



Dear Subscriber,

We are pleased to enclose the October 2021 Update for your 6-volume TSCA Compliance Guide and Online Service.™

This update contains:

- 1) **PIP (3:1) Extension.** On September 3, 2021, EPA announced it was extending the compliance deadline from March 8, 2021, to March 8, 2022, for the processing and distribution in commerce of certain articles containing PIP (3:1) and the PIP (3:1) used to make those articles. EPA also extended the record keeping requirements contained in those same regulations from March 8, 2021, to March 8, 2022. The updated language is reflected in 40 CFR 751.407 and on pages R19-20. *See* 86 FR 51823.
- 2) **Health and Safety Data Reporting Extension.** On October 1, 2021, EPA extended the deadline for manufacturers of 50 chemicals to submit to EPA certain unpublished health and safety studies. The original deadline was September 27, 2021. EPA has extended the deadline to December 1, 2021, for 20 chemicals designated as high-priority substances and January 25, 2022, for 30 organohalogen flame retardants. This amends the final rule published in June and was included in your July 2021 Update. The updated language is reflected in 40 CFR 716.120(d) and reflected on portions of pages E37-39. *See* 86 FR 54386.

Please also note these recent EPA activities:

- **Scientific Integrity.** EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) has recently been confronted with allegations regarding the scientific integrity of its operations. Four whistleblowers came forward and alleged that OCSPP has for several years downplayed or minimized the risks posed by new chemicals or otherwise inappropriately interfered with the risk assessments conducted pursuant to TSCA. Allegations include that political appointees of the Trump Administration pressured career EPA officials and scientists to downplay or remove evidence of potential harms to health and the environment. Allegations were also made that scientific findings and assessments were altered without the consent of the scientists who wrote them. On August 17, 2021, several members of Congress, in response to these allegations, requested information from EPA about its New Chemical Review Program and further requested a briefing from EPA on several specific topics. On October 14, 2021, EPA announced several measures to help restore scientific integrity to the chemical review process. First, OCSPP is creating the OCSPP Scientific Policy Council to provide advisory support on science policy and scientific integrity. Second, OCSPP is doing a top-down review of the New Chemicals Division's standard operating procedures in an effort to update and improve those procedures. Third,

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OCSPP has formed the New Chemicals Advisory Committee which will review the scientific and science policy issues of new chemical submissions under TSCA. Fourth, based on feedback from OCSPP staff, OCSPP is updating and improving its human health risk assessment process by increasing opportunities for the resolution of differing scientific opinions and inviting input from subject matter experts outside the New Chemicals Division. Lastly, OCSPP has improved and enhanced their internal recordkeeping requirements for decisions and differing scientific opinions.

- **Section 21 Petitions.** In August of 2021, a citizen filed TSCA Section 21 petitions, related to cigarettes and cosmetics, with the EPA. TSCA Section 21 permits any person to petition EPA to initiate rulemaking, amendment, or rescission proceedings. The petitions filed in August specifically pertain to cigarettes and cosmetics. As to the former, the petition requests that EPA determine that the chemicals within cigarettes represent an unreasonable risk of injury to health and the environment, order cigarette manufacturers to eliminate hazardous chemicals used in cigarettes, and mandate that cigarettes be redesigned to reduce or eliminate cigarette “butt” waste. Regarding cosmetics, the petition requests that EPA determine that chemical mixtures in cosmetics present an unreasonable risk to health and the environment, and that EPA order cosmetics manufacturers to remove hazardous chemicals used in their products. EPA is required to respond to the petitions within 90 days of receipt. More information can be obtained from <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-21#cigarettes>.
- **TSCA CBI ICR.** On August 12, 2021, EPA announced it has submitted notice of an Information Collection Request (ICR) renewal request to the Office of Management and Budget (OMB) regarding expanded access to TSCA Confidential Business Information (CBI). The 2016 Lautenberg Amendments expanded the categories of people to whom EPA may disclose information designated CBI under TSCA and this ICR is an extension of that authority. See 86 FR 44357.
- **EPA-Unilever Agreement.** On August 19, 2021, EPA announced it had formed an agreement with Unilever to develop new methods to assess the chemical risks associated with consumer products. The agreement, building on a similar prior agreement, will focus on developing New Approach Methods (NAMs) to take the place and reduce the use of testing on animals in chemical risk assessments. More information can be obtained from: <https://www.epa.gov/newsreleases/epa-and-unilever-announce-major-research-collaboration-advance-non-animal-approaches>.

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- **CDR Guidance.** On August 21, 2021, EPA announced the availability of draft Guidance for Preparing and Submitting a Petition under the Chemical Data Reporting (CDR) rule. The guidance specifically pertains to petitions for the full exemption of byproduct substances that are recycled or otherwise used within site-limited, physically enclosed systems (40 CFR 711.10(d)(1)) and petitions for partial exemptions of chemicals for which the CDR processing and use information has been determined to be of “low current interest” by EPA (40 CFR 711.6(b)(2)). Public comments are being accepted until December 21, 2021, on Docket ID No. EPA-HQ-OPPT-2018-0321. *See* 86 FR 47102.
- **Methylene Chloride ICR.** On August 31, 2021, EPA announced it has submitted notice of an Information Collection Request (ICR) renewal request to the Office of Management and Budget (OMB) titled “Methylene Chloride; Regulation of Paint and Coating Removal for Consumer Use Under TSCA Section 6(a)”. This ICR consists of the downstream notification requirement of Methylene Chloride prohibitions under 40 CFR part 751 and the applicable TSCA recordkeeping requirements. This ICR reflects a lower estimated respondent burden, based on submissions over during the course of the current ICR. *See* 86 FR 48700.
- **Access to CBI.** On August 31, 2021, EPA announced that contractors Eastern Research Group and PG Environmental have been authorized to access information submitted to EPA under TSCA, some of which may have been claimed as confidential business information (“CBI”) by reporting parties. *See* 86 FR 48696.
- **TSCA Inventory Update.** On August 31, 2021, EPA announced that the TSCA inventory had been updated. The TSCA Inventory is the comprehensive list of all chemicals manufactured, processed, or imported in the US. This update is part of EPA’s biannual update of the TSCA Inventory. The next scheduled update is in the Winter of 2022. More information can be found at <https://www.epa.gov/tscainventory>.
- **Final Scope Risk Evaluations.** On August 31, 2021, EPA announced the availability of the final scope risk evaluations for Di-isodecyl Phthalate (DIDP) and Di-isononyl Phthalate (DINP). These final documents contain the relevant factors EPA will consider when conducting risk evaluations, including conditions of use, hazards, and exposures. These final documents reflect the policy changes for risk evaluations EPA announced this past summer, as discussed in your July 2021 update letter. EPA will now proceed to conduct a risk evaluation for each chemical. *See* 86 FR 48693; 86 FR 48695.

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- **Five PBT Chemicals.** On September 3, 2021, EPA announced several actions related to the five Persistent Bioaccumulative Toxic (PBT) chemicals (2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP); decabromodiphenyl ether (decaBDE); hexachlorobutadiene (HCBD); pentachlorothiophenol (PCTP); and phenol, isopropylated phosphate (3:1) (PIP (3:1)) subject to recent risk assessments.
  - First, EPA announced that it is considering revising all five PBT rules. EPA anticipates issuing a proposal for new rules on all five PBT chemicals in the Spring of 2023. Until that time, the present rules will remain in effect, with the exception of the rule relating to PIP (3:1), discussed in more detail below.
  - Second, EPA extended certain compliance dates for PIP (3:1) for an additional 180 days to March 8, 2022. As referenced in prior TSCA Compliance Guide communications, EPA did not fully understand the extent to which PIP (3:1) was present in consumer products and did not anticipate, partially due to a lack of stakeholder input, the potential disruption to supply chains when it announced the final PIP (3:1) rule in January of 2021. EPA had previously issued a “No Action Assurance” for the PIP (3:1) rule in March of 2021 to alleviate stakeholder concerns and provide EPA with more time to study the problems associated with the rule. Based on industry feedback over the past six months, EPA will issue a final rule extending specified compliance dates for certain PIP (3:1) containing articles until March 8, 2022.<sup>1</sup> Additionally, EPA plans to issue a proposed rule to extend the compliance dates beyond March 8, 2022, to better align with stakeholder feedback.<sup>2</sup>
  - Third, updated rules for PIP (3:1) will still be a part of EPA’s 2023 new rulemaking. To help EPA fully understand PIP (3:1)’s place in supply chains, EPA will rely on industry to provide specific documentation “of the specific uses of PIP (3:1) in articles throughout their supply chains, documentation of concrete steps taken to identify, test, and qualify substitutes for those uses, documentation of specific certifications that would require updating and an estimate of the time that would be required.” This information will also be used to determine whether an additional extension to the PIP (3:1) compliance dates is necessary.
- **Draft Scope D4 Risk Evaluation.** On September 8, 2021, EPA announced the availability of a draft scope of the risk evaluation for Octamethylcyclotetra-Siloxane (D4). The risk evaluation was manufacturer requested and will determine whether the chemical substance represents an unreasonable risk to health or the environment under conditions of use. EPA will publish the final scope of the risk evaluation within three months of publishing the draft scope. See 86 FR 50347.

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<sup>1</sup> This final rule was published on September 3, 2021, as discussed herein.

<sup>2</sup> This proposed rule was published on October 28, 2021, as discussed herein.

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- **CDR ICR.** On September 21, 2021, EPA announced the proposed renewal of an Information Collection Request (ICR) sent to the Office of Management and Budget (OMB) for Chemical Data Reporting (CDR) under TSCA. This ICR reflects a higher estimated respondent burden, based on TSCA submissions over during the course of the current ICR. Public comments are due by November 22, 2021, on Docket ID No. EPA-HQ-OPPT-2013-0721. See 86 FR 52457.
- **Confidential Status Update.** On October 15, 2021, EPA announced updates to the confidential status of chemicals on the TSCA inventory. Of the 390 chemicals reviewed for the removal of confidential status, 13 were chemicals already available on the public portion of the TSCA inventory. The 377 remaining chemicals were all reported as non-confidential by at least one manufacturer during the previous three CDR reporting periods. All 390 chemicals were removed from the confidential inventory. A full list of the chemicals can be found at <https://www.epa.gov/tsca-cbi/updates-confidential-status-chemicals-tsca-inventory>.
- **PFAS Roadmap.** On October 18, 2021, EPA announced the release of the PFAS Strategic Roadmap and the PFAS National Testing Strategy. The Strategic Roadmap details EPA’s plans to regulate PFAS in the coming three years. Notable actions included in the Roadmap include reviewing past actions on PFAS under TSCA to address those which are insufficiently protective, designating PFAS a hazardous substance under CERCLA, and timelines to set PFAS drinking water standards. As to the Testing Strategy, EPA will require PFAS manufacturers to provide toxicity data and information. EPA will use its TSCA Section 4 authority to require manufacturers to conduct and fund studies pursuant to test orders. The first test orders should be issued by the end of 2021. For more information, please see [https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap\\_final-508.pdf](https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf); <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/national-pfas-testing-strategy>.
- **TSCA User Fees ICR.** On October 22, 2021, EPA announced it has submitted notice of an Information Collection Request (ICR) extension request to the Office of Management and Budget (OMB) for User Fees for the Administration of TSCA. The 2016 Lautenberg Amendments adjusted TSCA’s fee schedule as it relates to TSCA sections 4, 5, and 6, and permitted EPA to recover a portion of the administration costs of those TSCA sections. This ICR reflects a higher estimated respondent burden, based on TSCA submissions over the course of the current ICR. Public comments are accepted for 30 days from publication in the Federal Register on Docket ID No. EPA-HQ-OPPT-2020-0616. See 86 FR 58653.
- **Mercury ICR.** On October 22, 2021, EPA announced it has submitted notice of an Information Collection Request (ICR) extension request to the Office of Management and Budget (OMB) for TSCA Mercury Inventory Reporting. The 2016 Lautenberg Amendments required EPA to publish

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in the Federal Register an inventory of Mercury supply, use, and trade within the United States. 15 U.S.C. § 2601 *et seq.* EPA collects this information to help inform agency and legislative action to reduce mercury use in the United States. Public comments are accepted for 30 days from the publication of this notice on Docket ID No. EPA-HQ-OPPT-2020-0617. See 86 FR 58651.

- **PCB Extraction Methods.** On October 22, 2021, EPA announced proposed alternate PCB extraction methods and amendments to PCB cleanup and disposal regulations. EPA is proposing to expand the number of extraction and determinative methods used to characterize and verify the cleanup of PCB waste. The proposed changes aim to reduce the use of solvents in PCB extraction processes, as well as result in quicker and less costly cleanups. “EPA also proposes several other amendments to the PCB regulations, including the amendment of performance-based disposal option for PCB remediation waste; the removal of the provision allowing PCB bulk product waste to be disposed as roadbed material; the addition of more flexible provisions for cleanup and disposal of waste generated by spills that occur during emergency situations (e.g., hurricanes or floods); harmonizing the general disposal requirements for PCB remediation waste; and making other amendments to improve the implementation of the regulations, clarify ambiguity and correct technical errors.” Comments on the proposed changes are due by December 21, 2021, and can be made on Docket ID No. EPA-HQ-OLEM-2021-0556. See 86 FR 58730.
- **Adverse Reactions ICR.** On October 25, 2021, EPA announced it has submitted notice of an Information Collection Request (ICR) extension request to the Office of Management and Budget (OMB) for the ICR titled “Allegations of Significant Adverse Reactions to Human Health or the Environment”. Section 8(c) of TSCA requires companies that manufacture, distribute, or process chemicals to maintain records of any allegations that such chemicals cause significant adverse reactions to human health or the environment. EPA is authorized to request such information pursuant to 40 CFR 717. The EPA ICR number for this request is 1031.12 and the OMB Control Number for this request is 2070-0017. Public comments are accepted for 30 days from the publication of this notice on Docket ID No. EPA-HQ-OPPT-2015-0688. See 86 FR 58905.
- **OIG SNUR Evaluation.** On October 25, 2021, EPA published a memorandum revealing that the Office of the Inspector General (OIG) for the EPA will begin to evaluate whether the proper procedures and protocols were followed for changes made to the Significant New Use Rule (SNUR) for long-chain perfluoroalkyl carboxylate (LCPFAC) and perfluoroalkyl sulfonate chemical substances, published in July of 2020, between the EPA administrator signing of the final rule to the rules publication in the Federal Register. The evaluation is being undertaken pursuant to a congressional request.

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- **EPA Reviewer Nominations.** On October 27, 2021, EPA announced it was soliciting nominations of scientific experts to assist in reviewing the draft EPA TSCA Systemic Review Protocol, and the draft EPA TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities. Instructions for making nominations can be found in the Federal Register. See 86 FR 59382.
- **PIP (3:1) Proposed Rule.** On October 28, 2021, EPA published the proposed rule further extending the compliance deadlines for PIP (3:1). The Office of Management and Budget’s Office of Information and Regulatory Affairs completed its review of this proposed regulation on October 8, 2021, and EPA announced the planned publication of this rule on October 21, 2021. The proposed rule will extend “the compliance date applicable to the processing and distribution in commerce of certain PIP (3:1)- containing articles, and the PIP (3:1) used to make those articles until October 31, 2024, along with the associated recordkeeping requirements for manufacturers, processors, and distributors of PIP (3:1)-containing articles.” EPA also announced its intention to commence a new rulemaking for the five PBT chemicals and anticipates issuing a proposal at the end of 2023. See 86 FR 59684.

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

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