2013

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Citation/Publisher Attribution
Lohmann, Rainer, Heather M. Stapleton and Ronald A. Hites. "Science Should Guide TSCA Reform." *Environmental Science and Technology* 47.16 (2013).
Available at: http://dx.doi.org/10.1021/es403027y

(VIEWPOINT): SCIENCE SHOULD GUIDE TSCA REFORM

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The Toxic Substances Control Act (TSCA) of 1976 tasks the U.S. Environmental Protection Agency (EPA) with managing chemical safety in the United States. TSCA works by a system of pre-manufacture notifications (PMNs), which are submitted to the EPA by industry when a company wants to market a new chemical or an old one for a new use. The notification to the EPA includes information on the chemical's composition and intended use. However, one of the major shortcomings of TSCA is the lack of health testing of new chemicals. If a company has any toxicity data, they are required to submit the data with the PMN, but there are no requirements to collect health data prior to PMN submission. After reviewing the PMN, the EPA then responds with permission to produce or market the chemical, a request for additional data, or with a denial. Certain substances are generally excluded from TSCA, such as foods, drugs, cosmetics, and pesticides.[1]

TSCA has not been as effective as originally hoped; in fact, some refer to it as the Toxic Substances *Conversation* Act in tribute to its slow pace. Reform is needed. Much has changed

since 1976. PCBs, DDT, mirex, and endosulfan are no longer on the market; the Stockholm Convention on persistent organic pollutants (POPs) has come into force; and the European Union has passed sweeping legislation focused on chemical safety called Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).[2]

TSCA reform is underway. Stakeholders in this effort include governmental, industrial, non-governmental organizations, and academic scientists. While many scientists typically avoid the political process, we maintain that the scientific community has valuable expertise and must be at the table as TSCA is rewritten. With scientific input, the U.S. can learn from past mistakes and benefit from decades of research on chemical fate and effects.

What are the key elements to a reformed TSCA?

1. "Innocent until proven guilty" should not apply to chemicals. TSCA is based on the assumption that a chemical is safe until proven harmful. This is a fatal flaw. Numerous studies have suggested that there are hundreds to thousands of chemicals that have the properties of POPs.[3] New legislation needs to turn the proof of chemical safety over to manufacturers. No agency is capable of adequately assessing all chemicals for their safety. It is the manufacturer's responsibility to demonstrate safety of their product, and the EPA's role to critically review these assessments. This is how REACH is designed.[2]

2. "Grandfathering in" of chemicals spells trouble for the future. When TSCA was implemented in 1976, substances that were or had been produced at that time were exempt from the legislation. Obviously, it was in the chemical industry's best interests to have as many of their products or potential products on this list as possible, and as a result, at least 50,000 substances were exempted from regulation. These exemptions formed the initial TSCA Inventory,

and these exemptions must be re-assessed. REACH provides a mechanism for exemptions, but requires industry to justify the need for an exemption..[2]

3. Single-compound replacements are no alternative for structural reform. When polybrominated biphenyls (PBBs) contaminated Michigan in 1977, they were withdrawn from the flame retardant market and replaced by polybrominated diphenyl ethers (PBDEs). When the environmental ubiquity of PBDEs became apparent in 2000, they were withdrawn from the market and replaced by polybrominated benzoate and phthalate esters.[4] This stepwise approach is not sustainable in the long term, and indeed, the flame retardant industry is shifting to products that save lives but do not leak into the environment.

4. There are many biological and ecological endpoints to consider. Toxicology is a difficult science. What toxic effects should one consider? How does one evaluate long-term chronic exposures? How can particularly sensitive populations (e.g. young and elderly) be protected? Can biochemical, proteomic, or genomic experiments (vs. whole animal experiments) be used for regulatory purposes? Any changes to TSCA should recognize these challenges and be less proscriptive and more holistic.

5. Mixtures of chemicals may have greater environmental impacts than the chemicals alone. Traditional legislation has focused on a single chemical at a time. Yet environment exposures occur in complex mixtures. Key studies have shown that a cocktail of many individual compounds below their respective no observed effect levels can still result in significant adverse effects.[5] While TSCA is currently designed to evaluate chemicals independently, many chemical manufacturers sell their products as mixtures; therefore, evaluations should be conducted not only on individual chemicals, but also on the marketed mixture. It is also important to assess the toxicity of impurities in mixtures.

6. Restrictions on access to proprietary information submitted to the EPA by industry should not be permanent. TSCA does not limit the period in which a chemical can be considered proprietary or trade secret. In the pharmaceutical arena, new drugs are patented for up to 20 years, providing drug company time to recoup its research investment and make a profit. When the patent expires, other companies can produce generic versions of the drug. This arrangement is a suitable compromise between industry's right to a protected market and the public's right to less-costly drugs. Within TSCA, the chemical industry should have a limited time during within which the information submitted to the EPA will be considered proprietary. After this time, information should be publicly available. Site-specific production volumes should also be publicly available after a reasonable embargo. In addition, because research on many chemicals is hindered by a lack of authentic standards, samples of any chemical substance produced or imported into the United States should be archived in a national repository funded by the chemical industry.

7. Scientists are willing to help. Many of us have dedicated their professional lives to better understanding chemicals' environmental concentrations, properties, transport, fates, and effects. Can we afford to just stand-by? If TSCA is not reformed, the unrestricted production, use, and release of unsafe chemicals could continue, and with it the on-going exposure of the American public to a complex mixture of these chemicals. We have an obligation to make our voices heard and to promote proven scientific principles as a basis for TSCA reform. We can do this through our scientific organizations and via our representatives in Congress.

Acknowledgements

We acknowledge valuable comments from Dr Todd Royer (Indiana University).

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