

## Recent Federal Developments in Chemical Law January 2023

Article By:

Government Regulation

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### TSCA/FIFRA/TRI

***EPA Announces Removal Of PFAS Chemicals From Approved Inert Ingredient List For Pesticide Products:*** On December 14, 2022, EPA announced the removal of 12 chemicals from the [current list of non-food inert ingredients](#) approved for use in pesticide products because the inert ingredients have been identified as per- and polyfluoroalkyl substances (PFAS) and are no longer used in any registered pesticide product. [87 Fed. Reg. 76488](#). On September 13, 2022, EPA [published a proposal](#) to remove the 12 chemicals from the list of approved inert ingredients. In response to EPA's request for comments, no specific information regarding those 12 chemical substances or any products that may include them was provided to EPA. For more information, please read our December 27, 2022, [blog item](#).

***EPA Announces Updates To New Chemicals Review Program Web Page:*** On December 15, 2022, EPA [announced](#) a redesign and updates to the [statistics web page](#) for the New Chemicals Review Program. According to EPA, the update includes additional information and metrics on the Agency's review of new chemicals under TSCA, increasing transparency for the public, the regulated community, and other stakeholders. EPA will update the data displayed on the enhanced web page monthly. The web page provides More Detailed Breakdown of New Chemical Submissions; Status Tracker for New Chemical Exemptions; and Information on the New Chemicals Review Process. More information is available in our December 16, 2022, [blog item](#).

***EPA Requests Nominations For Ad Hoc Reviewers To Assist SACC In Reviewing Phthalate Documents, Will Hold Meeting In May 2023:*** On December 21, 2022, EPA announced that it seeks public nominations of scientific and technical experts whom EPA can consider for service as *ad hoc* reviewers assisting the Science Advisory Committee on Chemicals (SACC) with the peer review of two draft documents entitled "Draft Proposed Principles of Cumulative Risk Assessment Under the Toxic Substances Control Act" and "Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer Requested Phthalate Under the Toxic Substance Control Act." [87 Fed. Reg. 78103](#). EPA states that it will submit the two draft documents to SACC and release them for public review and comment in **late February 2023**. Nominations are due **January 20, 2023**. The public virtual meeting will be held **May 8 to 11, 2023, from 10:00 a.m. to approximately 5:30 p.m. (EDT)**.

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***EPA Finds Carbon Tetrachloride, As A Whole Chemical Substance, Poses An Unreasonable Risk To Human Health:*** EPA announced on December 27, 2022, the availability of the final revision to the risk determination for the carbon tetrachloride risk evaluation issued under TSCA. [87 Fed. Reg. 79303](#). EPA determined that carbon tetrachloride, as a whole chemical substance, presents an unreasonable risk of injury to human health when evaluated under its conditions of use (COU). EPA states that the revision to the risk determination reflects its announced policy changes to ensure the public is protected from unreasonable risks from chemicals in a way that is supported by science and the law. For more information, please read our December 28, 2022, [memorandum](#).

***Nonprofit Organizations File Suit Claiming That Plastic Containers Treated With Fluorine Gas Leach PFAS In Violation Of EPA Regulations:*** On December 27, 2022, the Center for Environmental Health (CEH) and Public Employees for Environmental Responsibility (PEER) filed a lawsuit in the U.S. District Court for the District of Columbia to prevent Inhance Technologies USA from generating PFAS when fluorinating plastic containers. According to CEH and PEER's joint [press release](#), testing conducted by EPA, Notre Dame researchers, and other organizations "has found PFAS chemicals on the inner and outer surfaces of fluorinated containers and in the contents of the containers. The PFAS in the containers are likely formed as a result of chemical reactions that occur during the fluorination process conducted by Inhance." According to the press release, Inhance "conducts fluorination operations at several facilities in the U.S. and is the leading supplier of post-mold fluorination services" in the United States. The press release notes that in 2020, EPA issued a significant new use rule (SNUR) under TSCA barring firms from producing perfluorooctanoic acid (PFOA) and certain other PFAS until EPA had been notified and determined whether the proposed uses of these PFAS might present an unreasonable risk to health. The press release states that "[i?]n this event, the law required EPA to ban or restrict the PFAS for these uses." According to the lawsuit, Inhance did not notify EPA in 2020 and has been subsequently manufacturing PFOA and other PFAS in violation of TSCA. CEH and PEER seek a court order restraining Inhance from continued manufacture of PFAS in violation of the SNUR, "requiring it to stop all distribution of fluorinated containers in commerce until and unless TSCA requirements are met and directing it to inform purchasers and users of these containers of the dangers of exposure to PFOA and other PFAS." More information is available in our January 6, 2023, [blog item](#).

***EPA OIG Renders "Qualified" Opinion On FYs 2020 And 2019 TSCA Service Fee Fund Financial Statements:*** On December 29, 2022, the EPA Office of Inspector General (OIG) published a report entitled [The EPA's Fiscal Years 2020 and 2019 Toxic Substances Control Act Service Fee Fund Financial Statements](#). OIG rendered a "qualified opinion" on EPA's fiscal years (FY) 2020 and 2019 TSCA Service Fee Fund financial statements, "meaning that, except for material errors in expenses and income from other appropriations, the fiscal years 2020 and 2019 financial statements were fairly presented." OIG notes one material weakness, stating that "EPA materially understated the fiscal year 2019 'Expenses from Other Appropriations' line item of the financial statements by nearly \$25 million." OIG did not identify any instances of noncompliance that would result in a material misstatement to the audited financial statements. More information is available in our December 30, 2022, [blog item](#).

***EPA Reopens Dockets For 20 High-Priority Substances:*** On January 3, 2023, EPA authorized reopening dockets for [20 chemicals](#) characterized in December 2019 as high-priority substances for risk evaluation. According to [EPA's memorandum](#), EPA is re-opening the dockets to receive additional information from the public. EPA states that it will use these data, and other information as appropriate, to inform the risk evaluation processes for these chemicals. Information should be submitted by **July 3, 2023**, since the dockets will close on this date.

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**EPA Announces Next Test Order Issued Under National Testing Strategy For PFAS Used In Plastics, Chemical Manufacturing:** EPA [announced](#) on January 4, 2023, that it issued the next TSCA test order requiring testing on PFAS under its the [National PFAS Testing Strategy](#). The test order requires companies to conduct and submit testing on trifluoro(trifluoromethyl)oxirane (HFPO), a perfluoroalkyl substance used in making plastics. EPA states that this is “the second test order under the strategy and the latest action taken under EPA’s PFAS Strategic Roadmap to confront contamination from forever chemicals nationwide.” According to the press release, EPA will use the information received under the order to improve its understanding of human health effects of HFPO, as well as “the effects of dozens of PFAS that are structurally similar to HFPO and in the same Testing Strategy category of PFAS, improving the agency’s overall data on PFAS.” More information will be available in our [forthcoming memorandum](#).

**EPA’s Fall 2022 Unified Agenda Includes Proposed And Final TSCA And TRI Rules:** EPA’s fall 2022 Unified Agenda, published on January 4, 2023, includes a number of proposed and final rulemakings under TSCA or the Toxics Release Inventory (TRI). More information on the rulemakings, including links to our memoranda, is available in our January 17, 2023, [blog item](#).

**EPA Announces Release Of New PFAS Analytic Tools, Holds Webinar On January 10:** On January 5, 2023, EPA [announced](#) the release of a new interactive web page on the “PFAS Analytic Tools” that provides information about PFAS across the country. EPA states that this information will help the public, researchers, and other stakeholders better understand potential PFAS sources in their communities. According to EPA, the PFAS Analytic Tools draw from multiple national databases and reports to consolidate information on one web page. The PFAS Analytic Tools include information on Clean Water Act (CWA) PFAS discharges from permitted sources; reported spills containing PFAS constituents; facilities historically manufacturing or importing PFAS; federally owned locations where PFAS are being investigated; transfers of PFAS-containing waste; PFAS detection in natural resources, such as fish or surface water; and drinking water testing results. EPA held a webinar to demonstrate the tools on **January 10, 2023**. More information is available in our January 9, 2023, [blog item](#).

**EPA Opens Registration For January 18, 2023, Webinar On Reducing Vertebrate Animal Testing:** EPA [announced](#) on January 5, 2023, that [registration](#) is open for a **January 18, 2023**, webinar on reducing vertebrate animal testing using NAMs. EPA is partnering with the People for the Ethical Treatment of Animals (PETA) Science Consortium International and Physicians Committee for Responsible Medicine (PCRM) to host public webinars on various topics related to reducing, refining, or replacing vertebrate animal testing. The **January 18, 2023**, webinar, “Frameworks for Establishing Scientific Confidence in New Approach Methodologies: Part 2,” is also part of PCRM’s NAM Use for Regulatory Application DyNAMic Discussions [webinar series](#).

**EPA Announces Automatic Addition Of Nine PFAS To TRI List:** On January 6, 2023, EPA [announced](#) the automatic addition of nine PFAS to the TRI list. EPA states that these PFAS were added to the TRI list pursuant to the Fiscal Year 2020 National Defense Authorization Act (NDAA), which provides the framework for the automatic addition of PFAS to TRI each year in response to certain EPA activities involving such PFAS. For TRI Reporting Year 2023 (reporting forms due by **July 1, 2024**), reporting is required for nine additional PFAS, bringing the total PFAS subject to TRI reporting to 189. Because they are no longer confidential, pursuant to the NDAA, the following four chemicals were added to the TRI list:

- Alcohols, C8-16, ?-?-perfluoro, reaction products with 1,6-diisocyanatohexane, glycidol and stearyl alc. (2728655-42-1);

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- Acetamide, N-[3-(dimethylamino)propyl]-, 2-[(?/?-perfluoro-C4-20-alkyl)thio] derivs. (2738952-61-7);
  - Acetic acid, 2-[(?/?-perfluoro-C4-20-alkyl)thio] derivs., 2-hydroxypropyl esters (2744262-09-5); and
  - Acetamide, N-(2-aminoethyl)-, 2-[(?/?-perfluoro-C4-20-alkyl)thio] derivs., polymers with N1,N1-dimethyl-1,3-propanediamine, epichlorohydrin and ethylenediamine, oxidized (2742694-36-4).

The 2020 NDAA includes a provision that automatically adds PFAS to the TRI list upon EPA's development of a final toxicity value. In December 2022, EPA adopted a final toxicity value for perfluorobutanoic acid (PFBA), its anion, and its related salts. Pursuant to the NDAA, the following five chemicals have been added to the TRI:

- PFBA (375-22-4);
- Perfluorobutanoate (45048-62-2);
- Ammonium perfluorobutanoate (10495-86-0);
- Potassium perfluorobutanoate (2966-54-3); and
- Sodium perfluorobutanoate (2218-54-4).

As of January 1, 2023, facilities that are subject to reporting requirements for these chemicals should start tracking their activities involving these PFAS as required by Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA). EPA notes that it proposed a rule in December 2022 to enhance PFAS reporting to TRI by eliminating an exemption that allows facilities to avoid reporting information on PFAS when those chemicals are used in *de minimis* concentrations. EPA states that because PFAS are used at low concentrations in many products, the rule would ensure that covered industry sectors and federal facilities that make or use TRI-listed PFAS will no longer be able to rely on the *de minimis* exemption to avoid disclosing their PFAS releases and other waste management quantities for these chemicals.

***Deadline For Filing Annual Pesticide Production Reports -- March 1, 2023:*** The **March 1, 2023**, deadline for all establishments, foreign and domestic, that produce pesticides, devices, or active ingredients to file their annual production for the 2022 reporting year is fast approaching. Pursuant to Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 7(c)(1) (7 U.S.C. § 136e(c)(1)), “Any producer operating an establishment registered under [Section 7] shall inform the Administrator within 30 days after it is registered of the types and amounts of pesticides and, if applicable, active ingredients used in producing pesticides” and this information “shall be kept current and submitted to the Administrator annually as required.”

Reports must be submitted on or before March 1 annually for the prior year's production. The report, filed through the submittal of EPA Form 3540-16: Pesticide Report for Pesticide-Producing and Device-Producing Establishments, must include the name and address of the producing establishment; and pesticide production information, such as product registration number, product

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name, and amounts produced and distributed. The annual report is always required, even when no products are produced or distributed.

EPA has created the electronic reporting system to submit pesticide-producing establishment reports using the Section Seven Tracking System (SSTS). Users will be able to use SSTS within EPA's Central Data Exchange (CDX) to submit annual pesticide production reports. Electronic reporting is efficient, saves time by making the process faster, and saves money in mailing costs and/or courier delivery and related logistics. EPA is encouraging all reporters to submit electronically to ensure proper submission and a timely review of the report.

Links to EPA Form 3540-16, as well as instructions on how to report and how to add and use EPA's SSTS electronic filing system, are available below.

- [EPA Form 3540-16: Pesticide Report for Pesticide-Producing and Device-Producing Establishments](#);
- [Instructions for Completing EPA Form 3540-16 \(available within the ZIP file\)](#); and
- [Electronic Reporting for Pesticide Establishments](#).

Further information is available on [EPA's website](#).

***EPA Finds TCE, As A Whole Chemical Substance, Poses An Unreasonable Risk To Human Health:*** EPA announced on January 9, 2023, the availability of the final revision to the risk determination for trichloroethylene (TCE) risk evaluation issued under TSCA. [88 Fed. Reg. 1222](#). EPA determined that TCE, as a whole chemical substance, presents an unreasonable risk of injury to human health when evaluated under its COUs. EPA states that the revision to the risk determination reflects its announced policy changes to ensure the public is protected from unreasonable risks from chemicals in a way that is supported by science and the law. More information will be available in a [forthcoming memorandum](#).

***EPA Opens Registration For ECOTOX Knowledgebase Encore Training Being Held February 7:*** EPA has opened registration for the second ECOTOXicology Knowledgebase (ECOTOX) virtual training on **February 7, 2023**. ECOTOX is a comprehensive, publicly available tool providing environmental toxicity data on aquatic life, terrestrial plants, and wildlife. According to EPA, the virtual training will be a live encore of the training offered in May 2022, presenting the same material and featuring expanded opportunity for live interaction in Session 2. Participants may register for one or both sessions; registration is free but required to attend each session.

#### [Session 1 \(Presentation and Questions and Answers \(Q&A\)\)](#)

11:00 a.m.-12:30 p.m. (EST)

This session will provide an overview of the knowledgebase content and function with opportunities for participation and Q&A.

#### [Session 2 \(Breakout Sessions\)](#)

12:30-1:30 p.m. (EST)

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This session will break participants into breakout groups to work on case study exercises in small groups, aided by facilitators.

### ***EPA Adds Nine Chemicals And Removes One PFAS From Safer Chemical Ingredients***

**List:** EPA announced on January 12, 2023, that it is updating the [Safer Chemical Ingredients List](#) (SCIL) by adding nine chemicals and changing the status for one chemical (1-octanesulfonic acid, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-) that has recently been identified as a PFAS. According to EPA, the chemical is not used in any Safer Choice-certified products. EPA updated the SCIL listing for this chemical to a grey square because of a growing understanding of the toxicological profiles for certain PFAS and incomplete information on the potential health and environmental effects of these substances. A grey square notation means that the chemical may not be allowed for use in products that are candidates for the Safer Choice label, and any current Safer Choice-certified products that contain this chemical must be reformulated unless relevant health and safety data are provided to justify continuing to list this chemical on the SCIL. More information is available in our January 13, 2023, [blog item](#).

### **RCRA/CERCLA/CWA/CAA/PHMSA/SDWA**

***EPA Announces Final Standards For Heavy-Duty Vehicles:*** On December 20, 2022, EPA [announced](#) the “strongest-ever national clean air standards to cut smog- and soot-forming emissions” from heavy-duty trucks beginning with model year **2027**. According to EPA, relative to current rules, the new standards are more than 80 percent stronger, increase useful life of governed vehicles by 1.5-2.5 times, and will yield emissions warranties that are 2.8-4.5 times longer. The final rule includes provisions for longer useful life and warranty periods. EPA states that these provisions guarantee that as target vehicles age, they will continue to meet EPA’s more stringent emissions standards for a longer period of time. The rule also requires manufacturers to ensure better that vehicle engines and emission control systems work properly on the road. For example, manufacturers must demonstrate that engines are designed to prevent vehicle drivers from tampering with emission controls by limiting tamper-prone access to electronic pollution controls.

***EPA Publishes Final Reconsideration Of 2020 NESHAP For Miscellaneous Organic Chemical Manufacturing Residual Risk And Technology Review:*** On August 12, 2020, EPA published the final risk and technology review (RTR) for the Miscellaneous Organic Chemical Manufacturing National Emission Standards for Hazardous Air Pollutants (NESHAP) (2020 MON final rule). Subsequently, EPA received and granted petitions for reconsideration on two issues, specifically, on the use of the EPA’s Integrated Risk Information System (IRIS) value for ethylene oxide in assessing cancer risk for the source category, and the use of the Texas Commission on Environmental Quality’s (TCEQ) risk value for ethylene oxide as an alternative risk value to the IRIS value for purposes of evaluating risk as part of the Clean Air Act (CAA) residual risk review. On February 4, 2022, EPA proposed the Reconsideration of the 2020 NESHAP: Miscellaneous Organic Chemical Manufacturing Residual RTR to address these two issues and request public comment. On December 21, 2022, EPA published its final decision to use the IRIS value for ethylene oxide in the risk assessment for the 2020 MON final rule and its decision to reject the use of TCEQ’s risk value for ethylene oxide as an alternative risk value to the IRIS value. [87 Fed. Reg. 77985](#). In the final action, EPA made no changes to the risk assessment or related regulatory text for the miscellaneous organic chemical manufacturing source category. The final action was effective on December 21, 2022.

***PHMSA Revises HMR For Lithium Cells And Batteries Transported By Aircraft:*** On December 21, 2022, the Pipeline and Hazardous Materials Safety Administration (PHMSA) issued a final rule

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revising the Hazardous Materials Regulations (HMR) for lithium cells and batteries transported by aircraft. [87 Fed. Reg. 77995](#). PHMSA notes that the final rule is consistent with the previously published Interim Final Rule, which responded to Congressional mandates; prohibited the transport of lithium ion cells and batteries as cargo on passenger aircraft; required lithium ion cells and batteries to be shipped at not more than a 30 percent state of charge aboard cargo-only aircraft when not packed with or contained in equipment; and limited the use of alternative provisions for smaller lithium cell or battery shipments to one package per consignment. In response to comments, the final rule provides editorial amendments and modification of certain provisions, including marking requirements, requests for an extension on the compliance date, and exception for lithium cells or batteries used for medical devices with approval by the Associate Administrator. The final rule will be effective on **January 20, 2023**.

***EPA Amends NESHAP For Site Remediation Source Category:*** On December 22, 2022, EPA published a final rule amending the NESHAP for the site remediation source category. [87 Fed. Reg. 78545](#). The amendments remove exemptions from the rule for site remediation activities performed under authority of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) as a remedial action or a non-time-critical removal action, and for site remediation activities performed under Resource Conservation and Recovery Act (RCRA) corrective actions conducted at treatment, storage, and disposal facilities. The final rule was effective on December 22, 2022.

***PHMSA Makes Editorial Corrections And Clarifications To HMR:*** On December 27, 2022, PHMSA published a final rule that corrects editorial errors and improves the clarity of certain provisions in PHMSA's program and procedural regulations and in the HMR. [87 Fed. Reg. 79752](#). According to PHMSA, the intended effect of the rulemaking is to enhance accuracy and reduce misunderstandings of the regulations. PHMSA states that the amendments contained in the final rule "are non-substantive changes and do not impose new requirements." The final rule will be effective **January 26, 2023**.

***EPA And Army Announce Final Rule Establishing Definition Of WOTUS:*** On December 30, 2022, EPA and the U.S. Department of the Army [announced](#) a final rule establishing a durable definition of "waters of the United States" (WOTUS) to reduce uncertainty from changing regulatory definitions, protect people's health, and support economic opportunity. EPA states that the final rule will restore essential water protections that were in place prior to 2015 under the CWA for traditional navigable waters, the territorial seas, and interstate waters, as well as upstream water resources that significantly affect those waters. EPA has posted a [pre-publication version](#) of the *Federal Register* notice. The final rule will take effect 60 days after publication in the *Federal Register*.

***EPA Proposes To Amend Lime Manufacturing NESHAP:*** On January 5, 2023, EPA published a proposed rule that would amend the NESHAP for Lime Manufacturing Plants (Lime Manufacturing NESHAP). [88 Fed. Reg. 805](#). EPA states that to ensure that all emissions of hazardous air pollutants (HAP) from sources in the source category are regulated, it is proposing HAP emissions standards for the following pollutants: hydrogen chloride (HCl), mercury, total hydrocarbon (THC) as a surrogate for organic HAP, and dioxin/furans (D/F). Comments are due **February 21, 2023**. EPA notes that under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of the comments on or before **February 6, 2023**.

***EPA Will Propose To Strengthen PM<sub>2.5</sub> NAAQS:*** On January 6, 2023, EPA [announced](#) that it will propose to revise the primary annual standard for particulate matter 2.5 (PM<sub>2.5</sub>) by lowering it.

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According to the [pre-publication version](#) of the *Federal Register* notice, EPA will propose to retain the current primary 24-hour PM<sub>2.5</sub> standard and the primary 24-hour PM<sub>10</sub> standard. EPA will also propose not to change the secondary 24-hour PM<sub>2.5</sub> standard, secondary annual PM<sub>2.5</sub> standard, and secondary 24-hour PM<sub>10</sub> standard at this time. EPA will also propose revisions to other key aspects related to the PM national ambient air quality standards (NAAQS), including revisions to the Air Quality Index (AQI) and monitoring requirements for the PM NAAQS. Publication of the notice in the *Federal Register* will begin a 60-day comment period. EPA will hold a virtual public hearing on the proposed rule, and it will announce the details in a separate *Federal Register* notice.

***EPA “Tentatively” Denies Petition To Classify Discarded Polyvinyl Chloride As RCRA***

***Hazardous Waste:*** EPA announced on January 12, 2023, its response to a rulemaking petition from the Center for Biological Diversity requesting that discarded polyvinyl chloride (PVC) be listed as a hazardous waste under RCRA. [88 Fed. Reg. 2089](#). EPA states that after careful consideration, it “is tentatively denying the petition.” According to EPA, the petition does not provide sufficient evidence to suggest that listing discarded PVC as a hazardous waste would have a meaningful impact, if any, on reducing exposure to phthalates, including phthalates used as plasticizers in some PVC products. EPA states that based on information presented in the petition, the resources that EPA would have to allocate to list PVC as a hazardous waste are unwarranted and would preclude EPA from pursuing more pressing rulemakings, implementation, and reviews with respect to currently identified hazards under RCRA. Comments on EPA’s tentative denial are due **February 13, 2023**.

## **FDA**

***FDA Releases FSMA Webinar And Slides:*** On December 9, 2022, the U.S. Food and Drug Administration (FDA) [announced](#) the releases of the [webinar recording](#) and [presentation slides](#) for the FSMA Food Traceability Final Rule Webinar on the recently released Food Traceability final rule issued under the FDA Food Safety Modernization Act (FSMA). The Food Traceability Final Rule, issued on November 21, 2022, is effective on **January 20, 2023**.

***FDA Opens Registration For Consumer Food Safety Education Conference:*** On December 14, 2022, FDA [opened](#) registration for the eighth national Consumer Food Safety Education Conference (CFSEC 2023), which will be held **March 1 - 3, 2023**, in Arlington, VA. Speakers will include:

- Frank Yiannas, Deputy Commissioner for Food Policy and Response with the FDA; and
- Sandra Eskin, Deputy Under Secretary for Food Safety, U.S. Department of Agriculture (USDA).

***FDA Sends Reminder Of Requirements For Sesame As A Major Food Allergen:*** On December 15, 2022, FDA [reminded](#) manufacturers that effective January 1, 2023, foods containing sesame will be subject to specific food allergen regulatory requirements, including labeling and manufacturing requirements.

***FDA Announces Update To The New Era Of Smarter Food Safety Website:*** On December 19, 2022, FDA [announced](#) an update to the New Era of Smarter Food Safety website, which now includes separate web pages for each of the four Core Elements of the program. This re-organization will allow stakeholders better insight into FDA-specific initiatives, and intentions for each Core Element. FDA includes, in Core Element 4: Food Safety Culture, details on its recently concluded [systematic literature review](#) that is intended “...to provide FDA with a synthesis of the available research on how FSC is defined, created, and assessed, as well as insight into the



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challenges and opportunities related to fostering [food safety culture].”

***FDA And Federal Partners Issue Request For Information On The Regulation Of***

***Biotechnology:*** On December 20, 2022, the White House Office of Science and Technology Policy (OSTP) -- in coordination with FDA, EPA, and USDA -- announced a request for information related to the Coordinated Framework for the Regulation of Biotechnology. [87 Fed. Reg. 77900](#). Comments are due **before 5:00 p.m. (EST) on February 3, 2023**. OSTP, FDA, EPA, and USDA held a virtual listening session on January 12, 2023.

***FDA Issues Final Guidance For Convening GRAS Panels:*** On December 21, 2022, FDA announced the availability of a final guidance for industry entitled “Best Practices for Convening a GRAS Panel.” [87 Fed. Reg. 77983](#). FDA includes guidance on definitions of substances that are subject to the generally recognized as safe (GRAS) provisions, and not subject to premarket review. In addition, FDA provides that the voluntary GRAS notification procedure, using a GRAS panel, relies on its members to act as a proxy for the larger scientific community knowledgeable about the safety of the substances. FDA indicates that it received 13 comments on its draft guidance, issued in November of 2017, prior to issuing the final guidance.

***FDA Opens The Voluntary Qualified Importer Program (VQIP) Portal:*** On January 1, 2023, FDA [opened](#) the Voluntary Qualified Importer Program (VQIP) [application portal](#) for FY **2024**.

***Deadline For Proposals For FDA Funding Due January 23, 2023:*** On January 4, 2023, FDA [reminded](#) the public that proposals for advanced research and development projects supporting regulatory science and innovation are due by **5:00 p.m. (EST) on January 23, 2023**. Eligible applicants include “responsible sources and Small Businesses are strongly encouraged to respond.” Additional details for the Broad Agency Announcement (BAA) are available at the link [here](#).

## **NANOTECHNOLOGY**

***EUON Announces Results Of Desk Study On (Bio)Degradation, Persistence, And SbD Of Nanomaterials:*** On December 12, 2022, the EU Observatory for Nanomaterials (EUON) [announced](#) the results of a desk study entitled [Study on \(bio\)degradation, persistence and safe by design of nanomaterials](#). The study found proposed SbD strategies that are already available for nanomaterials. EUON notes that in the expert survey complementing the study’s literature search, 30 percent of the survey participants suggested that the sustainability domain should be part of the SbD framework and should specifically integrate the environmental and societal dimension.

***ANSES Applies Methodology To Assess Risks Of Nanomaterials In Food To Titanium Dioxide:*** As reported in our October 19, 2021, [blog item](#), in 2021, the French Agency for Food, Environmental and Occupational Health and Safety (ANSES) released a scientific guide to assess the risks posed by nanomaterials in food. On December 16, 2022, ANSES [announced](#) that the methodology has been “tested” on the food additive E171, titanium dioxide. ANSES states that the test has “confirmed the relevance of [its] methodology and the need for a nanospecific approach.” Based on its findings, ANSES “reiterat[es] its recommendation to limit exposure of workers and consumers to nanomaterials until their safety can be demonstrated, and avoid the dispersal of these particles in the environment.”

***Australia Publishes Additional Guidance For Assessment Certificate Applicants Introducing Nanoscale Chemicals:*** On December 19, 2022, the Australian Industrial Chemicals Introduction Scheme (AICIS) posted a [news item](#) reminding assessment certificate applicants that extra

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information is required for chemicals at the nanoscale. AICIS has published [extra guidance](#) on the data concerning the nanoscale-specific physicochemical properties that must be provided. AICIS states that nanoscale means a particle size range of one to 100 nanometers (nm). More information is available in our December 21, 2022, [blog item](#).

***EUON Publishes Nanopinion On Controlling Exposure To Nanomaterials:*** On December 20, 2022, EUON published a Nanopinion entitled “[Controlling Exposure to Nanomaterials](#)” by Dr Araceli Sánchez, Spanish Institute of Health and Safety (INSST). Sánchez notes that over the last 15 years, scientists have paid attention to the development of new instruments capable of measuring personal exposure to nanosize particles, and new frameworks, methodologies, and standards to assess and control exposure to engineered nanomaterials in the workplace have been published. Sánchez states that some advances on this front have been published recently, such as Visser *et al.* (2022), which provides recommendations from an expert panel to establish health-based nano reference values differentiating six groups of engineered nanomaterials.

***SweNanoSafe Publishes Notes From Fifth Annual Research Network Workshop:*** On November 25, 2022, the Swedish National Platform for Nanosafety (SweNanoSafe) and the Swedish University of Agricultural Sciences held the Fifth Annual Research Network Workshop. According to SweNanoSafe’s December 20, 2022, [announcement](#), the online workshop was chaired by Geert Cornelis and attracted some 40 participants. SweNanoSafe has [posted an overview](#) of the workshop contents that includes a summary of the key outcomes.

***OECD Accepting Comment On Draft Study Report On Applicability Of The Key Event Based TG 442D For In Vitro Skin Sensitisation Testing Of Nano-Materials:*** The Organization for Economic Cooperation and Development (OECD) has published a draft Study Report on [Applicability of the key event based TG 442D for in vitro skin sensitisation testing of nano-materials](#). Comments are due **January 31, 2023**. More information is available in our December 23, 2022, [blog item](#).

***Registration Begins For NNI Webinar On EHS Implications Of Metal Nanoparticles In Aquatic Environments:*** On February 1, 2023, the National Nanotechnology Initiative (NNI) [will hold a webinar](#) on the environmental, health, and safety (EHS) implications of metal nanoparticles in aquatic environments. According to NNI, the focus will be on copper and copper oxide, nickel, and silver nanoparticles. Each expert panelist will provide an overview on the current state of knowledge for a particular metal nanoparticle. The panelists will discuss methods used for identifying, measuring, and assessing the potential effects of the metal nanoparticle in aquatic environments. More information is available in our January 9, 2023, [blog item](#).

## **BIOBASED/RENEWABLE PRODUCTS/SUSTAINABILITY**

***B&C® Biobased And Sustainable Chemicals Blog:*** For access to a summary of key legislative, regulatory, and business developments in biobased chemicals, biofuels, and industrial biotechnology, go to <https://biobasedblog.lawbc.com>.

## **LEGISLATIVE**

***Bipartisan Omnibus Appropriations Bill Includes \$10.125 Billion For EPA:*** On December 23, 2022, Congress passed the bipartisan FY 2023 omnibus appropriations bill, providing \$10.135 billion for EPA, an increase of \$576 million to the FY 2022 enacted level. The bill includes increases for EPA enforcement and compliance programs (+\$72 million), clean air programs (+\$32 million), water programs (+\$33 million), and toxic chemical programs (+\$20 million). The [Explanatory Statement](#) for

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Interior, Environment, and Related Agencies includes the following directions to EPA:

- *PFAS and Contaminants of Emerging Concern* -- The Committees encourage EPA to continue to take action on PFAS, including addressing contamination, advancing clean up and treatment solutions, conducting research, and undertaking needed rulemaking actions. Within 60 days of enactment, EPA is directed to brief the Committees on planned FY 2023 PFAS-related actions and provide the Committees with a spend plan that details funding at the program project level.
- *Toxics Risk Review and Prevention* -- EPA is directed to follow the guidance regarding the Service Fees Rule included in the joint explanatory statement accompanying Public Law 117-103. The Committees “support the Safer Choice program and direct that the program be funded at no lower than the enacted level and operated consistent with prior years.”
- *Chemical Reviews* -- To help ensure that unreasonable risks from chemicals are addressed in a timely manner, the Committees “encourage the Office of Chemical Safety and Pollution Prevention to develop improved outreach and guidance so that submitters understand information needs, processes, and requirements prior to and during submission of pre-manufacturing notices.” In addition, the Committees urge EPA, as resources allow, “to enhance existing submitter engagement procedures to facilitate timely communication and resolution of any issues that may arise during the review period while continuing to protect public health.”

The bill provides for the Office of Chemical Safety and Pollution Prevention and the Office of Water in FY 2023 to use up to \$2,000,000 to hire students and recent graduates as contractors on a temporary or intermittent basis.

## MISCELLANEOUS

***OECA Announces FY 2022 Enforcement And Compliance Accomplishments:*** On December 16, 2022, EPA’s Office of Enforcement and Compliance Assurance (OECA) [announced](#) the FY 2022 Annual Environmental Enforcement Results report, highlighting increased inspections in the aftermath of the pandemic, reductions in significant noncompliance under the CWA, and “aggressive actions to target the most serious water, air, land, and chemical violations that impact communities across the country.” According to EPA, taken together, OECA’s criminal, civil, and administrative enforcement cases reduced, treated, or eliminated pollutants by 95 million pounds and required violators to pay over \$300 million in penalties, fines, and restitution. In keeping with EPA’s Strategic Plan, OECA focused on working to mitigate the effects of climate change and advance environmental justice in the enforcement program.

***Comments On FTC’s Green Guides Due February 23, 2023:*** On December 20, 2022, the Federal Trade Commission (FTC) requested public comment on its [Guides for the Use of Environmental Claims](#) (Green Guides). FTC intends the Green Guides to help marketers avoid making environmental marketing claims that are unfair or deceptive under Section 5 of the FTC Act. [87 Fed. Reg. 77766](#). FTC states in its December 14, 2022, [news release](#) that it seeks to update the Green Guides “based on increasing consumer interest in buying environmentally friendly products.” As noted in our December 16, 2022, [memorandum](#), publication of the notice in the *Federal Register* began a 60-day comment period. Comments are due **February 21, 2023**.

***EPA Publishes IRIS Handbook:*** On December 22, 2022, EPA [announced](#) the availability of *The*

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*Office of Research and Development (ORD) Staff Handbook for Developing IRIS Assessments (IRIS Handbook).* EPA states that the IRIS Handbook “transparently provides procedures for staff developing IRIS assessments, including how to apply systematic review approaches.” According to EPA, the procedures set forth in the IRIS Handbook will apply to newly initiated IRIS assessments moving forward. EPA notes that many elements of the Handbook have already been incorporated in recent final assessments and assessments that are currently in progress, however. EPA will update the Handbook as needed based on method advancements and experience gained through its application to a broader spectrum of assessments to ensure consistent application of best practices in future IRIS assessments.

***EPA Publishes Final PFBA IRIS Assessment:*** On December 22, 2022, EPA [announced](#) the release of the final IRIS assessment of PFBA and related salts. According to EPA, “PFBA is a breakdown product of other PFAS that have been used in stain-resistant fabrics, paper food packaging, carpets, and consumer products; it has also been used for manufacturing photographic film.” EPA states that the final IRIS assessment reviews the evidence on the potential noncancer and cancer human health effects resulting from exposure to PFBA. The final assessment found that sufficient oral exposure to PFBA likely causes thyroid, liver, and developmental effects. The final assessment also includes a noncancer estimate of the amount of PFBA that can be ingested every day that is likely to be without harmful effects. Regarding PFBA’s potential cancer effects, the final assessment concludes that there is “inadequate information to assess carcinogenic potential.” According to EPA, the final IRIS assessment “can be used to support a wide variety of decision-making needs across EPA’s program offices and regions, and state agencies.”

***Petitions Filed To Add Polyoxymethylene And Polyphenylene Sulfide To List Of Chemical Substances Subject To Superfund Excise Tax:*** On December 28, 2022, the Internal Revenue Service (IRS) announced that it received a petition requesting the addition of polyoxymethylene to the list of taxable substances under Section 4672(a) of the Internal Revenue Code. [87 Fed. Reg. 79938](#). The IRS announced on December 30, 2022, that it received a petition requesting the addition of polyphenylene sulfide to the list of taxable substances under Section 4672(a) of the Internal Revenue Code. [87 Fed. Reg. 80579](#). Comments and requests for public hearings are due **February 27, 2023**, and **February 28, 2023**, respectively. More information on the Superfund excise tax on chemicals is available in our July 13, 2022, memorandum, “[Superfund Tax on Chemicals: What You Need to Know to Comply](#)” and our May 19, 2022, memorandum, “[Reinstated Superfund Excise Tax Imposed on Certain Chemical Substances](#).”

***ACGIH Announces First Comment Period Of 2023 Is Now Open:*** The American Conference of Governmental Industrial Hygienists (ACGIH<sup>®</sup>) [announced](#) on January 6, 2023, that the first of two comment periods for 2023 are now open. According to ACGIH<sup>®</sup>, all substances that are on the [notice of intended changes](#) (NIC) currently will have the opportunity to be adopted by the Board of Directors in **summer 2023** and are available on ACGIH<sup>®</sup>’s website via [Data Hub](#) and in the [Publications Store](#). ACGIH<sup>®</sup> states that new substances include endotoxins, triclosan, formic acid, and methyl ethyl ketone. All comments can be submitted to [science@acgih.org](mailto:science@acgih.org) following the process [outlined on the website](#).

***CEQ Requests Comments On Interim Guidance On Consideration Of GHG Emissions And Climate Change:*** On January 9, 2023, the Council on Environmental Quality (CEQ) issued interim guidance to assist agencies in analyzing greenhouse gas (GHG) and climate change effects of their proposed actions under the National Environmental Policy Act (NEPA). [88 Fed. Reg. 1196](#). According to CEQ, the guidance will facilitate compliance with existing NEPA requirements, improving the efficiency and consistency of reviews of proposed federal actions for agencies,

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decision makers, project proponents, and the public. The guidance provides federal agencies a common approach for assessing their proposed actions, while recognizing each agency's unique circumstances and authorities. CEQ states that it is issuing the guidance as interim guidance "so that agencies may make use of it immediately while CEQ seeks public comment on the guidance." CEQ intends to either revise the guidance in response to public comments or issue it as final guidance. The interim guidance is effective immediately. Comments are due **March 10, 2023**.

***EPA Announces Availability Of \$100 Million Through IRA For Environmental Justice***

**Grants:** EPA [announced](#) on January 10, 2023, the availability of approximately \$100 million for projects that advance environmental justice in underserved and overburdened communities across the country. According to EPA, this funding, made possible through President Biden's Inflation Reduction Act (IRA), "marks the largest amount of environmental justice grant funding ever offered by the Agency." EPA has published two requests for applications for this funding:

- The Environmental Justice Collaborative Problem-Solving (EJCPS) Cooperative Agreement Program: The EJCPS Program will provide an estimated \$30 million in funding directly to community-based nonprofit organizations (and partnerships of these organizations), with \$5 million reserved for small community-based nonprofit organizations with five or fewer full-time employees. The EJCPS Cooperative Agreement Program provides financial assistance to eligible organizations working on or planning to work on projects to address local environmental and/or public health issues in their communities.
- The Environmental Justice Government-to-Government (EJG2G) Program: The EJG2G Program will provide an estimated \$70 million in funding. The EJG2G Program works to support and/or create model state activities that lead to measurable environmental or public health results in communities disproportionately burdened by environmental harms and risks.

***EPA Releases Updated Legal Guidance On Identifying, Addressing Cumulative Impacts To Advance Environmental Justice, Equity:***

EPA [announced](#) on January 11, 2023, that its Office of the General Counsel (OGC) released the [Cumulative Impacts Addendum to EPA Legal Tools to Advance Environmental Justice](#) (EJ Legal Tools). According to EPA, the Addendum "is a first-ever collection of examples of the Agency's legal authorities to identify and address cumulative impacts through a range of actions, including permitting, regulations, and grants, in order to consider the lived experience of communities overburdened by pollution and advance environmental justice." The Addendum builds on the EJ Legal Tools, which OGC released in May 2022, by identifying for EPA decisionmakers and partners a wide range of authorities that can be deployed to address the cumulative impacts of pollutants in the environment and other factors affecting human health and well-being that have a disproportionate impact on communities with environmental justice concerns.

***EPA Seeks Public Comment On NEICs For FYs 2024-2027:*** On January 12, 2023, EPA announced that it is soliciting public comment and recommendations on the National Enforcement and Compliance Initiatives (NECI) for FYs **2024-2027** (formerly called "National Compliance Initiatives"). [88 Fed. Reg. 2093](#). EPA states that it "focuses enforcement and compliance resources on the most serious and widespread environmental problems by developing and implementing national program initiatives." EPA is collecting comment on which of the current national initiatives should continue into the FY **2024-2027** cycle, as is or modified, or be returned to the standard or "core" enforcement program at the end of FY 2023. Initiatives returned to the core program will continue to be addressed by enforcement and compliance assurance measures as appropriate. The current NEICs include:

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- Creating Cleaner Air for Communities by Reducing Excess Emissions of Harmful Pollutants (EPA plans to continue this initiative for the FY **2024-2027** cycle);
  - Stopping Aftermarket Defeat Devices for Vehicles and Engines (EPA proposes to return this initiative to the standard “core” enforcement program);
  - Reducing Hazardous Air Emissions from Hazardous Waste Facilities (EPA proposes to return this initiative to the standard “core” enforcement program);
  - Reducing Risks of Accidental Releases at Industrial and Chemical Facilities (EPA plans to continue this initiative for the FY **2024-2027** cycle);
  - Reducing Significant Non-Compliance in the National Pollutant Discharge Elimination System (NPDES) Program (EPA plans to continue this initiative for the FY **2024-2027** cycle); and
  - Reducing Non-Compliance with Drinking Water Standards at Community Water Systems (EPA plans to continue this initiative for the FY **2024-2027** cycle).

In addition, EPA specifically invites comment on two potential new NEClS and two other areas under consideration for further evaluation as potential NEClS. The two potential new NEClS are:

- Mitigating Climate Change; and
- Addressing PFAS Contamination.

The two additional areas for further consideration for possible development as NEClS are:

- Reducing Exposure to Lead; and
- Addressing Coal Combustion Residuals (CCR).

EPA also invites the public to propose other areas for consideration as an NECl. Comments are due **March 13, 2023**.

***OSTP Releases Framework For Strengthening Federal Scientific Integrity Policies And Practices:*** On January 12, 2023, OSTP [announced](#) the release of [A Framework for Federal Scientific Integrity Policy and Practice](#), “a roadmap that will help strengthen scientific integrity policies and practices across the federal government.” The framework builds on the assessment of federal scientific integrity policies and practices described in the January 2022 report, [Protecting the Integrity of Government Science](#), and draws from extensive input from federal agencies, as well as from across sectors, including academia, the scientific community, public interest groups, and industry. According to OSTP, the framework has several key components that federal departments and agencies will use to improve scientific integrity policies and practices, including:

- A consistent definition of scientific integrity for all federal agencies;
- A model scientific integrity policy to guide agencies as they build and update their policies; and
- A set of tools to help agencies regularly assess and improve their policies and practices.

The framework requires all agencies to designate a scientific integrity official, and agencies that fund, conduct, or oversee research to designate a chief science officer, and it establishes the National Science and Technology Council (NSTC) Subcommittee on Scientific Integrity to oversee implementation of the framework, and evaluate agency progress.

***EPA Announces SAB Public Meetings On Hexavalent Chromium:*** EPA announced on January 12, 2023, that the Science Advisory Board Hexavalent Chromium Review Panel will hold two public meetings. [88 Fed. Reg. 2092](#). The Science Advisory Board Hexavalent Chromium Review Panel will receive a briefing from EPA on **February 15, 2023, from 12:00 to 5:00 p.m. (EST)**. The Science Advisory Board Hexavalent Chromium Review Panel will meet to peer review EPA's draft IRIS Toxicological Review of Hexavalent Chromium on **March 29-31, 2023**.

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