

TSCA in 2022: Fasten Your Seatbelt



A year into the Biden Administration’s implementation of the 2016 amendments of the Toxic Substances Control Act (TSCA), EPA is planning an ambitious suite of actions under sections 4, 5, 6, 8, 14, and 23. Companies and trade associations should be prepared to take appropriate action.

Section 4 – Testing

In January 2021, at the tail end of the Trump Administration, EPA issued [test orders](#) for 9 of the 20 high-priority substances. It had also begun development of test orders for the other 11 substances. The Biden EPA is now reviewing the results of the [section 8\(d\) rule for all 20 high-priority substances](#) (see our [alert](#)), for which studies were required to be submitted by [December 1, 2021](#). Based on that review, EPA is likely to issue test orders to fill data gaps, possibly for all 20 substances. The original 9 test orders required designated manufacturers to conduct specific toxicology and/or ecotoxicology studies. They also required both those manufacturers and designated processors to conduct human and environmental exposure studies.

In October 2021, EPA issued its [National PFAS Testing Strategy](#). It identified 24 categories of PFAS based on similarities of structure, physical/chemical properties, and existing test data, for which it could identify manufacturers to whom it could issue test orders. EPA will likely issue its first round of test orders under that Strategy within the next few months. Details on those test orders appear in a

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December 2021 [letter](#) reversing the Trump EPA's [denial](#) of a section 21 petition to require testing of 54 PFAS:

Under the testing strategy, EPA's first test orders for 24 data-poor categories of PFAS will provide data that cover 30 of the 54 petition chemicals. Seven orders will be issued specifically for petition chemicals, which are in categories that also include 14 additional PFAS identified in the petition. Four orders will be issued for non-petition chemicals, which are in categories that include nine additional PFAS identified in the petition. The initial test orders will include animal tests that measure most of the specific human health related toxicity endpoints identified as a concern by the petitioners (e.g., systemic, reproductive, developmental, thyroid, and immunological toxicity). Subsequent tiers of testing that will be specified in the initial test orders may include additional endpoints (e.g., cancer), depending on the results of the initial tiers of tests and consistent with the TSCA statutory requirement regarding tiered testing.

Section 5 – New Chemical Substances and Significant New Use Rules

EPA will continue to deal with a significant [backlog](#) of PMNs (313 open cases of PMNs, SNUNs, and MCANs as of January 1, 2022). Some of the backlog apparently results from ongoing incremental changes to its Working Approach for Making Determinations under TSCA Section 5. EPA [expects](#) to complete its revamping of the [2019 Working Approach](#) to align with statutory intent and policy shifts (e.g., orders, SNURs, reasonably foreseen uses, and worker protection) by March 2024.

In an effort to complete PMN reviews within 90 days, EPA [plans to issue a notice of proposed rulemaking](#) (NOPR) in September 2022 to revise the procedural regulations in 40 C.F.R. Part 720 to improve the efficiency of EPA's PMN review process and to align its processes and procedures with the 2016 TSCA amendments. The proposed changes will be intended to increase the quality of information initially submitted in PMNs and other notices and improve EPA's processes to reduce unnecessary rework in the risk assessment and, ultimately, the length of time that new chemicals are under review.

EPA [plans](#) to finalize a 2016 [proposed rule](#) in September 2022 to update its SNUR regulations, 40 C.F.R. Part 721. The changes will include amendments to the provisions on protection in the workplace and hazard communication to bring them into alignment with current OSHA requirements.

New PFAS chemical substances are likely to receive increased scrutiny in 2022. In April 2021, EPA [announced](#) that it would no longer process low volume exemption applications for PFAS. In October 2021, EPA released its [PFAS Strategic Roadmap](#) for 2021-2024 that declared: "Moving forward, EPA will apply a rigorous premanufacture notice review process for new PFAS to ensure these substances are safe before they enter commerce."

More generally, EPA is planning to improve its approaches for overall tracking and enforcement of requirements in section 5(e) orders and SNURs to ensure that companies are complying with the terms of those agreements and regulatory notice requirements. Companies subject to section 5(e) orders or SNURs may want to review their own compliance in advance of EPA enforcement.

Section 6 – Existing Chemicals

EPA plans to be particularly active under section 6 in 2022.

Risk Evaluations for Initial 10 Chemical Substances

By the end of the Trump Administration, EPA had published “final” risk evaluations for each of the initial 10 chemical substances. In June 2021, EPA [announced](#) that it was reviewing those risk evaluations and would revise them. In December, it [announced](#) the availability of a draft revised risk determination for the first of the 10, HBCD, in a format likely to be followed for the remaining ones. The draft utilizes a “whole chemical” approach, i.e., it makes one risk determination (that HBCD presents an unreasonable risk to health and the environment), rather than making separate risk determinations for each condition of use, as did all of the “final” Trump EPA risk evaluations. It does not alter the underlying scientific analysis of the risk evaluation in the risk characterization section of the risk evaluation,

Draft revised risk determinations for the other 9 initial risk evaluations are expected throughout 2022. Those for asbestos Part 1 (chrysotile asbestos) and Pigment Violet 29 are likely to be next. Affected companies may want to comment to EPA on the draft risk determinations as well as the subsequent risk management rules.

Also in December 2021, EPA [announced](#) and [released](#) the draft scope document for Part 2 of its asbestos risk evaluation (legacy uses). Comments are due by February 14, 2022. The Office of Pollution Prevention and Toxics (OPPT) [Strategic Plan for FY2021 – FY2023](#) calls for completion of Part 2 by December 2024, so work on it is likely already underway.

Risk Management Rulemaking for Initial 10 Chemical Substances

Expect EPA to publish proposed risk management rules for 5 of the 10 initial chemical substances in 2022. EPA predicted publication on the following schedule:

- ◆ December 2021 – [Asbestos](#) Part 1 (chrysotile asbestos) (EPA [submitted](#) the draft NOPR to OMB on December 16, 2021)
- ◆ September 2022 – [HBCD](#)
- ◆ October 2022 – [1-Bromopropane](#), [carbon tetrachloride](#), [trichloroethylene](#)

The other 5 NOPRs are expected in 2023. Manufacturers, processors, and users of those substances may want to submit comments before and certainly after EPA publishes the proposed rules.

Risk Evaluations for First 20 High-Priority Substances

EPA will continue work on the ongoing risk evaluations for the first 20 high-priority substances during 2022. Under section 6(b)(2), EPA must complete all 20 ongoing risk evaluations between December 2022 and June 2023, since risk evaluations must take 3 to 3½ years and EPA [designated](#) the current 20 high-priority substances in December 2019.

Nevertheless, EPA is already predicting that it will not fully meet the statutory deadline. The OPPT [Strategic Plan](#) predicts publication of 10 of the 20 final risk evaluations by June 2023, with the remaining 10 predicted by December 2024.

As noted, EPA is currently evaluating the studies submitted under the [section 8\(d\) rule for all 20 high-priority substances](#), for which studies were required to be submitted by [December 1, 2021](#). It may then issue test orders to fill remaining data gaps.

Another factor that may affect the first 20 risk evaluations is the Biden EPA's work to replace the Trump EPA's [Systematic Review Protocol](#) for identifying and evaluating evidence for the hazard and exposure assessments that support risk evaluations. The National Academies of Sciences, Engineering, and Medicine published a severe [critique](#) of that Protocol. EPA has [released](#) for public comment a draft replacement Protocol. Comments are due by February 18, 2022. The TSCA Scientific Advisory Committee on Chemicals (SACC) [will review](#) the draft in April 2022. The draft [scope document](#) for the legacy uses of asbestos risk evaluation indicates that EPA plans to utilize the Systematic Review Protocol in that risk evaluation.

Affected companies may want to provide information to assist EPA in completing these risk evaluations, particularly with respect to their use of engineering controls and personal protective equipment, and industrial hygiene monitoring results.

PBTs

In 2021, many companies and trade associations pleaded with EPA to provide more time to comply with EPA's January 6 rule on PIP (3:1) in 40 C.F.R. § 751.407 as it relates to articles (see [our alert](#)). EPA [plans](#) to finalize its October 2021 [proposed rule](#) extending the compliance deadline for importers of articles containing PIP (3:1) by March 2022. The proposal would further extend the compliance deadline for articles containing PIP (3:1) to October 31, 2024.

Challenges to the decaBDE rule, 40 C.F.R. § 751.405, may be decided in late 2022. In December, the Ninth Circuit set the briefing schedule in *Alaska Community Action on Toxics v. EPA* and a consolidated case, Nos. 21-70168 and 21-70670, with the final briefs due June 24, 2022.

Prioritization of the Second 20 High-Priority Substances

EPA is already hard at work on identifying the candidates for the second set of 20 high-priority substances. The OPPT [Strategic Plan](#) predicts preliminary analyses of prioritization candidates for the pre-prioritization phase during the first quarter of 2022. The final list of candidates for designation as high-priority substances may come by the end of 2022.

Manufacturers and processors of the second 20 high-priority substances should consider submitting information to EPA about their processes and occupational exposures once EPA publicly identifies them.

Risk Evaluation Procedural Rule

The Biden EPA is [considering](#) amendments to the Trump EPA rule on how it conducts risk evaluations, 40 C.F.R. Part 704, Subpart B. Among other things, that rule arguably requires condition-of-use-by-condition-of-use risk determinations, which approach the new administration has [rejected](#) in favor of a whole chemical approach, although the [HBCD notice](#) found that the whole chemical approach is permissible under the current rule.

EPA says that it is reconsidering that rule in keeping with new executive orders concerning the advancement of racial equity and support for underserved communities through the Federal government (EO 13985), the protection of public health and the environment and restoring science to tackle the climate crisis (EO 13990), tackling the climate crisis at home and abroad (EO 14008), and other Administration priorities (such as the Presidential memorandum on restoring trust in government through scientific integrity and evidence-based policymaking). If it determines to amend the existing rule, it expects to publish a NOPR in September 2022.

Section 8 – Reporting Rules

EPA [plans](#) to publish a NOPR on tiered data reporting in July 2022. The rule would establish reporting requirements based upon a chemical's status in the Risk Evaluation/Risk Management Lifecycle and update the reporting requirements under the Chemical Data Reporting rule (CDR). It would seek to obtain information about potential hazards and exposure pathways related to certain chemicals, particularly occupational, environmental, and consumer exposure information. The final rule would affect many companies, so they or their trade associations should consider commenting on the proposal once it is published.

Asbestos is arguably exempt from reporting for the CDR as a naturally occurring substance. Per a court order (see our [alert](#)), EPA [plans](#) to propose a rule under Part 704 in March 2022 that would require the maintenance of records and submission to EPA of reports by manufacturers, importers and processors of asbestos and mixtures and articles containing asbestos (including as an impurity). The information sought would include data on the quantities of asbestos used in making products, employee exposure data, and waste disposal data. A final rule is due by November 2022, meaning that reporting would likely be required in 2023.

Mercury reports are due every 3 years, with the next report due July 1, 2022 for calendar year 2021. EPA's rule under section 8(b)(10) for certain manufacturers (including importers) and processors of mercury and mercury compounds appears in 40 C.F.R. Part 713. EPA [amended](#) the rule in November 2021 per a court order to eliminate a previous exemption for companies that manufacture (including import) a mercury-added product where that company is "engaged only in the import of a product that contains a component that is a mercury-added product." As explained in our [alert](#), the amendment broadens the scope of companies required to report to include importers of articles qualifying as a mercury-added product.

In 2021, EPA [proposed](#) a reporting rule for PFAS that would apply to manufacturers of PFAS, including importers of articles containing PFAS (see our [alert](#)). Under section 8(a)(7), EPA must finalize the rule by January 1, 2023. EPA is likely to publish the final rule in late 2022, with reporting due in 2023. Despite arguments by commenters, EPA has signaled that it plans to apply the rule to article importers.

Section 14 – Confidential Information

EPA is [considering](#) proposing new and amended rules concerning the assertion and maintenance of claims of business confidentiality (i.e., confidential business information) to conform to the 2016 TSCA amendments. The proposals would relate to procedures for submitting and supporting such claims in TSCA submissions, including substantiation requirements, exemptions, electronic reporting enhancements, and maintenance or withdrawal of confidentiality claims. EPA is also considering whether the proposals should elaborate on the procedures for reviewing and communicating with TSCA submitters about confidentiality claims. EPA predicts publication of the proposals in April 2022. Any company that submits confidential information to EPA under TSCA may want to consider commenting, either directly or through its trade association.

Section 26(b) – Fees

Fees for a wide range of actions under TSCA [increased](#) on January 1, 2022 as a result of inflation. The new fees include, among others, the following (with lesser fees for small businesses):

- ◆ Test order: \$11,650
- ◆ PMN or SNUN: \$19,020
- ◆ LVE: \$5,590

- ◆ EPA-initiated risk evaluation: \$1,605,000 (to be shared by all manufacturers of the substance)

EPA's rule on fees appears in 40 C.F.R. Part 700, Subpart C. Following a debacle when it assessed fees for manufacturers of the first 20 high-priority substances (see our [alert](#)), the Trump EPA [proposed](#) amendments to those rules that would, among other things, include certain exemptions. The Biden EPA [plans](#) to issue a supplemental proposed rule in February. It would make unspecified changes to the fees rule. Again, commenting may be important.

Conclusion

This summary of expected EPA actions under TSCA in 2022 demonstrates that EPA has an ambitious agenda. It may not be able to complete all that it intends to do, in part because it is strapped for resources and OPPT staff are complaining of burnout. Nevertheless, companies and trade associations are strongly encouraged to pay close attention to TSCA developments throughout the year, and to comment or submit information to influence EPA's final actions. This is particularly the case with importers of articles, whom EPA is increasingly targeting under TSCA.

Beveridge & Diamond's [Chemicals Regulation practice group](#) provides strategic, business-focused advice to the global chemicals industry. We work with large and small chemical companies whose products and activities are subject to EPA's broad chemical regulatory authority under TSCA and state chemical restrictions. For more information, please contact the authors.