FEDERAL GOVERNMENT REWRITES THE RULES ON GETTING AND USING CHEMICALS IN THE MARKETPLACE

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Environmental, Land, and Natural Resources Alert

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This client alert is the second in a series that discusses the significant changes instituted by the passage of a new federal Toxic Substances Control Act. The first alert addressed broadly the law's myriad of changes. Future alerts will cover enforcement of the new law, protection of confidential information, preemption of state law, and international impacts of the amendments.

On June 22, 2016, President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act (the "Lautenberg Act"), which significantly reforms the 1976 Toxic Substances Control Act ("TSCA"). For chemical manufacturers, importers, and processors, one of the most important changes in this statute is the process by which new chemicals are reviewed by the United States Environmental Protection Agency (EPA) before they can be brought to market. As with other components of the Lautenberg Act, the amendments present manufacturers with a mixed bag by requiring more stringent review of new and existing chemicals, but also clarifying the priorities of that review and providing mechanisms for manufacturers to expedite the process. As a result, manufacturers will need to develop a strategy to bring new chemicals to market quickly by becoming familiar with EPA's new requirements and by developing information proactively to take advantage of the measures to speed up the process.

NEW CHEMICALS OR SIGNIFICANT NEW USES

Under both the original TSCA and the amended statute, manufacturers must submit notice of new chemicals, or significant new uses of existing chemicals, 90 days before manufacture or processing. Previously, if the EPA failed to reject the application within that 90-day period, then the new chemical or significant new use of an existing chemical could proceed to the marketplace. By contrast, under the new statute, EPA must, within 90 days, review the notice and make ***an affirmative determination***:

> a. that the chemical or new use presents an unreasonable risk of injury to health or the environment, b. that EPA has insufficient information or that the chemical or use may present an unreasonable risk, or c. that the chemical or use is likely not to present an unreasonable risk.

If EPA fails to act within the 90 days, the applicant cannot proceed with manufacturing, processing, or importing, although EPA must refund the processing fee. This change has the potential to result in delays for new chemicals. Industry should be prepared to provide and substantiate quickly any information requested by EPA in order to efficiently move chemicals through the review process and minimize delay. Moreover, EPA may issue additional policies, procedures, and guidance on the submission requirements, and industry should be proactive in ensuring that any requirements are met in the initial submission.

Significantly, the Lautenberg Act prohibits EPA from considering cost in determining whether the chemical presents an unreasonable risk or whether more information is necessary. The statute, however, does not define what an "unreasonable risk" is. If EPA does determine that a chemical presents an unreasonable risk, EPA may nevertheless regulate that chemical for use, but EPA's decision on how to regulate that chemical must include a cost-benefit analysis.

Once EPA decides to regulate the chemical, its options include banning the chemical, creating labeling requirements, or establishing use restrictions. In establishing label or use requirements, EPA is no longer limited to employing only the "least burdensome requirements" but must impose requirements "so that the chemical substance or mixture no longer presents such [unreasonable] risk." Additionally, the Lautenberg Act provides EPA with significant authority to require the development of new information relating to a chemical substance or mixture by rule, order, or consent agreement. EPA can request this information both in the context of evaluating whether the chemical poses an unreasonable risk and in the context of imposing restrictions or labeling requirements on a chemical. By authorizing EPA to act by order or consent agreement, the amendments may reduce delays in requesting or obtaining new information.

With respect to premanufacture notices already in the review pipeline, EPA has taken the position that the Lautenberg Act resets the 90-day clock on its deadline to complete its review. Nevertheless, EPA has also stated that it intends to make efforts to review and issue determinations on those notices by the original deadlines. EPA's determination appears to reflect a view on its part that the Lautenberg Act's amendments apply to notifications submitted prior to June 22 that have not yet reached the 90-day deadline for EPA to act.

EXISTING CHEMICALS

The Lautenberg Act also requires EPA to prioritize its review of existing chemicals based on certain identified risks. In 2012, EPA developed a listing of certain existing chemicals and assigned those chemicals a hazard score, an exposure score, and a persistence and bioaccumulation score. That listing served as a work plan to help EPA direct and focus its Existing Chemicals program under the original TSCA. The work plan was revised in 2014 based on additional data submitted to the EPA and termed the TSCA Work Plan for Chemical Assessments: 2014 Update (the "Work Plan"). The Work Plan is available on the EPA website.

In reviewing existing chemicals under the Lautenberg Act, EPA must prioritize its review of chemicals listed in the Work Plan having persistence and bioaccumulation scores of 3 (the highest score) and those in the Work Plan that are known human carcinogens and have high acute and chronic toxicity. EPA has stated that it will publish a list and formally initiate risk evaluations of ten Work Plan chemicals by mid-December 2016, at which point it will also publish (1) a proposed rule establishing EPA's process and criteria for identifying high and low priority chemicals, and (2) a proposed rule establishing the process for evaluating the risk of high priority chemicals.

Manufacturers may also request that a specific chemical be evaluated, but will be required to pay an enhanced fee for the privilege. In deciding whether to grant such requests, the EPA will consider whether state restrictions on that chemical have the potential to have a significant impact on interstate commerce, health, or the environment. For evaluations of chemicals on the Work Plan performed pursuant to requests from manufacturers, EPA will set the evaluation fee at 50 percent of the costs of conducting the risk evaluation. For all other risk evaluations performed pursuant to request, the fee set shall defray the whole cost of the evaluation. By contrast, the fee is set at the lower of 25 percent or $25,000,000 for other evaluations. Chemical manufacturers and other parties will also have an opportunity to submit draft risk evaluations of their own to the EPA. EPA is to develop guidance to assist interested persons in developing and submitting such draft risk evaluations within the next year.

Risk evaluations, whether initiated by EPA or based on a request, must be completed no later than three years after the initiation of the risk evaluation. If EPA finds that a chemical presents an unreasonable risk, it must propose a rule for the chemical no more than one year after the final risk evaluation and a final rule no more than two years after the final risk evaluation for that chemical is published. EPA will provide deadlines for compliance in each rule promulgated.

Finally, in order to create an inventory of active and inactive chemicals, EPA will require industries to report chemicals manufactured or processed in the previous ten years. EPA expects to publish a proposed rule for this industry reporting in mid-December. The current nonconfidential TSCA inventory has over 67,500 listings. The designation of chemicals as active or inactive will allow EPA to more efficiently prioritize its review of existing chemicals.

ARTICLES

The Lautenberg Act imposes new limits on EPA's ability to require significant new use notifications for articles (manufactured goods) or category of articles that contain a chemical. Under the new law, EPA may require notification of the importation or processing of a chemical substance as part of an article only if EPA has made an affirmative finding in a significant new use rule that the reasonable potential for exposure to a chemical through an article justifies notification. EPA can regulate such articles "only to the extent necessary to address the identified risks from exposure" to the chemical, so that the chemical does not present an unreasonable risk identified in EPA's risk evaluation.

Although EPA has had the authority to regulate manufactured goods containing chemicals, the agency has generally not regulated articles, until recently. For example, EPA's proposal to regulate polybrominated diphenylethers ("PBDEs") includes provisions addressing goods containing PBDEs. That significant new use rule, however, was proposed prior to enactment of Lautenberg Act and has not yet been finalized so EPA may need to repropose the rule in accordance with the new limitations on regulating articles in the act.

Additionally, EPA may exempt articles (and chemicals) from requirements for specific conditions of use that are deemed critical and for which no technical and economically feasible alternative available; where compliance would significantly disrupt the national economy, national security, or critical infrastructure; or when the specific use exempted provides a substantial benefit to health, the environment, or public safety. Replacement parts for

complex durable goods and complex consumer goods designed prior to the date of publication of a rule are also exempt from the rule, unless EPA finds that such replacement parts contribute significantly to the risk.

These amendments are likely to result in more certainty and less delay in connection with the use of chemicals in manufactured goods and should provide industry with increased transparency with respect to the TSCA's application to articles.

CONCLUSION

The most important takeaway is that entities that are knowledgeable regarding these changes and that stay abreast of EPA's implementing regulations will be comparatively advantaged in speeding new chemicals and uses to market. Moreover, EPA will exercise significant discretion in implementing the Lautenberg Act and there will be opportunities to influence EPA in its interpretation of the amendments. For example, Congressional Record statements from Democrats and Republicans reflect divergent views on preemption, confidentiality, and "conditions of use." Interested entities and individuals will be able to submit comments to EPA at several points over the next few years as EPA develops rules and guidance and may be able to use these different interpretations to bolster their arguments. Engagement with legal and policy professionals with agency experience will be critical to identify the appropriate time and circumstances in which an industry participant should make its views known to the regulator.

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