WEBINAR - Register Now For “Domestic Chemical Regulation And Achieving Circularity,” May 18 2022, 12:00 p.m. EDT: A circular economy requires new thinking about what products we make, from which materials we make them, and where products go at the end of their useful lives. An important but often overlooked aspect of new product development is an understanding of the consequences of the product’s chemical composition and the end-of-life implications of the decisions made at the front end of the process. Working within this framework plays a critical role in building a resilient, dependable, and sustainable system that fosters
innovation to develop a circular economy. Register now to join Lynn L. Bergeson, Managing Partner, Bergeson & Campbell, P.C. (B&C®); Richard E. Engler, Ph.D., Director of Chemistry, B&C; Kate Sellers, Technical Fellow, ERM; and Mathy Stanislaus, Vice Provost and Executive Director of Drexel University’s Environmental Collaboratory, as B&C presents “Domestic Chemical Regulation and Achieving Circularity.”

TSCA/FIFRA/TRI

PODCAST - Trends In Product Sustainability And Circularity — A Conversation With Kate Sellers: In this episode Lynn L. Bergeson sits down with Kate Sellers, Technical Fellow at ERM, to discuss the business value of product stewardship, including implementation of the Toxic Substances Control Act (TSCA), life-cycle assessment, circular economy programs, and sustainability initiatives. Kate is an adjunct professor at Harvard Extension School and Indiana University’s School of Public Health, where she is an instructor in the Master of Science in Product Stewardship program. Listen now.

PODCAST - A Look Into The Household & Commercial Products Association — A Conversation With Steven Bennett, Ph.D.: In this episode, Lynn L. Bergeson and Dr. Steven Bennett, Executive Vice President, Scientific & Regulatory Affairs, Household & Commercial Products Association, discuss a diverse and challenging range of scientific, regulatory, and science policy issues, from consumer exposures, to chemicals used in cleaning products, to the role HCPA members play in addressing COVID-19 and related public health issues. Listen now.

Meeting Recordings And Transcript Available For TSCA SACC Peer Review Of Screening Level Approach For Assessing Ambient Air And Water Exposures To Fenceline Communities: On March 15-17, 2022, EPA held a meeting of the Science Advisory Committee on Chemicals (SACC) to peer review EPA’s “Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0” (screening methodology). EPA has posted the following materials:

- Biographical sketches of selected ad hoc reviewers;
- The draft screening methodology and supporting documents;
- Agenda and roster for the meeting;
- Meeting transcript;
- Recording of the March 15, 2022, meeting;
- Recording of the March 16, 2022, meeting; and
- Recording of the March 17, 2022, meeting.

EPA Issues In Final Certain Pesticide Product Performance Data Requirements To Improve Clarity And Reduce Burden For Registrants: On April 15, 2022, EPA announced final product performance data requirements for
products claiming efficacy against certain pests. 87 Fed. Reg. 22464. This action officially incorporates EPA’s already existing product performance standards requirements for certain invertebrate pests into the Code of Federal Regulations (CFR). EPA states this action also increases the efficiency of its approval process and will save registrants time and money. The final rule is effective on June 14, 2022. For more information on this final rule, please see our blog item.

**EPA Publishes Receipt And Status Information For Certain New Chemicals For March 2022**: On April 22, 2022, EPA published the receipt and status reports for the period from March 1, 2022, to March 31, 2022. 87 Fed. Reg. 24154. EPA states that it is providing notice of receipt of a premanufacture notice (PMN), significant new use notice (SNUN), or microbial commercial activity notice (MCAN), including an amended notice or test information; an exemption application (Biotech exemption); an application for a test marketing exemption (TME), both pending and/or concluded; a notice of commencement (NOC) of manufacture (including import) for new chemical substances; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review. Comments identified by the specific case number provided by EPA are due May 23, 2022.

**EPA Holds Meeting On New Chemicals Collaborative Research Program**: On April 20-21, 2022, EPA held a virtual public meeting to provide an overview of the TSCA New Chemicals Collaborative Research Program and give stakeholders an opportunity to provide input. As described in EPA’s draft document entitled “Modernizing the Process and Bringing Innovative Science to Evaluate New Chemicals Under TSCA,” the Office of Chemical Safety and Pollution Prevention (OCSPP) proposes to develop and implement a multi-year collaborative research program focused on approaches for performing risk assessments on new chemical substances under TSCA. EPA has posted the following presentations from the April 20-21, 2022, meeting:

- Louis (Gino) Scarano, Ph.D., New Chemicals Division, “Collaborative Research Program to Modernize the Process and Bring Innovative Science to Evaluate New Chemical[s] Under TSCA: Current Approaches and Opportunities.” Cathy Fehrenbacher, EPA, co-authored the slides.
- Katie Paul Friedman, Ph.D., Office of Research and Development (ORD), “Collaborative Research Program to Modernize the Process and Bring Innovative Science to Evaluate New Chemicals Under TSCA.”
- Warren Casey, Ph.D., DABT, Division of the National Toxicology Program, National Institute of Environmental Health Sciences, “NIH Collaborators: NIEHS DNTP and NCATS DPI.”

More information on the meeting is available in our April 22, 2022, memorandum, and more information on EPA’s draft document is available in our March 14, 2022, memorandum. Written comments on the draft document were due May 10, 2022.

On April 26, 2022, the TSCA New Chemicals Coalition (NCC) submitted comments to EPA expressing strong support for EPA’s proposed update to its approach to review and evaluate new chemicals under TSCA Section 5. More information on NCC’s
House Subcommittee Holds Hearing On FY 2023 Budget Request For EPA: On April 29, 2022, the House Appropriations Subcommittee on Interior, Environment, and Related Agencies held a hearing on President Biden’s fiscal year (FY) 2023 budget request for EPA. In his written testimony, EPA Administrator Michael S. Regan notes that “[c]hemicals and toxic substances are ubiquitous in our everyday lives and are often released into the environment from their manufacture, processing, use, or disposal.” Regan acknowledges that EPA has “significant responsibilities” under the Frank R. Launtenberg Chemical Safety for the 21st Century Act (Lautenberg Act) amendments to TSCA to ensure the safety of chemicals in or entering commerce and to address unreasonable risks to human health or the environment. The budget would provide $124 million and 449 full-time equivalents (FTE) to implement TSCA, an increase of more than $60 million. According to Regan, “[t]hese resources will support EPA-initiated chemical risk evaluations, issue protective regulations in accordance with statutory timelines, and establish a pipeline of priority chemicals for risk evaluation.” Regan states that EPA also has “significant responsibility under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to screen new pesticides before they reach the market and ensure pesticides already in commerce are safe.” He notes that in addition, EPA is responsible for complying with the Endangered Species Act (ESA) and ensuring that federally endangered and threatened species are not harmed when EPA registers pesticides. The proposed FY 2023 budget includes an additional $4.9 million to enable the pesticide program to integrate ESA requirements in conducting risk assessments and making risk management decisions that protect federally threatened and endangered species from exposure to new active ingredients. For more information, please see our May 2, 2022, memorandum.

EPA Proposes TSCA Reporting And Recordkeeping Requirements For Asbestos: On May 6, 2022, EPA proposed reporting and recordkeeping requirements for asbestos under Section 8(a) of TSCA. 87 Fed. Reg. 27060. EPA proposes to require certain persons that manufactured (including imported) or processed asbestos and asbestos-containing articles (including as an impurity) in the four years prior to the date of publication of the final rule to report electronically certain exposure-related information. The proposed rule would result in a one-time reporting obligation. EPA “emphasizes that this proposed requirement would include asbestos that is a component of a mixture.” According to the notice, the information sought includes quantities of asbestos (including asbestos that is a component of a mixture) and asbestos-containing articles that were manufactured (including imported) or processed, types of use, and employee data. EPA and other federal agencies will use reported information in considering potential future actions, including risk evaluation and risk management activities. EPA requests public comment on all aspects of the proposed rule and also has identified items of particular interest for public input. Comments are due July 5, 2022. More information is available in our May 6, 2022 memorandum.

EPA Requests Comments On Aquatic Toxicity Data Of Chitosan Salts -- Proposal To Add Chitosan To The Minimum Risk Pesticide Active Ingredient List: On May 6, 2022, EPA published a notice in the Federal Register announcing the availability of, and requesting comments on, data related to aquatic toxicity of
chitosan salts. 87 Fed. Reg. 27059. Specifically, EPA is seeking comments on the following two aquatic toxicity reports submitted by Tidal Vision Products, LLC (Tidal Vision), the company that submitted a petition to EPA on October 10, 2018, requesting that EPA add chitosan to the list of active ingredients eligible for EPA’s minimum risk pesticide exemption under FIFRA Section 25(b):


EPA is seeking input on how these reports may be used by EPA in its assessment of aquatic toxicity of chitosan and its salts. EPA states “chitosan may form as a salt (e.g., acetate, lactate, hydrochloride, and salicylate) when it is solubilized in acids for end use product formulation and subsequently applied in the environment” and the new information submitted by Tidal Vision pertains to these salts. Comments on the aquatic toxicity reports are due on or before June 6, 2022, in Docket EPA-HQ-OPP-2019-0701. More information is available in our May 12, 2022, blog.

**EPA Research Team Develops Framework To Determine What Products To Classify And Evaluate As Nanopesticides:** According to a May 9, 2022, news item published by EPA, “Advancing EPA’s Understanding of the Next Generation of Pesticides,” over the past decade, EPA “has received an increasing number of pesticide product applications that potentially contain nanomaterials.” According to the item, an EPA research team developed a review framework “that includes a simple decision tree to determine what products should be classified and evaluated as a nanopesticide.” Products determined to contain nanomaterials are subject to additional assessment or data needs from the manufacturer. For more information, please read our May 10, 2022, blog.

**EPA Holds Webinar On Reducing Vertebrate Animal Testing:** On May 11, 2022, EPA held a webinar entitled “Data-Driven Solutions to Reducing Animal Use in Ecotoxicity.” Speakers included:

- Carlie LaLone, Ph.D., ORD, on “The Sequence Alignment to Predict Across Species Susceptibility (SeqAPASS) Tool: Extrapolating Knowledge Computationally”; and

- Michael Lowit, Ph.D., EPA Office of Pesticide Programs (OPP), on “Exploring Potential Reductions in Fish Testing in a Regulatory Context.”

The webinar was co-organized by the People for the Ethical Treatment of Animals (PETA) Science Consortium International, EPA, and the Physicians Committee for Responsible Medicine (PCRM).

**EPA Proposes To Update CBI Requirements Under TSCA:** On May 12, 2022, EPA published a proposed rule relating to the assertion and maintenance of confidential business information (CBI) claims under TSCA. 87 Fed. Reg. 29078. EPA states in its
May 12, 2022, press release that the proposed rule includes new and amended requirements that, if made final, would increase transparency, modernize reporting and review procedures, and ensure consistency with the 2016 amendments to TSCA. In addition to providing increased clarity for TSCA submitters, EPA expects the changes to allow it to review and make determinations on CBI claims more efficiently, meeting the statutory review deadline in TSCA and more promptly making required notifications to submitters of claims. Comments are due July 11, 2022. Our forthcoming memoranda will include a detailed summary of the proposed rule and an insightful commentary.

**EPA Publishes Statements Of Findings For February 2022 For Certain New Chemicals Or Significant New Uses:** On May 12, 2022, EPA published its statements of findings made after reviewing notices submitted under TSCA Section 5(a) that certain new chemical substances or significant new uses are not likely to present an unreasonable risk of injury to health or the environment. 87 Fed. Reg. 29155. The notice presents statements of findings made by EPA during the period from February 1, 2022, to February 28, 2022.

**EPA Publishes 2020 CDR Information:** On May 12, 2022, EPA announced the publication of information collected during the 2020 Chemical Data Reporting (CDR) cycle to increase public awareness of chemicals being manufactured in communities and to enable citizen and stakeholder access and use of the reported information. The 2020 CDR information primarily covers manufacture, processing, and use activities for calendar year 2019. The data released include company and site information, manufacturing (including import) information, production volume, and processing and use data, as well as information on chemicals not included in previous releases. According to EPA, this includes chemicals that lost their confidential status on the TSCA Inventory because one or more manufacturers reported the chemical identities as non-confidential during the 2012, 2016, and/or 2020 CDR reporting periods. Therefore, the 2020 CDR database will include information related to those chemical identities that could not be revealed publicly in previous publications of CDR data. More information is available in our May 13, 2022, blog item.

**EPA Publishes Notice Concerning Court-Ordered Stay Of Effectiveness For Pesticide Application Exclusion Zone Provision Of The Agricultural Worker Protection Standard:** As reported in our November 2, 2020, blog item, on October 30, 2020, EPA issued a final rule on the Agricultural Worker Protection Standard (WPS) regulation that revises the requirements on the pesticide application exclusion zone (AEZ), defined as an “area surrounding the point(s) of pesticide discharge from the application equipment that must generally be free of all persons during pesticide applications.” The final AEZ requirements were scheduled to go into effect on December 29, 2020, but on December 28, 2020, the U.S. District Court for the Southern District of New York issued an order in the case of State of New York et al. v. EPA that resulted in a stay of the requirements. EPA published a May 16, 2022, Federal Register notice stating that as of February 15, 2022, the effectiveness of the WPS final rule is stayed by court order until August 22, 2022. 87 Fed. Reg. 29673. According to the notice, EPA intends to publish another document in the Federal Register to address the status of the 2020 final rule if the stay of effectiveness expires or is lifted, but EPA “does not intend to publish
additional *Federal Register* documents to announce any additional court orders entered to further stay the effectiveness of the 2020 final rule.”

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

*M*embers *O*f *C*ongress *U*rge *E*PA *T*o *I*mplement *“R*obust” *P*revention *A*n *d *S*afety *S*tandards *A*t *H*i gh-Risk *C*hemical *F*acilities: On April 14, 2022, Senator Cory Booker (D-NJ) and Representative Nanette Diaz Barragán (D-CA) and 29 of their colleagues sent a letter to EPA urging the implementation of “strong safeguards at high-risk chemical facilities to protect fenceline environmental justice communities, facility workers, and first responders from chemical disasters.” According to Booker’s [press release](#), the letter notes that upcoming revisions to the Risk Management Plan (RMP) rule “provide a critical opportunity to protect vulnerable communities from the ‘double disasters’ that result when chemical disasters coincide with climate-related disasters like hurricanes, floods, and wildfires.” To prevent future chemical disasters, the letter urges EPA to prioritize prevention in updates to the RMP rule, including requiring “hazard reduction and best practice prevention measures, such as transitioning to inherently safer chemicals and processes, implementing root cause analyses following incidents, and requiring third-party audits to verify facility compliance.” As severe weather events become more frequent, “the rule should also recognize climate change as a threat multiplier.”

**IRS Provides Temporary Relief From Penalty For Failure To Deposit Superfund Chemical Taxes:** In April 2022, the Internal Revenue Service (IRS) issued [Notice 2022-15](#), “Temporary Relief from Penalty for Failure to Deposit Superfund Chemical Taxes.” Effective **July 1, 2022**, Section 80201 of the Infrastructure Investment and Jobs Act, Public Law 117-58, reinstates the Superfund chemical taxes with certain modifications. In December 2021, the IRS provided initial guidance related to the Superfund chemical taxes and requested comment on whether any issues related to the reinstated Superfund chemical taxes require clarification or additional guidance. According to the Notice, the Department of the Treasury (Treasury Department) and the IRS have received seven public comments to date. One of the comments requested relief from failure to deposit penalties, which is provided by Notice 2022-15. The Notice states that during the first, second, and third calendar quarters of **2023**, the IRS will not exercise its authority under Section 40.6302(c)-1(b)(2)(v) of the Excise Tax Procedural Regulations to withdraw the taxpayer’s right to use the deposit safe harbor of Section 40.6302(c)-1(b)(2) due to a failure to make deposits of Superfund chemical taxes as required, provided the taxpayer satisfies the requirements of Section 3(a) of the Notice for the look-back quarter at issue. The Treasury Department and the IRS continue to consider the other comments.

**EPA Proposes To Add Substance To List Of Compounds Excluded From Definition Of VOCs:** EPA proposed on April 28, 2022, to revise the EPA’s regulatory definition of volatile organic compounds (VOC) under the Clean Air Act (CAA). [87 Fed. Reg. 25170](#). EPA proposes to add (2E)-1,1,1,4,4,4-hexafluorobut-2-ene (also known as *trans*-1,1,1,4,4,4-hexafluorobut-2-ene, and HFO-1336mzz(E)) to the list of compounds excluded from the regulatory definition on the basis that this compound makes a negligible contribution to tropospheric ozone formation. Comments are
EPA Announces Three Actions Intended To Protect Communities And The Environment From PFAS In Water: EPA announced on April 28, 2022, three actions to protect communities and the environment from per- and polyfluoroalkyl substances (PFAS) in water:

- A New Testing Method Will Help Detect PFAS in Water: EPA’s new Screening Method for the Determination of Adsorbable Organic Fluorine (AOF) in Aqueous Matrices by Combustion Ion Chromatography (CIC) provides an aggregate measurement of chemical substances that contain carbon-fluorine bonds. PFAS are a common source of organofluorines in wastewater. Multi-laboratory validation will take place in summer 2022 and EPA intends to publish an updated version of the method later in 2022;

- New Permitting Direction Will Help Reduce Discharges of PFAS to Water: EPA issued a memorandum entitled “Addressing PFAS Discharges in EPA-Issued NPDES Permits and Expectations Where EPA is the Pretreatment Control Authority.” The memorandum provides instructions for monitoring provisions, analytical methods, the use of pollution prevention, and best management practices to address discharges of PFAS. EPA plans to issue new guidance to state permitting authorities to address PFAS in National Pollutant Discharge Elimination System (NPDES) permits in a future action; and

- New Protective Levels Will Help Support Healthy Fish and Aquatic Ecosystems: On May 3, 2022, EPA proposed the first Clean Water Act (CWA) aquatic life criteria for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS). 87 Fed. Reg. 26199. The criteria are intended to protect aquatic life in the United States from short-term and long-term toxic effects of PFOA and PFOS. Following the comment period, EPA intends to issue final PFOA and PFOS recommended criteria, considering public comments and any new toxicity data. States and Tribes may consider adopting the final criteria into their water quality standards or can adopt other scientifically defensible criteria that are based on local or site-specific conditions. Comments are due June 2, 2022.

EPA Releases Draft Policy Assessment For The Reconsideration Of The Ozone National Ambient Air Quality Standards: On April 29, 2022, EPA announced the availability of a draft document entitled Policy Assessment for the Reconsideration of the Ozone National Ambient Air Quality Standards, External Review Draft. 87 Fed. Reg. 25485. EPA prepared the draft document as a part of the current reconsideration of the 2020 final decision on the national ambient air quality standards (NAAQS) for ozone. When final, the policy assessment is intended to “bridge the gap” between the scientific and technical information assessed in the 2020 Integrated Science Assessment for Ozone and Related Photochemical Oxidants, as well as any air quality, exposure and risk analyses available in the reconsideration, and the judgments required of the Administrator. The primary and secondary ozone NAAQS are set to protect the public health and the public welfare from ozone and other photochemical oxidants in ambient air. Comments are due May 31, 2022.

EPA Lists HFO-1234yf Under SNAP Program For Motor Vehicle Air Conditioning In Nonroad Vehicles And Servicing Fittings For Small Refrigerant
Cans: On May 4, 2022, pursuant to its Significant New Alternatives Policy (SNAP) program, EPA listed the refrigerant 2,3,3,3-tetrafluoroprop-1-ene, also known as HFO-1234yf or R-1234yf, as acceptable, subject to use conditions, in the motor vehicle air conditioning end-use for certain types of newly manufactured nonroad vehicles, which includes some vehicles that are also considered heavy-duty vehicles. 87 Fed. Reg. 26276. EPA also adopted the current versions of the industry safety standards SAE J639, SAE J1739, and SAE J2844 by incorporating them by reference into the use conditions for the listings in nonroad vehicles and previous listings for certain onroad vehicles covered in final rules issued separately in March 2011 and December 2016. In addition, EPA is requiring unique servicing fittings for use with small refrigerant cans (two pounds or less) of 2,3,3,3-tetrafluoroprop-1-ene that are used to service onroad and nonroad vehicles. Finally, EPA added a reference to its TSCA regulations for 2,3,3,3-tetrafluoroprop-1-ene for the listings in nonroad vehicles and previous listings for certain onroad vehicles. The final rule will be effective June 3, 2022.

Proposed Consent Decree Would List Discarded PVC As Hazardous Waste Under RCRA: EPA published a notice on May 4, 2022, of a proposed consent decree that resolves Center for Biological Diversity v. EPA, a case that alleges EPA unreasonably delayed taking action on a petition to list discarded polyvinyl chloride (PVC) as hazardous waste under the Resource Conservation and Recovery Act (RCRA). 87 Fed. Reg. 26351. The proposed consent decree states that no later than January 20, 2023, EPA shall sign a tentative decision on Plaintiff’s petition to classify discarded PVC as hazardous waste under RCRA. Furthermore, it states that no later than two years after the signature of the consent decree by the Center for Biological Diversity, April 12, 2024, EPA shall sign a final decision on Plaintiff’s petition. Comments are due June 3, 2022.

EPA Requests Nominations For Mobile Sources Technical Review Subcommittee: On May 11, 2022, EPA invites nominations from a diverse range of qualified candidates to be considered for appointment to its Mobile Sources Technical Review Subcommittee. 87 Fed. Reg. 28827. The Subcommittee provides the CAA Advisory Committee with independent advice, counsel, and recommendations on the scientific and technical aspects of programs related to mobile source air pollution and its control. Nominations are due July 11, 2022. EPA anticipates filling vacancies by October 17, 2022.

EPA Will Hold Webinar Workshop To Obtain Input On Initial Draft Materials For Lead ISA: EPA is preparing an Integrated Science Assessment (ISA) as part of its review of the primary and secondary NAAQS for lead. 87 Fed. Reg. 27147. As part of the review, EPA will hold a public workshop to evaluate preliminary draft materials that will inform the development of the lead ISA. The workshop is being organized by EPA’s Center for Public Health and Environmental Assessment within ORD and will be held by webinar and teleconference on May 26, June 7, June 22, and June 29, 2022. The workshop will be open to attendance by interested public observers on a first-come, first-served basis and participation will be by webinar and teleconference only.

EPA Extends Comment Period On Proposed CWA Hazardous Substance Worst Case Discharge Planning Regulations: EPA announced on May 16, 2022, that it
extended the comment period for its March 28, 2022, proposed rule requiring an owner or operator of a facility to prepare and submit a plan for responding, to the maximum extent practicable, to a worst case discharge, and to a substantial threat of such a discharge, of a hazardous substance. 87 Fed. Reg. 29728. EPA proposes to require planning for worst case discharges of CWA hazardous substances for onshore non-transportation-related facilities that could reasonably be expected to cause substantial harm to the environment by discharging CWA hazardous substances into or on the navigable waters, adjoining shorelines, or exclusive economic zone. Comments are due July 26, 2022.

FDA

**FDA Issues Draft Guidance For Food Allergens:** On April 18, 2022, the U.S. Food and Drug Administration (FDA) issued draft guidance titled “Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act.” 87 Fed. Reg. 23181. The guidance outlines FDA’s approach to non-listed food allergens, specifically on immunoglobulin E antibody (IgE)-mediated food allergies, which are considered the most severe and immediately life-threatening. Comments may be submitted on or before August 17, 2022.

**FDA Revises Standard For Added Fluoride In Bottled Water:** On April 20, 2022, FDA revised a quality standard specifying that bottled water to which fluoride is added may not contain in excess of 0.7 milligrams per liter (mg/L), which is a reduction from the currently allowed levels of 0.8 to 1.7 mg/L. 87 Fed. Reg. 23434. The action will not affect allowable levels of fluoride in bottled waters to which fluoride is not added by the manufacturer. The effective date is June 21, 2022. The compliance date is October 17, 2022.

**FDA Issues Draft Guidance For Levels Of Lead In Juice:** On April 27, 2022, FDA issued draft guidance titled “Action Levels for Lead in Juice; Draft Guidance for Industry,” which provides an action level for lead in apple juice of 10 parts per billion (ppb). 87 Fed. Reg. 25491. FDA issues action levels to inform industry of levels of contamination at which FDA may regard specific foods to be adulterated. Comments are due on or before June 28, 2022.

**FDA Announces Food Safety Culture Webinar:** On April 27, 2022, FDA announced a webinar titled “Building a Coalition of Food Safety Culture Champions Across Your Organization” that will take place on May 18, 2022, at 12:30-1:30 p.m. ET. The webinar will feature speakers from the public and private sectors discussing the importance of a robust food safety culture.

**NANOTECHNOLOGY**

**Germany’s Federal Institute For Risk Assessment Announces Fourth Joint Symposium On Nanotechnology:** On April 20, 2022, Germany’s Federal Institute for Risk Assessment (BfR) announced that the fourth joint symposium on nanotechnology will be held May 30-31, 2022. During the symposium, experts will present their findings on topics such as the use of nanotechnology in textiles and packaging, its application in agriculture, the effects of nanomaterials on the body,
and future-oriented assessment approaches. The symposium is open to the public. The registration deadline is May 20, 2022.

**FDA Publishes Final Guidance For Industry On Drug Products, Including Biological Products, That Contain Nanomaterials:** On April 22, 2022, FDA announced the availability of a final guidance for industry entitled “Drug Products, Including Biological Products, that Contain Nanomaterials.” 87 Fed. Reg. 24169. FDA states that the guidance applies to human drug products, including those that are biological products, in which a nanomaterial is present in the finished dosage form. The guidance discusses both general principles and specific considerations for developing drug products containing nanomaterials through abbreviated pathways, as well as considerations for quality, nonclinical, and clinical studies as they relate to drug products containing nanomaterials throughout product development and production.

**NanoHarmony Holds Webinar In The “Improving the OECD Test Guidelines Process” Series:** On May 4, 2022, NanoHarmony held a webinar in its series of webinars covering the different phases that an Organization for Economic Cooperation and Development (OECD) test guideline (TG) progresses through during its journey from a science-based initial idea through to use by industry to fulfill regulatory obligations. The webinar covered phases 2 and 3 of the TG process, technical development and commenting and approval.

**Registration Opens For NanoHarmony And NANOMET Workshop On OECD Test Guideline Development:** The NanoHarmony and NANOMET projects are holding their first face-to-face joint workshop on the development of OECD TGs for nanomaterials back-to-back with the OECD Working Party on Manufactured Nanomaterials (WPMN) at the OECD Conference Center in Paris on June 29-30, 2022. Registration will close June 8, 2022, at 15:00 (CEST) to ensure time for OECD to make relevant security checks.

**BIOBASED/RENEWABLE PRODUCTS**

**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 [http://blog.braginfo.org](http://blog.braginfo.org).

**LEGISLATIVE**

**Bill Would Ban Use Of PFAS In Firefighting Foam:** On April 27, 2022, Senator Kirsten Gillibrand (D-NY) and Representative Dan Kildee (D-MI) announced the introduction of the PFAS Firefighter Protection Act (H.R. 7597, S. 4076). According to Gillibrand’s April 27, 2022, press release, PFAS are found in a special foam used to fight fires called aqueous film forming foam (AFFF) and have been linked to certain cancers, thyroid disease, reproductive problems, decreased immune function in children, and other serious adverse health effects. The bill would ban firefighting foam containing PFAS chemicals.

**Senate Committee Votes To Advance Kigali Amendment To The Montreal Protocol:** On May 4, 2022, the Senate Committee on Foreign Relations voted to
advance the Kigali Amendment to the Montreal Protocol on Substances that Deplete the Ozone Layer. The Committee's May 4, 2022, press release states that the Kigali Amendment is a global agreement for the transition away from hydrofluorocarbons (HFC), gases commonly used for refrigeration, air conditioning, and as propellants, to next-generation chemicals developed and produced by U.S. manufacturers. The amendment moves next to the floor for consideration by the full Senate.

House Committee Unveils FDA User Fees Legislative Package: On May 4, 2022, Representatives Frank Pallone, Jr. (D-NJ), Chair of the House Energy and Commerce Committee, Cathy McMorris Rodgers (R-WA), Ranking Member, Anna G. Eshoo (D-CA), Chair of the Health Subcommittee, and Brett Guthrie (R-KY), Subcommittee Ranking Member, released a comprehensive legislative package to reauthorize the FDA user fee agreements. According to the Committee’s May 4, 2022, press release, the legislative package reauthorizes the Prescription Drug User Fee Act, the Generic Drug User Fee Act, the Biosimilar User Fee Act, and the Medical Device User Fee Act. The press release states that the bipartisan agreement includes many provisions led by Committee members to support patients by lowering costs and providing a clear path for innovators, such as improvements and program integrity for Accelerated Approval, requirements regarding clinical trial diversity, policies to improve generic drug competition, and authorities to strengthen supply chains through accountability in FDA’s inspections programs.

Bill Would Set Deadlines For EPA To Develop Water Quality Criteria And Limits On Industrial PFAS Discharges: On May 6, 2022, Senator Kirsten Gillibrand (D-NY) and Representative Chris Pappas (D-NH) announced their plan to introduce the bicameral Clean Water Standards for PFAS 2.0 Act (H.R. 7696, S. 4161), which would further regulate PFAS by setting deadlines for EPA to develop water quality criteria and limits on industrial PFAS discharges into water and to water treatment plants. Gillibrand’s May 6, 2022, press release states that the bill would require EPA to develop water quality criteria for all measurable PFAS or classes of PFAS, and develop effluent limitations guidelines and standards for all measurable PFAS or classes of PFAS. The legislation would set deadlines for these criteria and limits within the next few years, in accordance with the EPA PFAS Roadmap. This includes establishing pretreatment standards to prevent the introduction of PFAS into publicly-owned water treatment facilities to help stop PFAS at the source before it gets into the municipal water system.

Bipartisan Bill Would Amend FIFRA To Improve Biostimulant Approval Process: On May 13, 2022, Representative Jimmy Panetta (D-CA) introduced the Plant Biostimulant Act (H.R. 7752). Panetta’s May 13, 2022, press release states that the bill, authored by Panetta and introduced with Representative Jim Baird (R-IN), would create a uniform process for approving commercial plant biostimulant use and require more federal research on the technology’s benefits for soil health. According to the press release, there currently is not a consistent and predictable path to market for plant biostimulants, and the legislation “would help remedy that problem” with federal guidance from EPA and the U.S. Department of Agriculture (USDA).

House Committee Will Hold Budget Hearing With EPA Administrator Michael Regan: The House Energy and Commerce Subcommittee on Environment and Climate Change...
Change will [hold a hearing](#) on May 17, 2022, with EPA Administrator Michael Regan on the FY 2023 budget request for EPA.

**Senate Committee Will Hold Hearing On Implementation Of The Lautenberg Act:** On June 22, 2022, the Senate Committee on Environment and Public Works will hold a hearing to examine implementation of the Frank R. Lautenberg Chemical Safety for the 21st Century Act’s (Lautenberg Act) amendments to TSCA.

**MISCELLANEOUS**

**Lynn L. Bergeson Authors “California Eyes Proposition 65 Modifications,” For Chemical Processing:** On April 5, 2022, the California Office of Environmental Health Hazard Assessment (OEHHA) issued a notice recommending additional revisions to its proposal to modify Proposition 65 (Prop 65) Article 6 “clear and reasonable warnings” regulations for “short-form” warnings. OEHHA first proposed to change the short-form warning requirements on January 8, 2021. [This column explains the significance of this development](#).

**OEHHA Announces Modification To Proposed Regulation On Safe Harbor Warnings For Glyphosate And Addition Of Documents To Rulemaking File:** On April 13, 2022, OEHHA issued a Notice of Modification to Proposed Regulation on Safe Harbor Warnings for Glyphosate and Addition of Documents to Rulemaking File ([Notice](#)). OEHHA first proposed this regulation by publishing a Notice of Proposed Rulemaking on July 23, 2021. OEHHA provided a 75-day comment period on the original proposal and its Initial Statement of Reasons (ISOR), including an extension to file comments until October 7, 2021. It held a public hearing on September 9, 2021. For more information, please see our April 26, 2022, [blog](#).

**CEQ Amends NEPA Implementing Regulations To Restore Earlier Provisions:** On April 20, 2022, the Council on Environmental Quality (CEQ) issued a final rule to amend certain provisions of its regulations for implementing the National Environmental Policy Act (NEPA), addressing the purpose and need of a proposed action, agency NEPA procedures for implementing CEQ’s NEPA regulations, and the definition of “effects.” [87 Fed. Reg. 23453](#). According to CEQ, the amendments “generally restore provisions that were in effect for decades before being modified in 2020.” The final rule amends three provisions of its regulations implementing NEPA:

- CEQ is revising 40 C.F.R. Section 1502.13 to clarify that agencies have discretion to consider a variety of factors when assessing an application for an authorization, removing the requirement that an agency base the purpose and need on the goals of an applicant and the agency’s statutory authority. The final rule also makes a conforming edit to the definition of “reasonable alternatives” in 40 C.F.R. Section 1508.1(z);

- CEQ is revising 40 C.F.R. Section 1507.3 to remove language that could be construed to limit agencies’ flexibility to develop or revise procedures to implement NEPA specific to their programs and functions that may go beyond the CEQ regulatory requirements; and

- CEQ is revising the definition of “effects” in paragraph (g) of 40 C.F.R. Section
1508.1 to include direct, indirect, and cumulative effects.

The final rule will be effective **May 20, 2022.**

**Draft ATSDR Toxicological Profiles Available For Comment:** The Agency for Toxic Substances and Disease Registry (ATSDR) announced on April 27, 2022, the opening of a docket to obtain comments on drafts of four updated toxicological profiles: nitrobenzene, nitrophenols, mercury, and copper. 87 Fed. Reg. 25023. ATSDR seeks public comments and additional information or reports on studies about the health effects of these four substances for review and potential inclusion in the profiles. ATSDR will evaluate the quality and relevance of such data or studies for possible inclusion in the profile. Comments are due **July 26, 2022.**

**EPA Requests Nominations Of Experts To ORD’s Human Studies Review Board Advisory Committee:** On May 3, 2022, EPA invited nominations from qualified candidates with expertise in the areas of toxicology, bioethics, and statistics to be considered for appointment to its Human Studies Review Board (HSRB) federal advisory committee. 87 Fed. Reg. 26198. According to EPA, HSRB typically reviews protocols and completed studies involving pesticide studies, such as worker exposure studies with agricultural handlers applying pesticides in field conditions; janitorial maintenance personnel applying antimicrobial pesticides in commercial settings; and field efficacy studies for skin applied insect repellent products. Nominations are due **May 31, 2022.**

**BOSC Executive Committee Reviews ORD’s Draft Strategic Research Action Plans:** On May 4-5, 2022, the EPA Board of Scientific Counselors (BOSC) Executive Committee met to review ORD’s six Strategic Research Action Plans (StRAP) for FYs 2023-2026. 87 Fed. Reg. 23861. The draft StRAPs for ORD’s six National Research Programs include:

- **Air, Climate, and Energy (ACE);**
- **Chemical Safety for Sustainability (CSS);**
- **Health and Environmental Risk Assessment (HERA);**
- **Homeland Security (HS);**
- **Safe and Sustainable Water Resources (SSWR);** and
- **Sustainable and Healthy Communities (SHC).**

The Executive Committee will continue its review on **June 2** and **June 10, 2022.** 87 Fed. Reg. 29312. Attendees must register by **June 1, 2022.**

**DOJ And EPA Announce New Enforcement Strategy To Advance Environmental Justice:** On May 5, 2022, the U.S. Department of Justice (DOJ) and EPA announced a series of actions intended to secure environmental justice for all Americans. In addition to launching a new Office of Environmental Justice within DOJ, Attorney General Garland also announced a new comprehensive environmental justice enforcement strategy to guide DOJ’s work and an interim final rule that will restore the use of supplemental environmental projects (SEP) in appropriate circumstances.
In its May 5, 2022, press release, EPA states that SEPs are considered in accordance with its SEP Policy, which ensures there is a sufficient connection to the violation. The SEP Policy provides for consideration of a defendant’s willingness to implement a SEP as part of EPA’s decision about whether, and on what terms, to settle an enforcement matter, just as EPA has discretion to consider, as appropriate, a defendant’s good faith and cooperation when deciding on a penalty and other terms of a settlement. Comments on the interim final rule are due July 11, 2022. More information is available in our May 6, 2022, blog item.

**SEC Extends Comment Period On Proposed Climate Disclosure Rule:** The Securities and Exchange Commission (SEC) announced on May 10, 2022, that it extended the public comment period for its proposed rule that would require registrants to provide certain climate-related information in their registration statements and annual reports. Comments are due June 17, 2022.

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