

Reproduced with permission from Daily Environment Report, 124 DEN 24, 6/29/17. Copyright © 2017 by The Bureau of National Affairs, Inc. (800-372-1033) <http://www.bna.com>

Chemicals

Practitioner Insights: New Chemical Bias Worse Than Ever

Since the early 1990s until Congress finally amended the Toxic Substances Control Act (TSCA) in June 2016, the statute's most frequent criticism was that it gave EPA inadequate authority to ban dangerous substances that were already in commerce and "grandfathered" when TSCA was passed in 1976 (so called "existing chemicals").

The Frank R. Lautenberg Safe Chemicals Act for the 21st Century (LCSA) was supposed to change that and revitalize public confidence in federal chemical control law. It is too early to know whether LCSA will fix these longstanding concerns over existing chemicals, but early indications suggest that EPA's new chemical program—the part of TSCA designed to bring innovative and safer new products to market—is now broken.

Since LCSA's passage, several problems have emerged. The first is a timing issue. During the first eight months after the law's passage, EPA's pace for reviewing new chemical submissions plummeted from an average of roughly 1,000 per year to fewer than 60 during the first eight months, leading to a sizable backlog of new chemical submissions. EPA has made progress in bringing this number down and has committed to eliminating the backlog by the end of July 2017—a positive sign that the agency is bringing in additional staff and resources to manage the constant flow of "pre-manufacture notice" (PMN) applications submitted for new chemicals each year.

The second problem is harder to detect, but may have more far-reaching consequences for federal efforts to phase out risky chemicals. As it has begun to whittle down its backlog of PMN applications, EPA appears to be conditioning market entry on significant use restrictions far more severe than those required previously, forcing a majority of submitters to withdraw their applications or agree to regulatory consent orders imposing onerous testing, use restrictions, and import and export requirements.

Consider this: During the 40 years before LCSA's passage, EPA processed roughly 39,000 PMNs. In roughly 2,100 cases, just under 6 percent of PMN submissions, applicants elected to withdraw their applications in the face of EPA concerns and the prospect of untenable regulatory restrictions. In roughly 1,800 cases, just under 5 percent of all submissions, EPA required applicants to enter into consent orders restricting the product's use or requiring testing as a condition of market entry. In contrast, since passage of LCSA, EPA has imposed consent orders and/or testing requirements in 50 percent of the completed reviews, and forced the withdrawal of another 21 percent, limiting or prohibiting market for an astounding 70 percent of completed reviews—a 600 percent increase over pre-LCSA practice.

This remarkable trend exacerbates a decades-old problem under TSCA called "new chemical bias," wherein review delays, testing requirements, onerous use restrictions, and import/export reporting requirements discourage the use, and sometimes the commercialization, of new safer chemicals, leaving more dangerous but less regulated existing chemicals as the only market options.

New chemical bias is a long-recognized problem under TSCA. Agency documents indicate that EPA officials have grappled with the issue since the early 1980s. Unfortunately, the EPA's interpretation of its new LCSA authority appears to be making the problem worse, not better.

The breakdown of the new chemical review process is particularly disturbing given that prior to LCSA's passage, EPA's new chemical program was widely seen as the one aspect of TSCA that worked. EPA had established systems and tools that allowed it to evaluate the pipeline of new chemicals efficiently and effectively, requiring additional testing and risk management steps where necessary, while bringing to market safer alternatives to existing risky chemicals. Indeed, during the four decades that EPA reviewed and added roughly 20,000 new chemicals to the TSCA Inventory, there is little documentation to suggest that even a fraction of approved new chemicals have required subsequent action to manage unreasonable risks.

EPA staff have asserted that the amended statute's requirement for an affirmative safety finding is driving the review delays and the need for more onerous restrictions on the manufacture and use of new chemicals. But LCSA's additional procedural burdens (EPA always reviewed new chemicals using an "unreasonable risk" safety standard) do not explain the unprecedented number of withdrawals and TSCA consent orders being imposed on new chemicals, or the agency's vocal dismissal of labeling as a means of risk mitigation in lieu of more costly and anti-competitive commercial requirements.

Ultimately, it will be new chemical innovations, not agency regulation, that will push dangerous chemicals and their uses off the market. Under a best-case scenario, EPA will complete risk evaluations on the first 10 of the 90 substances on its priority action plan by late 2019, and complete risk mitigation measures on those substances by late 2021, presuming EPA obtains the funding, staff, and political support necessary to meet LCSA's ambitious risk review quotas and deadlines. Even then, EPA will have difficulty banning or restrict-

ing substances and uses where no viable alternatives are available. This means that 80 of its priority chemicals, and the tens of thousands of other existing chemicals that may pose risks, will remain unregulated. For most high-risk chemicals on the market today, the real solution is to develop safer replacements. Transitioning to alternative chemicals will be difficult or impossible, however, if new chemical submissions cannot get through EPA, or emerge from the review process with commercially impracticable restrictions.

Before LCSA, the common refrain among TSCA critics was that TSCA was so weak that "EPA could not even ban asbestos." If EPA's implementation does not change, the new refrain may be that EPA can't even approve an asbestos substitute. If so, the new law will turn out to have been a bad bargain for everyone—the public, the environment, and industry.

Charles L. Franklin is a Senior Counsel in the Regulatory Practice at Akin Gump Strauss Hauer & Feld, LLP. Leonard W. Velsor is a Senior Attorney for Global Trade & Compliance at Eastman Chemical Company.