The Biden Administration Is Sharpening The TSCA's Sword

By **Susan Richardson, Jeffrey Davidson and Alexander Bullock** (May 6, 2021)

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The Toxic Substances Control Act, enacted in 1976, authorizes the U.S. Environmental Protection Agency to regulate the manufacture or importation of new and existing chemicals. The TSCA's regulations include reporting, record-keeping and testing requirements.

The TSCA's scope is very broad — reaching any entity that manufactures, imports, processes, distributes in commerce, uses or disposes of a chemical substance, regardless of the industry sector. In June 2016, Congress passed the Lautenberg Act, which sharpened the TSCA's tools for assessment and regulation of both existing and new chemical substances in the marketplace.

Consequently, the Trump administration was the first administration with the opportunity to most fully implement the 2016 amendments. In the view of its critics, Trump's EPA often exercised its discretion to the benefit of chemical companies, including a narrower scope for risk evaluation and procedures to accelerate the process of review and approval.

The Biden administration, in turn, has been urged by its supporters to exercise its discretion to broaden the scope of risk review and evaluation. Such a change in course could have significant impacts on the industry going forward.

High-Priority Chemical Risk Evaluations

The 2016 TSCA amendments require risk evaluations for existing chemicals identified as high-priority. The evaluation of the first 10 high-priority chemicals was completed in January of this year.[1] Each risk evaluation for these 10 chemicals identified some uses of the chemicals that present an unreasonable risk, triggering a one-year deadline for proposal of a rule to mitigate the unreasonable risk, and an additional year thereafter to finalize the rules.

The Biden administration has determined that, despite completion of these risk assessments, further evaluation of these chemicals is warranted. On Feb. 5, the EPA announced that it is reviewing certain TSCA actions, including chemical risk evaluations, issued under the previous administration, to ensure protections of human health and the environment.

The EPA stated that it "is actively reviewing the final risk evaluations in light of statutory obligations and policy objectives related to use of the best available science and protection of human health and the environment, in accordance with the Executive Orders and other direction provided by the Biden-Harris Administration."

The EPA's reevaluation of these 10 chemicals, along with its evaluation of another 20 chemicals that the agency proposed for review on Sept. 20, 2020, are anticipated to use an approach that is drastically different from that of the previous administration, increasing the possibility of finding that new and different uses present unreasonable risks.

Among other things, the TSCA's framework rule, which establishes the process for evaluation of existing chemicals, gives the EPA administrator discretion to exclude certain conditions for evaluation. The Trump administration arguably used this discretion to develop a narrow approach to chemical uses and exposure pathways.

Now the Biden administration may use this discretion in the other direction, to broaden the scope of evaluation. This approach could include expanding the range of potential exposures considered in the risk evaluation. For example, an increased emphasis on the impact upon vulnerable populations and potential routes of exposure, including through the ambient environment, is anticipated.

The EPA is also expected to reevaluate workplace exposures that are regulated by the U.S. Occupational Safety and Health Administration. The EPA may no longer assume that the use of OSHA-required personal protective equipment is presumptively sufficient in evaluating and managing risk.

The EPA has further indicated that it will change its standard practice to no longer exclude the evaluation of risks addressed under other EPA regulatory programs. The resulting broader evaluation is likely to result in more restrictions on the use of particular chemicals, and will certainly increase the cost and time for review.

Fee Assessment

The 2016 TSCA amendments allow the EPA to set up a fee structure that will cover 25% of its TSCA implementation costs. These fees, which are collected from chemical manufacturers and imports, are to be reviewed every three years.

Proposed revisions to the fee rule that would cover fiscal years 2022-2024 were issued on Dec. 21, 2020. The proposed revisions include a number of exemptions for importers of articles; chemicals that are manufactured as a byproduct, or manufactured/imported as an impurity; and chemicals used solely for research, development and manufacture of a chemical in de minimis amounts.

The proposal also establishes a product-volume-based fee, and new chemical fee categories. The EPA extended the comment period to March. The EPA's new leadership will evaluate the comments, and is expected to revise how the agency calculates the fees and grants exemptions.

Chemical Data Reporting Rule

Companies that manufacture and/or import 25,000 pounds or more of a chemical must report specific data on the use of such chemicals every four years. This data provides important information that helps the EPA assess and manage risks presented by these chemicals.

The deadline for the most recent reporting period, which ran from 2016 to 2019, was extended from Sept. 30, 2020, to Jan. 29, 2021. The Biden administration's evaluation of this data will play a part in its risk evaluations of these chemicals.

New Chemicals Program

On March 29, the EPA issued a public notice that it is evaluating its policies, guidance, templates and regulations under the TSCA's new chemicals program, to confirm that such information adheres to statutory requirements, and identified a number of specific actions that it would undertake.

It is not clear how much the agency's new procedures will change the health and safety review of new chemicals. But they will clearly front-end any party's burden in seeking TSCA approval for a new chemical.

First, in its March 29 notice, the EPA rejected the previous administration's process for how a new chemical is reviewed. Under the Trump administration, the agency would issue new chemical determinations of "not likely to present an unreasonable risk" based upon the existence of a proposed significant new use rule.

A significant new use rule prohibits parties from manufacturing or processing a chemical for a new use, absent advance notification to the agency, and the submission of a significant new use notice. Such a notice enables the EPA to evaluate the chemical use in the same manner as if a premanufacture notice had been filed for the chemical.

The EPA's March 29 notice indicates that it is rejecting this practice. The agency now intends to broaden its inquiry regarding all conditions of use of the chemical at its first opportunity, and regulate all such uses through an individual order, rather than put off such an evaluation of foreseeable uses.

Essentially, the EPA is questioning the appropriate scope of a foreseeable use review of a new chemical, and at what stage that foreseeable use should be addressed. The manner in which this issue plays out in practice remains to be seen.

Second, the March 29 notice provides that the EPA intends to increase its focus on worker protections when it reviews any foreseeable impact on workers from exposures to a new chemical. The agency previously assumed that such potential worker hazards would be addressed by the personal protective equipment and hazard communication policies mandated by OSHA.

Now the EPA states that it "will no longer assume that workers are adequately protected under OSHA's worker protection standards and updated Safety Data Sheets." Rather, such hazards will be considered reasonably foreseen conditions of use, and the EPA will move to impose necessary protections through a TSCA Section 5(e) order.

How that will play out in practice on a factory floor also remains to be seen. It is possible that there could be tensions between the agencies with regard to how OSHA restrictions are recognized in risk evaluations.

Persistent, Bioaccumulative and Toxic Chemicals

The 2016 TSCA amendments required the EPA to take expedited action on certain persistent, bioaccumulative and toxic, or PBT, chemicals, and promulgate final risk management actions no later than December 2020. To meet that requirement, the EPA fast-tracked final rules to reduce exposure to five PBT chemicals.

These rules went into effect on Feb. 5. The Biden administration has determined that a second look at these chemicals is warranted. On March 9, the EPA announced a public comment period to provide additional comments on the PBT chemical rules, including whether the rules are sufficient to address the risk of exposure to these chemicals:

> EPA will review and consider revising the final PBT rules with an eye towards reducing exposure to the extent practicable, environmental justice, scientific integrity, and EPA's mission of protecting human health and the environment, taking into consideration information received while the rules were under development as well as any new information submitted since the rules were finalized and information received in response to this document.

The EPA will use information from the public comments to assess the path forward with regard to these chemicals. This path forward could include amending the current rules to include additional or alternative exposure reduction measures.

Going forward, the TSCA is likely to be a significant tool for promoting President Joe Biden's environmental equity initiatives and protecting vulnerable communities. Among other things, the TSCA requires the EPA to consider "potentially exposed and susceptible subpopulations" in conducting risk assessments.

Although this requirement has always been a part of the TSCA, the impact on vulnerable communities has not been a driving force for regulation of chemicals. Given the Biden administration's push for greater environmental equity, the regulated community should expect increased data submission requirements, longer review and approval processes, and increased enforcement.

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[1] The chemicals include 1,4-dioxane, 1-bromopropane (final), asbestos, carbon tetrachloride, cyclic aliphatic bromide cluster, methylene chloride, N-methylpyrrolidone, pigment violet 29, tetrachloroethylene and trichloroethylene.