THE BLOG

The Flaws in the Emerging Toxics Reform Legislation and How They Can Be Fixed

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Congress is about to take action on reforming the Toxic Substances Control Act (TSCA), addressing the slow progress since its passage in 1976 in advancing protection from exposure to toxic substances, as well as a significant set-back rendered by a Fifth Circuit Court of Appeals decision in 1991.

TSCA was heralded as a much-needed protection for greater worker, consumer, and public health protection. It provided the authority for both regulation and testing of chemicals, but it hasn't lived up to its hope and promise, even compared to its parallel effort — the REACH Directive — which was begun three decades later in the European Union.

TSCA has two fundamental flaws: First, its regulatory approach is built on an outdated two-step process of "risk assessment" followed by "risk management." Second, the risk assessment done relies almost exclusively on either animal testing or human epidemiological evidence. Evidence based on chemical structure alone is not sufficient.

The initial regulatory attention to a particular chemical generally emerges when there is some evidence or concern about potentially harmful exposure or incomplete data about its risk. Hence, the regulatory process has focused primarily on improving risk assessment, an inexact science at best and a costly and time-consuming process to boot. This has resulted in endless debates about risk (the origin and quality of the data, the methodologies used, and balancing conflicting studies), which, in turn, has led to enormous delays and, finally, judgments that often are more political than scientific.

the EPA becomes aware of information that suggests toxicity or adverse health effects associated with a chemical, the agency should first look for clearly safer alternatives — whether existing or capable of being easily developed — in lieu of embarking on the traditional two-step process of risk assessment followed by risk management. This approach could avoid an extensive and time-consuming risk analysis and speed up public health protections.

California and Massachusetts toxics regulations are moving in this direction, which is probably why some supporters of TSCA reform seek to remove the power of the states to regulate chemicals covered by TSCA through federal preemption of state law. Such a preemption provision would not advance health protections and should not survive the legislative process.

If opportunities can be identified or created for changing the chemicals or their associated processes, even the present version of TSCA could allow action to be taken on suspect chemicals, without a full risk assessment. Section 6(c) of TSCA instructs EPA to take risks, costs, and benefits into account when establishing a rule. But most importantly, TSCA also requires EPA to consider the availability of substitutes.

In reauthorizing TSCA, Congress needs to support a regulatory approach that considers alternatives alongside risks, costs, and benefits. Where clearly safer chemicals and chemical processes exist, a protracted and costly risk assessment exercise would be unnecessary. This would also satisfy the objections raised by the Fifth Circuit in Corrosion Proof Fittings v. EPA, a case which stopped EPA's regulation of asbestos in its tracks — and dealt a near death blow to TSCA regulation — because the agency had not properly considered alternatives.

Risk assessment has always been the bottleneck in TSCA testing and regulation. To date, EPA has used the statute to designate only a handful of chemicals for testing. An amendment to TSCA's section 4 could easily rectify this bottleneck in the U.S. Recognizing the slow progress of TSCA due insufficient human data and limited resources for animal testing, the EU established the REACH Directive. Convinced that there are other bases for assessing hazard or risk, the EU initiative specifically encourages structure activity relationships (i.e., chemical structure and its relationship to toxicity) as an often-preferred option for hazard or risk assessment.

Of course, any of these changes will likely be resisted because the risk assessment bottleneck serves to delay or defeat regulation. But an early and serious examination of alternatives to suspect chemicals would not only accelerate the regulation of potentially harmful chemicals, it would also stimulate innovation in products and processes which would benefit the economy and the industry. We can hope that the legislation that emerges from Congress is strong and provides opportunity for these sensible changes to be made, heralding a period of better health protection, innovation-friendly regulation, and a TSCA more in line with REACH.