



Dear Subscriber,

We are pleased to enclose the Winter 2023 Update for your 6-volume TSCA Compliance Guide and Online Service.™

- 1) **Civil Monetary Penalty Inflation Adjustment.** On January 6, 2023, EPA announced a final rule adjusting the maximum and minimum statutory civil monetary penalty amounts under the statutes EPA administers. The new amount, listed in the third column of Table 1 of 40 CFR 19.4, will apply to all civil monetary penalties assessed on or after January 6, 2023, for violations that occurred after November 2, 2015. The new maximum penalty is \$46,989. See 88 FR 986. The text of Introduction pages 16 & 17 has been updated to reflect this development.
- 2) **Reporting Requirements for Microorganisms.** On December 2, 2022, EPA announced a new section of 40 CFR 725. Part 725 is titled Reporting Requirements and Review Processes for Microorganisms. EPA added a section for *Trichoderma reesei* modified (MCAN J-16-26) in 725.1081. EPA requires reporting from any person who manufactures, processes, or uses the microorganism in any way other than a specifically defined fermentation system. Individuals and organizations subject to this section also have associated recordkeeping requirements. See 87 FR 73941. The text of Section V, pages D7 and D35-D37 have been updated to reflect this development.

Please also note these recent EPA activities:

- **Electric Vehicle Chemicals Efforts.** On October 5, 2022, EPA announced a new effort to streamline the process for conducting TSCA risk assessments for new chemicals with applications in batteries, electric vehicles, semiconductors, and renewable energy generation. Specifically, the new process is for mixed metal oxides, including new and modified cathode active materials. EPA is expected to discuss specifics related to this effort in a March 30, 2023 webinar. More information can be found at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/integrated-approach-mixed-metal>
- **ORD BOSC review of New Chemical Program.** On October 11, 2022, EPA announced that the Office of Research and Development (ORD) Board of Scientific Counselors (BOSC) will review the TSCA New Chemicals Collaborative Research Program (Program). BOSC met to review the Program at the end of October of 2022. No report from that meeting has been issued. See 87 FR 61313.

TSCA Compliance Guide & Online Service

www.TSCA.com

info@TSCA.com

“The World’s Leading Source of Up-to-Date TSCA Information”

- **CSB Hydrofluoric Acid Recommendations.** On October 11, 2022, the U.S. Chemical Safety Board (CSB) released its final report into the June 2019 Philadelphia Energy Solutions Refinery fire. CSB attributed the fire to the rupture of a corroded pipe elbow, releasing fluids into the hydrofluoric acid alkylation unit. CSB also recommended that EPA evaluate whether hydrofluoric acid is a high-priority substance for TSCA risk evaluation. CSB’s final report can be viewed here: https://www.csb.gov/assets/1/6/pes_final_report_published_october_2022.pdf
- **PFAS LVE Petition.** On October 13, 2022, Earthjustice petitioned EPA to revoke approximately 600 per- and polyfluoroalkyl substances (PFAS) low volume exemptions (LVEs) or low release and low exposure exemptions (LoREXs) to premanufacture notice requirements. Generally speaking, the petition requests EPA review the LVEs/LoREXs for compliance with TSCA Section 5(h)(4) or 40 C.F.R. 723.50(d) and prohibit the use of LVEs/LoREXs for new PFAS.
- **TRI Reporting Rule.** On October 21, 2022, EPA announced the availability of a final rule codifying the definition of “parent company” for Toxic Release Inventory (TRI) reporting purposes. Existing regulations required facilities reporting to TRI to identify their parent company in the reporting forms, but the regulations did not define “parent company”. The new definition can be found in 40 CFR 372.3, 372.85, and 372.95. *See* 87 FR 63950.
- **Updated TRI Data.** On October 26, 2022, EPA announced the availability of updated 2021 TRI data for chemical releases. Updated TRI data can be found at <https://www.epa.gov/toxics-release-inventory-tri-program/tri-data-and-tools>.
- **EPA Information Collection Activities.** On October 27, 2022, EPA announced it had submitted an information collection request (ICR) renewal to the Office of Management and Budget. The request is titled “Notification of Substantial Risk of Injury to Health and the Environment under TSCA Section 8(e).” This is a proposed extension of an already existing ICR, scheduled to expire on October 31, 2022. Under TSCA Section 8(e), persons who manufacture, process, or distribute in commerce a chemical mixture or substance are required to immediately inform EPA of any obtained information that supports a reasonable conclusion that the substance or mixture presents a substantial risk of injury to health or the environment. This ICR is in furtherance of those information collection activities. *See* 87 FR 65060.
- **EPA’s FY 2023 Top Challenges.** On October 28, 2022, EPA Office of the Inspector General (OIG) released an annual report on EPA’s Fiscal Year 2023 Top Management Challenges. Number three on the list of the eight largest challenges facing EPA was “Providing for the Safe Use of Chemicals. The public must be able to depend on the EPA’s ability to conduct credible and timely assessments of the risks posed by pesticides, toxic chemicals, and

TSCA Compliance Guide & Online Service

www.TSCA.com

info@TSCA.com

“The World’s Leading Source of Up-to-Date TSCA Information”

other environmental chemicals.” OIG identified a lack of resources, both human and financial, as a major driver of delays in EPA’s meeting several of TSCA’s statutorily required deadlines. Without more investment in the chemicals program, OIG believes that EPA will continue to struggle to ensure the safety of chemicals. More information, including the full report, can be found at <https://www.epa.gov/office-inspector-general/report-epas-fiscal-year-2023-top-management-challenges>

- **EPA’s TSCA Report to Congress.** In October of 2022, EPA released their Report to Congress on the EPA’s Capacity to Implement Certain Provisions of the Frank A. Lautenberg Chemical Safety for the 21st Century Act (the “Report”). EPA is required to submit the Report under TSCA section 26(m), which requires reporting to Congress no less frequently than every five (5) years. Of note in the Report, EPA expects that President Biden’s proposed \$59 million increase in TSCA funding would assist in modernizing information technology systems and increase and diversify EPA’s expertise in the TSCA program’s scientific workforce, decreasing TSCA implementation costs and time. The full Report can be found here: <https://www.epa.gov/system/files/documents/2022-10/October%202022%20Report%20to%20Congress%20on%20the%20EPAs%20Capacity%20to%20Implement%20Certain%20Provisions%20of%20the%20Frank%20R.%20Lautenberg%20Chemical%20Safety%20for%20the%2021st%20Century%20Act.pdf>
- **Methylene Chloride Risk Determination Revision.** On November 10, 2022, EPA announced the availability of the finalized revision to the risk determination for methylene chloride. This revision was developed in accordance with the Biden Administration’s pledge to revisit the first ten TSCA risk evaluations in light of the Administration’s updated priorities, including analyzing the risk evaluation for environmental justice concerns, scientific integrity, and not assuming, as the Trump administration did, that works will always wear personal protective equipment. The finalized revision makes a revised determination of unreasonable risk for methylene chloride as a whole chemical substance. EPA will now proceed to risk management to address the unreasonable risks posed by methylene chloride. See 87 FR 67901.
- **Polyvinyl Alcohol Petition.** On November 15, 2022, a coalition petitioned EPA under TSCA Section 21 to require testing for polyvinyl alcohol as it is used in consumer-packed goods. Specifically, the petition focused on the presence of polyvinyl alcohol in laundry and dishwasher detergent pods and sheets. EPA had 90 days from the date of the petition to grant or deny the petition. But on January 26, 2023, Petitioners withdrew the petition and resubmitted a new petition. The new petition also requests a TSCA section 4 order requiring manufacturers who participate in the Safer Choice Program for dishwasher and laundry pods (among others) to fund and conduct testing on polyvinyl alcohol. The petition also requests EPA regulate polyvinyl alcohol as a toxic substance when used in laundry or dishwasher products, pending testing results. More information can be found

TSCA Compliance Guide & Online Service

www.TSCA.com

info@TSCA.com

“The World’s Leading Source of Up-to-Date TSCA Information”

at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-21#polyvinyl>

- **TSCA Fees Rule Supplement.** On November 16, 2022, EPA announced the availability of a document modifying and supplementing the proposed TSCA fees rule, first announced on January 11, 2021. When EPA conducted a comprehensive budget analysis regarding TSCA implementation costs, it determined that the current fees rule was only collecting approximately 12% of TSCA administration costs, or about half of what EPA is mandated to collect. To address this situation, the 2021 proposed rule proposed three new fee categories, new classifications of fee exemptions, updated TSCA administration cost estimates, new fee allocation methodology for EPA-initiated risk evaluations, and changes to the timing of select activities throughout the fee payment process. After the 2021 proposed rule, EPA conducted further analyses to more accurately determine the anticipated costs of continued TSCA implementation. The 2022 supplement is intended to ensure that the fees charged accurately reflect the level of effort and resources needed to implement TSCA. Additionally, the supplement would narrow certain proposed exemptions for those subject to risk evaluation fees while also proposing new exemptions “for the test rule fee activities; to propose modifications to the self-identification and reporting requirements for EPA-initiated risk evaluation and test rule fees; to propose a partial refund of fees for premanufacture notices withdrawn at any time after the first 10 business days during the assessment period of the chemical; to propose modifications to EPA’s proposed methodology for the production volume-based fee allocation for EPA-initiated risk evaluation fees in any scenario where a consortium is not formed; to propose expanding the fee requirements to companies required to submit information for test orders; to propose modifying the fee payment obligations to require payment by processors subject to test orders and enforceable consent agreements (ECA); to propose extending the timeframe for test order and test rule payments; as well as to propose changes to the fee amounts and the estimate of EPA’s total costs for administering TSCA.” Persons subject to TSCA administration fees should anticipate increases of 50%-100% in the fees charged by EPA, if this rule is finalized and codified. See 87 FR 68647.
- **TSCA Risk/New Chemical Submission Transparency.** On November 21, 2022, EPA announced that it was improving public access to specific reports submitted by chemical companies. EPA has published in ChemView, EPA’s web application for public access to non-confidential business information on TSCA chemicals, previously unpublished new chemical notices received under TSCA section 5, notices of substantial risk provided by companies under TSCA section 8(e), and chemical health and safety studies received under TSCA section 8(d). EPA will continue to make these available in real time and seek to identify older submissions that should be published.
- **EPA Information Collection Activities.** On November 23, 2022, EPA announced it had submitted an information collection request (ICR) renewal to the Office of Management

TSCA Compliance Guide & Online Service

www.TSCA.com

info@TSCA.com

“The World’s Leading Source of Up-to-Date TSCA Information”

and Budget. The request is titled “Polychlorinated Biphenyls (PCBs); Consolidated Information Collection Activities”. This is a proposed renewal of an already existing ICR, scheduled to expire on November 30, 2022. Under TSCA section 6(e)(1), EPA is directed to regulate the marketing and disposal of PCBs. TSCA section 6(e)(2) bans the manufacture, distribution in commerce, processing, and use of PCBs other than in a totally enclosed manner. EPA has promulgated regulations contained in 40 CFR 761 regarding the reporting and record keeping requirements necessary to achieve EPA’s mandates. This ICR provides EPA with the information necessary to fulfill its statutory and regulatory obligations. See 87 FR 71634

- **PFAS Reporting and Recordkeeping.** On November 24, 2022, EPA announced the availability of an Initial Regulatory Flexibility Analysis and Updated Economic Analysis for the proposed rule for PFAS reporting and record keeping requirements under TSCA. These analyses followed a June 28, 2021 proposed rule on PFAS reporting and record keeping requirements. See 86 FR 33926. The proposed rule would require all manufacturers of a chemical substance or of a mixture containing that chemical substance that is a PFAS to report certain information to EPA. Those manufacturers would also be required to keep relevant records for five (5) years following submission to EPA. When EPA initially proposed the rule, it certified that the rule would not have a significant economic impact on a substantial number of small entities. However, information gained from comment since the initial proposed rule indicated that EPA’s certification was incorrect and a substantial number of small entities would see an economic impact from the proposed rule. EPA now expects industry-wide compliance costs to approach \$876 million, with up to \$1.8m in costs for each manufacturer and \$224,000 for each importer. Small businesses would be responsible for the bulk of EPA’s estimates, with EPA projecting more \$863 million being born by those entities. In the analyses, EPA proposed several alternatives that would decrease the burdens on small businesses. EPA is considering the information gained in the analyses released on November 25, 2022, as well as from comments on the analyses, as it determines the next steps for the proposed rule. See 87 FR 72439.
- **Perchloroethylene Risk Determination Revision.** On December 14, 2022, EPA announced the availability of the finalized revision to the risk determination for perchloroethylene (PCE). This revision was developed in accordance with the Biden Administration’s pledge to revisit the first ten TSCA risk evaluations in light of the Administration’s updated priorities, including analyzing the risk evaluation for environmental justice concerns, scientific integrity, and not assuming, as the Trump administration did, that workers will always wear personal protective equipment. The finalized revision makes a revised determination of unreasonable risk to human health or the environment for PCE as a whole chemical substance due to risks identified in 60 out of 61 conditions of use evaluated. EPA will now proceed to risk management to address the unreasonable risks posed by PCE. See 87 FR 76481.

TSCA Compliance Guide & Online Service

www.TSCA.com

info@TSCA.com

“The World’s Leading Source of Up-to-Date TSCA Information”

- **New Chemicals Review Program Webpage.** On December 15, 2022, EPA announced a redesign of and the availability of new information on the webpage for the New Chemicals Review Program. The website now contains more detailed breakdowns of new chemical submissions, a status tracker for new chemical exemptions, and updated information on the new chemical review process. These changes are part of EPA’s ongoing effort to increase transparency. More information can be found at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review>
- **1-Bromopropane Risk Determination Revision.** On December 19, 2022, EPA announced the availability of the finalized revision to the risk determination for 1-bromopropane (1-BP). This revision was developed in accordance with the Biden Administration’s pledge to revisit the first ten TSCA risk evaluations in light of the Administration’s updated priorities, including analyzing the risk evaluation for environmental justice concerns, scientific integrity, and not assuming, as the Trump administration did, that works will always wear personal protective equipment. The finalized revision makes a revised determination of unreasonable risk to human health or the environment for 1-BP as a whole chemical substance due to risks identified in 23 out of 25 conditions of use evaluated. EPA will now proceed to risk management to address the unreasonable risks posed by 1-BP. *See* 87 FR 77603.
- **n-Methylpyrrolidone Risk Determination Revision.** On December 19, 2022, EPA announced the availability of the finalized revision to the risk determination for n-methylpyrrolidone (NMP). This revision was developed in accordance with the Biden Administration’s pledge to revisit the first ten TSCA risk evaluations in light of the Administration’s updated priorities, including analyzing the risk evaluation for environmental justice concerns, scientific integrity, and not assuming, as the Trump administration did, that works will always wear personal protective equipment. The finalized revision makes a revised determination of unreasonable risk to human health or the environment for NMP as a whole chemical substance due to risks identified in 29 out of 37 conditions of use evaluated. EPA will now proceed to risk management to address the unreasonable risks posed by NMP. *See* 87 FR 77596.
- **Carbon Tetrachloride Risk Determination Revision.** On December 27, 2022, EPA announced the availability of the finalized revision to the risk determination for carbon tetrachloride. This revision was developed in accordance with the Biden Administration’s pledge to revisit the first ten TSCA risk evaluations in light of the Administration’s updated priorities, including analyzing the risk evaluation for environmental justice concerns, scientific integrity, and not assuming, as the Trump administration did, that works will always wear personal protective equipment. The finalized revision makes a revised

TSCA Compliance Guide & Online Service

www.TSCA.com

info@TSCA.com

“The World’s Leading Source of Up-to-Date TSCA Information”

determination of unreasonable risk to human health or the environment for carbon tetrachloride as a whole chemical substance due to risks identified in 13 out of 15 conditions of use evaluated. EPA will now proceed to risk management to address the unreasonable risks posed by carbon tetrachloride. See 87 FR 79303.

- **Transfer of Data.** On December 27, 2022, EPA announced that chemical information submitted to EPA under TSCA, including information that may have been claimed as confidential business information (CBI), was being transferred to Datawiz Corporation and its subcontractors, DMI and WIPRO. The transfer of data was done pursuant to CBI regulations. Datawiz Corporation, DMI, and WIPRO have been awarded a contract to do work for EPA's Office of Chemical Safety and Pollution Prevention and transferring the data will enable the contractors to meet their obligations. See 87 FR 79297.
- **EPA OIG Opinion on TSCA Fees.** On December 29, 2022, EPA's OIG published a report titled "The EPA's Fiscal Years 2020 and 2019 Toxic Substances Control Act Service Fee Fund Financial Statements." The 2016 Lautenberg Amendments require EPA's OIG to audit the TSCA service fee financial statements each year. The OIG did so to determine if the financial statements were fairly stated in all material respects, if EPA's internal controls over financial reporting were in place, and if EPA management complied with laws and regulations. The OIG issued a qualified opinion that the financial statements were fairly presented. The OIG also found that the TSCA fee structure in place during 2020 and 2019 was reasonable. More information is available at <https://www.epa.gov/office-inspector-general/report-epas-fiscal-years-2020-and-2019-toxic-substances-control-act>
- **PFAS Test Orders.** On January 4, 2023, EPA announced the next round of PFAS test orders under the National PFAS Testing Strategy. These test orders pertain to trifluoro(trifluoromethyl)oxirane (HFPO), a perfluoroalkyl substance used in making plastics. The test order was issued to only four companies: The Chemours Company FC LLC, DuPont De Nemours Inc., E. I. du Pont de Nemours and Company, and 3M Company. This is the second round of test orders issued under the National PFAS Testing Strategy and more test orders are expected. More information is available at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/list-chemicals-subject-section-4-test-orders>
- **Fall 2022 Unified Agenda.** On January 4, 2023, EPA published their Fall 2022 Unified Agenda ("Agenda"). This Agenda sets for EPA's expected regulatory and deregulatory actions for both the near and long term. Many of these actions relate to EPA's TSCA authority. Some notable inclusions are:¹

¹ Descriptions of regulatory or deregulatory are primarily taken verbatim, but with minor editing for brevity, from the Agenda.

TSCA Compliance Guide & Online Service

www.TSCA.com

info@TSCA.com

"The World's Leading Source of Up-to-Date TSCA Information"

- **Updates to New Chemical Regulations Under TSCA (2070-AK65)** - This rulemaking seeks to revise the new chemicals procedural regulations in 40 CFR parts 720, 721, 723, and 725 to clarify and improve the efficiency of EPA’s review process and align its processes and procedures with the 2016 statutory requirements. This rulemaking seeks to increase the quality of information initially submitted in new chemicals notices and improve EPA’s processes for timely, effective completion of the risk assessment and, the new chemicals review. This rulemaking also seeks to improve EPA’s existing practices related to the review of certain groups of chemical substances under Pre-Manufacture Notification (PMN) exemptions. EPA anticipates publishing a notice of proposed rulemaking in July 2023 and a final rule in November 2024.
- **Procedures for Chemical Risk Evaluation under TSCA (2070-AK90** – As required under section 6(b)(4) of the Toxic Substances Control Act (TSCA), EPA published a final rule on July 20, 2017, that established a process for conducting risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use. The Agency is now considering revisions to that final rule and will solicit public comment through a notice of proposed rulemaking. EPA anticipates publishing a notice of proposed rulemaking in May 2023.
- **Asbestos Part 1: Chrysotile Asbestos; Regulation of Certain Conditions of Use Under Section 6(a) of TSCA (2070-AK86)** - On April 12, 2022, EPA proposed a rule under the Toxic Substances Control Act (TSCA) to address the unreasonable risk of injury to health that EPA identified for conditions of use of chrysotile asbestos following completion of the TSCA Risk Evaluation for Asbestos, part 1: Chrysotile Asbestos. EPA proposed to prohibit manufacture (including import), processing, distribution in commerce and commercial use of chrysotile asbestos for chrysotile asbestos diaphragms for use in the chlor-alkali industry, chrysotile asbestos-containing sheet gaskets used in chemical production, chrysotile asbestos-containing brake blocks used in the oil industry, aftermarket automotive chrysotile asbestos-containing brakes/linings, other chrysotile asbestos-containing vehicle friction products, and other chrysotile asbestos-containing gaskets. EPA also proposed to prohibit manufacture (including import), processing, and distribution in commerce of aftermarket automotive chrysotile asbestos-containing brakes/linings for consumer use, and other chrysotile asbestos-containing gaskets for consumer use. Finally, EPA also proposed disposal and recordkeeping requirements for these conditions of use. EPA anticipates issuing a final rule.

This is a non-exhaustive list of EPA’s planned TSCA activities. More information is available at <https://www.reginfo.gov/public/do/eAgendaMain>

TSCA Compliance Guide & Online Service

www.TSCA.com

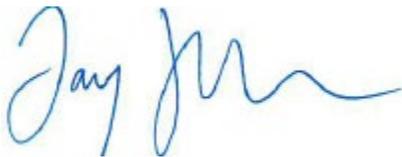
info@TSCA.com

“The World’s Leading Source of Up-to-Date TSCA Information”

- **Trichloroethylene Risk Determination Revision.** On January 9, 2023, EPA announced the availability of the finalized revision to the risk determination for trichloroethylene (TCE). This revision was developed in accordance with the Biden Administration’s pledge to revisit the first ten TSCA risk evaluations in light of the Administration’s updated priorities, including analyzing the risk evaluation for environmental justice concerns, scientific integrity, and not assuming, as the Trump administration did, that works will always wear personal protective equipment. The finalized revision makes a revised determination of unreasonable risk to human health or the environment for TCE as a whole chemical substance due to risks identified in 52 out of 54 conditions of use evaluated. EPA will now proceed to risk management to address the unreasonable risks posed by TCE. See 88 FR 1222.
- **PFAS SNUR.** On January 26, 2023, EPA announced a proposed significant new use rule (SNUR) for those PFAS that have not been manufactured or imported for many years and are thus designated “inactive” on the TSCA Inventory and not already subject to a SNUR. This SNUR would require persons subject to it to notify EPA at least 90 days before commencing any manufacturing, importing, or processing of the implicated PFAS for a significant new use. EPA estimates that approximately 300 PFAS are subject to this SNUR. See 88 FR 4937.

If there are any questions about these or any other environmental compliance matters, please feel free to contact us. We are here to assist you as part of your subscription.

Best regards,



Larry Silver

TSCA Compliance Guide & Online Service

www.TSCA.com

info@TSCA.com

“The World’s Leading Source of Up-to-Date TSCA Information”