EPA's Spring 2022 Unified Agenda Includes Proposed and Final TSCA and TRI Rules

The U.S. Environmental Protection Agency's (EPA) spring 2022 Unified Agenda, published on June 21, 2022, includes the following rulemakings under the Toxic Substances Control Act (TSCA) or the Toxics Release Inventory (TRI).

Proposed Rule Stage

- Tiered Data Reporting to Inform Prioritization, Risk Evaluation, and Risk Management under TSCA (2070-AK62): EPA is developing a rulemaking under TSCA Sections 8(a) and (d) to establish reporting requirements based upon a chemical's status in the Risk Evaluation/Risk Management (RE/RM) Lifecycle and update the reporting requirements under the 40 C.F.R. Part 711 Chemical Data Reporting (CDR) regulation. Specifically, EPA is seeking occupational, environmental, and consumer exposure information. EPA is developing this rule to obtain information about potential hazards and exposure pathways related to certain chemicals, particularly occupational, environmental, and consumer exposure information. According to the Unified Agenda item, EPA needs this information to inform prioritization, risk evaluation, and risk management of chemical substances under TSCA Section 6. EPA intends to issue a notice of proposed rulemaking (NPRM) in May 2023 and a final rule in September 2024. More information on EPA's July 27, 2021, webinar on development of the proposed rule is available in our July 29, 2021, memorandum.
- Revisions to the TSCA Fees Rule (2070-AK64): In January 2021, EPA proposed updates and adjustments to the 2018 TSCA fees rule. EPA proposed modifications to the TSCA fees and fee categories for fiscal years (FY) 2022, 2023, and 2024 and explained the methodology by which the proposed TSCA fees were determined. EPA proposed to add three new fee categories: A Bona Fide Intent to Manufacture or Import Notice, a Notice of Commencement of Manufacture or Import, and an additional fee associated with test orders. In addition, EPA proposed exemptions for entities subject to certain fee-triggering activities, including an exemption for research and development (R&D) activities; an exemption for entities manufacturing less than 2,500 pounds of a chemical subject to an EPA-initiated risk evaluation fee; an exemption for manufacturers of chemical substances produced as a non-

isolated intermediate; and exemptions for manufacturers of a chemical substance subject to an EPA-initiated risk evaluation if the chemical substance is imported in an article, produced as a byproduct, or produced or imported as an impurity. EPA updated its cost estimates for administering TSCA, relevant information management activities, and individual fee calculation methodologies. EPA proposed a volume-based fee allocation for EPA-initiated risk evaluation fees in any scenario where a consortium is not formed and is proposing to require export-only manufacturers to pay fees for EPA-initiated risk evaluations. EPA also proposed various changes to the timing of certain activities required throughout the fee payment process. In light of public comments, EPA states that it has decided to issue a supplemental NPRM in October 2022 and seek additional public comment on changes to the January 2021 proposal. More information on the proposed rule is available in our December 30, 2020, memorandum.

- New Chemicals Procedural Regulations to Reflect the 2016 Amendments to TSCA (2070-AK65): On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act) was signed into law, amending TSCA and impacting how EPA reviews and makes determinations on new chemical notices under TSCA Section 5. EPA states that as a result of these increased responsibilities, it has become more challenging to complete reviews within 90 days. This rulemaking seeks to revise the new chemicals procedural regulations in 40 C.F.R. Part 720 to improve the efficiency of EPA's review process and to align its processes and procedures with the new statutory requirements. This rulemaking seeks to increase the quality of information initially submitted in new chemicals 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 intends to publish an NPRM in February 2023.
- Confidential Business Information (CBI) Claims under TSCA (2070-AK68): EPA is considering proposing new and amended rules concerning the assertion and maintenance of claims of CBI under TSCA. Amendments to TSCA in 2016 included several new provisions concerning the assertion and EPA review and treatment of confidentiality claims. EPA states that it is considering 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 proposed rule should also elaborate on EPA's procedures for reviewing and communicating with TSCA submitters about confidentiality claims. EPA expects the proposed rule to include new provisions, as well as revisions to existing rules on asserting confidentiality claims to conform to the 2016 amendments to TSCA. As reported in our May 17 and May 18, 2022, memoranda, EPA issued a proposed rule on May 12, 2022. EPA intends to issue a final rule in May 2023.
- Chemical-Specific Rulemakings under TSCA Section 6(a): TSCA Section 6 requires EPA
 to address unreasonable risks of injury to health or the environment that the Administrator has
 determined are presented by a chemical substance under the conditions of use. Following
 risk evaluations for the following chemicals carried out under the authority of TSCA Section 6,
 EPA initiated rulemakings to address unreasonable risks of injury to health identified in the
 final risk evaluations:
 - Methylene Chloride (2070-AK70): EPA's risk evaluation for methylene chloride, describing the conditions of use and presenting EPA's determinations of unreasonable risk, is in docket EPA-HQ-OPPT-2019-0437, with additional information

in docket EPA-HQ-OPPT-2016-0742. EPA intends to issue an NPRM in February 2023 and a final rule in August 2024. More information on EPA's draft revision to its risk determination for methylene chloride will be available in a <u>forthcoming</u> memorandum;

- 1-Bromopropane (<u>2070-AK73</u>): EPA's risk evaluation for 1-bromopropane, describing the conditions of use and presenting EPA's determinations of unreasonable risk, is in docket EPA-HQ-OPPT-2019-0235, with additional information in docket EPA-HQ-OPPT-2016-0741. EPA intends to publish an NPRM in May 2023 and a final rule in August 2024;
- Carbon Tetrachloride (2070-AK82): EPA's risk evaluation, describing the conditions of use and presenting EPA's determinations of unreasonable risk, is in docket EPA-HQ-OPPT-2019-0499, with additional information in docket EPA-HQ-OPPT-2016-0733. EPA intends to publish an NPRM in April 2023 and a final rule in August 2024;
- Trichloroethylene (TCE) (2070-AK83): EPA's risk evaluation for TCE, describing the conditions of use and presenting EPA's determinations of unreasonable risk, is in docket EPA-HQ-OPPT-2019-0500, with additional information in docket EPA-HQ-OPPT-2016-0737. EPA intends to publish an NPRM in March 2023 and a final rule in August 2024. More information on EPA's draft revision to its risk determination for TCE will be available in a forthcoming memorandum;
- Perchloroethylene (PCE) (2070-AK84): EPA's risk evaluation for PCE, describing
 the conditions of use and presenting EPA's determinations of unreasonable risk, is in
 docket EPA-HQ-OPPT-2019-0502, with additional information in docket EPA-HQOPPT-2016-0732. EPA intends to publish an NPRM in February 2023 and a final rule
 in August 2024. More information on EPA's draft revision to its risk determination for
 PCE will be available in a forthcoming memorandum;
- N-Methylpyrrolidone (NMP) (2070-AK85): EPA's risk evaluation for NMP, describing
 the conditions of use and presenting EPA's determinations of unreasonable risk, is in
 docket EPA-HQ-OPPT-2019-0236, with additional information in docket EPA-HQOPPT-2016-0743. EPA intends to publish an NPRM in May 2023 and a final rule
 in August 2024. More information on EPA's draft revision to its risk determination for
 NMP will be available in a forthcoming memorandum; and
- Asbestos (Part 1: Chrysotile Asbestos) (2070-AK86): EPA's risk evaluation for chrysotile asbestos, describing the conditions of use and presenting EPA's determinations of unreasonable risk, is in docket EPA-HQ-OPPT-2019-0501, with additional information in docket EPA-HQ-OPPT-2016-0736. More information on EPA's proposed rule to prohibit ongoing uses of chrysotile asbestos is available in our April 7, 2022, memorandum. EPA intends to publish a final rule in November 2023.
- Procedures for Chemical Risk Evaluation under TSCA (2070-AK90): As required under TSCA Section 6(b)(4), 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. This process incorporates the science requirements of the amended statute, including best available science and weight of the scientific evidence. The final rule established the steps of a risk evaluation process, including: scope, hazard assessment, exposure assessment, risk characterization, and risk determination. EPA states that it is now considering revisions to that final rule and will solicit public comment through an NPRM. EPA intends to publish the NPRM in September 2022. More information on EPA's 2017 rule is available in our June 26, 2017, memorandum.

- Asbestos; Reporting and Recordkeeping Requirements under TSCA (2070-AK99): This rulemaking, under the authority of TSCA Section 8(a), would require certain persons that manufactured (including imported) or processed asbestos and asbestos-containing articles (including as an impurity) to report certain exposure-related information, including quantities of asbestos and asbestos-containing articles manufactured (including imported) or processed, types of asbestos used, and employee data. Reported information would be used by EPA and other federal agencies in considering the regulation of asbestos. EPA notes that this rulemaking is the result of a settlement agreement stemming from litigation pursuant to TSCA Section 21. See Asbestos Disease Awareness Organization v. EPA, No. 19-CV-00871; State of California et al. v. EPA, No. 19-CV-03807. More information on EPA's proposed reporting and recordkeeping requirements is available in our May 6, 2022, memorandum. EPA intends to publish a final rule in November 2022.
- Other Chemical Substances Undergoing TSCA Section 6 Risk Evaluation; Significant New Use Rule (SNUR) for Certain Non-Ongoing Uses (2070-AL05): EPA is developing TSCA Section 5(a)(2) SNURs on conditions of use identified as not currently ongoing in the final scope documents for the high-priority substances undergoing TSCA Section 6 risk evaluations. EPA states that it will use the SNURs to require notice to EPA before chemical substances and mixtures are used in new ways that might create concerns. Persons subject to a SNUR who intend to manufacture (including import) or process the chemical substance for the significant new use must notify EPA at least 90 days prior to initiating activities via a significant new use notice (SNUN). EPA intends to publish an NPRM in December 2022 and a final rule in May 2024.
- The Unified Agenda includes the following chemical-specific SNURs for certain non-ongoing uses:
 - Phthalates; SNUR for Certain Non-Ongoing Uses (2070-AL06): EPA intends to publish an NPRM in November 2022 and a final rule in May 2024;
 - Flame Retardants; SNUR for Certain Non-Ongoing Uses (<u>2070-AL07</u>): EPA intends to publish an NPRM in December 2022 and a final rule in November 2023; and
 - Certain Solvents; SNUR for Certain Non-Ongoing Uses (2070-AL08): EPA intends to publish an NPRM in December 2022 and a final rule in May 2024.
- Inactive Inventory Per- and Polyfluoroalkyl Substances (PFAS) SNUR (2070-AL10): EPA is developing a SNUR under TSCA Section 5(a)(2) for certain uses of Inactive Inventory PFAS. Persons subject to the Inactive Inventory PFAS SNUR would be required to notify EPA at least 90 days before commencing manufacture or processing for any use that EPA has determined is a significant new use. The required notifications would initiate EPA's evaluation

of the intended use within the applicable review period. Manufacture and processing for the significant new use would be unable to commence until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination. EPA intends to publish an NPRM in September 2022 and a final rule in June 2023.

- TRI; Response to Petition to Add Diisononyl Phthalate (DINP) to the TRI List of Toxic Chemicals (2025-AA17): According to EPA, this action arises from a petition received by EPA to add DINP to the list of toxic chemicals reportable under Section 313 of the Emergency Planning and Community Right to Know Act (EPCRA). In response to the petition, EPA initiated a rulemaking on September 5, 2000, proposing to add DINP to the TRI list. On June 14, 2005, EPA issued a notice of data availability seeking comments on EPA's revised hazard assessment for DINP in further support of EPA's proposal to add DINP to the TRI list. EPA states that the addition of DINP to the TRI list would make it subject to all the reporting requirements under the Toxic Chemical Release Reporting Rule. EPA intends to publish a supplemental NPRM in July 2022 and a final rule in May 2023;
- Changes to Reporting Requirements for PFAS; Community Right-to-Know Toxic Chemical Release Reporting (2070-AK97): EPA is developing a proposal to add PFAS subject to reporting under EPCRA Section 313 and Section 6607 of the Pollution Prevention Act (PPA) to the list of Lower Thresholds for Chemicals of Special Concern (Chemicals of Special Concern). EPA states that the addition of the PFAS to the Chemicals of Special Concern list will eliminate the use of the de minimis exemption, eliminate the option to use Form A, and limit the use of range reporting. In addition, EPA is proposing to eliminate the use of the de minimis exemption under the Supplier Notification Requirements for facilities that manufacture or process all chemicals included on the Chemicals of Special Concern list. According to EPA, Chemicals of Special Concern may be found in products below de minimis levels; this is especially true for PFAS that are used at low concentrations in many products. Because of the widespread use of PFAS and their (or their degradants) persistence in the environment, however, even concentrations below de minimis levels can contribute significantly to environmental loading. The elimination of the de minimis exemption for supplier notification purposes will help facilities to identify potential sources of PFAS and other Chemicals of Special Concern. EPA believes that the elimination of the de minimis exemption under the Supplier Notification Requirements for PFAS and other Chemicals of Special Concern will result in a more complete picture of the releases and waste management quantities for these chemicals. EPA intends to publish an NPRM in September 2022 and a final rule in November 2023.
- Addition of Certain PFAS to the TRI (2070-AL03): EPA is developing a rulemaking to add certain PFAS to the list of chemicals reportable under EPCRA Section 313. EPA states that the addition of these PFAS is in direct response to a statutory mandate under Section 7321(d) of the National Defense Authorization Act for Fiscal Year 2020 (NDAA). Under Section 7321(d), EPA was required to evaluate whether certain specific PFAS meet the EPCRA Section 313 listing criteria by December 2021 and is required to add any PFAS that EPA determines meet the listing criteria by December 2023. EPA intends to publish an NPRM in February 2023 and a final rule in November 2023.
- Community Right-to-Know; Adopting 2022 North American Industry Classification
 System (NAICS) Codes for TRI Reporting (2070-AL09): EPA is developing a proposed rule to incorporate the revised 2022 North American Industry Classification System (NAICS)

codes for TRI reporting purposes. According to EPA, the Office of Management and Budget (OMB) updates the NAICS codes every five years. OMB approved the 2022 NAICS codes on December 21, 2021 (86 Fed. Reg. 72277), with an effective date of January 1, 2022. EPA currently uses 2017 NAICS codes, and with this proposed rule would implement the 2022 codes for TRI Reporting Year 2022. Facilities reporting to the TRI would be required to use 2022 NAICS codes on reports that are due to EPA by July 1, 2023. This rule also proposed to update the C.F.R. to clarify the scope of facilities required to report to the TRI. According to EPA, the actual data required by a TRI form would not change as a result of this rulemaking, nor would the rule affect the universe of TRI reporting facilities that are required to submit reports to EPA under EPCRA Section 313. EPA intended to publish an NPRM in June 2022 and a final rule in November 2022.

Final Rule Stage

- Significant New Uses of Chemical Substances; Updates to the Hazard Communication Program and Regulatory Framework; Minor Amendments to Reporting Requirements for Premanufacture Notices (PMN) (2070-AJ94): In 2016, EPA proposed changes to the existing regulations governing significant new uses of chemical substances under TSCA (40 C.F.R. Part 721, specifically "Protection in the Workplace" (40 C.F.R. Section 721.63) and "Hazard Communication Program" (40 C.F.R. Section 721.72)) to align these regulations with revisions to the Occupational Safety and Health Administration's (OSHA) Hazard Communications Standard (HCS) (29 C.F.R. Section 1910.1200), which are proposed to be cross referenced, and with changes to the OSHA Respiratory Protection Standard and the National Institute for Occupational Safety and Health (NIOSH) respirator certification requirements pertaining to respiratory protection of workers from exposure to chemicals. EPA also proposed changes to the significant new uses of chemical substance regulations based on issues that have been identified by EPA and issues raised by public commenters for SNURs previously proposed and issued under these regulations. Additionally, EPA proposed a minor change to reporting requirements for PMNs and other TSCA Section 5 notices. EPA states that it expects these changes to have minimal impacts on the costs and burdens of complying, while updating the significant new use reporting requirements to assist in addressing any potential effects to human health and the environment. EPA is reviewing the comments received and is planning to issue a final rule. EPA intends to issue a final rule in October 2022. More information on the proposed rule is available in our July 29, 2016, memorandum.
- Reporting and Recordkeeping for PFAS under TSCA Section 8(a)(7) (2070-AK67): EPA published a proposed rule on June 28, 2021, addressing reporting and recordkeeping requirements for PFAS under TSCA Section 8(a)(7). In accordance with obligations under TSCA Section 8(a), as amended by NDAA Section 7351, persons that manufacture (including import) or have manufactured these chemical substances in any year since January 1, 2011, would be subject to the reporting and recordkeeping requirements. In addition to fulfilling statutory obligations under TSCA, EPA states that it expects that the proposed rule would enable it to characterize better the sources and quantities of manufactured PFAS in the United States. EPA intends to publish a final rule in December 2022. More information on EPA's proposed rule is available in our June 11, 2021, memorandum.
- TRI; Response to Petition from the Toxics Use Reduction Institute (TURI) to Add 25 Chemicals (2070-AK26): The Toxics Use Reduction Institute (TURI) submitted a petition

under EPCRA Section 313(e)(1) to add 25 chemicals to the EPCRA Section 313 list of toxic chemicals subject to reporting under the TRI. Three of the 25 chemicals were added to the EPCRA Section 313 list through actions unrelated to the petition. EPA states that it evaluated the remaining 22 chemicals to determine if they met the listing criteria of EPCRA Section 313(d)(2). EPA proposed the addition of 12 of the 22 chemicals that were determined to meet the EPCRA Section 313(d)(2) criteria and for which reports were expected to be filed. EPA is reviewing the comments received and is planning to issue a final rule. EPA intends to issue a final rule in November 2022.

- Parent Company Definition for TRI Reporting (2070-AK42): In 2021, EPA proposed to codify the definition of "parent company" for purposes of reporting to the TRI. Although the existing regulation requires facilities reporting to the TRI to identify their parent company in annual reporting forms, no codified definition of this data element exists. Among the facilities reporting to the TRI are those with complicated corporate ownership structures. As such, effort is required each year by reporting facilities and EPA to clarify how the parent company data element should be represented on the form. According to EPA, a codified definition of parent company would allow EPA to address various corporate ownership scenarios explicitly and reduce the reporting burden caused by regulatory uncertainty. EPA states that the proposed rule would clarify existing regulations to reporting facilities and add a foreign parent company data element, if applicable, while improving EPA's data quality. EPA is reviewing the comments received and is determining next steps. EPA intends to publish a final rule in October 2022.
- NDAA Mandated Addition of Certain PFAS to the TRI for Reporting Year 2022 (2070-AL04): According to EPA, NDAA Section 7321 provides a framework for PFAS to be added automatically to the TRI list on January 1 of the year following certain EPA actions. In December 2021, EPA announced the statutory addition of the PFAS chemicals covered by the NDAA to the list of chemical substances subject to reporting for the TRI. This regulatory action amends the EPCRA regulations in 40 C.F.R. Part 372 to reflect this statutory addition. EPA intended to publish a final rule in June 2022.

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