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Changes on the Horizon for Toxic Substance Control Regulation

By [Emily Tabak](#)

The year ahead promises to be a busy one for regulation of new and existing chemicals under the 2016 reforms to the Toxic Substances Control Act (TSCA). TSCA gives EPA expanded authority to regulate both new and existing chemicals, as the agency must make findings on the risks presented by new chemicals, as well as review all active existing chemicals to identify “high priority” chemicals that must undergo risk evaluations and risk management plans as needed. The law applies broadly to any “person” who manufactures, processes, distributes in commerce, uses, or disposes of a chemical substance, including companies that have manufactured chemical products or importing retailers, regardless of industry sector.

These entities are subject to TSCA requirements and should be aware of the business and legal implications, including upcoming chemical data reporting, evolving rules on risk evaluations and management, changes in fees, and rising enforcement penalties. A number of TSCA regulations are on the Biden Administration’s list of agency actions slated for review, consistent with an Executive Order. This alert provides a summary of these recent TSCA developments and expected changes in the new year for the regulated community.

CDR Rule Reporting Now Due on January 29, 2021

The TSCA Chemical Data Reporting (CDR) rule requires manufacturers (including importers) to provide EPA with information on the production and use of chemicals in commerce every four years, generally when production volumes for the chemical are 25,000 pounds or greater for a specific reporting year. The 2020 CDR submittal, which covers the calendar years 2016-2019, was originally due on September 30, 2020, and later extended to November 30, 2020. However, due to technical issues with EPA’s electronic reporting tool, the agency announced on November 19th that it would extend the deadline to January 29, 2021, following the inauguration of President Joe Biden.

The CDR data is used by EPA to support chemical prioritization and screening, assessment, evaluation, and management of risks based on chemical types, amounts, exposures, industrial processing and uses, and consumer and commercial uses. In addition, EPA uses CDR data for rulemaking and enforcement purposes. We encourage companies that manufacture, import, process, distribute, use, or dispose of chemical substances to consider any exemptions that may be available, as well as to monitor for confidentiality protections and potential compliance issues in consultation with counsel, as they review and finalize their reporting.

Chemical Risk Evaluations Finalized, Rule Review and Regulations for Risk Mitigation to Follow

The Trump Administration EPA finalized the last of its chemical risk evaluations for 10 existing chemicals that have been identified as “high priority” under the implementation of the 2016 TSCA amendments. Final risk evaluations have been issued for chrysotile asbestos; certain solvents such as 1,4-dioxane and methylene chloride; and certain flame retardants. Each chemical final risk evaluation issued has found that

some uses of the identified chemicals present “unreasonable risk,” triggering a one-year deadline for the incoming Biden Administration EPA to propose rules intended to mitigate that unreasonable risk, and an additional year thereafter to finalize any proposals. Additional regulatory uncertainty has been created due to the Biden Administration fact sheet released on Inauguration Day, which outlined a [list of agency actions](#) that EPA is directed to review consistent with an accompanying [Executive Order](#). Both the risk evaluation for methylene chloride, as well as the rule outlining procedures for chemical risk evaluation under amended TSCA, are on the list of targets for review, as are the final (for now) regulations governing risk management for five Persistent Bioaccumulative Toxics (PBTs) released in December.

As EPA begins the process of reviewing the previous administration’s TSCA rulemaking and the crafting, rollout, and implementation of new risk management rules, industry (including manufacturers as well as many small processors and users of the chemicals at issue) should prepare for a potential increase in TSCA enforcement, which may be a priority for the new Administration. The upcoming proposed rules also represent an opportunity for interested parties and groups to make recommendations to EPA during the public comment period regarding the best approach to TSCA risk management. Lastly, finalized rules governing risk mitigation are also likely to face lawsuits from environmentalists, if not perceived as sufficiently stringent or protective.

Proposed Fee Assessment Changes

The 2016 TSCA amendments provided EPA with additional authority to collect fees from chemical manufacturers and importers to help defray up to 25% of TSCA implementation costs and required EPA to establish a fee structure by rule. Proposed revisions to the current TSCA fees rule, which must be reviewed every 3 years, were released on December 21, 2020. The proposed changes would apply for fiscal years 2022, 2023, and 2024, and include narrowing the scope of the rule by introducing exemptions for importers of articles; companies that produce a chemical as a byproduct or manufacture or import as an impurity; companies that use chemicals solely of research and development; companies that produce a chemical in de minimis amounts; and companies that manufacture a chemical produced as a non-isolated intermediate. Additional changes include new chemicals fee categories; using more up-to-date cost data; proposing a production-volume based fee allocation; allowing corrections to the manufacturer list; extending the time to form fee-sharing consortiums; and allowing payments in installments.

Enforcement Penalties Rising

Regarding enforcement, the maximum statutory civil monetary penalties under TSCA have been increased with the annual inflation adjustment promulgated by EPA on December 23, 2020. Effective on that date, civil enforcement penalties for TSCA violations have increased to \$41,056 per day, per violation. The agency’s civil penalty policies provide guidance to enforcement personnel on how to exercise discretion on penalty amount, taking into account fact-specific considerations including the seriousness of the violation, good faith efforts to comply, economic benefit gained as a result of noncompliance, and ability to pay.

The regulated community, including chemical manufacturers and importing retailers, should prepare for increased scrutiny in the coming years with the help of experienced environmental counsel and consultants.

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