicity, exposure, health and environmental risks; 2) costs and benefits of the regulation; and 3) potential impacts on small businesses. Development of these analyses to support regulatory proposals typically takes several years, sometimes a decade or more.

The U.S. process for development of the scientific and technical analyses that underlay chemical regulations provides numerous opportunities for industry influence. The EPA undertakes an extensive review of the scientific and technical literature to assess chemical risks to human health and has developed risk-based acceptable exposure levels for the more than 550 chemicals included in this program, known as the Integrated Risk Information System (IRIS). Additionally, the U.S. National Toxicology Program develops reports that have evaluated the scientific information for 240 substances (the majority of which are chemicals) that are listed as proven, or likely to be considered, carcinogenic.

Industry and their technical consultants dominate the agency meetings held to review the results of these assessments. They regularly challenge the selection and interpretation of the studies and risk assessment models used for these review processes, request delays in the processes in order to submit new industry-funded studies, or obtain requirements for additional reviews through legislative mandates from industry-friendly members of Congress.

Proposed rules and their various underlying scientific, technical and economic assessments must then undergo review and approval by the U.S. Office of Management and Budget (OMB) before they can be issued, which can result in further delays in release of a proposed regulation, ranging from several months to years. Industry actively influences this centralized review process, which often results in required changes to regulations that result in less protection than what was originally considered by the proposing agency.

Once a regulation has completed the OMB review process, it is then subject to a formal public notice and comment period, typically lasting another three months or longer. Industry again exerts massive influence throughout this process.

The Failed Asbestos Ban

As a result of the U.S. law’s high hurdles to action, EPA has restricted the use of only five substances in the almost four decades since passage of TSCA, and one of those actions

(restricting the use of asbestos) was overturned by courts due to a lack of “substantial evidence” that a less restrictive requirement wasn’t sufficient to address the problem.

Asbestos is a known human carcinogen that can cause lung cancer and other diseases. Asbestos has been used widely in products such as fireproofing; thermal insulation; and friction products, including brake linings. In contrast to the United States, the EU and a number of other countries have banned all, or almost all, asbestos and asbestos-containing products.

The EPA spent 10 years investigating the need for the asbestos ban and developing the regulation. On the basis of its review of over 100 studies of the health risks of asbestos, as well as public comments on the proposed rule, EPA determined that asbestos is a carcinogen with no known safe exposure level. The EPA’s 1989 rule prohibited the future manufacture, importation, processing, and distribution of asbestos in almost all products. In response, some manufacturers of asbestos products filed a lawsuit against EPA arguing, in part, that the rule was not issued on the basis of substantial evidence regarding unreasonable risk.

A 1991 U.S. Court of Appeals decision agreed with the manufacturers, concluding that EPA had failed to provide the “substantial evidence” required under the law to justify its asbestos ban. Specifically, the court concluded that EPA did not consider all necessary evidence and failed to show that the control action it chose was the least burdensome regulation that would adequately protect human health or the environment. EPA had not calculated the risk levels for intermediate levels of regulation because it appropriately believed there was no asbestos exposure level for which the risk of illness or death was zero. The court, however, indicated that to conform with the law’s requirements, the EPA would have to consider all possible regulatory options available under the law, beginning with the least burdensome, and assess the costs and benefits of each option.

In response to the court decision, the EPA has not since attempted to ban the use of asbestos in products, and the importation of a wide variety of products containing asbestos still continues in the United States today. Since 1989, due to the legal precedent from the asbestos case, EPA has completed only one other regulation to ban or limit the production or use of an existing chemical: hexavalent chromium in 1990.

Conclusion

Efforts to “harmonize” components of the U.S. chemical risk management regime with the more protective and effective EU approach provides the chemical industry the opportunity to exert the extensive influence seen in U.S. regulatory process to the European approach. Rather than improving the process for managing chemical risks, proposals such as a joint EU-U.S. scientific council to develop consensus on risk assessment methods and imposing requirements for cost-benefit analyses of regulations that include assessments of trade impacts stand to undermine European and U.S. state chemical management efforts.