



## **Guest Column: Why the US EPA can, and should, evaluate the risk-reducing role a new chemical may play if allowed on the market**

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In the 21st century, we take as given a continuous stream of new and better products. From electronics to building materials to transportation solutions, the flow of new and better products and applications seems unending. New chemical substances play a fundamental role in creating those products and making existing products better. If the pipeline of new chemicals were closed off, the flow of new products and applications would slow to a trickle and eventually dry up. Modern life as we know it would not exist without the continued invention, production and use of new chemicals.

In the US, all new chemicals must be reviewed by the US EPA before they can enter commerce. The agency looks at new chemicals to determine whether their manufacturing, processing and use would adversely affect people or the environment. If the EPA identifies risks that it determines to be unreasonable, then it either prohibits use of the chemical, or requires restrictions on the chemical to control for risks. Since the 1970s, tens of thousands of chemicals have come through the EPA for review and have been allowed into US commerce.

The federal statute that governs new chemical reviews is TSCA, originally enacted in 1976, and substantially updated in 2016 through the Frank R Lautenberg Chemical Safety for the 21st Century Act. While under TSCA the EPA must determine whether or not a new chemical

substance presents or may present an unreasonable risk of injury to health or the environment, the statute also requires that this be done "in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation" [15 USC 2601]. What exists under TSCA, therefore, is a confluence of requirements to both ensure environmental protection and support chemical-based innovation.

### **Risk reduction**

Unfortunately, current practice presents a significant barrier to balancing innovation and protection. Because the EPA typically evaluates each new chemical substance solely on its own hazards and potential for exposure to people and the environment, it does not fully account for the risks that may be *reduced* through the introduction of new substances. There are circumstances where, while a new substance may present some risk, its introduction into commerce would lead to an overall reduction in health or environmental risk, as it either:

- substitutes for existing chemicals that are either more toxic or otherwise less green; or
- creates or improves a product, or enhances performance, in ways that reduce environmental or health risk more than any additional risk incurred through the introduction into society of the new substance.

The EPA does provide one way to consider some health and environmental benefits of a new chemical's introduction into commerce, but it is limited and rarely used in risk evaluations. On the form companies submit to make their pre-manufacture notice (PMN) to the EPA, there is a section titled 'Optional Pollution Prevention Information'. The instructions for this section state

that "information about the technology being replaced will assist the EPA in its relative risk determination". However, the EPA does not, as a matter of course, evaluate the relative risk of a new chemical as compared to existing chemicals for which the new one may be a substitute, nor does the EPA typically consider pollution prevention information in its risk management decisions. Therefore, while the EPA provides companies with an opportunity to describe any pollution prevention attributes of their new chemicals, experience does not suggest that such information will be a significant factor in the EPA's pre-manufacture risk determinations. As a result, there exists what is known as 'new chemical bias'.

### **New chemical bias**

With most existing chemicals to remain unevaluated for years to come, and new chemicals being evaluated solely on their own properties – without consideration to whether they are less hazardous or risky than existing chemicals for which they may substitute – the system privileges unevaluated existing chemicals over the EPA-evaluated new chemicals, irrespective of the health or environmental gains that could be achieved through the introduction of new chemicals into commerce.

For example, let's say that an existing chemical has a hazard profile indicating the potential for human toxicity if the chemical is inhaled, but the chemical is not subject to restrictions under TSCA (perhaps because it was 'grandfathered' in when TSCA first passed). Until that chemical is evaluated under the TSCA existing chemical review process, it will continue to remain unregulated by TSCA. A new chemical is submitted for pre-manufacture review, and the submitter indicates that it will have the same uses as the existing chemical. The EPA reviews the

new chemical and determines that it may present unreasonable risk to humans through inhalation, although the toxicity is less severe than that of the existing chemical. To address its risk concerns, the EPA mandates that the new chemical can only be used in situations where any people potentially exposed wear a full facepiece respirator with an assigned protection factor of 50. This respirator requirement typically also triggers respirator training, fit testing and compliance reporting. The regulation will also likely trigger recordkeeping, supply chain communication and export notice requirements. With such onerous requirements for a new chemical as compared to a less-restricted but more toxic existing chemical, it is unlikely – without the new chemical having other overriding advantages, such as a much lower cost or much greater performance – that the new chemical will find a viable market. As a result, a more toxic chemical remains on the market, while the new chemical has little chance for commercial success.

We all would benefit by changing this situation. We need to move toward a place where, if a new chemical moves us in the direction of lower risk, we encourage such movement. This will not be easy, because the above example poses a real dilemma: we want to reduce overall risk, but we do not want to introduce new risks into society. The new chemical bias problem is not an easy one, but we believe it can be solved. Therefore, we offer a path forward that can preserve the necessarily protective nature of the EPA's new chemicals decision making, while reducing the bias against new chemicals. That path forward consists of an approach that we offer for the consideration of the EPA and its stakeholders, and a recommendation for making this approach actionable in new chemicals evaluation.

## **A new approach**

Our approach involves accepting a fuller meaning of the statutory term 'unreasonable risk' as it is used in section 5 of TSCA. To date, the EPA's determination of whether a new chemical presents or may present unreasonable risk has been made by looking at the hazard and exposure potential of each new chemical under evaluation in isolation, rather than within the current product space. We argue that whether or not a risk is unreasonable requires a broader set of considerations. In most risk-related decisions made in life, the notion of what's reasonable is not so limited. For example, a person may consider it an unreasonable risk to cross a busy highway on foot to help a stranded motorist push their car to the shoulder. But the same person may consider it worth the risk to run across the highway and pull someone from a burning car. The example is extreme, but in both cases the hazard and exposure potential of crossing the highway are the same. However, more goes into determining the reasonableness of the risk than just the attributes of the highway and the traffic on it. What makes the risk reasonable or unreasonable, holding the highway constant, are the potential benefits – which also can be framed in terms of risks reduced – of reaching the other side.

The potential health or environmental benefits of commercialising a PMN substance are not 'costs or other non-risk factors' (which the EPA is not permitted to consider in TSCA risk determinations) – they are risk-related considerations that are integral to the full meaning of unreasonable risk. Therefore, determining whether a new chemical presents or may present unreasonable risk should include an analysis of whether the introduction of the new chemical in commerce has the potential to prevent pollution, lower chemical-related hazard (recognising

differences in hazard profiles between substitute chemicals) or reduce exposure (likewise, recognising different exposure pathways or chemical properties between substitute chemicals) associated with the conditions of use described in the PMN.

We acknowledge that, as with all aspects of new chemical evaluation, estimating the potential benefits from chemical substitution, or health and environmental gains inherent in a new chemical's conditions of use (for example, reduced air pollution-related morbidity and mortality because a new chemical supports advancing the development and use of non-polluting vehicles) involves some speculation. Review of a chemical that has not yet been introduced to commerce is necessarily forward looking and involves making predictions.

This is where the likelihood element of section 5's 'not likely to present unreasonable risk' language also comes into play. Is a new chemical likely to reduce health or environmental risks through its use in commerce? Likelihood is a concept based on probability: every time a coin is flipped, it is equally likely (probable) to land heads or tails. It may not be possible to quantify during PMN review the risk-reducing role a chemical may play if allowed into commerce, but the likelihood of that role can nevertheless be evaluated. If, for example, a new chemical is much less persistent in the environment than existing chemicals under the same conditions of use, it seems likely that the new chemical will reduce long-term chemical exposure resulting from those uses. Or, if a new chemical is critical to advancing the performance of batteries for electric vehicles or storing solar energy, at PMN evaluation it could be determined that the chemical is likely to contribute to reductions in those risks that are presently incurred through fossil fuel emissions. The likelihood of achieving net health or environmental risk reduction

through use of the new chemical should be a factor in determining whether the chemical is not likely to present unreasonable risks.

### **Two step risk evaluation**

Therefore, in our view, new chemical risk evaluation should be done in two steps. First, the hazard and exposure of the substance under review should be evaluated. If the determination is 'not likely to present unreasonable risk', the evaluation is done. If, however, the determination is 'may present unreasonable risk', then the next step would be to determine whether the use of the chemical would reduce health or environmental risks either through its substitution for other chemicals, or through other health or environmental risks reduced through its use. An initial step in this second-phase evaluation would be characterising the likelihood of any such risk reductions. If they are not likely, then there is no point in attempting to characterise them. However, if likely risk reductions are identified, then a next step should be to determine whether the introduction of the new chemical is likely to result in net reductions in health or environmental risk.

Our recommendation for making this approach actionable is the development of a new analytical framework for evaluating new chemicals. To date, the section 5 concepts of unreasonable risk and likelihood have not been part of meaningful dialogue between the EPA and the public, and therefore should be a priority in 2021. Not all TSCA implementation activities need, or even should, be initiated by the EPA and, in this instance, we believe that a draft analytical framework should be developed by stakeholders and presented to the EPA for its consideration.

Specifically, we call upon industry to take a leadership role in drafting this framework, and leading dialogue around its development and implementation. That said, for its part the EPA must signal its willingness to consider the framework seriously, despite its heavy load of new and existing chemical reviews. This is especially important now that the Sustainable Chemistry Research and Development Act has passed into law. The law's goals of promoting and enabling sustainable chemistry may be substantially thwarted if the fruit of sustainable chemistry research and development are commercially disadvantaged by new chemicals bias.

The TSCA new chemicals programme has a long and distinguished history of serving to provide frontline protection of people and the environment from harmful chemical exposure, while supporting chemical innovation. We offer our thoughts and recommendations in the spirit of making the programme's future as successful as its past has been in achieving this balance.

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