



Dear Subscriber,

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

This update contains:

- 1) **Health and Safety Data Reporting Update.** On June 29, 2021, EPA promulgated a final rule requiring manufacturers and importers of 50 specific chemical substances to report to EPA a specified list of unpublished health and safety studies. Of the 50 chemical substances, 20 were previously designated by EPA as High-Priority Substances and the other 30 are organohalogen flame retardants being evaluated for risks by the Consumer Product Safety Commission under the Federal Hazardous Substances Act. See 86 FR 34147. The updated language and regulations can be found beginning on page E9.

Please also note these recent EPA activities:

- **TSCA Section 21 Rulemaking Denial.** On May 21, 2021, EPA announced its reasons for denying a requested rulemaking under TSCA § 21. On February 8, 2021, multiple petitioners requested EPA initiate rulemaking proceedings and health and environment testing on phosphogypsum and process wastewater. EPA denied their requests and enumerated their reasons in the Federal Register. See 86 FR 27546.
- **Environmental Justice Consultations.** Throughout the summer of 2021, EPA has been engaging with stakeholders and environmental justice communities through environmental justice consultations (“consultations”) to inform EPA’s development of proposed risk management actions under TSCA § 6(a). EPA has thus far held consultations for N-methylpyrrolidone (NMP), trichloroethylene (TCE), and perchloroethylene (PCE). Given the Biden Administration’s focus on environmental justice issues, we can expect further consultations to occur over the next several years as more TSCA risk assessments are finished.
- **Methylene Chloride Risk Evaluation.** In May of 2021, as part of ongoing litigation surrounding EPA’s 2020 risk evaluation for Methylene Chloride, EPA requested the Ninth Circuit remand review of the risk evaluation but also leave in place the risk evaluation while the review was taking place. Environmental groups oppose remanding the review and argue that the remand should either be denied or have

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court-imposed conditions on EPA’s review process. The case is *Neighbors for Environmental Justice et al. v. Environmental Protection Agency et al.*, case number 20-72091.

- **Three New PFAS Actions.** On June 10, 2021, EPA announced three new actions on PFAS:
 - EPA is proposing a new rule that requires reporting on PFAS manufactured in the United States. The proposed rule, a statutory requirement under the FY2020 National Defense Authorization Act (NDAA), proposes to require all importers and manufacturers of PFAS since 2011 to report specific information to EPA. The proposed deadline for reporting PFAS data is one year from the final rule’s effective date. The proposed rule was published in the Federal Register on June 28, 2021. See 86 FR 33926. EPA has extended the public comment period through September 27, 2021, via docket EPA-HQ-OPPT-2020-0549. Notice of the extension has not been published in the Federal Register as of the date of this publication.
 - EPA has withdrawn a January 2021 compliance guide that weakened a July 2020 Significant New Use Rule (“SNUR”) which prohibited companies from importing “surface coating” long-chain PFAS without prior EPA approval. The withdrawn compliance guide, issued in the final days of the Trump administration, was seen by career EPA staff as unnecessary and a push by political appointees to create loopholes in regulations without public participation. To that end, the January 2021 compliance guide is no longer on EPA’s website and is no longer in effect. The July 2020 SNUR remains in effect and importers of articles, but not processors, are subject to its restrictions.
 - EPA issued a final rule officially incorporating the requirements of the FY2020 NDAA, which, because they are subject to a SNUR under TSCA, mandated three PFAS be added to the Toxic Release Inventory (“TRI”).¹ These changes are effective for TRI reporting year 2021, reporting forms for which are due by July 1, 2022.
- **Electronic Option for Export Notification.** On June 12, 2021, EPA announced the availability of an electronic option for submitting export notifications required under TSCA § 12(b). While hardcopies will still be accepted, EPA has begun accepting electronic copies through the Central Data Exchange and

¹ As this rule is related to the TRI and is not a TSCA rule, it is not included in this update. This information is included solely for reference. Should you have any questions regarding your obligations under the TRI, please reach out to the authors for more information.

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recommends parties submit the information electronically whenever possible. The electronic option is available as of the date of this publication. See 86 FR 31502.

- **Access to CBI.** On June 26, 2021, EPA announced that contractor Avanti Corp. has 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 34005.

- **CDR Lawsuits.** On June 29, 2021, non-governmental organization Center for Environmental Health filed a lawsuit accusing three companies of violating the chemical data reporting rule (“CDR”). The companies allegedly imported chemicals without appropriate CDR compliance. Plaintiff is requesting the court compel Defendants to file the proper CDR reports. A fourth company was also identified by Plaintiff as having violated the CDR but agreed with Plaintiff to audit its operations and come into compliance. The complaints were filed in the United States District Court for the District of Columbia. The cases, unconsolidated to date, are *Center for Environmental Health v. Harwick Standard Distribution Corporation*, Case No. 21-1723; *Center for Environmental Health v. 3N International, Inc.*, Case No. 21-1720; *Center for Environmental Health v. Braskem America, Inc.*, Case No. 21-1724.

- **Risk Evaluation Policy Updates.** On June 30, 2021, EPA announced policy changes surrounding risk evaluations conducted by the Trump administration and future risk evaluations conducted by the Biden administration:
 - The first policy change is to expand consideration of exposure pathways and create a fenceline community exposure screening-level approach. The first 10 risk evaluations conducted under the Trump administration did not assess multiple exposure pathways because they either were or could be regulated under other statutory authorities. EPA is reviewing the risk assessments for methylene chloride, trichloroethylene, carbon tetrachloride, perchloroethylene, NMP, and 1-bromopropane, to determine whether considering additional exposure pathways will show that the Trump administration’s methodology failed to identify and protect fenceline communities. To this end, EPA will develop a screening-level approach to conduct assessments of fenceline communities. These screening-levels and their application to risk assessments will be presented for public comment later in calendar year 2021.
 - The second policy change is to no longer assume that personal protective equipment (“PPE”) was provided to and appropriately used by workers. The Trump administration, when conducting

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risk evaluations, had generally assumed that workers were always provided and used PPE. EPA's position now is that such an assumption is not supported by the data. While the first evaluations included exposure analysis with and without PPE, rendering new analysis unnecessary, the shift in assumption could change the "no unreasonable risk" findings for some conditions of use. Chemicals potentially impacted are methylene chloride, 1-bromopropane, HBCD, NMP, perchloroethylene, and 1,4-dioxane.

- The third policy change is to begin issuing cumulative determinations of unreasonable risk. Under the Trump administration, there were several chemicals for which an unreasonable risk determination was made for every condition of use. While EPA will continue to analyze each individual condition of use, when it is clear that the majority of uses present an unreasonable risk, EPA will issue a single determination of unreasonable risk for the chemical per se. EPA will withdraw any orders in the first ten risk evaluations where all conditions of use were deemed to present an unreasonable risk and reissue "whole substance" unreasonable risk determinations. EPA will seek public comment on this new approach.
- **CBI Info Released in Litigation.** On July 1, 2021, EPA announced that pursuant to their discovery obligations in pending litigation, EPA was transferring to the Department of Justice ("DOJ") information that may have been claimed as CBI by reporting parties under TSCA. DOJ is, in turn, transferring that information to parties involved in the litigation *In Re: Aqueous Film-Forming Foams Products Liability Litigating* (MDL No. 2:18-mn-2873-RMG) (D.S.C.). The transfer of information is being done in accordance with applicable CBI regulations governing the disclosure of CBI during litigation. Documents containing CBI would be filed under seal and will not be made public unless both the information contained therein is not subject to protected status and all CBI has been redacted. See 86 FR 35087.
- **Risk Assessment Accusations.** On July 2, 2021, it was reported that four EPA scientists submitted a letter to the House Committee on Oversight and Reform's Subcommittee on Environment accusing EPA of improperly eliminating or reducing the risk calculations conducted during risk assessments. The scientists allege that this conduct has occurred during all three of the Obama, Trump, and Biden administrations. The scientists claim that internal attempts at EPA to have the problem addressed have proven unsuccessful.
- **Test Marketing Exemptions.** On July 3, 2021, EPA issued approvals and denials for test marketing exemptions for certain new chemicals. TSCA § 5(h)(1) permits EPA to exempt from premanufacture notice

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certain persons and allow the manufacture or import of certain new chemicals if EPA finds that the test marketing purposes will not result in an unreasonable risk of injury to health or the environment. Regulations governing TSCA § 5(h)(1) can be found at 40 CFR 720.38. The full list of denied and approved test marketing exemptions can be found in the Federal Register. See 86 FR 35499.

- **PIP (3:1) Downstream Notifications.** Downstream notifications under the final PIP (3:1) regulations, promulgated in January of 2021, 40 CFR 751.407, began on July 6, 2021. Under these regulations, “[e]ach person who processes or distributes in commerce PIP (3:1) or PIP (3:1)-containing products for any use after July 6, 2021 must, prior to or concurrent with the shipment, notify persons to whom PIP (3:1) is shipped, in writing, of the restrictions described in this subpart.” 40 CFR 751.407(e)(2). The regulations specify the means of notification acceptable. See 40 CFR 751.407(e)(3).
- **New TSCA SACC Members.** On July 13, 2021, EPA announced the appointment of nine new members to the Toxic Substances Control Act Science Advisory Committee on Chemicals (“TSCA SACC”). TSCA SACC is comprised of technical and scientific experts in fields directly relevant to risk assessments and evaluations, as well as general TSCA chemical regulation. TSCA SACC is the primary peer review mechanism for EPA’s Office of Chemical Safety and Pollution Prevention and provides EPA with independent scientific advice and recommendations to assist in the forming of final rules and regulations.
- **Tiered Data Reporting.** On July 14, 2021, EPA announced it was considering a data reporting rule that is tiered to specific stages of the TSCA existing chemicals program: prioritization, risk assessment, and risk management. Each stage requires targeted data for the specific analyses undergone during that stage, and EPA is considering adjusting the reporting requirements to reflect these needs. EPA is accepting comment on this rule concept on docket number EPA–HQ–OPPT–2021–0436. Written comments are due by August 15, 2021. See 86 FR 37152.
- **PFAS LVE Stewardship Program.** On July 14, 2021, EPA announced the formation of a stewardship program encouraging the voluntary withdrawal of previously granted low-volume exemptions (“LVE”) for PFAS. To participate in this program, companies currently holding LVEs for PFAS may choose to voluntarily withdraw the LVEs and certify that they will no longer import or manufacture PFAS. Companies may also choose to withdraw the LVEs following submission of the appropriate pre-manufacture notice. Companies

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choosing to participate in the stewardship program will be recognized on EPA's website. EPA previously announced in April of 2021 that it would be unlikely to grant any further LVEs for PFAS. Further information can be found at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/pfas-low-volume-exemption#What%20it%20Means>.

As a general reminder, EPA has a public list of chemicals it plans to review in the coming years. EPA published the TSCA Chemical Work Plan for Chemical Assessments: 2014 Update in October of 2014. This Work Plan contains the list of chemicals EPA has prioritized for risk evaluations in the coming years. It is prudent to review this list, understand if a chemical listed therein is central to your product line, and be prepared to closely follow the risk evaluation process for that chemical. As we have seen from EPA's handling of PIP (3:1) these past seven months, where EPA did not fully grasp the extent to which PIP (3:1) was included in commercial products (EPA's PIP (3:1) rule from January 2021 would have inadvertently prohibited the sale of numerous commercial products due to their containing PIP (3:1), had EPA not issued the No Action Assurance in March 2021), EPA actions may have a quick, substantial, and immediate impact on consumer products and industry.

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,

A handwritten signature in blue ink that reads "Larry Silver". The signature is fluid and cursive, with the first name "Larry" being more prominent than the last name "Silver".

Larry Silver

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