

The Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act is no doubt generating significant conflict, including claims of undue industry influence, competing bills from prominent members of the same party, consternation among states, and divisions among health and environmental groups. And it may also be the closest we have gotten to TSCA reform—ever. So it's worth taking a step back from the fray and taking a close look at its provisions. Overall, it is a mixed bag. There are clear improvements to some parts of the widely assailed existing law. But there are significant problems with the bill, and some road mines with the potential to explode into litigation down the road. Today I start by considering one of the central parts of the bill: the safety determination.

Under the bill, EPA is charged with determining whether a high-priority substance meets the "safety standard." If it does not meet the safety standard, the agency must issue a rule imposing restrictions necessary to ensure that the chemical meets the safety standard. If restrictions will not do the job, the agency must ban or phase out the substance. The critical term here is "**safety standard**." It is defined as "a standard that ensures, without taking into consideration cost and other nonrisk factors, that no unreasonable risk of harm to health or the environment will result. . . ."

The snag here is that "unreasonable risk" is essentially a term of art. It has a history, having been used in tort law and in a variety of environmental and other statutes, with case law from the Supreme Court down defining it. The common understanding of unreasonable risk is that it calls for a balancing of the harms associated with an activity against the benefits that activity provides to society, including economic and non-health benefits. In fact, the legislative history of TSCA defines it as: "balancing the probability that harm will occur and the magnitude and severity of that harm against the effect of proposed regulatory action on the availability to society of the benefits of the substance or mixture, taking into account the availability of substitutes for the substance or mixture which do not require regulation, and other adverse effects which such proposed action may have on society."

My main concern is not that the bill rejects the use of classic unreasonable risk as a standard. Reasonable people can disagree whether unreasonable risk (as commonly understood) is the appropriate standard to use. One advantage of the standard is that it recognizes the contextual nature of setting acceptable risk levels; that is, most of us willing to accept greater risk where substances serve important purposes. But there are plenty of good reasons for using less malleable standards. The point is that the bill essentially leaves us in between the two with no guidance as to what the new "unreasonable risk" actually means. Unreasonable risk essentially calls for balancing the harm of the substance to society against the cost to society of restricting or prohibiting its use, so how does one do that under a bill that excludes consideration of "cost and other nonrisk factors"?

The Environment Defense Fund, which has been at the center of negotiations that produced the bill, released a [bill analysis](#) explaining major provisions of the bill. But that analysis provides no help on this question. In speaking to the safety standard, the analysis compares the bill to TSCA as it exists. It notes that an unreasonable risk determination under TSCA “requires cost-benefit analysis and balancing” while the bill “explicitly precludes EPA from considering costs and other non-risk factors in making safety determinations.” (By the way, unreasonable risk determinations under TSCA do not require formal cost-benefit analysis. Even the Corrosion Proof Fittings court, which struck down EPA’s asbestos rule in 1991, acknowledged that “Congress did not dictate that the EPA engage in an exhaustive, full-scale cost-benefit analysis.” And the House report on the bill that ultimately became TSCA expressly stated that it did not intend “to involve the Administrator in any cost-benefit justifications.”)

So we are left in limbo. Perhaps this neo-unreasonable risk standard is meant to be a health-based standard in which the agency sets an acceptable risk level, without balancing and without consideration of costs. Or maybe there will still be some balancing, but of unspecified things other than cost and other nonrisk factors. Who knows? And that’s the point. Who wants TSCA reform anchored by an excruciatingly ambiguous safety standard?

Next up...examining the bill’s trade-in of the “least burdensome” alternative requirement for formal cost-benefit analysis.