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Chemicals

Practitioner Insights: Should Firms Ask for Chemical Risk Reviews?

As a general rule, chemical manufacturers (and their counsel) avoid actions that will encourage or increase regulatory scrutiny of their products or operations. Regulatory scrutiny generally is bad for business, since it exposes companies to risk of reputational injury, fines and injunctive actions, competitive disadvantage, and general market uncertainty.

In 2016, the chemical industry seemingly bucked conventional wisdom by supporting legislation to enhance the Environmental Protection Agency's authority and mandate to review and manage risks from the tens of thousands of chemicals already in U.S. commerce and the hundreds of new chemicals proposed for commercialization each year. The statute also allows companies to volunteer their own chemical products for expedited review and to pay for that privilege. With the applicable regulations now in place, will there be any takers? For at least a small subset of steely manufacturers, the answer is yes.

On June 22, 2016, President Barack Obama signed the landmark Frank R. Lautenberg Chemical Safety Act for the 21st Century (LCSA) into law. The signing capped off a multiyear bipartisan effort by public and private stakeholders—including leading voices in the manufacturing and chemical industry—to amend the Toxic Substances Control Act for the first time since the law's passage in 1976.

Among other changes, the LCSA clarified and strengthened the EPA's authority to review the roughly 62,000 chemicals already in U.S. commerce in 1975 that were added to the TSCA Chemical Substance Inventory without formal review. At the time, it was expected that the EPA would review and address risky chemicals already in use under the statute's existing chemical review authority, but by 1990, the existing chemical review process was all but abandoned due to budgetary, legal, and policy obstacles.

A goal of the LCSA amendments was to reverse this trend and restore public confidence in the regulatory system by clarifying and strengthening the EPA's regulatory authority, setting quotas and deadlines for the agency's prioritization and review of existing chemicals. At the request of the chemical industry itself, the LCSA amendments also included provisions allowing manufacturers to request reviews for specific chemicals and requiring that these manufacturer-requested risk evaluations constitute between 25 percent and 50 per-

cent of new chemical risk evaluations, presuming adequate industry demand.

In June 2017, as required by LCSA, the EPA issued rules for the conduct of chemical risk evaluation for existing chemicals (Risk Evaluation Rule). With the regulatory framework now in place, as well as guidance on preparing manufacturer-submitted risk assessments, a more fundamental question looms: Why would a manufacturer voluntarily subject itself to this risk evaluation process?

EPA's Risk Evaluation Process Before answering this question, a quick overview of the process is in order. The EPA's risk review process is designed to evaluate and characterize the risks to human health and the environment from a chemical substance, based on its conditions of use, i.e., the circumstances under which that substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed, used, and disposed of (known as conditions of use, or COUs). Whether requested by a manufacturer or identified through the EPA's independent prioritization process, the agency appears to be subjecting all substances undergoing risk evaluation to the same rigorous, multistep risk evaluation process.

As a first step in a manufacturer-requested evaluation, the manufacturer must submit a detailed request package identifying the substance at issue and the specific COUs proposed for evaluation (the EPA will still conduct its own scope assessment to identify any additional conditions of use that should be included in the evaluation).

Because risk evaluations are highly technical and data-intensive exercises, manufacturers requesting an evaluation must provide a robust dossier of human health and environmental hazard data, exposure data, and detailed information on the storage, production, and use characteristics for the relevant conditions of use. This data must reflect the Best Available Science, defined generally as "science that is reliable and unbiased."

Presuming the applicant's proposed conditions of use warrant consideration in a risk evaluation and the data the applicant provided is adequate and compliant with agency standards, the EPA will conduct a risk evaluation for the manufacturer-identified COUs and any other conditions of use the agency may deem relevant for the chemical.

The EPA has three years to complete the risk assessment (with a potential six-month extension), including several public comment opportunities during the process. The agency's evaluation will consider data, models, and default assumptions on potential hazards and exposure to characterize the risk from each applicable

condition of use. Upon characterizing the relevant risks, the EPA will compare the risks identified for each COU against the federal safety standard established under the amended TSCA statute: “unreasonable risk of injury to health or the environment . . . based on the weight of the scientific evidence.”

The risk evaluation process culminates with the EPA issuing a determination of “unreasonable risk” or “no unreasonable risk” for each COU considered, either in a single notice or in staged notices as analyses for specific conditions are completed. When the EPA determines that a condition of use poses an “unreasonable risk,” the agency then has two more years to impose specific risk mitigation requirements. For conditions of use deemed to pose “no unreasonable risk,” the EPA’s COU-specific risk mitigation process ends for that use.

Why Request a Risk Evaluation? Manufacturer-requested risk evaluations will not make sense for most companies or chemicals. The evaluations are costly and data-intensive in the best of cases. Moreover, the EPA has yet to issue its required regulation establishing fee requirements for manufacturer-requested evaluations, creating further uncertainty regarding the financial investment required for a request. Cost aside, the first manufacturers to request evaluations will face considerable uncertainty with respect to how the EPA will implement its nascent and untried risk evaluation process, how it will evaluate manufacturer-submitted data, and how it will weigh these and other data in making risk determinations.

With these caveats in mind, the EPA’s manufacturer-request provision does appear to offer strategic opportunities for certain data-rich companies with targeted objectives, including market differentiation, strategic pre-emption, litigation risk management, or defensive review.

1. Market Differentiation

During the past decade, a sizable market for “greener” and “safer” chemicals has developed, fueled by increased consumer interest, advocacy by nongovernmental organizations and social media, and the growth of government and third-party sustainability standards (the EPA Safer Choice, LEED, Green Seal, etc.). Manufacturers and retailers, in turn, are scrutinizing suppliers and products more carefully, and some are even imposing their own standards when making purchasing decisions.

The increased demand for “sustainable” chemistries provides competitive opportunities for companies that can document the safety of their products. A “no unreasonable risk” determination for a chemical or specific condition of use could provide the manufacturer and its customers with tangible evidence of the product’s lower risk profile, positioning it as a preferable alternative to other products that have yet to be tested against federal standards.

This strategy could be particularly promising for chemical ingredients that the EPA has already recognized as low-hazard substances, such as the roughly 850 substances covered under its Safer Choice voluntary labeling program. Because the EPA’s risk evaluation rule allows manufacturers to limit their evaluation requests to specific conditions of use and to focus their data submissions on the requested uses, market differentiation opportunities also could be present for manufacturers that submit only a few specific low-risk condi-

tions of use for evaluation, even where concerns might be present for some other COUs for the chemical.

2. Strategic Pre-Emption

One of the major drivers for industry support of the 2016 TSCA amendments was the desire to rein in state chemical regulations that could subject manufacturers to different standards and requirements in different states. In turn, states lobbied heavily to protect their right to impose state-specific restrictions they deemed necessary to protect the health and safety of their citizenry.

The LCSA reflects a careful balance of these goals, pre-empting state action targeting the same conditions of use covered by a “no unreasonable risk” determination or a final risk management action, while protecting certain state regulatory prerogatives and pre-existing regulatory programs.

For example, states remain free to impose nonduplicative monitoring or reporting requirements; implement state water quality, air quality, waste treatment, and disposal laws (except to the extent they impose restrictions on the manufacture, processing, distribution, or use of the chemical at issue); implement state laws established before Aug. 31, 2003, or enforce chemical actions taken before April 22, 2016.

A prominent example of an exempted program is California’s Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65), which requires businesses to notify Californians about significant amounts of certain listed chemicals in products, businesses, and the workplace, and prevent discharges of listed substances to sources of drinking water. States also can seek a waiver from an applicable pre-emption.

For chemicals with strong and compelling safety data, a “no unreasonable risk” determination would not only provide an imprimatur of safety, but also pre-empt certain types of state actions that could threaten the marketability of the product in interstate commerce. Conversely, companies with chemicals likely to require risk management in the future are apt to find it strategically preferable to negotiate with the EPA on risk management rather than multiple state regulators.

Indeed, the EPA implicitly recognized this in its regulations governing prioritization of manufacturer evaluation requests. The Risk Evaluation Rule states that the “EPA will give preference to requests where there is evidence that restrictions imposed by one or more States have the potential to have a significant impact on interstate commerce or health or the environment.”

3. Litigation Risk Management

Under the express terms of the amended statute, federal risk determinations do not pre-empt private rights of action under state or federal law and do not constitute dispositive evidence in favor of plaintiffs or defendants. Courts retain the discretion, however, to admit or deny evidence from the EPA risk evaluations and TSCA risk management actions, consistent with each court’s rules. Courts might be more amenable to admitting such evidence where it was sought and paid for by the defendant to ensure product safety. As such, a federal determination of unreasonable risk could be a valuable tool in discouraging future product liability litigation or in defending against such claims.

4. Defensive Review

Even before the EPA’s risk evaluation procedures had been finalized, manufacturers submitted risk evaluation requests for at least two substances, both fragrance in-

redients. Each had already been identified as a potential persistent, bioaccumulative, and toxic (PBT) substance in the EPA's 2014 chemical work plan, subjecting it to an expedited statutory review process that would have skipped risk evaluation altogether and gone straight to issuance of proposed and final risk management requirements.

Under the statute's persistent, bioaccumulative, and toxic provision, however, by requesting the risk evaluation the manufacturers halted the expedited process and reverted to the longer, more methodical risk evaluation and management process established for non-PBT chemicals.

By using the risk evaluation request process, the manufacturers likely accomplished multiple strategic objectives, including buying additional time in the EPA's risk management process, providing an additional opportunity to shape the agency's risk evaluation for the substances and potentially reducing the scope and impact of any imposed restrictions. The requests in this case reflect the unique regulatory pressures imposed on PBTs under the statute, however, and it is not clear whether manufacturers will see a similar business case for non-PBT chemicals.

Bottom Line The EPA's manufacturer-requested risk evaluation program is a high-stakes game. Companies can burnish the reputation of low-risk products, reduce the risk of state regulatory action, hedge against future product liability claims, and help shape federal reviews. The price is steep, however.

Developing evaluation request data and documentation will be costly, both in terms of time and money, and application fees will only increase that cost. These financial barriers alone will price many smaller companies out of the market.

A bigger barrier may be the uncertainty regarding the manner in which the EPA will interpret and conduct its risk evaluation process in practice. The Risk Evaluation Process rule gives the EPA considerable discretion in

interpreting critical terms like "reasonably available information," "best available science," "weight of scientific evidence," and "unreasonable risk." While this administration appears receptive to industry perspectives, companies have no guarantee that the EPA's scientific and policy staff will interpret the available data in a manner consistent with the findings of company scientists and consultants.

Companies also will have to contend with the scrutiny of competitors and nongovernmental organizations that will have multiple opportunities to review and comment throughout the risk evaluation process. Product opponents or skeptics may offer conflicting data, analyses, or public criticism to cloud the EPA's evaluation or undermine the company's attempts to highlight the safety of the product in the marketplace.

Given the potentially catastrophic consequences for the marketability of a chemical product and the reputation of the manufacturer from an unexpected adverse risk determination, companies have to be supremely confident in the safety of their product, as well as the business benefits of a review.

Finally, companies must be confident in the agency's ability to implement an industry-friendly process. On this last point, in particular, interested companies should be moving quickly to assess candidate chemicals/COUs for voluntary review. It's unlikely that future administrations will be as receptive to industry arguments as the current one.

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