The new TSCA: challenges remain

Reformed TSCA does little to advance the protection of the public

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It has taken 40 years to muster the congressional support to enact reforms to the Toxic Substances Control Act. While applauded by many as a significant improvement, there are some serious challenges posed by the new TSCA and there are weaknesses.

On the eve of the reform's passage, I argued that fundamental flaws in the legislation remain, specifically:

» continuation of a two-step sequential approach to regulating chemicals (that is to say, risk assessment followed by risk management); and

» the failure to place the identification, assessment and development of safer technology alternatives early in the process, and therefore avoid the need for extensive risk assessment.

The availability and reliability of risk assessment data have always been, and will continue to be, an impediment to effective and responsive regulation under TSCA. Furthermore, with the anti-regulatory fervour in Washington, DC, the EPA administrator's discretion is not likely to work in favour of public health protection or help innovation. Finally, the federal preemption of state action to regulate, or to decide not to regulate, a chemical, severely limits protection of public health with some notable exceptions in California law[1].

The new TSCA clearly separates risk management from risk assessment, and removes cost and 'non-risk factors' in determining unreasonable risk. Many see these as significant improvements, but a closer look is warranted.

[1] Polsky, Claudia (2016). "California Chemicals Regulation after TSCA Reform" *Environmental Law News* 25(2):22-30

Will new TSCA fare any better under an anti-regulatory administration?

The original TSCA viewed risk assessment as one determinant of unreasonable risk. The new law appears to require – or invite – risk assessment to be firmly based on science and the weight of the evidence. Of course, I support improvements to risk assessment in regulatory activities, but in the context of TSCA, that is not enough. In fact, this is a step backwards because the existence of conflicting studies can be used to defeat what has been the EPA's essentially discretionary determination that a risk is unreasonable.

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To clarify: the conclusions of a scientific risk assessment should not be equated with a determination of acceptable risk or, in the context of TSCA, with unreasonable risk. Nor does this align with the precautionary principle developed under previous US regulatory court decisions. Science informs but it is just one element which determines acceptable or unreasonable risk.

A concern with the new TSCA is that only risks supported with strong, and *essentially unequivocal*, risk assessment results are likely to be considered and addressed as unreasonable. This may be further compounded by an EPA administrator who believes the agency's regulatory powers should be constrained, probably with influence and support from the Office of Information and Regulatory Affairs, within the Office of Management and Budget, (OMB/OIRA). Once again, risk assessment equating unreasonable risk with the conclusions reached in a scientific risk assessment will be an impediment to protective regulation.

The new TSCA also removes some important language from the Act's original regulatory mandate. Take a look at the original text excised from the revised section 6(a). Under this, the administrator must take action if he/she finds that a chemical substance:

presents ~~or will present~~ "unreasonable risks to health or the environment" ~~taking into account costs, effects on health & the~~

~~*environment, technological innovation, and the availability of substitutes.*~~

The removal of "will present" may seem like a small change, but it is a further erosion of precaution. And the deletion of language related to costs and "non-risk"" elements (technological innovation and the availability of substitutes) means that these factors no longer enter into the EPA's determination of unreasonable risk. They are, however, reintroduced in the risk management step.

Now, you may ask, what is wrong with that? The removal of these considerations from the determination of unreasonable risk, leaving it to be more purely scientific, can be defended. But the relegation and reinsertion of these considerations into the risk management component [that is to say the regulatory decision] codifies the paralysing effect of the Fifth Circuit Court decision. Decided under the previous version of the statute; this requires comprehensive cost-benefit analysis of safer substitutes before a chemical can be regulated.

Availability of substitutes

The removal of the original TSCA requirement that the EPA take into consideration "the *availability* of substitutes" in determining unreasonable risk removes the potential major driver of innovation – that is the *availability* of existing technology options or alternatives. The unappealed Fifth Circuit's decision in 1991's Corrosion Proof Fittings case committed legal error by ignoring the statutory words "availability of substitutes". The decision requires that substitutes also be individually and specifically assessed for their unreasonable risk potential, through an adequate examination of their costs and benefits. As a result of that case, the EPA concluded that even in the case of asbestos, the most notorious recognised industrial human carcinogen, it did not have the resources to examine in detail the risks and benefits of substitutes and alternatives. This judicial ruling effectively stopped future regulation of chemicals under TSCA.

The newly added section C, in the promulgation of rules in section 6, does almost nothing to extinguish that onerous burden:

(C) CONSIDERATION OF ALTERNATIVES. – Based on the information published under subparagraph (A), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, the Administrator shall consider, to the extent practicable, ***whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute*** *when the proposed prohibition or other restriction takes effect (emphasis added).*

While the consideration of alternatives is welcomed, the language implies that a thorough investigation of costs and benefits of the substitutes might well be required, an acknowledged unrealistic burden on the EPA.

By simply shifting economic concerns from determination of what constitutes unreasonable risk to a risk management decision does nothing in practice to address the reality that economics will trump public health and environmental protection. With more stringent requirements to determine whether a risk is unreasonable, fewer chemicals are likely to cross the threshold for implementing mandatory risk management.

The new requirement that new chemicals be attended by adequate safety evidence before marketing, while seeming like an industry concession, essentially codifies what industry is already doing. Since the beginning of TSCA, it has been conducting screening studies voluntarily because it would not want to introduce a new chemical that would later be withdrawn after considerable start-up and manufacturing investments were made. In practice, this improvement is thus no real concession.

Finally, the new TSCA requirements that ten chemicals be placed in the pipeline for expedited risk *evaluations*, with the EPA giving priority to industry's candidates, is actually pernicious. The availability of a risk *assessment* is likely to be required, before the EPA can undertake an actual risk evaluation. This may not be possible unless testing has already been done. All this does is to create a diversionary opportunity in favour of industry. It would take industrial resources away from testing chemicals that are likely to provide evidence that industry would rather not have – and that would otherwise lead to pressure for unwanted regulation on other chemicals. Industry would effectively control the testing and hence the regulatory agenda. It could thus game the system.

Little advance

For all these reasons, the 2016 TSCA does little to advance the protection of the public, consumers and workers. It is possible under an administration more dedicated and willing to exercise its discretion towards the protection of public health, the new Act could make some needed progress. If the administrator were to determine a risk were unreasonable and aggressively seek safer substitutes, perhaps environmentally superior substitutes might emerge, but his/her burden is high. The federal preemption of aggressive state initiatives makes things even worse[1]. Only five chemicals were regulated under the 1976 TSCA. Will the 2016 TSCA fare any better under an anti-regulatory administration, seeking to phase out two regulations for every new one?

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