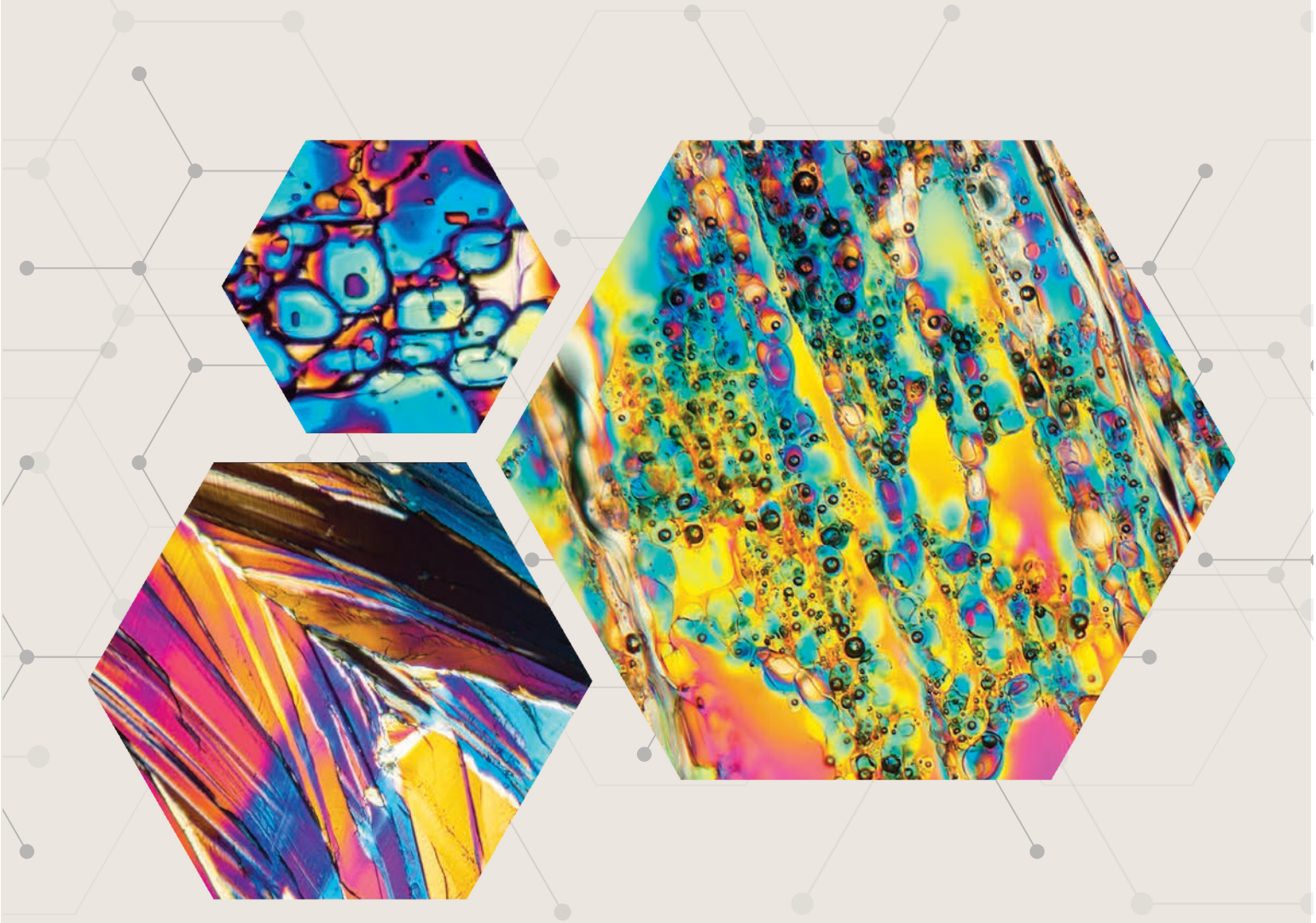

BERGESON & CAMPBELL, P.C.

Forecast for U.S. Federal and International Chemical Regulatory Policy 2024

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Forecast 2024

Bergeson & Campbell, P.C. (B&C®) and its global consulting affiliate The Acta Group (Acta®) and consortia management affiliate B&C® Consortia Management, L.L.C. (BCCM) are delighted to share with you our Forecast 2024. This carefully curated document represents our seasoned team's collective take on what to expect regarding global industrial, agricultural, and biocidal chemical initiatives in the New Year. Given the global state of play, speculating on how things will shake out in 2024 is challenging.

In an election year, competing priorities will dominate the U.S. Environmental Protection Agency's (EPA) actions. EPA will understandably wish to complete as many actions on its agenda as possible while tempering its expectations as necessary to avoid any significant pre-election missteps. While there is no consensus on whether the Biden-Harris Administration's commitment to consequential policy shifts in chemical management has elicited the results promised, reasonable people will agree that the Administration tried hard to fulfill campaign promises in a political climate that is hyperpolarized if not broken entirely. Similarly, reasonable people will disagree on whether the Administration's chemicals management policies have achieved enhanced environmental and human health protection, greater environmental equity, and a clearer sense of what scientific integrity looks like. These are tough issues to navigate under the best of circumstances, but the devil is in the details and for those of us laser-focused on the Toxic Substances Control Act (TSCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and global chemical governance issues, much work remains to be done.

The Republicans' razor-thin margin in the U.S. House of Representatives will continue to invite a high degree of oversight of EPA actions, and the Republican Party's dysfunction will continue to be a significant impediment to getting anything done, especially in an election year. Many of the core TSCA implementation issues that remained controversial and unresolved in 2023, including "reasonably foreseen," "to the extent necessary," "systematic review," and "best available science," could, according to critics of EPA's record over the past two years, continue to evolve in unpredictable and incoherent ways in the New Year. The possibility of a change in the White House only fuels continued disarray. Similar policy shifts and uncertainties are seen under FIFRA and the Endangered Species Act (ESA) in the agricultural and biocidal area but perhaps to less dramatic effect. How the 2024 general election will influence EPA's policy choices is anyone's guess.

Internationally, the European Union's (EU) commitment to net-zero global warming emissions by 2050 advances, but its own election cycle invites significant uncertainty on the policy trajectory in 2024. The EU's proposed per- and polyfluoroalkyl substances (PFAS) regulation has captivated the world's attention as, if implemented as proposed, it will be exceedingly consequential. Further progress will be made in 2024 as the EU and United Kingdom (UK) continue to manage Brexit consequences and the evolution of chemical governance programs globally picks up steam, making up for lost time due to the pandemic. Federal elections in the fall in Canada also invite an element of added uncertainty.

Our unique and exceptionally successful business platform and expanding global team of highly skilled professionals are well-suited to offer this 2024 Forecast. Our core business is laser-focused on the fascinating intersection of chemical law, science, regulation, and policy. This is what we do, and we love doing it. Our highly acclaimed team of lawyers; scientists including toxicologists, chemists, exposure experts, and geneticists; and regulatory and policy experts is deeply versed in chemical law, science, regulation, and policy. We seamlessly leverage the integration of law, science, regulation, and policy to deliver successful outcomes for our clients at every level and in all parts of the globe.

We offer you our very best wishes for good health, happiness, and success in the New Year.

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I. UNITED STATES CHEMICAL MANAGEMENT FORECAST

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A. Introduction

2024 will be exciting, in the good sense. There is an exceptional level of uncertainty in Washington, D.C., for the New Year, even in comparison to past election years: Two wars tugging at the national attention and the federal budget, divided government now referring to the House of Representatives alone, and an election year with one of the presumptive Presidential candidates under 91 indictments in multiple jurisdictions. Other than that, for the U.S. Environmental Protection Agency (EPA), it will definitely not just be "another day at the office." As an example, the new House Speaker marshaled a House budget bill that would cut EPA funding by almost 40 percent!

1. Election 2024

Federal executive agencies, or more precisely, the political leaders of agencies, will have two main goals in 2024: complete actions that are Administration priorities started since President Biden's Inauguration and work to convince voters to re-elect the President. Hoping to finish priorities is unsurprising but made difficult by the long time needed to formulate, propose, and issue final rules and program changes that must complete the gestation process before **January 20, 2025**, just in case. The second goal is even more obvious and imperative — the President and his Administration need to be re-elected if current political appointees are to have time to implement further program goals into a second term.

Accordingly, the agenda for 2024 Biden-Harris Administration activity in EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) will be to refine and complete actions under development and now ripe for specific actions to capture this Administration's interpretation of statutory requirements and important policy definitions. Examples will include chemical risk assessments under the Toxic Substances Control Act (TSCA) and endangered species protections as part of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) label requirements. Such program achievements will then be included in the Agency-wide list of accomplishments (climate change initiatives, toxic waste cleanup, and related initiatives) for the first term and to convince voters of the justification for a second term.

EPA and OCSPP will also continue the general priorities announced at the beginning of 2021. These include a focus on climate issues, environmental justice, scientific integrity, and a review and often reversal of actions taken, or not taken, by the Trump Administration.

Will 2024 be impactful for OCSPP? It may be the most impactful year in recent history. If the Office of Pollution Prevention and Toxics (OPPT) establishes how to assess and regulate older, widely used chemicals, that alone would be a signature achievement. This is not to diminish the significant intensity of the ongoing debate on requirements for premanufacture review of new chemicals, a debate that continues seven years after passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg).

For the pesticide program, meeting decision deadlines in the legislative fee scheme (PRIA — the Pesticide Registration Improvement Act) would be impressive, but the program is

finally attempting to figure out an effective way to integrate FIFRA and the requirements of the Endangered Species Act (ESA). If the Office of Pesticide Programs (OPP) can solve that puzzle, it may be asked next to determine how to balance the federal budget (about ESA integration or balancing the federal budget, it can be said: "many have tried, all have failed").

These examples would indeed be signature achievements, but like any regulatory office, both programs have much to do on a regular basis as the government's main regulators of industrial chemical and pesticide use. Every day, the more than 1,060 employees of OCSPP work to regulate approximately 40,000 industrial chemicals, including per- and polyfluoroalkyl substances (PFAS), lead, mercury, flame retardants, along with almost 1,100 active ingredient pesticides subject to periodic reviews, including herbicides such as dicamba, Enlist, and glyphosate, along with organophosphate and neonicotinoid insecticides such as chlorpyrifos and imidacloprid. Yep, just "another day at the office."

2. Operating Environment

The election year will bring more emphasis on signaling to supportive groups that the Administration has "delivered" on past commitments. Other than climate issues and the broad description of cleaning up and preventing pollution, most campaign issues will likely avoid most specific OCSPP issues. There will be critics of EPA's achievements as "over-regulation," with rhetoric to describe how the current EPA is imposing unnecessary or excessive regulatory costs for little clear benefit. Critics question whether EPA initiatives are supported by "sound science," often a subjective determination depending on the eye of the beholder. With divided government, both support and criticism of EPA will be heard differently depending on which side of Capitol Hill is doing the examination.

EPA's budget debate provides evidence of the dynamic: the White House has already given and proposed further increases in EPA spending, currently the Senate seems poised to provide a relatively small increase if any, and the House has passed significant cuts (almost 40 percent) as part of the effort to "rein in EPA" and control government spending generally. Regardless of the outcome, the budget uncertainty and election year roulette of what issues may gain oversight or campaign attention will be among the unknowns facing all EPA programs. Senior appointee time and energy will be spent at Congressional hearings, and later in the election season trips to, say, Michigan, Wisconsin, Pennsylvania, and Georgia, among other states. Activities that consume significant amounts of senior leadership time and attention take time away for meetings to make more routine program decisions. This, with the time and attention spent on "must complete" initiatives mentioned earlier, may further slow actions and decisions that, while important, are not on the shorter list of priorities.

For OCSPP, budget resources and staffing levels remain contentious. Leadership describes the critical need for significantly greater budget and staffing for OPPT to implement the 2016 TSCA amendments that added various deadlines for program activities and a general expectation to enhance program activities to review and regulate industrial chemicals. Now, seven years after these amendments became law, the program has seen increases but not the significant increases many believe are needed. OPP has seen an increase in the fees generated by the PRIA amendments of 2022 and has gotten small increases in appropriated funds, but meeting the PRIA deadlines remains a sore point with registrants. Added time to complete ESA assessments to pesticide reviews is likely to hinder meeting any deadlines put in place before EPA developed new ESA review plans.

Given the budget debate currently in Congress, neither program is likely to see a substantial increase in budget authorization anytime soon. The pace of TSCA implementation may see some oversight from Congressional committees concerned with broad subjects such as worker safety, community pollution risks, and environmental justice. FIFRA-related subjects may be considered as part of the broader discussion of a new Farm Bill that expired at the end of 2023. Congress may simply extend the current Farm Bill provisions to move consideration to sometime in 2024, which could then include discussion of pesticide issues.

3. Staffing and Morale

Budget decisions immediately affect pay scales for all federal employees. OCSPP has job openings available in both programs, but as they both are "science-heavy," recruitment

competes with the private sector. Like many agencies, the number of workers choosing to work remotely part- or full-time has significantly increased due to COVID. Remote work has probably helped EPA and other agencies with morale and job satisfaction.

2023 saw the long-sought achievement of physically integrating the staff of both OPP and OPPT. Ironically, however, since many staff are mostly or fully remote, the benefits of physical integration may be diminished.

At the same time, as the 2024 election nears, anecdotal reports have seen an increase in speculation about what would happen if there is a second Trump Administration in charge of executive agencies generally and EPA in particular. Given reports of the chasm and distrust between EPA career employees and the political leadership during the Trump first term, if Mr. Trump is elected again, there appears to be a chance (if not likelihood) of a mass exodus of EPA staff, especially among mid-level and senior-level career employees. Recruitment of new staff likely would be affected. This point is worth mentioning in a 2024 Forecast since, if there is a changed Administration, the personnel shifts expected either voluntarily or involuntarily could lead to uncertain impacts on program performance as the dust settles on who is in charge, what are new priorities, and the results of attrition, retirements, and personnel shifts.

We urge submitters who are waiting for consent orders to review the TSCA Section 5(e) order template so that you are aware of the bulk of the boilerplate order terms and can focus review on the specific terms for your substance.

B. TSCA: PREDICTIONS AND OUTLOOK FOR OCSPP'S OFFICE OF POLLUTION PREVENTION AND TOXICS

OPPT intends to accelerate its pace of regulatory actions under TSCA. EPA had an ambitious agenda for 2023 and, unsurprisingly, did not accomplish all that it intended. We expect 2024 to be similarly ambitious and, with the experience EPA gained in 2023, EPA is likely to have a productive year.

As of November 1, 2023, EPA published in final the asbestos reporting rule, the confidential business information (CBI) procedures rule, and the Section 8(a)(7) reporting rule for PFAS. EPA also proposed four additional risk management rules: methylene chloride (MC), perchloroethylene (PCE or PERC), carbon tetrachloride, and trichloroethylene (TCE), proposed updates to its new chemicals regulations, proposed updates to the Section 6 risk evaluation rules, published a revision to its fees rule proposal with a substantial fee increase, published its white paper on its approach to its Asbestos Part 2 Risk Evaluation, and published the Supplemental Risk Evaluation for 1,4-dioxane. EPA had expected to reopen the persistent, bioaccumulative, and toxic (PBT) rules for additional comments and propose tiered data reporting. EPA proposed revisions to two of the five PBT rules in November, decabromodiphenyl ether (decaBDE) and phenol, isopropylated phosphate (3:1) (PIP (3:1)), but additional action was not forthcoming. 88 Fed. Reg. 82287. EPA had also expected to publish draft risk evaluations for some of the "Next 20" prioritized chemicals. In October, EPA released a short list of 15 substances from which EPA will select five on which to focus for its next prioritization candidates. Recall that for each risk evaluation EPA completes, EPA is required to propose another chemical for prioritization.

Departures of key managers in late 2022 (Dr. Tala Henry, Deputy Office Director) and during 2023 (Madison Le, New Chemicals Division (NCD) Director) undoubtedly hampered OPPT's ability to accomplish more in 2023. While Ms. Le's deputy, Shari Barash, is a talented manager and capable as Acting Director, NCD is still short a manager. EPA has advertised for a permanent replacement for Ms. Le, but it will take time for EPA to complete this search (and a search for a new NCD Deputy Director if Ms. Barash ascends to be the permanent Director). In addition, OPPT Director Denise Keehner announced her retirement and remained until her replacement, Dr. Elissa Reeves, the former Director of the OPP Reregistration Division, assumed the role in December.

In 2023, NCD made great strides in bringing in new health assessors, a critical shortage that has hampered reviews on new chemical substance notifications (*e.g.*, premanufacture notices or PMN) for some time. NCD is next planning on hiring additional program managers (staff that manage PMNs and other notices through the new chemicals process), engineers, fate assessors, and chemists. Unfortunately, NCD's current full-time equivalent (FTE) ceiling will remain until Congress passes a budget, but there are vacant FTEs to fill in the meantime. While the pace of risk assessments picked up, the pace of completing cases slowed as cases began to back up with risk managers. We urge submitters who are waiting for consent orders to review the TSCA Section 5(e) order template so that you are aware of the bulk of the boilerplate order terms and can focus review on the specific terms for your substance. B&C encourages submitters to avoid letting orders linger.

EPA has not yet published in final any risk management rules. We had expected EPA to publish its final Asbestos Part 1: Chrysotile Asbestos rule in 2023, but according to the Fall 2023 Unified Agenda of Regulatory and Deregulatory Actions (Regulatory Agenda), EPA expects to publish the rule in final in **January 2024**. It remains to be seen if EPA's proposed very aggressive phaseout will remain

and if EPA will allow any exemptions to its proposed ban. Congress may attempt to supersede EPA's rulemaking with legislation, but we do not expect any bills to succeed. The final rule will likely be challenged in court; stakeholders should pay careful attention even if asbestos is not in your supply chain.

There is little transparency to how EPA is updating its risk evaluations for the "Next 20" prioritized substances. The first insight will probably come from the handful of draft risk evaluations that EPA expects to publish in **early 2024**. Lawsuits filed to force EPA to complete its risk evaluations will likely lead EPA to negotiate specific deadlines to complete each. A coalition of non-governmental organizations (NGO) filed suit on September 18, 2023, in the U.S. District Court for the District of Columbia, regarding EPA's failure to complete risk evaluations for 22 high-priority substances by the statutory deadline. *Cmty. In-Power and Dev. Ass'n v. EPA* (No. 1:23-cv-2715). The American Chemistry Council (ACC) moved to intervene on behalf of the plaintiffs on October 25, 2023. ACC noted that its High Phthalates Panel requested risk evaluations on two of the 22 chemicals, diisononyl phthalate (DINP) and diisodecyl phthalate (DIDP), and that EPA was required to complete the manufacturer-requested risk evaluations by July 2, 2023, but failed to do so. We hope that court-ordered deadlines do not lead EPA to compromise on the quality of those evaluations.

Unfortunately, new funding, new hires, and arrival of scientists from other offices have not improved EPA's pace of determinations for new chemical substances. EPA's Office of the Inspector General (OIG) issued a report on the lack of established policies, that shined a light on part of the problem: with so many new people, it is a challenge for NCD to complete reviews consistently and efficiently. In calendar year 2023, EPA received 129 PMNs, but completed determinations on only 79 — 66 of which are from earlier fiscal years (FY). An additional 29 were withdrawn or declared invalid, meaning that EPA's queue of PMNs under review grew in 2023 despite the number of submissions dropping to the lowest level in decades. We can quibble about the definition of a "backlog," but EPA continues to fall behind. In addition, EPA continued to regulate nearly every PMN with an order.

In 2023, 90 percent of PMN determinations resulted in consent orders. Unfortunately, the pace of significant new use rule (SNUR) proposals and promulgation essentially ground to a halt. EPA proposed one set of SNURs (*see* pyoil section below) and published two sets in final. Over 160 PMNs with consent orders await EPA to propose SNURs. Each of these cases represents a possibility that another manufacturer will enter the market without the protective measures established by the order and limits the PMN submitter's ability to commercialize fully the product due to the standard distribution limits in consent orders — limits that do not expire until after the corresponding SNUR is promulgated.

As we wrote last year, EPA proposed a significant increase in TSCA fees with comments due January 17, 2023. Many industry commenters questioned the basis for EPA's significant fee increase — a similar criticism to EPA's initial proposal in January 2021. As of this writing, EPA has yet to publish the fee increase in final, but the Fall Regulatory Agenda indicates EPA expected to publish the final rule in **February 2024**.

EPA's position that current fees are substantially less than 25 percent of the costs to administer TSCA is undermined by an EPA OIG audit of TSCA fees. In a report published October 12, 2023, the OIG concluded "The fees collected in FYs 2019–2021 met the intent of TSCA to defray 25 percent of the specified costs of carrying out sections 4 and 5, parts of section 6, and section 14. During the three-year period, relevant TSCA expenses were $135.3 million, and the EPA collected approximately $33.1 million of relevant TSCA service fees, which defrayed 24.47 percent of costs." EPA's responsibilities under Sections 4 and 6 have increased as EPA has issued test orders and has begun to work through risk management rules, but EPA's responsibilities under Section 5 have gone down as the number of PMNs submitted dropped again, from 214 in FY 2021, to 190 in FY 2022, to just 168 in FY 2023.

1. Section 4(a) — Test Orders

a. High-Priority Substances Undergoing Risk Evaluation

The TSCA test orders that EPA issued in 2021 and 2022 are likely nearing completion, although EPA has kept the dermal hand wipe sampling testing suspended. Under tremendous pressure to complete risk evaluations (*see* litigation section), it is our experience that EPA has been reviewing timely test protocols submitted by order recipients.

The judicial appeals of test orders from the Vinyl Institute (VI) for 1,1,2-trichloroethane and the TDCE Consortium for *trans*-1,2-dichloroethylene are still pending.

EPA has yet to begin issuing test orders for the remaining "Next 20" high-priority substances or for substances that EPA is considering prioritizing for potential risk evaluation. We are concerned that the same issues we have discussed in past years (*e.g.*, ordering testing to fill data gaps, rather than data needs) will be recurring themes in future test orders. On the other hand, EPA continues to express a willingness to work with potential test order recipients on addressing data needs before issuing test orders in the future to avoid the challenges that EPA and recipients have faced in the first two rounds of test orders. TSCA consortia managed by B&C® Consortia Management, L.L.C. (BCCM) continue to engage with EPA regarding potential testing.

b. National PFAS Testing Strategy

In 2023, EPA continued to order testing on additional PFAS and signaled that it would expand significantly the number of PFAS for which it will order testing. In the National PFAS Testing Strategy, EPA assigned PFAS into specific categories for test orders lacking toxicity data to inform EPA's human health effects assessment. In January 2023, EPA issued a second TSCA Section 4(a)(1) test order on trifluoro(trifluoromethyl)oxirane (HFPO), (Chemical Abstracts Service Registry Number® (CAS RN®) 428-59-1). EPA directed the test order to four companies based on their uses of HFPO as a reactant for plastics material and resin manufacturing and in other basic organic chemical manufacturing. EPA is requiring testing on physical-chemical properties (Organization for Economic Cooperation and Development (OECD) Testing Guideline (TG) 111, *Hydrolysis as a Function of pH*) and testing for health effects by the inhalation route. EPA tiered the required health effects testing as follows:

- Tier 1: *In vitro Respiratory Tract Epithelial Toxicity in Primary Human Cell Culture* and *Partition Coefficient and ADME Inhalation Study, Gargas, et al.*
- Tier 2: OECD 416 — *Two-Generation Reproduction Toxicity*, OECD 426 — *Developmental Neurotoxicity Study*, OECD 424 – *Subchronic Neurotoxicity Study in Rodents*, and OECD 453 — *Combined Chronic Toxicity/Carcinogenicity Studies*.

In our memorandum on the order, we note that EPA's approach for identifying existing data overlooked a considerable amount of information — a common theme. We also note that EPA's instructions for completing the specified testing were unclear. For example, the Tier 1 *in vitro* testing cited above states that it should be performed according to the "Protocols/Methodologies" provided in Mallek *et al.* (2022). This citation is for a method to measure "Trans-Epithelial Electrical Resistance (TEER)," which is one of many endpoints EPA requires in Tier 1 *in vitro* testing. EPA did not, however, provide reference to a protocol/methodology for performing the *in vitro* testing. These types of omissions create delays with performing the testing because of the required back and forth between test order recipients and EPA for clarification and the test order recipients and contract research organizations on designing the experiments.

The third EPA test order was announced in August 2023 and was issued to three companies to provide testing for the substance used as a reactant in organic chemical manufacturing for 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy) propanoyl fluoride (HFPO-DAF) (CAS RN 2062-98-8). The test order requires all tests under tier 1.1 and testing under tiers 1.2 and 1.3 in accordance with decision logic presented by EPA. Physical-Chemical Properties under tier 1.1 include: OECD 102 — *Melting Point/Melting Range*, OECD 103 - *Boiling Point*, OECD 104 — *Vapor Pressure*, OECD 105 — *Water Solubility*, OECD 122 — *Determination of pH, Acidity and Alkalinity*, and OECD 111 — *Hydrolysis as a Function of pH*. Health effects testing for dermal route tier 1.2 include OECD 431 — *In vitro Skin Corrosion: Reconstructed Human Epidermis (RHE)* and OECD 435 — *In vitro Membrane Barrier Test Method for Skin Corrosion*; and tier 1.3 OECD 428 — *Skin Absorption: In vitro Method*, OECD 497 — *Defined Approached on Skin Sensitization*, and OECD 439 — *In vitro Skin Irritation: Reconstructed Human Epidermis Test Method*. Health effects testing for the ocular route include tier 1.1 OECD 437 — *Bovine Corneal Opacity and Permeability Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage* and tier 1.2 OECD 492B — *Reconstructed Human Cornea-like Epithelium (RHCE) Test Method for Eye Hazard Identification*. Mechanistic health effects required under tier 1.2 include OECD 473 — *In vitro Mammalian Chromosomal Aberration Test*, OECD 487, *In vitro Mammalian Cell Micronucleus Test*, and OECD 490 — *In vitro Mammalian Cell Gene Mutation*

Tests using the Thymidine Kinase Gene. EPA seems to have identified all of the testing specified in its PFAS testing plan without regard to existing data or whether testing is appropriate. For example, EPA orders testing for melting point even though EPA predicts a melting point of -90 °C. Time will tell if legal challenges to EPA's test orders will lead EPA to consider carefully what information is available and what information it needs. For more information on this order, *see* our memorandum on the topic.

c. Section 4(a) Test Order Litigation

i. 1,1,2-Trichloroethane

As we wrote last year, on May 23, 2022, the Vinyl Institute (VI) filed suit in the U.S. Court of Appeals for the District of Columbia Circuit against EPA, seeking review of EPA's March 2022 Section 4(a)(2) test order for 1,1,2-trichloroethane, particularly the requirement for an Avian Reproduction Test. *VI v. EPA*, No. 22-1089. According to the VI, EPA failed to explain adequately why the Avian Reproduction Test is necessary to perform a risk evaluation of 1,1,2-trichloroethane, EPA failed to consider all available information and data regarding 1,1,2-trichloroethane, and EPA failed to consider the relative costs of the Avian Reproduction Test protocols required under the test order and the reasonably foreseeable availability of the facilities and personnel needed to perform the required testing.

After EPA asked the court in July 2023 to place the lawsuit on hold for 60 days while it decided whether the Avian Reproduction Test is feasible, on October 10, 2023, EPA asked the court to remove the case from abeyance and to reschedule oral argument. During the period of abeyance, EPA determined that the Avian Reproduction Test was feasible and notified the VI that testing as required by the test order should proceed. The court heard oral argument on December 1, 2023.

ii. 6:2 FTSB

National Foam, Inc. filed suit in the U.S. Court of Appeals for the District of Columbia Circuit on August 15, 2022, seeking review of a TSCA Section 4(a)(2) test order for 6:2 FTSB (6:2 fluorotelomer sulfonamide betaine), a PFAS. *Nat'l Foam v. EPA*, No. 22-1208. According to National Foam, EPA erred by issuing the test order to National Foam, given that it neither manufactures nor processes 6:2 FTSB. National Foam maintains that EPA erred by rejecting "substantial evidence" presented by National Foam showing that it "never purchases, possesses, handles, or otherwise uses 6:2 FTSB as a 'chemical substance' within the meaning of Section 3(2) of TSCA, … but rather only as a component of a mixture purchased from an independent vendor." National Foam also maintains that EPA erred in rejecting evidence that National Foam never purchases, possesses, handles, or otherwise uses 6:2 FTSB in its solid form, which is the form of the chemical substance about which EPA seeks testing under the test order.

In February 2023, EPA provided a notice to the Test order recipients stating that EPA had eliminated certain testing requirements because a test order recipient submitted existing testing information satisfying one of the data needs for which the test order required testing. After several months of settlement discussions, on May 8, 2023, EPA granted National Foam's testing exemption request, and the parties asked the court to hold the case in abeyance. According to a September 7, 2023, status report, "Test Order testing is ongoing and [] there have been no updates or changes to the Test Order's testing obligations." The next status report is due **January 5, 2024**.

iii. HFPO

On March 9, 2023, DuPont de Nemours filed a petition challenging EPA's naming DuPont on the January 2023 test order for HFPO. On March 15, 2023, the U.S. Court of Appeals for the Third Circuit ordered EPA to provide a record documenting its decision to order DuPont de Nemours Inc. to provide toxicity information about HFPO. *DuPont De Nemours Inc v. EPA* (No. 23-1444). In May 2023, EPA determined that DuPont de Nemours does not make HFPO, and the court granted the party's motion to dismiss the case on May 22, 2023.

iv. TDCE

On August 22, 2022, the TDCE Consortium filed a lawsuit to protect its legal interests while waiting for EPA's conclusion about the need for toxicity testing on sediment-dwelling organisms.

The lawsuit, *TDCE Consortium v. EPA*, No. 22-1216, has been voluntarily stayed while preliminary testing and negotiations continue.

2. Section 4(h) — NAMs

We are pleased that EPA's new approach methodologies (NAM) strategy expanded in 2023 with the incorporation of NAMs as part of its TSCA Section 4 test orders and with exposure models used in the *2023 Draft Supplement to the Risk Evaluation for 1,4-Dioxane* (the 2023 Draft Supplement). As discussed above, EPA ordered *in vitro* respiratory tract testing in the TSCA Section 4(a)(1) test order on HFPO. EPA stated the following in support of this requirement: "Portal-of-entry effects in the lung have been demonstrated in animal models but their relevance for use in human health assessment is uncertain. EPA is requiring an *in vitro* toxicity study using cells of human origin to examine portal-of-entry effects in human tissue." We are, however, perplexed by this statement, given that EPA routinely applies dosimetry adjustments for substances that cause portal-of-entry (POE) effects in rodent inhalation studies to derive human equivalent concentrations and has issued reference values on substances that cause POE effects as part of its human health assessments.

EPA expanded its use of NAMs to include "new methods and novel applications of existing methods" for evaluating additional human exposure pathways assessed in the 2023 Draft Supplement, which underwent peer review by the TSCA Scientific Advisory Committee on Chemicals (SACC) in September 2023. Though we are encouraged by EPA's innovation with developing these NAMs, we are concerned that EPA chose to use these models as part of a regulatory risk evaluation, despite the models not being previously peer reviewed. The issue here is with the level of rigor that members of the TSCA SACC will apply when simultaneously evaluating the models and the 2023 Draft Supplement. We note that the 2023 Draft Supplement is 484 pages long and includes thousands of pages of supporting documents.

We mention these issues because EPA maintains the "List of Alternative Test Methods and Strategies (or New Approach Methodologies [NAMs])" (List), which contains NAMs that the EPA Administrator has identified as scientifically reliable and relevant. EPA's use of NAMs that are not on the List is concerning because of the absence of transparency with the criteria that EPA is using when determining that a NAM is appropriate for regulatory activities under TSCA. After all, in 2020, EPA proposed the following five critical elements for nominating potential NAMs to the List: Nominal Information (What is it?), Development History (How was it developed and by whom?), Method Description (How does it work? What are the steps involved?), Relevance (Does it predict anything useful for decisions about TSCA chemicals?), and Reliability (Can we trust the output and justify our decisions based on it[s] use?). EPA did not, however, justify its requirement for performing *in vitro* respiratory tract testing nor its use of non-peer-reviewed models against these or other criteria.

The above issues create confusion for the regulated community on the use of NAMs. For example, since *in vitro* respiratory tract testing is not included on the List, questions may arise as to whether the regulated community should use this NAM, rather than the *in vivo* alternative, to explore potential POE effects as part of its submissions to EPA. Further, we are concerned that EPA may end up undermining confidence in NAMs in general if it continues to co-peer-review novel methods as part of its draft risk evaluations on high-priority substances, rather than peer reviewing the novel methods before using the methods as part of regulatory risk evaluations under TSCA.

3. Section 6 — Existing Chemical Substances

a. Updated Framework Rule

On October 30, 2023, EPA proposed a rule that would revise its process required under TSCA Section 6(b)(4) for conducting TSCA risk evaluations. This action includes revisions to the procedures for the framework rule for risk evaluation at 40 C.F.R. Part 702. Among other things, proposed changes include changes to, and elimination of, certain definitions, clarifications regarding the required scope of risk evaluations, considerations related to peer review and EPA's implementation of the scientific standards, the approach for risk determinations on chemical substances and considerations related to unreasonable risk, and the process for revisiting a completed risk evaluation. Included are proposals to codify its "whole chemical" approach, its assumption that not all workers use personal protective equipment (PPE) (although in practice, this means EPA assumes workers never use PPE in the absence of a TSCA rule), and to clarify that the scope will include all exposure pathways. EPA is also proposing to amend the process and requirements for manufacturer requests for EPA risk evaluations on specific chemicals. The comment deadline was December 14, 2023. We believe this proposed rule is potentially the most impactful that the Biden-Harris

We expect that EPA will issue a data call-in (DCI) under TSCA Section 8(d) for the five substances prioritized for risk evaluation to ensure that EPA has all existing data associated with some or all of these substances.

Administration has issued under TSCA and the revision of the risk evaluation procedures will be a key regulatory development in 2024. More information on EPA's proposed rule is available in our October 30, 2023, memorandum, "EPA Proposes to Amend TSCA Risk Evaluation Framework Rule."

The Fall 2023 Regulatory Agenda, issued by the Office of Management and Budget (OMB), includes **April 2024** as the planned date for publication of the final rule (2070-AK90).

b. Prioritization

In October, EPA issued a list of 15 substances it is considering for prioritization:

- Acetaldehyde;
- Acrylonitrile;
- Benzenamine;
- Benzene;
- Bisphenol A (BPA);
- Ethylbenzene;
- Naphthalene;
- Styrene;
- Tribromomethane;
- Triglycidyl isocyanurate;
- Vinyl chloride;
- Hydrogen fluoride;
- 4,4′-Methylenebis(2-chloroaniline) (MBOCA);
- 4-tert-octylphenol, 4-(1,1,3,3-Tetramethylbutyl)-phenol; and
- N-(1,3-Dimethylbutyl)-N′-phenyl-p-phenylenediamine (6PPD).

In December, EPA announced that it is beginning the process to prioritize five of these substances for risk evaluation under TSCA.

- Acetaldehyde;
- Acrylonitrile;
- Benzenamine;
- MBOCA; and
- Vinyl chloride.

We expect that EPA will issue a data call-in (DCI) under TSCA Section 8(d) for these substances to ensure that EPA has all existing data associated with some or all of these substances. Additionally, as discussed below, in December, EPA announced that it will issue a TSCA Section 8(c) DCI for MBOCA. As EPA narrows its list of potential targets, EPA may also issue test orders for key data gaps.

ARTICLE

"Toxic Substances Law Creating More Confusion for Legal Teams and Public," *Chemical Processing,* February 15, 2023

c. Risk Evaluations

i. "Next 20"

In addition to the "Next 20" chemicals EPA continued to review in 2023, EPA is trying to make progress on the manufacturer requests for risk evaluations under TSCA Section 6(b)(4)(C)(ii).

In July 2023, EPA released the *2023 Draft Revised Risk Determination for 1,4-Dioxane* as a whole chemical substance under TSCA. The proposed risk determination for 1,4-dioxane as a whole chemical substance includes chemical-specific changes in accordance with the "path forward" for the "First 10" risk evaluations under TSCA laid out by EPA in June 2021. EPA also released in July 2023 the *2023 Draft Supplement to the Risk Evaluation for 1,4-Dioxane*, which was available for public comment and peer review through September 8, 2023. The draft supplement considers air and water exposure pathways not evaluated in the December 2020 risk evaluation and exposure to 1,4-dioxane generated as a byproduct. EPA describes in the draft revised risk determination the conditions of use that contribute to the determination that 1,4-dioxane presents an unreasonable risk of injury to human health.

Additionally, EPA issued a white paper for its approach to its Asbestos Part 2 risk evaluation. The Asbestos Part 2 risk

evaluation is a result of the settlement in *Safer Chemicals Healthy Families v. EPA*, 943 F.3d 397 (9th Cir. 2019) in which EPA is obligated to publish a supplemental risk evaluation for asbestos (Part 2) related to legacy uses (*i.e.*, the circumstances associated with activities that do not reflect ongoing or prospective manufacturing, processing, or distribution) of asbestos and associated disposals. As part of that settlement, EPA also agreed to issue Part 2 of the risk evaluation of asbestos by **December 1, 2024.**

EPA continued the process of reviewing existing chemicals under amended TSCA. EPA designated 20 high-priority chemicals in December 2019 (the "Next 20"). The "Next 20" high-priority chemicals are:

1. *p*-Dichlorobenzene
2. 1,2-Dichloroethane
3. *trans*-1,2-Dichloroethylene
4. *o*-Dichlorobenzene
5. 1,1,2-Trichloroethane
6. 1,2-Dichloropropane
7. 1,1-Dichloroethane
8. Dibutyl phthalate (DBP)
9. Butyl benzyl phthalate (BBP)
10. Di-ethylhexyl phthalate (DEHP)
11. Di-isobutyl phthalate (DIBP)
12. Dicyclohexyl phthalate
13. 4,4′-(1-Methylethylidene)bis[2,6-dibromophenol] (TBBPA)
14. Tris(2-chloroethyl) phosphate (TCEP)
15. Phosphoric acid, triphenyl ester, also known as triphenyl phosphate (TPP)
16. Ethylene dibromide
17. 1,3-Butadiene
18. 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[γ]-2-benzopyran (HHCB)
19. Formaldehyde
20. Phthalic anhydride

There has been little apparent change in the status of the risk evaluation reviews of the "Next 20." As of December 22, 2023, EPA has completed a draft risk evaluation of TCEP. EPA intends to stagger completion of its risk evaluations, so they are not all being completed at once. This also staggers the requirement that EPA initiate prioritization for an additional substance for risk evaluation.

In late 2021, EPA issued a DCI under TSCA Section 8(d) with a January 2022 reporting deadline. Shortly thereafter, EPA issued additional test orders on the nine substances for which EPA had already issued orders; much of that testing is still underway. Based on anecdotal evidence, risk evaluation work continues on all 20 substances. The new policy changes reflected in the "First 10," which EPA has included, among other things, in amendments to its risk evaluation procedural rule proposed on October 30, 2023, will need to be incorporated in the scope documents for the "Next 20." There remain unanswered questions about whether EPA's view that PPE is not used meets the standard of the requirement that EPA rely upon "reasonably available information." The implementing regulations at 40 C.F.R. Part 702 Subpart B. TSCA Section 26(k) states the following:

> In carrying out sections [4, 5, and 6] of this title, the Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator.

EPA interpreted TSCA Section 26(k) in the proposed rule issued under the Obama Administration, the final rule promulgated under the Trump Administration at 40 C.F.R. Section 702.33, and most recently in the October 2023 proposed amendments to the risk evaluation procedural rule in nearly identical terms. The differences in the definition of "reasonably available information" between and among the Obama Administration proposed rule, Trump Administration final rule, and the Biden-Harris Administration proposed rule are shown below; the text in the Obama Administration proposed rule that differs from the final rule is underlined, and the text in the final rule that differs from the Biden-Harris Administration proposal is struck through:

> ~~[E]xisting~~ information that EPA possesses or can reasonably generate, obtain, and synthesize ***for use in risk evaluations***, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation [bolded emphasis added].

PODCAST:
Section 6 Advocacy and the Importance of Being Early — A Conversation with Richard E. Engler, Ph.D.

Importantly, the definitions, under the Obama, Trump, and Biden-Harris Administrations, do not say "for use in risk management." EPA states, however, the following in eight of the "First 10" draft or final revised risk determinations:

> [I]nformation on the use of PPE as a means of mitigating risk (including information received from industry respondents about occupational safety practices in use [*i.e.*, reasonably available information]) would [or will] be ***considered during the risk management phase***, as appropriate [emphasis added].

See, e.g., 1-Bromopropane (1-BP), Carbon Tetrachloride (CCl_4), Colour Index Pigment Violet 29 (PV29), Cyclic Aliphatic Bromide Cluster (HBCD), MC, N-Methylpyrrolidone (NMP), PCE, and TCE.

We believe that EPA will revise the final scope documents for the "Next 20" and provide an opportunity for public comment in 2024. Manufacturers, importers, and processors, among others, will need to continue to engage with EPA on the specific conditions of use as EPA progresses the risk evaluations. Given that EPA has several manufacturer-requested risk evaluations (MRRE) under way, B&C expects the risk evaluation work on the "Next 20" to continue through much of 2024.

Of note, under TSCA Section 26(n), EPA is required to publish an Annual Plan each calendar year that identifies the chemical substances for which risk evaluations are expected to be initiated or completed that year, describes the status of each risk evaluation that has been initiated but not yet completed, and includes an updated schedule for completion of risk evaluations. EPA published no Annual Plan for 2022 and, as of November 10, 2023, has not published one for 2023. We hope EPA can soon get back on track and publish its plan for risk evaluations in 2024, as it did in 2017 through 2021. These plans can help the public better anticipate when resources may be required to engage meaningfully in the risk evaluation development process.

ii. Manufacturer-Requested Risk Evaluations

EPA continues to review MRREs requested under TSCA Section 6(b)(4)(C)(ii). As with risk evaluations for high-priority chemicals, EPA has three years to complete MRREs, with an extension available for up to six months. There has been little public visibility into the status of the MRREs.

(a) Diisononyl Phthalate (DINP)/Diisodecyl Phthalate (DIDP)

There has been no visible progress on the risk evaluation for DINP and DIDP. In fact, the submitters of the DIDP and DINP MRREs have filed a notice of intent to sue seeking to force EPA to complete the two MRREs.

(b) Octamethylcyclotetra-siloxane (D4)

On October 12, 2022, EPA published its notes from the July 27, 2022, stakeholder meeting. In that document, EPA states that it intends to complete the D4 risk evaluation by the **end of 2024**.

d. Policy Changes

On multiple occasions in 2023, Dr. Freedhoff stated that EPA's view is that if EPA does not have data to support that a type of workplace can meet an existing chemical exposure limit (ECEL), EPA must propose a ban for that condition of use. We do not see support for this legal position. In our view, if EPA promulgates an ECEL for a substance, as long as a workplace can demonstrate compliance with that ECEL according to the standards set forth in the rulemaking (standards for methods and timing), that workplace should be allowed to continue to operate with the substance in question. While there is value to a workplace having inhalation monitoring data in advance of EPA's rulemaking, it should not be necessary to avert a ban.

i. Systematic Review

As we have discussed in years past, the U.S. National Academies of Sciences, Engineering, and Medicine (NASEM) issued a final report on EPA's 2018 *Application of Systematic Review in TSCA Risk Evaluations* (2018 Guidance Document) that was quite critical of EPA's approach, concluding that it was not "comprehensive, workable, objective, and transparent." The NASEM Committee generally found that "the systematic reviews within the draft risk evaluations considered did not meet the standards of systematic review methodology." In response, EPA began again, publishing a "draft TSCA Systematic Review Protocol" (Draft Protocol). That protocol was reviewed by the SACC in 2022, but EPA has not made any visible progress towards an updated final protocol.

The lack of a final peer-reviewed systematic review protocol leaves EPA's risk evaluations open to question and leaves risk

EPA's risk management rules for 1,4-dioxane may be a key indicator of how EPA will approach risk management under other statutory authority.

management actions with a significant legal vulnerability on whether EPA complied with the scientific standards under TSCA Section 26. We mention this because of EPA's previous conclusions that its use of the 2018 Guidance Document resulted in final risk evaluations that are "robust and upholding the standards of best available science and weight of scientific evidence per TSCA sections 26(h) and (i)."

A representative example of EPA not meeting the TSCA Section 26 standards is provided by EPA's evaluations on NMP. EPA first began evaluating NMP under TSCA in 2012 as a work plan chemical risk assessment. EPA subsequently published the final work plan chemical risk assessment for NMP in 2015. As part of its hazard assessment at that time, EPA concluded that the reproduction and developmental study performed by Sitarek and Stetkiewicz (2008) was "unreliable" due to inconsistencies in the published data. In comparison, EPA assigned a data quality rating of "High" to Sitarek and Stetkiewicz (2008) in the final risk evaluation for NMP. Under the systematic review method used in the final risk evaluation for NMP, a data quality rating of High was defined to mean:

> No notable deficiencies or concerns are identified in the domain metric that are likely to influence results [score of 1].

EPA did not, however, provide its rationale for reassigning a data quality rating of High to Sitarek and Stetkiewicz (2008) in the final risk evaluation for NMP, nor did EPA mention the inconsistencies between its conclusions on this study in the work plan chemical risk assessment versus the risk evaluation.

Another representative example in the final risk evaluation for NMP is EPA's evaluation and use of a two-generation oral dietary study in rats, designated by EPA as "Exxon (1991)" and discussed below. EPA assigned a data quality rating of High to Exxon (1991) in the final risk evaluation for NMP and used the data on decreased fertility from this study as the basis for quantifying chronic risks. As with the study performed by Sitarek and Stetkiewicz (2008), however, EPA's evaluation of the Exxon (1991) study in the final risk evaluation for NMP conflicted with its previous evaluation of Exxon (1991) in the final work plan chemical risk assessment for NMP in 2015, as well as with previous EPA evaluations of this study. For example, EPA concluded in the final work plan chemical risk assessment for NMP that development effects were the most relevant for quantifying risks because the reproductive toxicity findings (*e.g.*, decreased fertility) "lack[ed] consistency in findings, when looking at the complete database." Further, EPA evaluated the Exxon (1991) study under the OECD Screening Information Dataset (SIDS) Initial Assessment Report for NMP and assigned a data reliability score of 2 (*i.e.*, reliable with restrictions). In comparison, EPA assigned a data reliability score of 1 (*i.e.*, reliable without restrictions) to the subsequent two-generation studies that were unable to reproduce the findings of decreased fertility from the Exxon (1991) study.

The above discrepancies with EPA's evaluations of Sitarek and Stetkiewicz (2008) and Exxon (1991) in the final risk evaluation for NMP are problematic. EPA did not use established systematic review methods when evaluating these studies in the work plan chemical risk assessment for NMP, nor did EPA use a systematic review method when evaluating Exxon (1991) in the SIDS Initial Assessment Report for NMP. Therefore, it is unclear how EPA concluded that these studies warranted higher data quality and reliability ratings under its application of the 2018 Guidance Document as used in the final risk evaluation for NMP, recognizing that such a method should be more, not less, critical of the quality and reliability of the studies.

Unfortunately, there are multiple other examples of questionable scientific decisions in final risk evaluations that were developed using the 2018 Guidance Document and that EPA has no intention of revisiting. For additional examples, *see* our memorandum on 1-bromopropane dated July 21, 2022, and our memorandum on Pigment Violet 29 dated September 9, 2022.

ii. Exposures from Pathways Regulated by Other Federal Authorities

EPA's risk management rules for 1,4-dioxane may be a key indicator of how EPA will approach risk management under

other statutory authority. 1,4-dioxane is a contaminant in some drinking water sources because of legacy uses of the solvent. It is also a byproduct formed during the manufacture of ethoxylated substances, mostly surfactants used in a wide range of products, from detergents to paints to personal care products. Any TSCA risk management to reduce or eliminate 1,4-dioxane will not be able to protect against drinking water exposures from past contamination or from products regulated under the Federal Food, Drug, and Cosmetic Act (FFDCA). In this case, EPA could consider imposing a Maximum Contaminant Level (MCL) under the Safe Drinking Water Act (SDWA) to protect against 1,4-dioxane drinking water exposures regardless of the source in addition to use restrictions and workplace exposures limits.

e. Risk Management

i. "First 10" Chemicals

EPA made progress on several of the "First 10" chemicals selected for risk evaluation.

1. 1,4-Dioxane
2. 1-BP
3. Asbestos
4. CCl_4
5. HBCD
6. MC
7. NMP
8. PV29
9. PCE, also known as PERC
10. TCE

In 2023, EPA has proposed risk management rules for four of the "First 10" chemicals: MC, PCE, CCl_4, and TCE. A proposed rule was issued on asbestos in 2022. In all of these cases, EPA allowed very limited comment periods (60 days for MC, PCE, and asbestos; 45 days for CCl_4 and TCE).

(a) Asbestos

On April 12, 2022, EPA proposed a risk management rule for ongoing uses of asbestos, including a complete ban on the manufacture (import) and processing of chrysotile asbestos within two years of the effective date. EPA also considered an alternative of imposing an ECEL and a ban in five years that is also adequate. It is not clear how EPA can justify a ban in two years if an ECEL and five-year ban meet the criteria for EPA regulating "to the extent necessary" to mitigate the identified risk. The proposed rule drew extensive comments from stakeholders. The lack of action by EPA may lead Congress to seek a legislative change to ban asbestos, although the timeline of legislative action and the specific phaseout timeline have yet to be disclosed. More information regarding EPA's proposed rule is available in our April 7, 2022, memorandum, "EPA Will Propose to Ban Ongoing Uses of Asbestos." According to the Fall 2023 Regulatory Agenda, EPA intends to publish the final rule in **January 2024**.

Because of the litigation discussed above and more below, EPA continues to evaluate legacy asbestos uses and associated disposals of asbestos in a supplemental effort that will be the focus of Part 2 of the risk evaluation for asbestos. In August, EPA issued a White Paper in which EPA describes the approach it will take.

(b) Methylene Chloride

On May 3, 2023, EPA published a proposed rule to address the unreasonable risk of injury to human health presented by MC under its conditions of use as found in EPA's June 2020 risk evaluation for MC and the November 2022 revised risk determination for MC. The proposed rule would prohibit the manufacture, processing, and distribution in commerce of MC for any consumer use (expanding on the current prohibition of consumer use as a paint stripper); prohibit most industrial and commercial uses of MC; require a workplace chemical protection program (WCPP), which would include a requirement to meet an ECEL and exposure monitoring for certain continued conditions of use of MC; require recordkeeping and downstream notification requirements for several conditions of use of MC; and provide certain time-limited exemptions from requirements for uses of MC that EPA determined would otherwise significantly disrupt national security and critical infrastructure. More information regarding EPA's proposed rule is available in our April 25, 2023, memorandum, "EPA Will Propose to Prohibit Most Uses of Methylene Chloride under TSCA Section 6(a)."

The Fall 2023 Regulatory Agenda includes **March 2024** as the planned date for issuance of the final Section 6 rule for MC (2070-AK70).

(c) Perchloroethylene

On June 16, 2023, EPA published a proposed rule to address the unreasonable risk of injury to human health from PCE (also called PERC) under its conditions of use as

found in EPA's December 2020 risk evaluation for PCE and December 2022 revised risk determination for PCE. EPA proposed to prohibit most industrial and commercial uses of PCE; the manufacture (including import), processing, and distribution in commerce of PCE for the prohibited industrial and commercial uses; the manufacture (including import), processing, and distribution in commerce of PCE for all consumer use; and, the manufacture (including import), processing, distribution in commerce, and use of PCE in dry cleaning and related spot cleaning through a ten-year phaseout. For certain conditions of use that would not be subject to a prohibition, EPA also proposed to require a PCE WCPP that includes requirements to meet an ECEL and prevent direct dermal contact.

EPA also proposed to require prescriptive workplace controls for laboratory use, and to establish recordkeeping and downstream notification requirements. EPA additionally proposed to provide certain time-limited exemptions from requirements for certain critical or essential emergency uses of PCE for which it determined no technically and economically feasible safer alternative is available. More information regarding EPA's proposed rule is available in our June 16, 2023, memorandum, "EPA Proposes to Ban Most Uses of PCE and Establish a WCCP for Uses Not Prohibited."

The Fall 2023 Regulatory Agenda includes **July 2024** as EPA's planned date for issuance of the final Section 6 rule for PCE (2070-AK84).

(d) Carbon Tetrachloride

On July 28, 2023, EPA published a proposed Section 6 rule to address the unreasonable risk of injury to human health presented by CCl_4 under its conditions of use as found in EPA's 2020 risk evaluation for CCl_4 and 2022 revised unreasonable risk determination for CCl_4. EPA proposed to establish workplace safety requirements for most conditions of use, including the condition of use related to the making of low global warming potential hydrofluoroolefins; prohibit the manufacture (including import), processing, distribution in commerce, and industrial/commercial use of CCl_4 for conditions of use where information identified by EPA indicates use of CCl_4 has already been phased out; and establish recordkeeping and downstream notification requirements. More information on EPA's proposed rule is available in our July 26, 2023, memorandum, "EPA Will Propose to Ban Uses of CTC That Have Been Phased Out and Establish WCPP for Uses Not Prohibited."

The Fall 2023 Regulatory Agenda includes **August 2024** as EPA's planned date for issuance of the final Section 6 rule on CCl_4 (2070-AK82).

(e) Trichloroethylene

On October 31, 2023, EPA published a proposed Section 6 rule to address the unreasonable risk of injury to human health presented by TCE under its conditions of use as found in EPA's November 2020 risk evaluation for TCE and January 2023 revised unreasonable risk determination for TCE. EPA proposed to prohibit all manufacture (including import), processing, and distribution in commerce of TCE and industrial and commercial use of TCE for all uses, with longer compliance timeframes and workplace controls for certain processing and industrial and commercial uses (including proposed phaseouts and time-limited exemptions); prohibit the disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works, with a time-limited exemption for cleanup projects; and establish recordkeeping and downstream notification requirements. More information on EPA's proposed rule is available in our November 3, 2023, memorandum, "EPA Proposes to Ban TCE."

The Fall 2023 Regulatory Agenda includes **April 2024** as EPA's planned date for issuance of the final Section 6 rule on TCE (2070-AK83).

(f) Other of the "First 10" Chemicals

In 2024, EPA will continue to prepare Section 6(a) risk management rules on those of the "First 10" for which EPA has completed risk evaluations. TSCA Section 6(c) requires that EPA propose these Section 6(a) rules within one year after the final risk evaluation is published, and EPA must promulgate the final rules within one additional year.

The Fall 2023 Regulatory Agenda includes EPA's plans to publish proposed Section 6 risk management rules for NMP imminently, 1-BP (2070-AK73) in **January 2024**, HBCD (2070-AK71) in **May 2024**, PV29 (2070-AK87) in **August 2024,** and 1,4-dioxane (2070-AK88) in **August 2025**.

(i) PV29 Risk Evaluation

On September 6, 2022, EPA announced the availability of the final revision to the risk determination for the Colour Index Pigment Violet 29 (PV29) risk evaluation issued under TSCA. For discussion, *see* our memorandum dated September 9, 2022. EPA stated that the revision to the

PV29 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. EPA determined that PV29, as a whole chemical substance, presents an unreasonable risk of injury to health when evaluated under its conditions of use.

As we wrote last year, EPA's use of the Regional Deposited Dose Ratio (RDDR) software for dosimetric adjustment across species instead of the multiple-path particle dosimetry (MPPD) is questionable for a number of reasons.

It is not yet clear if EPA still ignores the scientific consensus that rats are more sensitive than humans to low-solubility particle exposures. An international workshop that included experts from EPA, the U.S. Occupational Safety and Health Administration (OSHA), and the National Institute for Occupational Safety and Health (NIOSH) concluded that the "rat is more sensitive than other species and humans in the lung response to [low solubility particles]," and yet in the PV29 risk evaluation, EPA applies an uncertainty factor that would only be appropriate if humans were *more* sensitive than rats.

B&C views EPA's use of the RDDR software as a vulnerability as EPA moves forward with drafting the risk management rule for PV29. For example, EPA stated that "The change in model [*i.e.*, RDDR rather than MPPD] *resulted in unreasonable risk determinations* for all ONUs [occupational non-users] and industrial and commercial use in automobile paint OEM [original equipment manufacturer] and refinishing condition of use" (emphasis added). These facts, coupled with conflicting statements within EPA's analysis, hint that EPA's model selection might have been based on the preferred outcome (that there is unreasonable risk), rather than an objective scientific evaluation to determine if there is unreasonable risk.

In October 2021, EPA verbally stated that it does not intend to develop an ECEL for PV29. B&C suspects that EPA initially decided not to develop an ECEL because of the inherent scientific issues in the PV29 risk evaluation, namely, using deposited dose as the dose metric for quantifying unreasonable risks. As we noted, the Fall 2023 Regulatory Agenda includes EPA's plans to publish a proposed Section 6 risk management rule for PV29 in **August 2024** (2070-AK87).We suspect that the post-posted release of the proposed risk management rule for PV29 is tied to delays with EPA's completion of the final peer-reviewed MPPD model, and EPA's intent on revising the final risk evaluation for PV29 to include an evaluation of unreasonable risks using the proper dose metric (*i.e.*, retained mass).

ARTICLE
"EPA Proposes Revised PBT Rules for decaBDE and PIP (3:1)," *Chemical Processing*, December 11, 2023

(ii) PBTs

On November 24, 2023, EPA published a proposed rule that would, if issued in final, amend the TSCA Section 6 regulations covering PBTs at 40 C.F.R. Part 751 Subpart E for decaBDE and PIP (3:1). These are two of the five chemicals addressed in the TSCA Section 6 final rules issued in January 2021. In the proposed rule, EPA states that after receiving additional comments following the issuance of the 2021 PBT final rules, it "determined that revisions to the decaBDE and PIP (3:1) regulations are necessary to address implementation issues and to reduce further exposures." Presumably, EPA believes the other three PBT rules do not require revision.

For decaBDE, EPA proposes in the November 2023 action revisions to the January 2021 final rule to require the use of PPE during certain domestic manufacturing and processing of decaBDE and decaBDE-containing products and articles and to require a label on plastic shipping pallets that are known to contain decaBDE. EPA also proposes to prohibit releases to water from manufacturing, processing, and distribution in commerce of decaBDE. Additionally, EPA proposes to extend the compliance date for the phaseout of processing and distribution in commerce of decaBDE-containing wire and cable insulation for nuclear power generation facilities and proposes to add a TSCA Section 12(b) export notification requirement for decaBDE-containing wire and cable for nuclear power generation facilities. This appears to be the first instance of EPA proposing to require a Section 12(b) export notice for an article other than for polychlorinated biphenyl (PCB) articles.

For PIP (3:1), the November 2023 proposed rule would revise the January 2021 final rule, as amended in September 2021 and March 2022, to require the use of PPE for the domestic manufacturing and processing of PIP (3:1) and certain PIP (3:1)-containing products and articles, and to phase-in prohibitions on processing and distribu-

tion for certain uses. EPA also proposes to add new exclusions from the prohibitions on processing and distribution in commerce of PIP (3:1) for use in wire harnesses and electric circuit boards and the processing and distribution in commerce of such PIP (3:1)-containing harnesses and circuit boards. EPA additionally proposes a new five-year compliance timeframe for the prohibition of processing and distribution in commerce of PIP (3:1), so that it may be used as an ingredient of a pesticide product registered under FIFRA for use in anti-fouling paint. EPA did not propose to revise the **October 2024** compliance date for articles not otherwise covered by an exclusion from a prohibition or by an existing or newly proposed extension to a phaseout compliance deadline.

Comments on the November 2023 proposed rule must be received on or before **January 8, 2024**. More information regarding EPA's proposed rule is available in our November 27, 2023, memorandum, "EPA Proposes to Amend PBT Rules for decaBDE and PIP (3:1)."

Relatedly, regarding the decaBDE PBT rule at 40 C.F.R. Section 751.405, on May 3, 2023, EPA announced its intent to extend the January 6, 2023, compliance date for the prohibition on the processing and distribution of decaBDE for use in wire and cable insulation in nuclear power generation facilities, and decaBDE-containing wire and cable insulation. The November 24, 2023, proposed PBT rule amendments include this intended extension. EPA also announced its issuance of a related temporary "Enforcement Statement," which indicates that it does not intend to pursue violations of the prohibition on processing and distribution of decaBDE-containing wire and cable insulation for use in nuclear power generation facilities, "as long as the entities involved are diligently working to qualify their alternative components in accordance with Nuclear Regulatory Commission (NRC) regulations and guidance." Additionally, according to the May 3, 2023, news release, EPA announced a settlement agreement with RSCC Wire & Cable, LLC (RSCC), "the only known supplier of qualified decaBDE-containing wire and cable, regarding TSCA violations."

f. Risk Evaluation Litigation

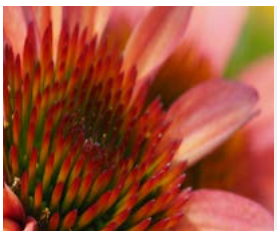
i. MC

Suits challenging EPA's June 2020 final risk evaluation for MC were filed in two different courts and were consolidated in the U.S. Court of Appeals for the Ninth Circuit in November 2020. *Neighbors for Envtl. Justice et al. v. EPA* (No. 20-72091); consolidated with *State of New York et al. v. Regan* (No. 20-73276). A coalition of environmental and labor organizations and a group of state and municipal petitioners challenged EPA's findings of unreasonable risk for MC, including assumptions that EPA made regarding the use of PPE and issues with underlying data. Petitioners claim that EPA impermissibly excluded review of exclusion of exposure pathways and risks to exposed communities or susceptible subpopulations in the evaluation. Petitioners also argue that EPA's "use-by-use" risk determinations were unlawful and that EPA should make one finding of unreasonable risk for MC. On May 13, 2021, EPA filed a motion for voluntary remand. On July 14, 2021, the court granted EPA's motion for the limited purpose of permitting EPA to reconsider the challenged no-unreasonable-risk determinations.

In November 2022, EPA released a final revised risk determination finding that MC, as a whole chemical substance, presents an unreasonable risk of injury to health under the conditions of use. In addition, the final revised risk determination does not reflect an assumption that workers always wear appropriate PPE. On May 3, 2023, EPA proposed a risk management rule that would prohibit the manufacture, processing, and distribution in commerce of MC for consumer use; prohibit most industrial and commercial uses of MC; require a WCPP, which would include a requirement to meet inhalation exposure concentration limits and exposure monitoring for certain continued conditions of use of MC; require recordkeeping and downstream notification requirements for several conditions of use of MC; and provide certain time-limited exemptions from requirements for uses of MC that would otherwise significantly disrupt national security and critical infrastructure. On June 12, 2023, the parties filed a joint stipulation of dismissal without prejudice. The court granted the motion on June 16, 2023. More information regarding EPA's final revised risk determination is available in our November 11, 2022, memorandum, "EPA Finds Methylene Chloride, as a Whole Chemical Substance, Presents an Unreasonable Risk to Human Health." More information regarding EPA's proposed risk management rule is available in our April 25, 2023, memorandum, "EPA Will Propose to Prohibit Most Uses of Methylene Chloride under TSCA Section 6(a)."

ii. 1,4-Dioxane

On January 26, 2021, the Environmental Defense Fund (EDF), the Sierra Club, and the Environmental Working Group petitioned the U.S. Court of Appeals for the Ninth



EPA policies implementing TSCA continue to be in flux, and TSCA stakeholders are expected to seek judicial intervention as they did in 2022 and 2023.

Circuit for review of EPA's final risk evaluation of 1,4-dioxane and EPA's determination that 1,4-dioxane does not present an unreasonable risk of injury to health or the environment under certain conditions of use. *EDF et al. v. EPA* (No. 21-70162); consolidated with No. 21-70194, No. 21-70727, No. 21-70684, and No. 21-70930. A coalition of 14 states and three municipalities also filed suit, and the court consolidated the cases. On June 8, 2021, EPA requested voluntary remand without vacatur to allow it to revisit the final risk evaluation. The court granted EPA's motion on August 10, 2021, for the limited purpose of permitting EPA to reconsider the challenged no-unreasonable-risk determinations.

The SACC released on November 17, 2023, its final report on the draft supplement to the risk evaluation for 1,4-dioxane. On July 26, 2023, EPA released the draft revision to the risk determination for 1,4-dioxane. Because EPA proceedings are ongoing, EPA asked that the case stay in abeyance. The next status report is due **January 29, 2024**. More information on the draft supplement to the risk evaluation and the draft revision to the risk determination is available in our July 31, 2023, memorandum, "Draft Supplement to Risk Evaluation and Draft Revised TSCA Risk Determination for 1,4-Dioxane for Public Comment."

iii. Asbestos

The Asbestos Disease Awareness Organization (ADAO), several scientists, and some public health groups filed a petition on January 26, 2021, in the U.S. Court of Appeals for the Ninth Circuit challenging Part 1 of the asbestos risk evaluation. *Asbestos Disease Awareness Organization et al. v. EPA* (No. 21-70160). The petitioners seek review of the final risk evaluation determining the risks of certain conditions of use of chrysotile asbestos fibers but declining to consider the risks of other asbestos fibers, conditions of use, health effects, and pathways of exposure that impact public health. The parties filed a joint motion for abeyance on October 13, 2021, pursuant to an agreement with EPA for conducting Part 2 of its risk evaluation of asbestos (Legacy Uses and Associated Disposals of Asbestos). The court granted the parties' motion on October 28, 2021. On October 10, 2023, EPA filed a status report, noting that it released a white paper on August 2, 2023, entitled "White Paper: Quantitative Human Health Approach to be Applied in the Risk Evaluation for Asbestos Part 2 – Supplemental Evaluation including Legacy Uses and Associated Disposals of Asbestos." Comments on the white paper were due October 2, 2023. EPA provided the white paper, final questions identifying the scientific and technical issues on which EPA would like feedback, and public comments received by October 2, 2023, to peer reviewers for consideration. EPA expected the peer review to end in November 2023. EPA will consider comment from the letter peer review in its development of the Part 2 risk evaluation for asbestos, a draft of which will be released subsequently for public comment, along with a separate response to comments document. EPA's next status report is due **April 8, 2024**. More information on the final scope document is available in our July 11, 2022, memorandum, "EPA Publishes Final Scope for Part 2 of Asbestos Risk Evaluation." More information on the final risk evaluation is available in our January 4, 2021, memorandum, "EPA Publishes Final Risk Evaluation for Asbestos, Part 1: Chrysotile Asbestos."

g. Risk Management Litigation

We expect that 2024 will again see litigation over several TSCA matters, including test orders and risk management rules (once they are published in final). EPA policies implementing TSCA continue to be in flux, and TSCA stakeholders are expected to seek judicial intervention as they did in 2022 and 2023. This is entirely predictable and not necessarily an undesirable outcome; rather, it reflects the back-and-forth between stakeholders and EPA on the interpretation of the new provisions of TSCA occasioned by Lautenberg.

i. decaBDE

As we wrote last year, EPA published a January 6, 2021, final TSCA Section 6 PBT rule that prohibits the manufacture, import, and processing of most uses of decaBDE and carve-outs, or delayed compliance dates or exclusions, for certain

uses. The carve-outs include uses in replacement parts for the automotive and aerospace industry and certain uses in the hospitality industry. Two cases were filed in the U.S. Court of Appeals for the Ninth Circuit challenging the rule, and the court has consolidated the cases: *Alaska Community Action on Toxics (ACAT) v. EPA* (No. 21-70168) (Jan. 27, 2021) and *Yurok Tribe, et al. v. EPA* (No. 21-70670) (Mar. 19, 2021). ACAT is concerned about the exemptions for recycled products and decaBDE's use in replacement parts in automotive and aerospace vehicles, arguing that TSCA requires EPA to eliminate exposure to the extent practicable, and the exemptions and failure to regulate how products are disposed or recycled are unlawful. On June 23, 2022, the court granted EPA's motion for a voluntary remand without vacatur to permit it to reconsider these determinations and conduct reconsideration proceedings.

The matter is remanded to EPA for the limited purpose of permitting the Agency to reconsider the rule at issue. The court denied petitioners' request that the court impose deadlines for EPA's reconsideration and potential amendment of the rule. The court is holding proceedings in these consolidated petitions in abeyance pending EPA's completion of reconsideration proceedings or further order of the court.

ii. PIP (3:1)

On March 4, 2021, several trade associations that represent heating, ventilation, air-conditioning, and refrigeration (HVACR), home-appliance, consumer technology industries, electrical equipment and medical imaging, and manufacturers from industrial sectors filed a petition for review of EPA's final TSCA Section 6 PBT rule on PIP (3:1) in the U.S. Court of Appeals for the D.C. Circuit. *Air-Conditioning, Heating, and Refrigeration Institute et al. v. EPA* (No. 21-1082). After the petition was filed, EPA issued a temporary No Action Assurance (NAA). In October 2021, EPA proposed to extend the compliance dates applicable to the processing and distribution in commerce of certain PIP (3:1)-containing articles and the PIP (3:1) used to make those articles until **October 31, 2024**, along with the associated record-keeping requirements for manufacturers, processors, and distributors of PIP (3:1)-containing articles. EPA made the October 2021 proposed changes in a March 8, 2022, final rule that has been challenged by petitioners. EPA has filed several motions to hold the case in abeyance, most recently on October 6, 2022. On October 7, 2022, the court granted EPA's unopposed motion for abeyance. On February 7, 2023, EPA filed an unopposed motion to hold the case in abeyance for ten additional months, through December 15, 2023. On February 8, 2023, the court granted the motion and directed the parties to file motions to govern further proceedings by December 15, 2023. More information on the March 2022 PIP (3:1) rule is available in our March 7, 2022, memorandum, "EPA Will Extend Compliance Dates for Articles Containing PIP (3:1)."

WEBINAR ON DEMAND

TSCA Reform — Seven Years Later The Environmental Law Institute (ELI), the George Washington University Milken Institute School of Public Health, and B&C hosted the seventh annual TSCA Reform conference, providing updates and insights regarding the current state of TSCA implementation, ongoing and emerging issues, and related developments. Topics include risk evaluations, risk management, new chemical review, and PFAS.

4. Section 5 — New Chemical Substances

a. Proposed New Chemicals Procedure Rule

In May, EPA proposed updates to the New Chemicals regulations (40 C.F.R. Parts 720, 721, 723, and 725). According to the Fall 2023 Regulatory Agenda (2070-AK65), EPA expects to publish the final rule in **April 2024**. EPA stated it is intended to "align the regulatory text with the amendments to TSCA's new chemicals review provisions contained in Lautenberg, enacted on June 22, 2016, improve the efficiency of EPA's review processes, and update the regulations based on existing policies and experience implementing the New Chemicals Program." According to EPA, the "rulemaking seeks to increase the quality of information initially submitted in new chemicals notices and improve the Agency's processes to reduce unnecessary rework in the risk assessment and, ultimately, the length of time that new chemicals are under review." The proposed rule emphasizes that submitters must provide information that is known or reasonably ascertainable and, if not known, that the submitter state that the information is not known or reasonably ascertainable. Even with more high-quality information, it is not clear that such information will change the outcomes of PMNs. In our experience, EPA often misses, ignores, or dismisses with little justification information provided. Among the most consequential changes proposed in this rule, EPA proposed to make PFAS ineligible for exemption notices and proposed to void categorically all

As of the December 14, 2023, update on EPA's PMN status website (the most recent update as of December 23, 2023), EPA has made only 88 determinations so far in calendar year 2023, a pace similar to the 95 completed in 2022.

previous low volume exemptions (LVE) and low release and low exposure exemptions (LoREX) for PFAS. For a more in-depth review, *see* our May 24, 2023, memorandum.

b. Scientific Updates

In April 2023, EPA released its standard methods for the development of EPA Transcriptomic Assessment Products (ETAP). The common theme of ETAP eligible chemicals is that they must be data poor, as is the case with many new chemical substances. The ETAP process includes the following primary components: (1) "initial database searches and systematic evidence map development"; (2) "short-term *in vivo* transcriptomic study for point-of-departure (POD) [footnote omitted] identification"; and (3) "assessment development and reporting."

ETAP component 1 includes various searches to ensure that the chemical substance is data poor. Once confirmed, the chemical substance may be eligible for the initiation of ETAP component 2, which includes performing a five-day *in vivo* oral gavage transcriptomic study in male/female rats (minimum of four rats/sex/group). The endpoints from the *in vivo* study are focused on tissue-specific total ribonucleic acid (RNA), which is isolated and subjected to sequencing to identify gene ontology (GO) biological processes. The GO datasets are used for dose-response modeling and subsequent transcriptomic reference value (TRV) derivation.

We note the novel nature of this approach, which according to EPA may result in the development of TRVs within six to nine months. We also note that although whole animals are used in the performance of these studies, the ETAP approach does reduce the use of experimental animals, one of the goals of TSCA Section 4. EPA presented the ETAP approach to the Board of Scientific Counselors (BOSC) in October 2023. As of the date of this publication, the BOSC has not issued a report of its review and recommendations of this approach.

Despite the novel and timely data generation aspect of this approach, B&C does not anticipate that it will be readily adopted by new chemical substance submitters. We mention this because of the limitations with the approach, namely, the current application is limited to oral gavage studies. This limitation could lead to an "insufficient information" finding under TSCA, given that EPA generally evaluates the potential for unreasonable risks from new chemical substances *via* the oral, dermal, and inhalation routes. Further, analog read-across is oftentimes scientifically more justified (than ETAP) for informing potential hazards from new chemistries that would otherwise be considered data poor than performing *in vivo* studies.

c. New Chemical Notice Review Case Updates

In 2023, the pace of EPA's review of new chemical notices has again been quite slow despite bringing in additional assessors. As of the December 14, 2023, update on EPA's PMN status website (the most recent update as of December 23, 2023), EPA has made only 88 determinations so far in calendar year 2023, a pace similar to the 95 completed in 2022.

EPA began the year with 380 cases under review; as of December 14, 2023, EPA received 137 cases in calendar year 2023, including 13 in FY 2024. EPA completed 88 determinations, declared one case invalid or incomplete, and submitters withdrew 29 cases. This would mean EPA ends the year with 399 cases under review.

Table 1 presents statistics on the number of PMNs submitted in each FY since 2016 and the outcomes obtained following completion of EPA's review. Table 2 provides for the length of review for cases reviewed since June 22, 2016, as the average number of days to completion, as well as the time trends for different types of outcomes. Table 3 shows the determinations made in each *calendar year* (rather than FY of the submission). We discuss below the results shown.

Table 1. Number of PMNs Submitted in FYs 2016-2024

				Determination Made; Regulated[1]			Determination Made; Not Regulated	No Determination Made; Completed	
FY	Submitted PMNs	Under Review	Completed PMNs	Consent Order	Not Likely Based on SNUR	Not Likely, Follow-Up SNUR	Not Likely	Invalid	Withdrawal
2016	364	5 (1%)	359 (99%)	141 (39%)	20 (5%)	11 (3%)	41 (11%)	26 (7%)	120 (33%)
2017	437	6 (1%)	431 (99%)	252 (58%)	12 (3%)	30 (7%)	43 (10%)	24 (5%)	68 (16%)
2018	411	28 (7%)	383 (93%)	86 (21%)	9 (2%)	125 (30%)	74 (18%)	14 (3%)	75 (18%)
2019	187	9 (5%)	178 (95%)	71 (38%)	14 (7%)	33 (18%)	33 (18%)	17 (9%)	10 (5%)
2020	178	24 (13%)	154 (87%)	49 (28%)	2 (1%)	11 (6%)	50 (28%)	15 (8%)	27 (15%)
2021	214	38 (18%)	176 (82%)	117 (55%)	0 (%)	0 (%)	22 (10%)	15 (7%)	22 (10%)
2022	193	125 (65%)	68 (35%)	43 (22%)	0 (%)	0 (%)	6 (3%)	7 (4%)	12 (6%)
2023	168	151 (90%)	17 (10%)	9 (5%)	0 (%)	0 (%)	3 (2%)	2 (1%)	3 (2%)
2024	13	13 (100%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Total	2165	399 (18%)	1766 (82%)	768 (35%)	57 (3%)	210 (10%)	272 (13%)	120 (6%)	337 (18%)

Counts based on PMN status posted on EPA's website as of December 23, 2023 (last updated December 14, 2023). FY 2016 cases exclude approximately 249 cases that were completed prior to June 22, 2016. Totals include 122 cases submitted prior to 2016 that were re-reviewed after June 22, 2016.

[1] Consent order, "Not Likely Based on SNUR," and "Not Likely, Follow-Up SNUR" are all regulated outcomes. "Not Likely Based on SNUR" are decisions in which EPA uses a SNUR to prohibit conditions of use that, while not intended, are reasonably foreseeable. EPA's view was that once the SNUR is proposed, those conditions of use are no longer reasonably foreseeable and EPA can then make a "not likely" determination. EPA, however, announced in March 2021 that it was stopping the issuance of determinations of "not likely to present an unreasonable risk" based on the existence of proposed SNURs. "Not Likely, Follow-Up SNUR" are decisions in which EPA did not identify unreasonable risk under the reasonably foreseeable conditions of use (RFCU), but EPA still has concerns for the substance and intends to propose a SNUR. In the past, B&C has counted withdrawn PMNs as regulatory outcomes because most withdrawals are in the face of regulation, but they may also be the result of the submitter making a business decision, so B&C does not count withdrawals as regulated outcomes, but neither does B&C count them as determinations made by EPA (although they are complete cases).

Table 2. Average Number of Days from Receipt (Day 1) to Final Decision for PMNs (by submission year)

FY	All PMNs[1]	Under Review[1]	Consent Order	Not Likely Based on SNUR	Not Likely, Follow-Up SNUR	Not Likely	Invalid	Withdrawal
2016	548	2740	467	949	1,082	389	50	558
2017	347	2368	232	842	820	257	41	466
2018	611	1992	640	634	418	426	19	672
2019	264	1586	222	281	111	165	54	507
2020	427	1266	420	233	131	205	53	448
2021	482	961	464	—	—	165	67	355
2022	486	561	390	—	—	385	16	378
2023	253	253	256	—	—	331	29	329
2024	51	51		—	—			

[1] As of December 23, 2023.

Table 3. Determinations by Calendar Year

Determination Year	Not Likely	Not Likely Based on SNUR	Not Likely, Follow-Up SNUR	Consent Order	Total Restricted	Determinations	Percent Determinations Include Restrictions
2016	29			8	8	37	22%
2017	39			283	283	324	88%
2018	24	13	19	150	182	206	88%
2019	57	27	155	54	236	293	81%
2020	76	17	34	106	157	235	68%
2021	36	1	N/A	50	51	87	59%
2022	5	N/A	N/A	90	90	95	95%
2023	9	N/A	N/A	79	79	88	90%

N/A — Not Available. OCSPP ceased using non-order SNURs in 2021. Based on data posted on EPA's PMN website as of December 23, 2023 (last updated December 14, 2023).

d. Discussion of Table 1

i. Total PMNs Submitted

Total PMNs submitted declined again to just 168 submitted in FY 2023 (although the highest PMN case number is P-23-0194, suggesting other cases may be incomplete or additional case numbers were generated as system errors). Unfortunately, other than two cases declared invalid and two that have been withdrawn by the submitter, only ten have received determinations; the remaining cases await a determination. As it has in years past, EPA continues to focus its effort on completing older cases. EPA completed 88 determinations as of December 14: 12 from FY 2023, 49 from FY 2022, and 21 from FY 2021; the remainder were submitted in FY 2016 to FY 2019. EPA will continue to struggle to review PMNs timely for some time to come.

ii. PMN Outcomes

EPA has continued its practice of issuing orders on nearly every PMN. In 2023, of the 88 total determinations, 79 (90 percent) were consent orders. Only nine were "not likely" determinations. This persistent pattern supports B&C's view that EPA continues to take an impermissible hazard-based approach: once EPA identifies a hazard other than low hazard for health and aquatic toxicity ("low/low" cases), EPA issues an order. About seven and a half years after enactment of the TSCA amendments, EPA has still not found a limit to what it foresees, nor does it consider how likely an exceedance is.

We question whether EPA's proposed changes to the New Chemicals Regulations proposed in 2023 will change EPA's approach to issuing regulations. At most, information provided in a PMN only changes EPA's conclusion from "insufficient information" to "may present an unreasonable risk." In either case, EPA issues an order.

e. Discussion of Table 2

i. Length of Review Period

Table 2 shows the mean number of days between "Day 1" and the final disposition of cases in each FY. We had hoped that the new assessors brought on board in 2023 would improve review times, but cases still languish. The average time that cases wait for a determination is over 454 days. It is not clear when the pace of completion will increase, but the problem is not simply one of staffing.

EPA's PMN statistics page lists 423 cases (PMNs, significant new use notices (SNUN), microbial commercial activity notice (MCAN)) awaiting completion as of December 22, 2023. The majority of cases are awaiting EPA action: 233 await risk assessment and another 107 await risk management decisions. An additional 39 cases wait for submitter input during risk assessment/risk management and 44 cases await submitter response on consent orders. It is vitally important that submitters not delay review of consent orders. We urge submitters to review the consent order template in advance of receiving the order from EPA. Nearly every case will lead to an order, so there is no reason to delay review. That way, when the order arrives, you can focus on reviewing the protective conditions rather than the boilerplate and respond promptly to EPA.

f. SNURs on New Chemicals

On an especially disappointing note, EPA proposed almost no SNURs for new chemicals in 2023. The only batch of proposed SNURs for new chemicals were for the Chevron PMNs (discussed below). Other than the Chevron PMN SNURs, EPA proposed no new chemical SNURs after December 2, 2022. By our count, EPA issued orders on 166 PMNs for which EPA has yet to propose corresponding SNURs. Of those orders, 29 had orders issued in 2020 or earlier. This means there are 166 products that submitters have limited ability to commercialize because of the standard distribution restrictions in orders and yet, if any is commenced, others may be able to commercialize with no restrictions whatsoever. To EPA's credit, it did publish in final two sets of SNURs, one set in March and one set in April, covering 57 substances. Unfortunately, EPA has not promulgated any additional SNURs since then.

As PMN submitters are likely aware, when EPA issues consent orders, those orders include a limit on distribution that sunsets 75 days after EPA promulgates the corresponding SNUR. That means, unless the direct customer of the manufacturer is the end-use, a manufacturer's customer cannot distribute the substance further down the supply chain. Under TSCA Section 5(f)(4), EPA is required to propose SNURs within 90 days of issuing an order or publish a statement describing the reasons for not initiating such a rulemaking. Unfortunately, EPA falls woefully short. EPA averages 340 days from issuing an order to proposing a SNUR, 414 days from SNUR proposal to promulgation. This two-year delay frustrates new chemical suppliers and their customers and leaves the market open to follow-on manufacturers that may commercialize without restriction.

EPA's latest action supports that it will begin using its SNUR authority under TSCA Section 5 to "prohibit" (pending EPA SNUN review and determination) those conditions of use that are no longer ongoing for existing chemical substances that are undergoing risk evaluation.

Consent orders only apply to the signatory. If the manufacturer commences commercial production and places the substance on the TSCA Inventory, a competitor can find the substance on the Inventory and begin to manufacture or import the substance without restriction unless and until the SNUR is published in final. Furthermore, that later market entrant can undertake a condition of use (COU) that is prohibited by the order and thereby defeat that protective measure in the SNUR if and when EPA proposes the SNUR. EPA must improve its performance on SNURs.

g. SNURs on Chevron PMNs

In 2023, EPA proposed only one set of SNURs — those on P-21-0144 to 0147, P-21-0148 to 0150, P-21-0152 to 0154, P-21-0155 to 0158, and P-21-0160 to 0163 — the cases that are the subject of *Cherokee Concerned Citizens v. EPA* (discussed below). This set of SNURs appears to have been hastily written and proposed in advance of submission of Notices of Commencement as an attempt to prevent the commercialization of those substances by making it impossible for a manufacturer to demonstrate compliance. Among the notable features, EPA proposes lifting the exemption to submitting a SNUN if the condition of use is allowed in an order. With this order, EPA is effectively voiding the order because the submitter will not be able document compliance with the SNUR conditions.

On April 7, 2023, Cherokee Concerned Citizens, a community group in Pascagoula, Mississippi, filed suit in the U.S. Court of Appeals for the District of Columbia Circuit for review of an Order for a New Chemical Substance under TSCA Section 5 authorizing Chevron U.S.A. Inc. to manufacture, process, distribute in commerce, use, or dispose of certain new chemical substances. *Cherokee Concerned Citizens v. EPA* (No. 23-1096). According to the non-binding statement of issues, the plaintiffs will raise issues in their challenge to the order, including "[w]hether EPA's issuance of the Order is arbitrary, capricious, contrary to TSCA, and not supported by substantial evidence because, as to certain New Chemical Substances for which EPA concluded that manufacturing, processing, distribution, use, and/or disposal of the chemical presents unreasonable risk to human health or the environment, the Order lacks prohibitions and/or limitations that are sufficient to protect against that unreasonable risk." More information is available in our April 17, 2023, blog item, "NGO Seeks Review of TSCA Section 5 Order for a New Chemical Substance."

h. SNURs on Existing Chemicals

On January 26, 2023, EPA proposed a SNUR for PFAS that are currently on the TSCA Inventory but that have not been actively manufactured (including imported) or processed in the United States since 2006 and are consequently designated as inactive on the TSCA Inventory. PFAS subject to existing SNURs would not be covered by the action. EPA states that there are 330 inactive PFAS that are not subject to an existing SNUR. Persons subject to the SNUR would be required to notify EPA at least 90 days before commencing the manufacture (including import) or processing of the chemical substance for any use. We believe EPA's proposal is an appropriate, protective use of its SNUR authority and will help guard against future reintroduction of these substances unless and until a submitter can demonstrate in a SNUN that the substance would not be an unreasonable risk. More information on the January 26, 2023, proposed rule is available in our January 27, 2023, memorandum, "EPA Proposes SNUR for PFAS Designated as Inactive on the TSCA Inventory."

On June 22, 2023, EPA published proposed SNURs for three flame retardants, TCEP, TBBPA, also known as tetrabromobisphenol A, and TPP, which are all undergoing risk evaluations under TSCA. The proposed significant new uses are manufacture (including import) or processing for any use, "with the exception that the conditions of use the Agency expects to consider within the scope of the TSCA section 6 risk evaluations are not proposed as significant new uses." The proposed SNUR provides further insight on the direction that EPA plans to take on chemical substances it identifies as high-priority substances under TSCA Section 6. EPA's latest action supports that it will begin using its SNUR authority under TSCA Section 5 to "prohibit" (pending EPA SNUN review and determination) those conditions of use that are no longer ongoing for existing chemical substances that are undergoing risk evaluation. By prohibiting conditions of use

that are not ongoing, EPA both protects against the risks that may arise from those conditions of use and limits the conditions of use that must be evaluated in the scope of the risk evaluation. EPA plans to issue the final SNURs on the flame retardants TCEP, TBBPA, and TPP (2070-AL07) in **May 2024**, according to the Fall 2023 Regulatory Agenda. More information on the June 22, 2023, proposed rule is available in our July 3, 2023, memorandum, "EPA Proposes SNURs for Flame Retardants in Support of Risk Evaluations."

Additionally, as reflected in the Fall 2023 Regulatory Agenda, EPA planned to propose SNURs in November 2023 and issue the rules in final in **November 2024** for certain other substances undergoing TSCA risk evaluation, including phthalates (2070-AL06), in **September 2024** for certain solvents (2070-AL08), and in **May 2024** for other High Priority Substances undergoing TSCA Section 6 risk evaluation (2070-AL05). As with the approach taken in the proposed SNURs for the flame retardants discussed above, we expect that the actions will include as significant new uses manufacture (including import) or processing for any use, with the exception of conditions of use that EPA expects to consider within the scope of the TSCA Section 6 risk evaluations.

Older SNURs, such as those proposed for nonylphenols and nonylphenol ethoxylates and toluene diisocyanates, remain in the proposal stage. At this point, B&C expects each to remain in the proposal stage until EPA decides to prioritize either substance for risk evaluation; given that neither is on EPA's pre-prioritization list, it seems likely that those SNURs will languish at least until **2025**.

5. Sections 8 and 14 — Reporting and Confidential Information

a. TSCA Section 8(a)(7) Rule on PFAS

The final TSCA Section 8(a)(7) reporting and recordkeeping rule on PFAS was published in the *Federal Register* on October 11, 2023. The rule is a statutory requirement under Section 7351 of the National Defense Authorization Act (NDAA) for FY 2020 that amended TSCA Section 8(a) to require EPA to, not later than January 1, 2023, promulgate a rule requiring each person who has manufactured a PFAS chemical in any year since January 1, 2011, to submit to EPA a report that includes, for each year since January 1, 2011, the chemical exposure and hazard information described in TSCA Section 8(a)(2)(A)-(G). The rule requires all manufacturers (including importers) of PFAS and PFAS-containing articles in any year since 2011 to report information related to chemical identity, uses, volumes made and processed, byproducts, environmental and health effects, worker exposure, and disposal to EPA. The final rule expands on the definition of PFAS in the June 2021 proposed rule to include additional PFAS. EPA states in the final rule that at least 1,462 PFAS that are known to have been made or used in the United States since 2011 will be subject to the final rule, but the number is undoubtedly higher. Reporting is due to EPA within 18 months of the effective date of the final rule, *i.e.*, by **May 13, 2025**, with an additional six months for reports from small businesses that are solely reporting data on importing PFAS contained in articles. The final rule follows the publication in the *Federal Register* of a notice of availability for an Initial Regulatory Flexibility Analysis and Updated Economic Analysis following the completion of a Small Business Advocacy Review Panel on the June 2021 proposed rule.

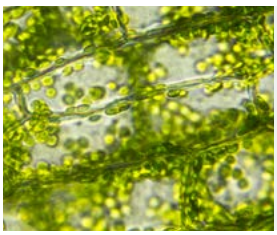
The final rule is largely unchanged from the proposed rule, providing nearly no exemptions to reporting, despite the many comments about the undue burden that potential reporters will face to determine if they have any information to report. We expect that reporters will have to spend tens or hundreds of millions of dollars in a futile attempt to develop meaningful information about PFAS that might have been manufactured or imported as substances or in articles, in any quantity, whether intentionally present or not. In the end, we expect that EPA will receive tens if not hundreds of thousands of reports that the information sought by EPA is not "known or reasonably ascertainable" (the reporting standard in the rule) and will provide little value over what EPA would have received if it had provided some limited exemptions.

More information on the October 2023 final rule is available in our October 3, 2023, memorandum, "EPA Releases Final TSCA Section 8(a)(7) Reporting Rule for PFAS."

i. Section 8(a) — Asbestos Reporting Rule

On July 25, 2023, EPA published a final TSCA Section 8(a) rule that requires reporting and recordkeeping for asbestos. Under the rule, manufacturers, importers, and processors of asbestos (in bulk form, as part of an article and/or prod-

ARTICLE
"Expanding PFAS Liability in the US," *Financier Worldwide,* July 2023



For the first time in recent history, EPA declined to propose changes to CDR reporting. The 2024 CDR reporting cycle will begin on June 1, 2024, and run until September 30, 2024.

uct, as an impurity, or as part of a mixture) between 2019 and 2022 with annual sales above $500,000 in any of those years are required to report exposure-related information that is "known or reasonably ascertainable," including quantities of asbestos manufactured or processed, types of use, and employee data. Companies subject to the rule have nine months following the rule's effective date (August 24, 2023), *i.e.*, until **May 24, 2024**, to collect and submit all required information to EPA. EPA states that it and other federal agencies will use reported information in considering potential future actions, including risk evaluation and risk management activities. The rule includes a three-month submission period for reporting that will begin **February 24, 2024**, six months from the effective date of the rule.

More information on this action can be found in our July 12, 2023, memorandum, "EPA Releases Final TSCA Section 8(a) Reporting and Recordkeeping Rule for Asbestos."

b. Section 8(a) — Chemical Data Reporting Rule

On June 22, 2023, EPA announced the start of the 2024 Chemical Data Reporting (CDR) reporting period (88 Fed. Reg. 40816). For the first time in recent history, EPA declined to propose changes to CDR reporting. The 2024 CDR reporting cycle will begin on **June 1, 2024**, and run until **September 30, 2024**. This decision relieved EPA of the burden of another rulemaking and will reduce the need for reporters again to adapt their approach to reporting. Note, however, as required by the April 9, 2020, CDR Revisions Rule (85 Fed. Reg. 20122), new for the 2024 and future submission periods, submitters are required to use for all reported chemical substances the OECD-based codes that were partially implemented for the 2020 CDR. CDR reporting will occur prior to the reporting period for the PFAS TSCA Section 8(a)(7) rule and after the Section 8(a) asbestos reporting period.

c. Section 8(c) DCI for MBOCA

On December 21, 2023, EPA announced that, under TSCA Section 8(c) and the implementing regulations at 40 C.F.R. Part 717, it will require persons that manufacture or process MBOCA to report records required to be kept of allegations that MBOCA causes significant adverse reactions to health or the environment. At the time of the announcement, EPA made available a pre-publication version of a *Federal Register* notice that, when published, would trigger the reporting requirements. The records that must be kept and that EPA is requiring the reporting of include, among other things, allegations by employees of health-related effects reported to companies over the last 30 years and any other allegations of health or environmental harm made in the past five years. Reporting will be required by the date 60 days after publication of the notice in the *Federal Register*. EPA states that it "plans to use data received through this request to support the prioritization process to better understand suspected adverse health or environmental effects of the chemical. Further, should EPA finalize the designation of this chemical as a high-priority substance for risk evaluation, then gathering this type of data before EPA initiates such a risk evaluation could help make the risk evaluation process more efficient and focused." EPA notes that it "anticipates issuing additional TSCA section 8(c) submission requirements for other chemical substances identified as candidates for prioritization." This will be the first time in decades that EPA is requiring the reporting of the TSCA Section 8(c) allegation records. Further details and commentary on this EPA action are available in our memorandum of December 27, 2023, "EPA Begins TSCA Prioritization Process for Five Chemicals, Requires Reporting on MBOCA."

d. Procedures for Submitting Confidential Business Information

On June 7, 2023, EPA published the final CBI procedure rule. The rule addresses several issues related to TSCA CBI under the Lautenberg amendments to TSCA and has significant implications for submitters and their ability and obligations to make and sustain CBI claims across all types of submissions. The final rule, among other things, addresses inconsistencies between the current regulations and Lautenberg's statutory text, codifies substantiation procedures, codifies a process to review generic names, addresses conflicting information disclosure standards between statutes (*e.g.*, TSCA and FIFRA), clarifies what information in a health or safety study may be claimed as confidential, and establishes a formal procedure to manage the sunsetting

or withdrawal of CBI claims. The rule also addresses EPA procedures for reviewing and communicating with TSCA submitters about confidentiality claims and includes a requirement that health and safety information be provided using the appropriate OECD harmonized template, when such a template is available, in addition to existing requirements to provide a full study report.

EPA's final rule consolidates all TSCA CBI claim assertion and review procedures, in a new, single section under 40 C.F.R. Part 703, except as modified elsewhere by more specific provisions in 40 C.F.R. Part 2 or other TSCA-specific regulations in Title 40 of the C.F.R. This increased consolidation of the TSCA CBI provisions, policies, and procedures will, in our view, make it more efficient for EPA to maintain the CBI regulations and for further stakeholders to find, review, and comply with those regulations. More information about the rule, including commentary on key aspects of the rule, is available in our June 12, 2023, memorandum, "EPA Updates TSCA CBI Requirements."

EDF filed suit in the U.S. Court of Appeals for the D.C. Circuit on June 29, 2023, asking the court to review EPA's rule. *EDF v. EPA* (No. 23-1166). EDF's statement of issues, filed on August 21, 2023, includes the following claims for why the final rule is arbitrary, capricious, an abuse of discretion, or otherwise contrary to law: it would allow submitters to assert CBI claims to shield the information from the public that TSCA makes categorically ineligible for CBI protection; it would not require substantiation or EPA review of a CBI claim that was asserted before a chemical's commercialization, for specific chemical identity, once the chemical is commercialized; it unlawfully adopts a regulatory definition of "health and safety study" that is narrower than TSCA's definition, denying TSCA-mandated public access to important information on chemicals; EPA purports to give itself unlawfully broad discretion through its regulations where TSCA imposes a duty on it; and it reduces the transparency previously required under EPA's CBI review procedures without adequate justification. The court consolidated EDF's suit with one filed by the ACC and American Fuel and Petrochemical Manufacturers (AFPM). *ACC v. EPA* (No. 23-1204).

e. Unique Identifier Implementation

We are confused by EPA's implementation of unique identifiers (UID). As readers may recall, under TSCA Section 14(g)(4), when EPA approves a CBI claim for a specific chemical identity, EPA is required to:

- Assign a unique identifier (UID) to that chemical identity;
- Apply this UID to other information or submissions concerning the same substance; and
- Ensure that any non-confidential information received by the Agency identifies the chemical substance using the UID while the specific chemical identity of the chemical substance is protected from disclosure.

EPA's approach for assigning and applying UIDs can be found here. EPA also now publishes its statistics for CBI review here.

EPA appears no longer to provide a separate, complete list of UIDs. In the past, the UID list included 1,296 entries. EPA has published an updated UID list (available here) in December 2019. The 2019 list appears to be 449 "new" UIDs, presumably approved since the last time EPA published a list. Unfortunately, nearly four years have passed since EPA published an updated list of UIDs. EPA has added UIDs to the public version of the TSCA Inventory. The confidential portion includes 835 UIDs (some of which include CBI claims approved in 2022), while the public portion includes 74 UIDs. These 74 cases had been assigned a UID when the identity was CBI, but the identity has since been declassified and moved from the confidential portion to the public portion of the Inventory.

This is a good indicator that EPA is making progress toward the openness that Congress contemplated in the Lautenberg amendments. Information that had, at one point, been claimed legitimately as CBI has become public, and the UID allows connection between the now public identity and the data that have been submitted on that substance. What is lacking is the complete list of UIDs that have been assigned

— those that have been assigned but the substances do not yet appear on the Inventory, those that appear on the confidential portion of the Inventory, and those that appear on the public portion of the Inventory. We expect that EPA will continue to work out the kinks on its assigning UIDs and publishing a list as required.

f. Mercury Reporting Rule

On December 21, 2023, EPA published the second triennial Mercury Inventory Report based on information submitted to EPA in 2022 for calendar year 2021. EPA prepared the national inventory report of supply, use, and trade of mercury pursuant to TSCA Section 8(b)(10), that defines "mercury" as "elemental mercury" or "a mercury compound." Based on the information collected, EPA states that it, "as appropriate, will identify any manufacturing processes or products that intentionally add mercury and recommend actions to achieve further reductions in mercury use as required by TSCA."

g. Section 8(d) — Health and Safety Data Reporting

EPA did not issue another Section 8(d) DCI in 2023. We expect EPA to issue Section 8(d) rules on some or all of the 15 prioritization candidates, in **early 2024** to inform EPA's prioritization efforts.

Another TSCA Section 8(d) rule would likely require persons (*i.e.*, manufacturers and importers) who proposed to manufacture (including import) or have manufactured any of the specified chemical substances in the ten years preceding the effective date of listing to submit the lists and copies of studies, consistent with the model TSCA Section 8(d) rule at 40 C.F.R. Part 716.

We expect EPA to continue using the information obtained on the 30 organohalogen flame retardant (OFR) substances as a result of a June 2021 Section 8(d) DCI to inform future prioritization and risk evaluation. B&C further expects that EPA will continue to use a combination of Section 8(d) rules and test orders to inform its prioritization and risk evaluations, with the planned TSCA Section 8 Tiered Data Reporting (TDR) Rule possibly coming into play by **2025**, as discussed below.

h. TSCA Section 8 Tiered Data Reporting Rule

EPA had expected to propose the TDR rule in 2023. The Fall 2023 Regulatory Agenda lists the proposal as being planned for **September 2024**, with a final rule in **July 2025** (2070-AK62). There has been little visibility into EPA's proposed TDR rule under TSCA Sections 8(a) and 8(d) to support its evaluation of existing chemicals.

As a reminder, EPA has stated that TDR would supplement quadrennial CDR. EPA envisions the following stages:

- Condition of Use Data Set: EPA would select a pool from the 8,000-9,000 CDR chemicals (or potentially other substances that might not be reported to CDR) to identify candidates for further data gathering in a condition of use stage. For the subset of condition of use data set chemicals, EPA would propose a TSCA Section 8(a) reporting rule that requires a wider set of information and annual reporting. Members of this condition of use pool would either be taken forward to the Prioritization Data Set stage or returned to the overall CDR pool;

- Prioritization Data Set: EPA would collect additional condition of use data to determine whether a chemical should be designated as a high priority, beginning the nine- to 12-month prioritization process; and

- The Risk Evaluation/Risk Management Data Set: Once EPA designates a chemical as a high priority, it would require submission of data by manufacturers (including importers) and processors to obtain detailed information on use, production, disposal, and environmental and health effects.

6. Section 26 — Administration of TSCA; Fees Rule

EPA has yet to publish the revised fees rule in final. In response to EPA's supplemental fees rule proposal in November 2022, EPA again received significant criticism for a lack of transparency for its estimates of the effort required to perform reviews under Sections 5 and 6. We had expected EPA to issue the final rule so that it could begin collecting increased fees in the new FY, but October 1 passed without EPA publishing the final rule. The Fall 2023 Regulatory Agenda (2070-AK64) lists **February 2024** as the date for publishing the final rule. It is not clear whether the final rule will include the near-doubling of fees, as proposed, or if EPA will propose a more modest increase, such as 20 percent based on Congress's additional appropriation in FY 2023.

Requests for correction of information (RFC) represent an important approach for exhausting administrative remedies and building a record if legal challenge is required on EPA's promulgated risk management rules.

7. Section 26 — Scientific Standards

a. Multiple-Path Particle Dosimetry

As we stated in last year's Forecast, on March 23, 2021, EPA's Office of Research and Development (ORD) announced its plan to convene an external peer-review panel to review the draft MPPD Model Software (MPPD EPA 2021 v.1.01) and Technical Support Documentation and User's Guide (External Review Draft). ORD's external peer review was held in May 2021. Since this time, ORD has been working diligently to revise the model based on the peer reviewers' comments. ORD had hoped to release the final peer-reviewed version of the MPPD model by the end of 2022. This goal has not been realized, however, and ORD has not posted updates on when the final peer-reviewed version will be available.

EPA likely anticipates challenges under TSCA Section 26(h) to the forthcoming risk management rule on PV29, given that it used deposited dose for quantifying risks, despite the best available science that supports the use of retained dose when quantifying risks for this type of substance. We anticipate that EPA will refrain from issuing its proposed risk management rule on PV29 until it has had time to reassess and reevaluate its conclusions in the final risk evaluation for PV29 using the peer-reviewed version of MPPD.

b. Scientific Challenges

Requests for correction of information (RFC) were submitted to EPA under the Information Quality Act (IQA) on EPA's risk evaluations for carbon tetrachloride (RFC submitted by the Halogenated Solvents Industry Alliance, Inc. [HSIA] on January 26, 2021) and N-methylpyrrolidone (RFCs submitted by the Semiconductor Industry Association [SIA] on June 3, 2021, and by the NMP Producers Group on April 19, 2023). The crux of each of these submissions was based on the submitters' concern that EPA failed to meet the IQA requirements and the scientific standards under TSCA Section 26 for best available science and weight of scientific evidence.

EPA's responses to the RFCs were delayed for the HSIA and SIA RFCs for more than two years. EPA did, however, post its denial responses to HSIA and SIA on July 27, 2023. EPA subsequently posted its denial response to the NMP Producers Group on August 15, 2023. We note that EPA's denial responses were not substantive. Rather, in each, EPA concluded that the appropriate mechanism for raising the issues in the RFCs was during the public comment period rather than through a separate mechanism under the RFC process. We note, however, that the RFC process is typically pursued by submitters when an agency fails to fulfill its legal obligation to "consider and respond to significant comments received during the period for public comment."

B&C recognizes that EPA's responses on the above RFCs are representative of how EPA intends to respond to future RFCs. EPA stated in March 2023 that it will address RFCs during the risk management rulemaking process. We note that EPA's plan contradicts its own IQA guidelines, which state in part, "In cases where the Agency disseminates a study, analysis, or other information prior to the final Agency action or information product, it is EPA policy to consider requests for correction prior to the final Agency action …." We further note that regulated entities should not be swayed by EPA's sweeping denial responses. We mention this because RFCs represent an important approach for exhausting administrative remedies and building a record if legal challenge is required on EPA's promulgated risk management rules.

8. Section 21 — Litigation and Petitions

In June 2020, the U.S. District Court for the Northern District of California held a bench trial in a case seeking a rulemaking under TSCA Section 6 to prohibit the addition of fluoridation chemicals to drinking water supplies. *Food & Water Watch, Inc. v. EPA* (No. 3:17-cv-02162-EMC). The plaintiffs filed suit following EPA's denial of a TSCA Section 21 petition requesting it to exercise its Section 6 authority to prohibit the addition of fluoridation chemicals to U.S. water supplies. The court scheduled a status conference on January 10, 2023, to discuss future scheduling. According to the parties' October 11, 2023, status report, the parties

completed fact discovery and exchanged expert disclosures. Counsel for the parties agreed to a deposition schedule for all experts and expected to complete expert discovery by the November 9, 2023, deadline with one exception: due to scheduling complications. The trial is scheduled to begin on **January 31, 2024**.

On October 14, 2020, a coalition of North Carolina NGOs petitioned EPA for a TSCA Section 4 test rule for 54 PFAS manufactured by The Chemours Company (Chemours) at its chemical production facility in Fayetteville, North Carolina. After their 2020 petition was rejected by EPA, on January 7, 2021, the North Carolina public health and environmental justice organizations filed suit in the U.S. District Court for the Northern District of California at San Francisco seeking judicial review of EPA's denial. *Center for Environmental Health (CEH) v. Nishida*, No. 21-cv-1535. Petitioners asked the court to compel EPA to initiate a proceeding under TSCA Section 4(a) to issue a rule or order requiring Chemours to fund the studies identified in the petition. As we wrote last year, EPA initially denied the petition, but reconsidered and in December 28, 2021, announced that it granted the petition because these substances include many of the chemicals identified in the petition, as well as additional PFAS that will inform a wider universe of categories of PFAS where key data are lacking. The case was then transferred to the U.S. District Court for the Eastern District of North Carolina. *CEH v. Nishida*, No. 7:22-cv-00073-M. On June 23, 2022, EPA filed a motion to dismiss, arguing that it granted the petition and is commencing "an appropriate proceeding" in accordance with TSCA Section 4. Petitioners opposed EPA's motion, noting that in "granting" their petition, EPA declined to require testing on 47 of the 54 PFAS.

On March 30, 2023, the U.S. District Court for the Eastern District of North Carolina issued an order granting EPA's motion to dismiss, finding that EPA granted the 2020 petition and that the court lacks jurisdiction to review such a grant. Petitioners filed an appeal in the U.S. Court of Appeals for the Fourth Circuit on August 7, 2023, claiming that the lower court wrongly concluded that EPA "granted" their petition; that the court misinterpreted TSCA by concluding that EPA could grant the petition on the basis of a preexisting testing strategy with different objectives; and that the court misread TSCA by concluding that neither the petitioners nor the court could compel EPA to issue test rules or orders requiring specific studies on particular chemicals. On October 10, 2023, EPA filed its response brief, maintaining the lower court correctly determined that EPA granted the petition and correctly dismissed their complaint.

ARTICLE
"TSCA, SNURs, and Plastic Waste-Based Feedstocks," *Chemical Processing*, July 18, 2023

On November 15, 2022, a coalition petitioned EPA to require human and environmental health and safety testing for polyvinyl alcohol (PVA or PVOH) as it is used in consumer-packaged goods, "with particular attention to the use of PVA in laundry and dishwasher detergent pods and sheets." On January 26, 2023, the petitioners withdrew the November 2022 petition and resubmitted a new petition. The updated petition requested a TSCA Section 4 order "requiring the manufacturers and processors of PVA who are part of the EPA Safer Choice Program, have products with the EPA Safer Choice certification, and who are seeking an EPA Safer Choice certification for pods or sheets products, to fund and conduct this testing under the guidance and direction of independent, third-party scientists" on PVA and "ultimately regulate PVA used in dishwasher and laundry pods and sheets as a toxic substance, pending the results from testing." On April 27, 2023, EPA announced that it denied the request to initiate an action under Section 4 because the petitioners did not provide the facts necessary for the Agency to determine that existing information and experience on PVA in dishwasher and laundry pods and sheets are insufficient and that testing PVA is necessary to develop such information. 88 Fed. Reg. 25590. More information is available in our May 1, 2023, blog item, "EPA Denies Petition Seeking TSCA Section 4 Testing of PVA."

On August 1, 2023, Earthjustice filed a citizen petition asking EPA to establish regulations prohibiting the manufacturing, processing, use, and distribution of N-(1,3-Dimethylbutyl)-N′-phenyl-p-phenylenediamine (6PPD) for and in tires. Earthjustice filed the petition on behalf of the Yurok Tribe, the Port Gamble S'Klallam Tribe, and the Puyallup Tribe of Indians. According to Earthjustice's August 1, 2023, press release, "[w]hen 6PPD reacts with ground-level ozone, it breaks down into 6PPD-q — the second most toxic chemical to aquatic species ever evaluated by the EPA." The Tribes contend that 6PPD in tires poses unreasonable risks to the environment, requiring EPA to regulate the chemical under TSCA. EPA included 6PPD among the 15 substances

from which it intends to select the next five prioritization targets for risk evaluation. On November 2, 2023, EPA granted the petition and announced that it intends to propose an "advanced notice of proposed rulemaking under Section 6 of the Toxic Substances Control Act (TSCA) by Fall 2024 in order to gather more information that could be used to inform a subsequent regulatory action." We expect this to be a complex Section 6 action, given the likely extensive presence of used tires in the environment and the necessity of protecting tires from degradation for safety purposes. EPA also plans to issue a final TSCA Section 8(d) rule to require manufacturers (including importers) of 6PPD to report lists and copies of unpublished health and safety studies to EPA by the **end of 2024**. More information is available in our November 3, 2023, blog item, "EPA Grants TSCA Section 21 Petition to Address 6PPD in Tires."

On August 22, 2023, Earthjustice filed suit in the U.S. Court of Appeals for the Ninth Circuit on behalf of a coalition of public health NGOs, seeking the conclusion to a rulemaking under TSCA to regulate lead wheel weights. *Ecology Center, Inc., et al. v. EPA* (No. 23-70158). Plaintiffs claim that in 2009 EPA granted their TSCA Section 21 petition for a rulemaking prohibiting the manufacture, processing, and distribution in commerce of lead wheel balancing weights. On October 5, 2023, the parties filed a joint motion to refer the case to the Ninth Circuit's Mediation Program.

9. Other Litigation

EPA filed suit against Inhance Technologies on December 19, 2022, in the U.S. District Court for the Eastern District of Pennsylvania, claiming that Inhance is generating PFAS when fluorinating plastic containers, in violation of the 2020 SNUR on long-chain perfluoroalkyl carboxylates. *USA v. Inhance Technologies* (No. 5:22-cv-05055). After the U.S. District Court for the District of Columbia dismissed a similar suit brought by CEH and Public Employees for Environmental Responsibility (PEER), the parties intervened in the EPA suit. *Center for Env'l Health v. Inhance* (No. 1:22-cv-03819). According to EPA, the burden was on Inhance to notify EPA during the rulemaking process that it wanted an exemption for ongoing uses. Inhance maintains that it had no knowledge at the time of the rulemaking that its fluorination process generated PFAS and that any PFAS generated are subject to exemptions for impurities and articles. Both EPA and Inhance have filed motions for summary judgment. The court heard oral argument on August 23, 2023.

Inhance filed SNUNs for the perfluorocarboxylic acids formed as byproducts of the fluorination process, even though Inhance's view is that, as impurities, the acids are exempt from the SNUN requirements and the activity has been ongoing for decades and therefore should not be considered a new use for purpose of the underlying SNUR. On December 1, 2023, EPA issued unilateral orders under TSCA Section 5(e) to restrict pending the development of information Inhance's manufacturing, processing, distribution in commerce, and disposal of certain of the perfluorocarboxylic acids formed as byproducts of the fluorination process and TSCA Section 5(f) to prohibit the manufacturing, processing, distribution in commerce, and disposal of others. Inhance has challenged the Sections 5(e) and 5(f) orders in court and has been granted a stay as to their effective dates, but if Inhance prevails on the suit brought by EPA, the SNUNs and Sections 5(e) and 5(f) orders would be moot.

For more than 25 years, B&C has offered clients an unparalleled level of experience and excellence in matters relating to TSCA. Our TSCA practice group includes eight former senior EPA officials, over a dozen scientists, including seven with Ph.D.s, and a robust and highly experienced team of lawyers and regulatory professionals. Contact lbergeson@lawbc.com if you would like to discuss how our team can assist you with product approval, product review, and general compliance measures under TSCA.

CONTRIBUTORS

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C. FIFRA: PREDICTIONS AND OUTLOOK FOR OCSPP'S OFFICE OF PESTICIDE PROGRAMS

1. PRIA 5 Implementation

PRIA was enacted in 2004. It established a new system for registering pesticides, including requiring fees for registration actions and guaranteed decision times, along with funding for farmworker protection activities. PRIA was reauthorized in 2007, 2012, 2019, and most recently on December 29, 2022 (PRIA 5).

PRIA 5 revised pesticide fees and review times, and included several new provisions:

- Bilingual labeling for pesticides;
- ESA guidance to registrants;
- PRIA process improvements, including renegotiation provisions for submissions;
- Information technology (IT) upgrades;
- Centralized web page for guidance and pesticide-related resources;
- Posting of data evaluation records (DER) for PRIA actions;
- Audit of OPP processes and workforce;
- Government shutdown provisions;
- Omnibus — **October 1, 2026**, deadline extension for certain registration review cases (identifications with measures to reduce exposure and risk); and
- Reports to Congress.

EPA has been working hard to meet the requirements in the law and each of the statutory deadlines imposed under PRIA. In 2024, OPP's core focus can be expected to be on PRIA 5 implementation.

In 2023, OPP took the first of many PRIA 5 implementation steps, including:

- Implementing maintenance fees;
- Updating fee tables;
- Working on bilingual labeling accessibility, including consulting with states on bilingual labeling implementation;
- Creating a centralized guidance web page;
- Developing ESA guidance; and
- Providing funding for the Pesticide Safety Education Program and/or the National Pesticide Information Center.

PRIA 5 provided an increase in fees and funding for OPP from PRIA 4, equal to an increase of $11 million for maintenance fees (average annual collection target raised from $31 million to $42 million), and an across-the-board 30 percent increase for pesticide registration services. PRIA 5 raised minimum appropriation triggers to $166 million (FY appropriations were $138.6 million). In 2024, EPA will continue PRIA 5 implementation work. In 2024, look for OPP to:

- **Make further website updates** — EPA is expected to post PRIA fee category interpretations tables and the updated fee determination decision tree tool to the main PRIA web page. EPA also is expected to continue to update fee category-specific web pages.
- **Final guidance** — Issue final ESA guidance for outdoor uses of a registered pesticide and ESA implementation itself as a priority (see next section, Endangered Species Act).
- **Establish and implement a Vector Expedited Review Voucher (VERV) program** — EPA is expected to establish the VERV program to incentivize expedited review of new insecticides to control the spread of vector-borne disease.
- **Improve the electronic registration submission process** — EPA is expected to establish an IT system for electronic registration submissions and application tracking.
- **Issue process assessment contract** — EPA is expected to issue a competitive contract to a private, independent consulting firm to conduct a process assessment for review of applications submitted under PRIA.

In 2024, EPA will need to focus on improving the serious delays in the front-end processing of registrant submissions and the lack of clear communication to the registrant community about solutions, both of which have undermined EPA's PRIA 5 implementation efforts.

In 2023, EPA faced a number of PRIA 5 implementation challenges, and we expect EPA to continue to face these challenges in the new year. This is especially likely, given EPA's ongoing funding and staffing hurdles. PRIA 5 included detailed and aggressive timelines that were hard to meet from their inception. We expect continued delays and frustration from both EPA and industry in the completion of PRIA actions in accordance with the law's prescribed timeframes.

Of note, in 2024 EPA will need to focus on improving the serious delays in the front-end processing of registrant submissions and the lack of clear communication to the registrant community about solutions, both of which have undermined EPA's PRIA 5 implementation efforts. To a large degree, OPP does not itself manage its IT infrastructure. OPP IT infrastructure and systems are managed in EPA's Office of Administration and Resources Management (OARM). As a result, outages of the Pesticide Submissions Portal (PSP) and related portals that allow registrants to upload submissions and provide EPA reviewers access to those submissions will be difficult for OPP to manage and to prioritize fixes and updates.

OPP has committed to ensuring these critical and legally required updates. Frequent and transparent communication with registrants will be critical in 2024, especially if EPA cannot access registrant submissions, which seems to have been the case in 2023. System delays and lack of communication will continue to create significant confusion for both registrants and EPA staff, overwhelming EPA with inquiries from registrants and frustrating those stakeholders when no response is forthcoming. The outages and continued communications issues are expected to add to an already large backlog of submissions that will make it more difficult for EPA to meet its PRIA deadlines. These delays can cause registrants to miss key seasons for the launch of new products, delays of which OPP is painfully aware.

Look for significant improvements in this area in 2024, or expect industry backlash and robust Congressional oversight. EPA also will need to communicate clearly and often to stakeholders, including the states, regions, and applicable enforcement agencies, so that EPA keeps this status in mind when processing registrations, processing import documentation, and considering enforcement actions. The development of alternative submission pathways also could be an important activity for OPP in 2024. Prioritizing and expediting the third-party audit required under PRIA 5 to review and recommend fixes to OPP's IT systems also will be critical.

Other 2024 OPP priorities, driven largely by PRIA 5 implementation, include:

- Registration and registration review;
- Progress on OPP ESA obligations;
- Implementation of Agency priorities;
- Environmental Justice;
- Climate change;
- Advancing "state-of-the-art-science";
- PFAS Endocrine Disruptor Screening Program (EDSP), nanotechnology, and NAMs;
- Rulemaking, guidance, litigation, OIG, and petition responses;

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- Increasing resources and IT improvements; and
- Employee experience, organizational development, process and IT improvements (Great Place to Work [GP2W]) (people, processes, and technology).

2. Endangered Species Act

The issue of how EPA should interact with other government agencies to implement ESA provisions has dogged the pesticide program and prompted repeated litigation challenges for more than 20 years. The pivotal issues are how extensive EPA's assessment must be to demonstrate compliance with ESA, how much autonomy EPA possesses to make critical decisions regarding ESA compliance, and the degree to which EPA assessments can coordinate and comply with requirements of the other agencies (*i.e.*, U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (Services)) that have responsibility for implementing ESA. The problem of "how much is enough" when conducting an assessment, and the degree of coordination of assessments between EPA and the Services (including who decides various issues, such as the need for consultation between EPA and the Services), have been debated for many years and subject to extensive litigation.

The Biden-Harris Administration's latest efforts in 2023 to address integrating the requirements of FIFRA and ESA resulted in significant progress in outlining programmatic reforms at EPA and outlining a path forward. Progress in 2023 built on renewed efforts by the Administration, which began to emerge in 2022. In April 2022, EPA released an ESA Workplan that was refreshingly candid in identifying the problems that characterized past efforts. The April 2022 ESA Workplan described how the past efforts are effectively impossible to succeed in any reasonable time. For example, current approaches result in a program that would take seven years to evaluate just five percent of pesticide uses, meaning that ESA program compliance at that rate would take an additional 140 years, an unsustainable metric by any standard.

In the 2022 ESA Workplan, EPA outlined ideas to fashion programmatic reforms and policies to have a more realistic approach to implement ESA-compliant pesticide label requirements using broad policies to ensure species protection. That document was followed by an "ESA Workplan Update" issued in November 2022, which included more specific mitigation measures that are expected to be imposed to protect species.

In 2023, EPA outlined how these specific mitigation measures might apply to a pesticide's use to protect threatened and endangered species (TES). Specifically, EPA released its "Vulnerable Listed (Endangered and Threatened) Species Pilot Project: Proposed Mitigations, Implementation Plan, and Possible Expansion" (Vulnerable Species Pilot (VSP)) in June 2023. This was followed in July 2023 by the "Herbicide Strategy," in which EPA announced its plans for ESA restrictions on herbicides as a class. In November 2023, EPA release an "Update on Vulnerable Species Pilot."

EPA has explained that the intended ESA approach will be based on the concepts of "avoidance" and "minimization." The approach would include Pesticide Use Limitation Areas (PULA) that would be implemented by restrictions on use added to pesticide labels. Avoidance appears to mean prohibiting a pesticide's use to ensure that this use would not directly (adversely) impact a critical habitat for a species. Minimization strategies would include instructions intended to reduce the estimated potential exposure to species from off-target movement of a pesticide, using extensions of practices that EPA already includes on labels to reduce estimated environmental exposures as part of its long-standing review and approval of pesticide labels. These standard practices include, for example, buffer zones where use is prohibited around a treated area and/or application methods (*e.g.*, coarser (heavier) droplet size using different nozzles when spraying the pesticide).

This VSP document and update, the Herbicide Strategy, and the earlier ESA Workplan and update documents describe utilizing "up front" mitigations such as the buffer zones around pesticide application areas. The sizes of the buffer zones are standardized values (*e.g.*, 100- or 300-foot buffers), depending on the data analysis EPA has reviewed and input into its conservative models of possible off-site movement. Buffer zone requirements can be adjusted down if the application meets criteria (*e.g.*, droplet size or vegetative buffer strips are in place to reduce expected off-site movement of the pesticide).

In 2024, EPA is expected to expand the Herbicide Strategy to similar approaches for other categories of pesticides (insecticides, fungicides, rodenticides) where EPA's calculated risk to species will be reduced by requiring the identified strategies to reduce potential pesticide migration to areas which are habitat for TESs. Until recently, as explained below, EPA has indicated that the imposition of default strategies will allow the pesticide review process to be manageable in terms of timeliness and budget. These

up-front mitigation strategies would use the standardized restrictions determined to reduce exposures — for example, buffer zones or heavier sprays. The strategy is designed to marry the EPA assessments of the required ecological risk studies with the habitat maps and species designations of the relevant sister agencies.

a. Stakeholder Reactions

For advocates of greater species protection, these measures to mitigate risks to species and comply with ESA are long overdue. The result of various litigation settlements imposed on EPA relatively stringent deadlines to issue strategies in final and complete ESA assessments of many widely used pesticides in the next few years.

For example, the Center for Biological Diversity (CBD), a long-standing advocate (and litigant) for more aggressive ESA action by EPA, commented on the VSP by stating, "The EPA is moving in the right direction with a common-sense, species-centric approach that could drastically simplify Endangered Species Act ("ESA") consultations and better protect some of the species most significantly imperiled by pesticides" (EPA-HQ-OPP-2023-0327-0189). CBD further stated, "The EPA's Vulnerable Species Pilot Project represents a very important step to ensure that conservation measures safeguard threatened and endangered species."

As EPA outlines new approaches to ESA-FIFRA integration, agricultural stakeholders are concerned about possible impacts on crop production in the affected areas. For agricultural producers, the complexities of this scheme are many, and much of the responsibility for compliance will be on the grower/applicator. Registrants of pesticides will have to add additional label requirements as outlined in the EPA documents to maintain their registration or as part of a new product approval. Meanwhile, there are many questions regarding how EPA will determine needed mitigation measures, assess additional information to refine restrictions, define more precisely those areas where restrictions are warranted, enforce requirements, accept proof of compliance with ESA measures, and confirm feasibility of EPA's approach to the ESA-FIFRA integration.

EPA staff have been inconsistent about what, if any, additional information regarding how the mapped habitat areas, crop production methods, and site- or region-specific considerations will be reviewed to refine label requirements. In the past, FIFRA review practices have generally allowed such refinements before final imposition of use restrictions. It is unclear how much EPA will be willing or able to incorporate additional review steps, given the overdue need to comply with ESA generally or specifically to meet agreed-upon court settlements with imposing assessment deadlines.

The VSP focuses on 27 species to illustrate how the mitigation options and habitat maps, along with the label Bulletins, can work together to comply with ESA. Scaling up any larger program is one the important unknowns: The Herbicide Strategy alone will cover approximately 400 pesticides. There also will be hundreds of insecticides and many fungicides to address. With more than 1,300 TESs now listed, the program over time will expand greatly. This leads to fears that very large areas of agricultural production could see significant disruption in current cropping practices.

For the VSP document, with a focus on only 27 species, comments submitted by a group of over 200 agricultural stakeholders included the following conclusion (EPA-HQ-OPP-2023-0327-0171):

> Realistically, the immense costs, lack of compliance options, and regulatory bottlenecks imposed by the proposed pilot will all but ensure many pesticide users in these areas are prohibited from using these vital tools in the future. This stands a strong likelihood of ending the continued viability of their farming and business operations, greatly harming the communities in which they reside.

Regarding the Herbicide Strategy, most of the same agricultural stakeholders (also more than 200 groups) submitted the following comments:

> This complex, unworkable proposal would result in significant new, costly regulatory burdens for millions of U.S. agricultural producers. Others would simply be unable to comply with the proposal, undermining their continued access to herbicides. As a result, we are concerned this proposal could jeopardize the continued viability of farming operations across the United States.
> ... if implemented as proposed, the herbicide strategy would be disastrous for U.S. farmers and our rural communities.

> ...This incredibly complex, costly, and onerous proposal presents a significant threat to U.S. agricultural herbicide users in the lower 48 states.

b. The November VSP Update

This "Update" issued in November 2023 appears to telegraph a number of important changes to EPA's approach to ESA compliance measures. Although earlier, EPA said it would accept comments on the VSP but not revise that document, this "Update" includes explicit responses to various stakeholder comments on the document, along with reference to comments received on the Herbicide Strategy. EPA refers to its expected changes as "current thinking" about its ESA approach and describes its views on "modifications it plans to make to the VSP framework based on the received comments."

The important changes described include:

1. Refine the species habitat areas expected to see use restrictions and only include locations most important for species conservation;

2. Clarify how ESA plans will apply to non-agricultural areas;

3. Clarify potential exemptions to the proposed mitigation plans;

4. Include additional mitigation options specific to non-agricultural uses and specialty crops (these could include rodenticides, turf use, or fruit and vegetable crops);

5. Revisit selected pilot vulnerable species; and

6. Develop a consistent approach for the strategies to reduce pesticide exposure from spray drift and runoff.

These may appear to be common-sense approaches to fashion a nationwide strategy flexible enough to apply to hundreds of species for hundreds of different crops using varied production systems across the entire United States. When compared to past statements by various EPA staff, however, they indicate significant changes to what has been stated publicly about the ESA plans prior to the November 2023 Update. The changes acknowledge and respond to important and repeated criticisms of aspects of EPA's plan, including imprecise habitat maps, "one-size-fits-all" plans that may be inappropriate for certain crops or production systems, and the very significant concession that once a mitigation plan for ESA-driven mitigation is proposed, EPA will allow some additional information to be considered to tailor more precisely requirements to protect species.

Other changes mentioned in the November 2023 Update that reverse past public statements include that "EPA's current thinking for agricultural uses is that the proposed VSP mitigation would not need to include avoidance, but rather would focus on minimization." This will be welcome to stakeholders who are able to reduce exposure to protected species but may have limited options to entirely avoid use of certain pesticides in all possible situations.

This VSP update indicates renewed interest by EPA in working with the Services and stakeholders to fashion a more flexible, or at least tailored, approach to implement ESA — and one that will address many important concerns raised during public comments on EPA's plans.

c. 2024

As mentioned in previous years, the Biden-Harris Administration has made significant progress in proposing a path forward finally to integrate the requirements of both FIFRA and ESA. The ESA Workplan and Update, VSP and Update, Herbicide Strategy, and the other strategy documents soon to follow outline specific programmatic details that can now be applied to specific pesticide cases better to protect species.

At the same time, there remains tremendous uncertainty about many important elements about how all this "strategy" will apply to specific pesticides needed to produce specific crops in specific production areas. The particular mitigations will likely only be resolved through a combination of "trial and error" combined with "learn by doing." With the potential for large impacts on aggregate food production while meeting the need for species protection, refining the current proposals will need to be done carefully to avoid what some in the past have seen as a possible, if not probable, "train wreck" when attempting to meet the goals of both statutes.

OPP is researching how to compare shallow private drinking water well locations in high agricultural areas to urban settings and to understand better pesticide exposure through drinking water for these populations.

3. Environmental Justice

Environmental Justice (EJ) remains a high priority issue for the Biden-Harris Administration and EPA. In 2024, EJ will continue to be an important theme potentially impacting every decision facing OPP. President Biden's executive order (EO) on "Tackling the Climate Crisis at Home and Abroad," issued on his eighth day in office, included the imperative for all federal agencies to incorporate an EJ framework into their decision-making. Following the EO, the Biden-Harris Administration released interim guidance for implementing the EO's "Justice40 Initiative." It designated 21 priority programs to begin enhancing benefits to disadvantaged communities as part of the President's pledge that 40 percent of climate, energy, and infrastructure spending will flow to overburdened and marginalized neighborhoods.

Of note for pesticides, the Justice40 Initiative includes policy recommendations such as "[f]inaliz[ing] the 2015 proposed rule revoking all food tolerances of chlorpyrifos," accounting for cumulative exposures to organophosphates in the registration review process, and other recommendations focused on agricultural worker safety and health.

In response to the EO, EPA has established a new national EJ program and a new Office of Environmental Justice and External Civil Rights. This office is envisioned to include a staff of over 200 to help implement and deliver over $3 billion in EJ-focused grants. With a renewed focus on EJ issues and an updated EJ strategic plan, each EPA program office is intended to play an integral part in fulfilling the Agency's mission by focusing attention on the environmental and public health issues and challenges confronting the nation's minority, low-income, Tribal, and indigenous populations. According to EPA, over the next several years, EPA will "advance environmental justice to a new level and make a more visible difference in the environmental and public health outcomes for all people in the nation." EPA states, "[s]trengthening our collaborations with the communities we serve, our governmental partners and interested stakeholders will be key to achieving this vision."

In 2024, OPP is expected to remain committed to making EJ a critical component of its work and to continue carrying out several initiatives. For example, OPP is researching how to compare shallow private drinking water well locations in high agricultural areas to urban settings and to understand better pesticide exposure through drinking water for these populations. OPP also is developing groundwater modeling scenarios for areas across the country where private drinking water wells overlap with vulnerable aquifers. A focus on chlorpyrifos, as recommended in the Justice40 report, also falls under EJ action. Focus on farmworkers and worker risks from pesticides will be an important consideration for OPP and EJ in 2024.

EPA in 2020 and 2021 expanded its Spanish language resources that assist with translating the health and safety portions of pesticide product labels. The Spanish Translation Guide for Pesticide Labeling resource is available for anyone to use, including pesticide manufacturers, to display parts of their pesticide product labels in Spanish. EPA generally allows pesticide registrants to include on the label other languages optionally in addition to the full English text if the translation is true and accurate. Some pesticide registrants already have their product labels fully translated into Spanish. Many product labels are, however, only available in English. With PRIA 5 mandates for bilingual labels, this will continue to be an important EJ area in 2024.

According to the EPA Annual Environmental Justice Progress Report FY 2020, EPA supported several activities over the last few years to implement the OSHA Worker Protection Standard (WPS). Through cooperative agreements, EPA helped provide Farmworker Health and Safety Training to over 6,000 farmworkers and agricultural employers "on pesticide safety, limiting family exposure to pesticides, and pesticide exposure, and heat stress prevention. In addition, the Pesticides Education Resources Collaborative developed resources on pesticide safety and the WPS for pesticide safety educators and trainers, agricultural employers, and pesticide regulatory agencies. Materials focused on WPS respirator requirements, WPS ventilation criteria, WPS contacts by state, and a WPS inspector

resource library." Programs like these are expected to expand in 2024.

As discussed in the PRIA 5 section above, EPA work in 2024 is expected to include continued work to issue final new requirements for bilingual labels in the next few years.

Other important EJ initiatives to look for in 2024 include:

- Increasing monitoring and enforcement of pesticide use;
- Reducing accidental or unintended harm from pesticides;
- Strengthening protections for children;
- Reducing export of pesticides no longer used in the United States to developing nations; and
- Setting more stringent standards for emissions from pesticide manufacturing facilities to protect fenceline communities.

In April 2023, the Biden-Harris Administration issued Executive Order 14096 on "Revitalizing Our Nation's Commitment to Environmental Justice for All," proposing a "whole of government" approach to EJ. In August 2023, EPA released an implementation plan for EJ and External Civil Rights, committing to an increased focus on facilities in EJ communities, as well as enhanced efforts to address EJ in enforcement actions. In November 2023, EPA published a notice seeking comment on draft guidance that, as proposed, would require EJ considerations in regulatory analyses, including for certain permits required to expand or maintain manufacturing operations. For example, the guidance aims to incorporate EJ concerns into Clean Water Act and Clean Air Act permit decision-making processes. In 2024, look for these new requirements to be finalized and implemented with many questions remaining regarding whether and how this will impact pesticide manufacturing, availability, and use.

PODCAST:
Community Outreach and Environmental Justice — A Conversation with Rachel James of the SELC

With the establishment of a robust national EJ program at EPA, the clear policy position that EJ will be an important priority across all decision-making, and PRIA 5 program requirements such as bilingual label requirements, look for EJ to continue to be an important policy area for OPP in 2024.

4. Climate Policy

Addressing climate change remains a priority of the entire Biden-Harris Administration, especially at EPA. President Biden has directed all federal agencies to integrate climate adaptation planning into their missions, programs, and management functions to ensure their success in enhancing preparedness for and resilience to the climate crisis. For EPA, this includes evaluating how climate change might affect efforts to attain environmental standards given heat waves and more intense storms, increased use of pesticides given expanded life spans, and habitat of insects and impacts of rising seas and storm surges on hazardous waste sites and critical water infrastructure.

In October 2021, EPA Administrator Regan released EPA's Climate Adaptation Action Plan that describes the steps EPA will take to address the impacts of climate change:

- Integrate climate adaptation and consideration of climate impacts into EPA programs, policies, rulemaking processes, and enforcement activities.
- Consult and partner with Tribes; state, local, and territorial governments and other federal agencies; community groups; scientists and adaptation experts; businesses; and other stakeholders to increase the resilience of the nation, with a particular focus on advancing EJ.
- Implement measures to protect the Agency's workforce, facilities, critical infrastructure, supply chains, and procurement processes from the risks posed by climate change.
- Modernize EPA financial assistance programs to encourage climate-resilient investments across the nation.

In the EPA Action Plan, EPA states that rising temperatures, changes in precipitation, runoff, soil moisture, and shifts in ecosystems can affect the presence and concentration of chemicals in the environment. EPA states that climate change and subsequent alteration of ecosystems

will likely result in changes in where crops are grown and in the presence of pests and diseases: "As pests move into new areas, pest management practices and application of pesticides may expand. This may lead to more chemicals present in soil and water. Chemical safety may be affected by changing chemical use patterns resulting from climate change. An increase in the frequency of new pest problems could trigger requests for emergency exemptions under [FIFRA] if currently registered pesticides are ineffective."

According to EPA and the Centers for Disease Control and Prevention (CDC), the development and survival of ticks, their animal hosts (such as deer), and the bacterium that causes Lyme disease are all strongly influenced by climatic factors, especially temperature, precipitation, and humidity. An expansion of the geographic area in which ticks can survive may lead to more people having contact with infected ticks. In regions where Lyme disease already exists, milder winters result in fewer disease-carrying ticks dying during winter. This can increase the tick population, thus increasing the risk of contracting Lyme disease in those areas. West Nile virus is another example of a vector-borne disease influenced by climate change. Preventing people from contracting West Nile virus is important because there are no medications to treat, or vaccines to prevent, this virus in humans, and recovery from severe disease may take several weeks or months. An increase in mosquitoes and ticks is a good example of pests that may thrive with climate change, and OPP may focus on these sorts of climate change public health concerns in 2024.

Extreme heat caused by climate change also may be an important policy consideration in 2024 for OPP as WPSs and other federal worker protection regulations are reviewed and potentially updated. In 2021, the Biden-Harris Administration established the Interagency Working Group on Extreme Heat to develop and coordinate a holistic response on the issue. Recommendations and action from the Working Group are expected in 2024.

According to EPA, pesticides can impact climate change throughout their manufacture, transport, and application. Pesticide manufacture emits three main greenhouse gases (GHG): carbon dioxide, methane, and nitrous oxide. It is unclear whether these sorts of climate change issues will be considered by or impact OPP decision-making.
Federal climate change policies will impact OPP decision-making in 2024, although it is unclear how these climate change policies will impact specific registration decisions. Farm groups have attempted to stake out a role for the important contributions agriculture might make as part of climate-positive solutions. These solutions include new technologies to enhance carbon capture capabilities, innovations in application technologies, and increased efficiency of pest control tools and technologies to reduce agriculture's carbon footprint.

In 2022, the U.S. Department of Agriculture (USDA) announced the establishment of Partnerships for Climate-Smart Commodities, based on public input received in 2021. Through this new program, USDA is financing partnerships to support the production and marketing of climate-smart commodities via a set of pilot projects lasting one to five years. In September 2022, USDA announced the selection of 70 projects representing $2.8 billion in climate-related agriculture initiatives. A second round of projects brought the total investment over $3 billion. Look for this work to increase the national discussion around agriculture, pesticides, and climate policy **throughout 2024**.

5. 2024 Farm Bill

Every five years, Congress passes legislation that sets national agriculture, nutrition, conservation, and forestry policy, commonly referred to as the "Farm Bill." The 2018 Farm Bill should have been replaced by a 2023 Farm Bill on or before October 1, 2023. With ongoing federal outyear budget disagreements in Congress and new House leadership and other challenges, the existing 2018 Farm Bill has been extended a full year, to **October 1, 2024**, through continuing resolution language agreed to in November 2023. Passing a $1.4 trillion agricultural bill in 2024 will be a priority for Congress, especially with a one-year extension in place. This will likely be the most consequential legislation for agriculture in 2024.

The 2018 Farm Bill included important provisions for OPP. The 2018 Farm Bill required EPA to submit to Congress reports regarding the implementation of the National Academy of Sciences report "Assessing Risks to Endangered and Threatened Species from Pesticides" and other steps being undertaken to minimize delays and increase transparency in integrating the ESA and FIFRA evaluations and public participation. The 2018 Farm Bill also established an interagency working group to discuss and address ESA and pesticide issues.

In 2024, look for every major agriculture association to weigh in with its priorities and expected outcomes, includ-

ing to some degree pesticide policy. For the 2024 Farm Bill, we expect the pesticide community to continue to look to strengthen the role of the USDA Office of Pest Management Policy (OPMP), especially OPMP's role in quantifying the risks and benefits to pesticides, and OPMP's work with EPA on registration review, ensuring that the needs of pesticide users are represented. Also, look for further support and an enhanced role of the FIFRA Interagency Working Group to make recommendations and implement improvements to the ESA Section 7 consultation process for pesticide registration and registration review, a special emphasis on adjuvants to increase pesticide efficacy and use-efficiency, a move to decrease impacts to non-target species, and a drive for the 2024 Farm Bill to reaffirm state pesticide preemption and the role of states as co-regulators of pesticides.

Other issues that will be discussed in Farm Bill negotiations will be calls to promote uniformity in pesticide labeling by reaffirming that EPA is the primary, federal authority under FIFRA for making pesticide findings and decisions, support for voluntary adoption of precision agriculture technologies and services, support for USDA's Foreign Agricultural Service's engagement in international institutions, especially related to Codex Alimentarius and pesticide standards, and calls to eliminate duplicative and burdensome water permits for pesticide applications under the National Pollutant Discharge Elimination System (NPDES).

6. Chemicals of Note

a. Chlorpyrifos

One might have thought that any 2024 Forecast would have finally seen the conclusion of a discussion about chlorpyrifos following EPA's action in October 2021 to revoke all tolerances for the pesticide, and subsequent actions that led to stopping all use of the remaining stocks of chlorpyrifos. In November 2023, however, the U.S. Court of Appeals for the Eighth Circuit found that EPA had been arbitrary and capricious when they revoked *all* tolerances, even when EPA had determined that some of the many uses nonetheless met the required safety standard. A discussion of the Eighth Circuit opinion can be found in our November 16, 2023, article.

Perhaps the most unusual element of EPA's 2021 chlorpyrifos decision was EPA's revocation of all food tolerances for the pesticide, even when EPA had determined that some of the many uses nonetheless met the required safety standard. The determination of safety included the required "extra 10x safety factor" to ensure protection of children along with the many standard conservative risk assessment assumptions. EPA's revocation assessment also reviewed epidemiology studies, including the pivotal "Columbia studies" (*i.e.,* studies conducted at the Columbia Center for Children's Environmental Health (CCCEH)) that many stakeholders cited as the major evidence of harm from the use of chlorpyrifos.

The Eighth Circuit decision relies especially on the EPA conclusion that some of the chlorpyrifos uses met the regulatory standards used by EPA, even as it explained the 2021 final rule to revoke all tolerances. The decision reviews, but rejects, EPA's rationale for its decision based on the urgency it faced following an extensive litigation trial where the Ninth Circuit had stressed that it had no further patience for EPA's delays in making final decisions.

Now that the Eighth Circuit has vacated EPA's final rule, the matter has been remanded to EPA, where, the court states, "more than just modification is on the table." In prior situations, when all was said and done following EPA's regulatory decisions, any registrant rebuttals, additional data, or general advocacy, and EPA had decided that some or nearly all current registrations had to be removed from use, the registrant was allowed to eliminate uses so that any remaining uses could "fit in the risk cup." This decision would seem to allow, if not require, EPA to consider registrant requests to tailor a registration for remaining uses that meet the food safety standard or at least make its own determinations regarding uses that it can determine meet, or no longer meet, the required standards.

In 2024, upon issuance of the Eighth Circuit's mandate, according to EPA, all chlorpyrifos tolerances will be automatically in effect once again. In conformance with the Eighth Circuit's ruling and after issuance of the mandate, EPA is expected to issue a notice correcting the Code of Federal Regulations to reflect the court's reinstatement of chlorpyrifos tolerances. Additionally, EPA states, "At this time, final cancelation orders, including their terms for existing stocks of products subject to those cancelation orders and related return programs for chlorpyrifos products, remain in place, unless and until amended by EPA." This statement seems to indicate that EPA expects at least to consider potential modifications to the cancellation orders that were a direct result of the tolerance revocations that are being reinstated. How EPA addresses these issues, and registrant potential challenges and response to EPA's decisions in this regard, will be of significant interest to registrants.

b. Organophosphates

Separate from any chlorpyrifos tolerance decisions, the other organophosphate pesticides are among those scheduled for registration review decisions. EPA already has concluded that the organophosphate class is subject to the Food Quality Protection Act (FQPA) requirement for a cumulative risk review, as they have a similar toxicological mode of action. That is, in simple terms, that all organophosphates have the same mode of action that may vary in potency but have the same effect (cholinesterase inhibition). EPA's cumulative assessment is then used to sum across the members of the class and will determine if individual organophosphate uses meet the standard.

Previous cumulative risk assessments of the organophosphate members reduced uses of various products, and now the current registration reviews are expected to further reduce uses. As part of the registration reviews of individual insecticides, there will be a revised organophosphate cumulative risk assessment. The renewed possibility of previously revoked chlorpyrifos tolerances will further add exposures to the risk cup calculations.

In March 2023, EPA determined that some uses of four organophosphates — diazinon, ethoprop, tribufos, and phosmet — have unacceptable risks and need additional early mitigation steps before completing registration review. At the time, EPA's press release included the following (emphasis in original):

> "The science is clear: some uses of these four pesticides pose a serious health risk to the people that are exposed to them," **said Michal Freedhoff, Assistant Administrator for the Office of Chemical Safety and Pollution Prevention.** "That's why we're taking early action now. While we know there's still a lot of work to finish our review of these pesticides, today's announcement helps deliver on our promise to protect farmworkers and uphold our commitment to environmental justice."

Registrants of these compounds disagree with the elements of EPA's assessments, but resolving any disagreements is expected to result in additional label restrictions or removed uses.

In 2024, EPA will continue its registration reviews of additional organophosphate insecticides, emphasizing similar concerns about possible risks to farmworkers and EJ concerns. Regarding these first four, EPA has scheduled them for proposed interim decisions (beyond mitigation EPA seeks to impose immediately) in **FYs 2024-2025**.

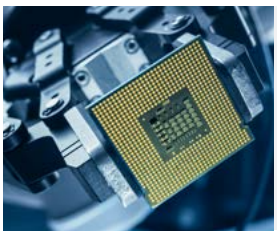
And not to be forgotten, as EPA continues to roll out its plans for ESA compliance, additional restrictions may be mandated as part of EPA's ESA reviews.

c. Rodenticides

Draft risk assessments for the rodenticides were completed in 2020, and in November 2022, EPA issued its Rodenticide Cluster Proposed Interim Decisions (PID). EPA proposed new measures to protect human health and the environment for 11 rodenticides, including measures to reduce potential exposures to three federally listed endangered and threatened ("listed") species and one critical habitat. Those proposed mitigation measures have brought significant political attention to EPA's rodenticide work. EPA's proposed mitigation measures would classify many rodent control products as restricted-use pesticides and require users to become licensed, state-certified applicators. Proposed mitigation measures would prohibit surface application methods for protecting crops and require growers to conduct carcass searches for up to two weeks after application.

In December 2023, EPA released a draft Biological Evaluation (BE) that includes EPA's draft effects determinations for listed species and critical habitats for 11 rodenticide active ingredients. When issued in final, which could be in 2024, the BE will serve as the Agency's Rodenticide Strategy as outlined in EPA's ESA Workplan to guide how the Agency addresses mitigation for rodenticides going forward. Based on the findings in this draft BE, EPA determined some changes were needed, including adding new measures not in the pilot (*i.e.*, prohibiting application directly to water) and modifying measures (*i.e.*, no longer prohibiting application in areas adjacent to species range or critical habitat because drift is not anticipated). EPA built upon the previous mitigation proposals from the 2022 proposed measures and pilot program to develop a list of mitigation options to be considered in this draft BE and will include a definitive list of measures with the final BE that will serve as the Rodenticide Strategy. These final materials will help EPA meet its ESA obligations.

EPA expects to complete the final BE for rodenticides in **November 2024**. Look for these actions on rodenticides to be a prominent topic **throughout 2024**.



While anticipated regulatory action is still unclear, expect OPP to make important regulatory decisions in 2024 with regard to PFAS and pesticide containers.

d. PFAS and Pesticide Containers

EPA continues to make information available about its testing results showing PFAS contamination from fluorinated pesticide containers, and EPA continues to develop a clearer sense of the prevalence of fluorinated pesticide containers. While anticipated regulatory action is still unclear, expect OPP to make important regulatory decisions in 2024 with regard to PFAS and pesticide containers.

In September 2020, EPA became aware of PFAS contamination of a mosquito control product used in Massachusetts. EPA studied the fluorinated high-density polyethylene (HDPE) containers used to store and transport the product and determined that the fluorination process used may be the source of the contamination.

EPA has become aware of additional mosquito products that may be contaminated with PFAS and released testing data showing PFAS contamination in the containers was extremely small. EPA released an internally validated method for the detection of 28 PFAS compounds in oily matrices, such as pesticide products formulated in oil, petroleum distillates, or mineral oils. The new method is intended to help pesticide manufacturers, state regulators, and other stakeholders test oily matrix products for PFAS.

In October 2021, EPA released its PFAS Strategic Roadmap that outlines EPA's commitments to action for PFAS from 2021 through 2024. Although this Roadmap does not reference PFAS in pesticide containers, we can expect that the issue will continue to be studied and better understood in 2024.

In May 2023, the Agency released a summary of laboratory results related to the analysis of ten pesticide products reported to contain PFAS residues. EPA did not find any PFAS in the tested pesticide products, differing from the results of a published study in the *Journal of Hazardous Materials*. EPA also released the newly developed analytical methodology used in the testing process alongside the summary of its findings. EPA seems confident in the results of this newly released method, which is specifically targeted to analyze for PFAS in pesticide products formulated with surfactants; this methodology will lead to a fuller understanding of PFAS in pesticide and other packaging in 2024.

Many experts and lawmakers point to Maine's 2021 passage of a law banning PFAS in all new products as a landmark moment. The measure, which will take effect in **2030**, bans any intentionally added PFAS, but allows for exceptions in products that are essential for health, safety, or the functioning of society and do not yet have a PFAS-free alternative. Look for this sort of state action to help drive debate on PFAS in 2024, and expect EPA to continue to focus on PFAS and pesticide containers, with further action and announcements possible as they further implement the PFAS Strategic Roadmap.

7. Import Enforcement

EPA remains focused on reviewing pesticides and devices that are being imported and refusing entry and initiating enforcement actions for any degree of non-compliance. This effort existed pre-pandemic but increased during the pandemic, when EPA was concerned with pesticide products and devices that were alleged to be marketed with unsubstantiated claims of efficacy against SARS-CoV-2 (the cause of COVID-19) and other pathogens. While issues related to the pandemic may still exist, EPA Regions have expanded reviews for issues with labels and Notices of Arrival (NOA) and have extended their review to claims on company websites and any related labeling materials (*e.g.,* brochures).

Any label language that does not match with EPA-approved labels can be considered a "misbranding" violation of FIFRA Section 12(a)(1)(E), while other misbranding violations can result if there are any "false or misleading" claims based on EPA's regulations and guidance. These issues can be more challenging for pesticide devices, since devices are not registered by EPA and thus have no process through which EPA reviews device claims and no established protocols for the development of product performance data for devices. If EPA moves forward with revisions to its pesticide device policy that has the potential to include significant new guidance to assist importers with compliance require-

ments, as discussed below in the Pesticide Devices section, then there could be hope that the uptick in enforcement actions will decrease. Without well-established guidance, however, importers of pesticide devices will continue in 2024 to be subject to shifting positions taken by different EPA Regions and various enforcement actions, including shipment holds, Notices of Refusal of Admission, Notices of Warning, and Notices of Detention.

8. Pesticide Devices

EPA has expressed its plans to update its 1976 policy statement regarding how it regulates pesticide devices under FIFRA. EPA's enforcement of pesticide devices increased dramatically following the pandemic and remains a major issue. EPA has attempted, following the pandemic, to issue "Compliance Advisories" regarding pesticide devices. The most recent Compliance Advisory was issued in February 2023 entitled "What You Need to Know About Producing, Distributing or Selling Pesticide Devices" and is intended to assist pesticide device producers, importers, and distributors seeking to ensure compliance with their devices. These advisories do not, unfortunately, provide new guidance to address a variety of issues that have arisen in enforcement contexts.

For example, the types of pesticide products and devices have expanded greatly since 1976, and the examples of pesticide devices from the 1976 *Federal Register* notice do not include many current devices. EPA also has not adequately set forth its explanation for why it considers some new products to be pesticide devices, or how companies can evaluate and classify their novel technologies. In addition, while one might think that labeling requirements and efficacy data requirements for pesticide devices would be issues for which EPA has provided guidance, most EPA labeling guidance relates to pesticide products, leaving companies to determine without certainty how to label their products or confirm what claims EPA will believe are compliant for pesticide device purposes. In the absence of clear guidance on efficacy data and related claims, enforcement across EPA Regions is inconsistent and overly rigid. If EPA proceeds with its plans in 2024, expect this to be a significant issue for companies involved with pesticide devices, as industry input in this process will be imperative.

9. Treated Article Exemption

On October 12, 2023, EPA published an advance notice of proposed rulemaking (ANPRM) to solicit public comment

PODCAST:
EPA's Proposed Registration of a Sprayable RNAi Biopesticide — A Conversation with Meibao Zhuang, Ph.D.

and suggestions on specific issues related to seed treated with conventional pesticides (treated seed) and paint treated with conventional or antimicrobial pesticides (treated paint). 88 Fed. Reg. 70625. EPA is considering whether a rule to regulate certain uses of treated seed and treated paint products or other administrative action is appropriate under FIFRA, considering questions raised by stakeholders. EPA notes in its October 12, 2023, press release that treated seed and treated paint are currently exempt from FIFRA registration requirements if they meet the exemption criteria pursuant to the treated article exemption.

EPA requests comment and information from all stakeholders on the use and usage of treated seed, including storage, planting, and disposal of the treated seed, and on whether or to what extent treated seed products are being distributed, sold, and used contrary to treating pesticide and treated seed product labeling instructions. Similarly, EPA requests comment from stakeholders on the addition of labeling requirements on the labels of treated paint products and potential language that should be included on those labels.

Comments were due by December 11, 2023. After reviewing public comments, EPA states that it will consider further actions, which may include regulations to limit the scope of the treated article exemption, enforcing use violations, and taking administrative action to clarify labeling requirements or reduce the use of a treating pesticide.

10. Antimicrobials Division Programmatic Actions of Note

EPA's Antimicrobials Division (AD) was involved heavily during the pandemic in policy decisions and guidance documents related to the use of antimicrobial products. While certain emergency measures that were enacted at the height of the pandemic are no longer in place, the aftereffects of the pandemic resulted in needs for further guidance related to the registration of antimicrobials. In 2023, AD released various guidance and proposals related to the registration of antimicrobials, and in 2024, AD and registrants of antimicrobial products are likely to continue facing these topics, as discussed below.

a. Control of Public Health Pathogens on Soft Surface Textiles

On August 29, 2023, EPA announced the release of final guidance and methods for evaluating efficacy claims of antimicrobial products registered to reduce bacteria and viruses on soft surface textiles. EPA states that throughout the guidance, the term "soft surface textile" refers to a soft, porous, or non-porous surface that includes the outer surface of non-clothing fabrics/textiles in clinical and institutional (non-residential) environments where spot treatment is the primary means of disinfection. Non-residential use sites include waiting rooms, hospitals, long-term care facilities, schools, daycare centers, hotels, office buildings, and retail establishments.

EPA's guidance and associated test methods address only products with both soft surface textile disinfectant claims and hard, non-porous surface disinfectant claims for clinical and institutional settings. Products that have only soft surface textile claims are not within the scope of the current guidance. EPA also states that the guidance is not intended to apply to claims on products for use on clothing, frequently laundered items, untreated wood, concrete and other hard porous materials, carpet or rugs, or the backing material/stuffing under the soft surface textile (*e.g.*, beyond what can be visibly observed), and the guidance is not intended to address claims against mycobacteria, fungi, yeasts, or bacterial endospores, nor to address claims of residual efficacy on soft surface textiles.

EPA recommends standardized quantitative efficacy test methods for both bacteria and viruses in its method for registrants wishing to add disinfectant claims for soft surface textiles pursuant to the guidance. The final test methods and guidance documents are available at docket EPA-HQ-OPP-2022-0337. The final test methods and guidance are also available on EPA's Microbiology Laboratory's Antimicrobial Testing Methods and Procedures web page and EPA's Efficacy Requirements for Antimicrobial Pesticides web page.

We expect in 2024 that EPA will be reviewing new or amended registrations to add soft surface textile claims to labels.

b. Extending Virus Claims to Sanitizer Products

On July 17, 2023, EPA announced the release of draft guidance for the evaluation of products for claims against viruses. This new guidance provides the framework for registrants who seek to make virucidal claims for antimicrobial products.

The draft guidance reiterates recommended test methods and regulatory guidance for the addition of virucidal claims to products that meet the criteria for hard surface disinfection claims consistent with EPA's Product Performance Test Guidelines; OCSPP 810.2200: Disinfectants for Use on Environmental Surfaces, Guidance for Efficacy Testing guideline and provides recommended test methods and regulatory guidance for the addition of virucidal claims to products that meet the criteria for food/non-food contact sanitizer claims consistent with EPA's Product Performance Test Guidelines; OCSPP 810.2300: Sanitizers for Use on Hard Surfaces — Efficacy Data Recommendations test guideline. The draft guidance only covers the addition of virucidal claims to a product that has met the criteria for a bactericidal disinfectant and/or sanitizer. The draft guidance also does not cover adding virucidal claims to sterilant products and is not intended to cover residual (long-lasting) sanitizer claims.

Products that meet the basic criteria to allow for sanitizer claims, as outlined in the current OCSPP 810.2300 test guideline, and have data to support the addition of virucidal label claims, may be used in non-healthcare use sites in residential, commercial, and institutional settings (*e.g.*, cafeterias, waiting rooms). Furthermore, addition of a virucidal claim to a product bearing only sanitizer claims does not imply that the product can be used in healthcare settings, due to the higher level of efficacy against bacteria that is expected in hospital patient care areas.

EPA states that the expansion of the availability of virucidal claims represents a significant policy shift. As such, EPA intends to grant the addition of virucidal claims to products that are *only* sanitizers for a time-limited period of a maximum of seven years, starting from the date the guidance is finalized for use. Registrants interested in registering sanitizer products with virucidal claims or adding virucidal claims to previously registered sanitizer products should do so within the seven-year period. A year prior to expiration of the time-limited registration, EPA will analyze the products registered under this guidance. Comments provided by industry and registrants, as well as product users, would be considered to determine if a revision to the guidance is necessary or if the guidance can be reissued without a time limitation. Prior to the end of the seven-year period, EPA will review the record and may make suggestions for

We expect EPA to continue in 2024 to review submitted comments on the draft guidance for the evaluation of products for claims against viruses and possibly issue final guidance.

changes to the policy, as necessary, or decide to make the policy permanent. The time-limited registration applies to all products seeking to obtain such registration, and it is not an individualized time.

Products registered under this time-limited registration will receive a registration with terms and conditions. These time-limited registrations will be tracked internally to capture all products under this registration and provide a way for communication with the registrants, as necessary. EPA states that the purpose of the seven-year time-limited registration timeframe is to allow registrants to use the guidance for registration and for EPA to evaluate the benefits, concerns, and related experience to inform a decision on the permanence of this interim guidance.

EPA states that should the guidance be terminated after seven years, the registrant(s) will engage with EPA on an appropriate pathway for sanitizer-only products with virucidal claims. Under the time-limited registration, the registrant(s) should contact EPA no later than one year prior to the expiration of the time-limited registration and inform EPA of any changes or comments regarding this guidance, as well as changes to the virucidal claims of the product(s), as necessary.

If the registrant(s) wish to remove the virucidal claims from their sanitizer product(s), the registrant(s) should provide EPA with its (their) proposed path forward and timeframe that will be associated with the removal of these time-limited claims.

EPA states that the draft guidance is "intended to allow registrants to provide consumers with additional products that are effective against viruses including SARS-CoV-2." The draft guidance is important for sanitizer registrants seeking to add virucidal claims, although EPA has provided several caveats to this process that may be equally important. The guidance, for example, does not apply to registrants of sterilant products that may be interested in adding virucidal claims. In addition, any approved registration or amendment adding viral claims to a sanitizer product will be limited to a maximum seven-year period. Prior to the seven-year expiration, EPA will evaluate the products against its guidance to determine if the guidance can be re-issued without a time limitation or if the guidance will be terminated after the seven years. If the guidance is terminated, then the registrant will need to engage with EPA on an appropriate pathway for its sanitizer-only products with virucidal claims. We expect EPA to continue in 2024 to review submitted comments on the draft guidance and possibly issue final guidance.

c. *Legionella pneumophila* Guidance

On October 2, 2023, EPA released for comment a draft guidance that includes a test method to evaluate efficacy claims for antimicrobial products against *Legionella pneumophila (L. pneumophila)* in cooling tower water. Legionnaires' disease (LD) is a serious type of pneumonia (lung infection) acquired by breathing in water droplets contaminated with *L. pneumophila* bacteria. Cooling towers are a potential breeding ground for this bacterium. Aerosolization of *L. pneumophila* can occur if cooling towers are not properly maintained.

EPA states that the incidence of LD in the United States has been increasing since 2000. Outbreaks and illness clusters have been associated with decorative, recreational, domestic, and industrial water systems, with the largest outbreaks being caused by cooling towers. Since 2006, six community-associated LD outbreaks have occurred in New York City, resulting in 213 cases and 18 deaths.

EPA has worked collaboratively with industry to develop the test method that simulates the normal operating conditions of cooling tower water to assess the efficacy of pesticides designed to kill free-floating *L. pneumophila* bacteria. In cooling towers, *L. pneumophila* may exist in multiple forms, including in biofilm attached to the surfaces or inside larger host organisms such as amoeba. The proposed guidance and test method is not intended to address these other forms.

EPA states that when finalized, the guidance would support antimicrobial products claiming to reduce free-floating *L. pneumophila* to be used in water management plans for

cooling tower systems, providing a multi-barrier approach to reduce the bacterium in cooling tower water. These water management plans would include routine maintenance and remediation treatments recommended by the American Society of Heating, Refrigerating and Air-Conditioning Engineers standards and/or applicable federal, state, or local regulation(s). Operating cooling towers in accordance with water management plans will ensure that the cooling towers are maintaining conditions that are appropriate for treatment with an antimicrobial product.

We expect EPA to continue to review submitted comments on the draft guidance and possibly issue final guidance in 2024.

d. Proposed Framework for Assessment of Antimicrobial-Resistance Risk with Pesticide Use

On September 26, 2023, EPA requested comment on a proposed framework to strengthen the assessment of antimicrobial-resistance risks associated with pesticide use. EPA, the U.S. Department of Health and Human Services (HHS), and USDA, under the oversight of the White House Executive Office of the President, published a concept note. EPA states that the concept note is the first step in creating the framework to improve assessments of potential risks to human and animal health where the use of certain pesticides could potentially result in antimicrobial resistance (AMR) that compromises the effectiveness of medically important antibacterial and antifungal drugs. EPA states that the proposed framework described in the concept note will expand EPA's current process for assessing the risk that antibacterial or antifungal pesticides may pose to the effectiveness of human and animal antibacterial and antifungal drugs when EPA evaluates pesticides under FIFRA.

AMR is a common phenomenon, occurring in response to threats to a microorganism. In human and agricultural contexts, AMR develops when pathogens such as bacteria or fungi acquire the ability to defeat the drugs designed to kill them. AMR is a growing global public health threat, and the World Health Organization (WHO) has identified AMR as a top health priority. Preserving the effectiveness of antibacterial and antifungal drugs is essential for protecting the health of humans, animals, and plants. The use of antibacterial or antifungal compounds across settings such as hospitals, veterinary clinics, and farms can contribute to the emergence of antimicrobial-resistant organisms and possibly increase the difficulty of treating future infections in humans, animals, and plants.

The concept note structures the framework into the following components:

- **Resistance Characterization:** EPA would evaluate whether a proposed pesticide use could compromise the effectiveness of a medically important human or animal drug. If the resistance characterization identifies such a concern, EPA would conduct a qualitative risk assessment.

- **Risk Assessment:** EPA would estimate the probability that the proposed use of the antibacterial or antifungal pesticide may result in resistant bacteria or fungi. EPA also would estimate the likelihood of humans or animals being exposed to the newly resistant bacteria or fungi. This assessment would determine the overall risk for resistance associated with the proposed pesticide's use.

- **Risk Management:** If the risk assessment identifies areas of concern, the results of the risk assessment are evaluated along with other considerations to decide whether risk reduction measures are needed and, if so, which ones.

The proposed framework would apply to antibacterial and antifungal pesticides with plant agricultural uses (*e.g.*, crops, turf, or ornamentals) or non-agricultural uses (*e.g.*, wood and paint preservation) that could promote AMR and adversely impact the effectiveness of medically important antimicrobials used as human or animal drugs. Pesticides that could compromise the effectiveness of an important human or animal drug might include those pesticides that share a drug class or mechanism of action and therefore may be rendered ineffective by a similar mechanism of resistance.

While antibacterial and antifungal pesticides can be effective at managing diseases on crops, there is emerging evidence that, in rare cases, the use of these pesticides can reduce the effectiveness of some human and animal antibacterial and antifungal drugs. This is because some antibacterial and antifungal pesticides share characteristics with antibacterial and antifungal drugs. If a strain of bacteria or fungi becomes "resistant" to a pesticide, that strain will also be resistant to human or animal drugs that share similar characteristics with the pesticide. As a result, a drug that would normally

EPA states that it is proposing updates to the Safer Choice Standard to keep current with the state of scientific and technological innovation; increase transparency and reduce redundancy; and expand the scope of the program as appropriate.

be used to treat a bacterial or fungal infection may not work well against those resistant bacteria or fungi.

The framework is expected to include resistance characterization, qualitative risk assessment, and risk mitigation steps. The goal of the effort is to reduce risks to human and animal health from antimicrobial-resistant pathogens due to pesticide use. EPA states that after receiving and reviewing public input, feedback will be incorporated as appropriate and a draft framework will be shared. We expect that EPA may share the draft framework in 2024. The public also will have the opportunity to comment on the draft framework before the final framework is published.

On November 15 and 16, 2023, the Food and Agriculture Organization of the UN (FAO) hosted the inaugural Plenary Assembly of the Antimicrobial Resistance (AMR) Multi-Stakeholder Partnership Platform on behalf of the Quadripartite (FAO, the UN Environment Programme (UNEP), WHO, and the World Organization for Animal Health (WOAH)). The AMR Multi-Stakeholder Partnership Platform, launched on November 18, 2023, is intended to ensure the growing threats and impacts of AMR are addressed globally. It will bring together stakeholders from all areas, sectors, and perspectives through a holistic and systemwide One Health approach to respond to the need to improve coordination of efforts by a large number of stakeholders. The Quadripartite will release publicly the One Health Legislative Assessment Tool (OHLAT) for AMR. The Quadripartite developed the OHLAT to help countries identify and assess the legal areas and elements that are important for AMR under a One Health approach. The OHLAT is divided into seven chapters addressing AMR institutional coordination, human health, food safety, animal health, pesticide management, plant health, and the environment.

11. Safer Choice and Design for the Environment Standard

In November 2023, EPA proposed updates to the Safer Choice Standard. The standard identifies the requirements that products and their ingredients must meet to earn EPA's Safer Choice or Design for the Environment (DfE) certification. The DfE program, related to the Safer Choice Standard, is used by EPA for the purpose of helping consumers and commercial buyers identify antimicrobial products that meet this Standard and are registered under FIFRA. The proposed updates include renaming the Standard as the "Safer Choice and Design for the Environment Standard."

The Safer Choice program promotes safer product design and green chemistry alternatives through "informed substitution," the considered transition from a chemical of particular concern to safer chemicals or non-chemical alternatives. A Safer Choice-certified product contains the safest possible ingredients, and the label offers a readily identifiable way to know that a product is as safe as possible for people and the environment. The Safer Choice label on a product means that the Safer Choice scientific review team has evaluated each ingredient for potential human health and environmental effects, and that based on the best available experimental data and EPA predictive models, the product contains only those ingredients that pose the least concern among chemicals in their functional classes.

EPA states that it is proposing updates to the Safer Choice Standard to keep current with the state of scientific and technological innovation; increase transparency and reduce redundancy; and expand the scope of the program as appropriate. EPA's proposed updates to the Standard include:

- New certification for cleaning service providers that use Safer Choice- and DfE-certified products to help protect workers who use cleaning products all day as well as the people who live or work in the spaces they clean;
- Strengthening sustainable packaging requirements in response to consumer demand and innovations in packaging materials and technologies;
- Expanded criteria specific to pet care products to ensure such products use only the safest possible ingredients for both humans and pets;

- Clarifying language on EPA's process for entering product classes and exiting those that pose unexpected risks despite safer chemistry;
- Clarifying language regarding the use of data from NAMs during Safer Choice chemical review;
- New, optional energy efficiency or use reduction criteria to encourage companies to reduce water use and carbon-based energy consumption;
- Updated criteria for wipe products to help reduce damage to wastewater treatment systems; and
- Potential creation of a new alternate logo, similar to the Fragrance-Free logo, to distinguish products used outdoors that meet additional EPA criteria for environmental safety.

More information on Safer Choice can be found here. We expect EPA to continue its efforts on this initiative and possibly issue final guidance in 2024.

B&C attorneys, scientists, and government affairs specialists have worked on some of the toughest FIFRA legal issues of our time, tackling the intersection of pesticide law and public policy. We have assisted clients in resolving and advocating on often precedent-setting, novel, and complex pesticide and food quality regulatory issues. Contact lbergeson@lawbc.com to discuss how we can assist you with product registration, reregistration, compliance, and defense.

CONTRIBUTORS

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D. FDA FOOD AND COSMETICS REGULATIONS

2023 was a challenging year for the U.S. Food and Drug Administration (FDA) due to infant formula shortages, a significant reorganization of the Office of Regulatory Affairs (ORA), a new unified Human Foods Program (HFP), and implementation of major revisions to cosmetic regulations with the enactment of the Modernization of Cosmetic Regulations Act of 2022 (MoCRA) at the end of December 2022. MoCRA will have a profound impact on the cosmetic product industry for the reasons discussed below. In addition, the June proposal to create the HFP and a new model for ORA will bring enhanced focus on chemical food safety in 2024.

As in previous years, FDA's progress in promulgating rules proposed years prior remains slow. FDA continues to delay issuing a notice of proposed rulemaking (NPRM) for Food Standards Modernization. The NPRM on Food Contact Substance Notification That Is No Longer Effective, expected in 2021, was issued in 2022. The comment period closed on April 11, 2022, with the final rule expected in **April 2024**. The Fall 2023 Regulatory Agenda remains flush with proposed rules from prior years. These include a rule intended to clarify changes to the Registration of Food Facilities rule, rules addressing requirements in hazard analysis and risk-based preventive controls for human and animal food, and rules amending procedural requirements for Color Additive Petitions and Food Additive Petitions. Some indicate proposed rules in 2024, while some now target **2025**. All such notices reflect a pattern of delay.

In August, FDA named former EPA OCSPP Assistant Administrator James J. Jones its first Deputy Commissioner for the proposed unified HFP. HFP is intended to focus on food safety, chemical safety, and innovative food products by unifying the Center for Food Safety and Applied Nutrition (CFSAN), the Office of Food Policy and Response (OFPR), and certain functions under the ORA. Other reorganizations are under way. Given Jones' background in FIFRA and TSCA risk evaluation and risk mitigation, there is much speculation and no small amount of interest where he takes the new role as Deputy Commissioner. Based on the limited information made publicly available, FDA intends to initiate post-market assessments for food ingredients, food additives, color additives, food contact substances (FCS), and contaminants.

In November, FDA issued a proposed rule to revoke the use of brominated vegetable oil as a food ingredient, the use of which has been codified since 1970. FDA indicated the proposed rule is based on recent data from animal studies. This action is viewed by some as a key reason for the necessity of the HFP and its mission to enhance reviews of food chemical safety.

1. Food and Food Additive Safety

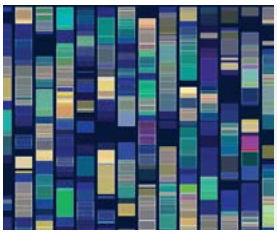
FDA is building content surrounding its "New Era of Smarter Food Safety" initiative, following announcement in July 2020 of the blueprint. FDA is focusing on the four core elements: Tech-Enabled Traceability, Smarter Tools and Approaches for Prevention and Outbreak Response, New Business Models and Retail Modernization, and Food Safety Culture. The Food Safety Modernization Act (FSMA)-based initiative sets deliverables, and tracks accomplishments in each priority area. FDA supplemented the initiative in 2023 with the addition of partnerships, podcasts, webinars, blogs, and related publications. FDA focused in 2023 on transparency, safety, and traceability for both manufactured and imported foods of all types, including soft cheese, seafood, and meal kits. FDA collaborated with the Retail Food Safety Regulatory Association Collaborative to provide additional tools, resources, and support to promote adoption of the FDA Food Code, after a 2023 analysis showed only 18 states had adopted the most recent edition.

FDA is developing tools for the implementation of various FSMA regulations. During 2023, FDA issued multiple guidance documents focusing on FDA's priorities and efforts to increase transparency. FDA issued the final Food Traceability Rule in late 2022, and provided tools translated into multiple languages on a new landing page to assist impacted parties with compliance of certain recordkeeping requirements mandated by **January 20, 2026**. More recently, FDA provided tools, including a Quick Response (QR) code and a graphic element, to promote awareness for two FSMA programs, the Accredited Third-Party Certification Program and the Laboratory Accreditation for Analyses of Foods Program.

Expect further progress with FSMA guidance and the New Era of Smarter Food Safety in 2024. With the HFP and ORA reorganization initiative, we can expect more streamlined approaches to the management of chemical safety in food products. What exactly this involves remains unclear, however.

2. Food Contact Substances

FDA authorized use of 37 FCSs notified via Food Contact Notification (FCN) in 2023, which is down slightly from the 50 FCNs approved in 2022. In 2023, FDA has stressed the development of a systematic post-market review process



Expect 2024 to be a busy year for FDA in implementing MoCRA, especially since facility registration and cosmetic product listing was not completed in 2023.

for food additives and FCSs. In July 2023, FDA released a list of substances not considered to be generally recognized as safe (GRAS) and a list of chemicals in the food supply currently under FDA review. FCSs either reviewed in 2023 or that are currently under post-market review by FDA include FD&C Red No. 3, titanium dioxide, BPA, PFAS, and phthalates. FDA's 2024 Fiscal Year Budget Summary, requesting a ten percent increase from the 2023 level, does not specifically mention food packaging or FCSs, but does highlight "Emerging Chemical and Toxicological Issues" as an area of interest. FDA's focus on post-market review and highlighting particular substances of concern in food packaging is taken to mean that FDA may seek to allocate additional resources in 2024 to re-reviewing authorized FCSs (*e.g.*, those approved in Title 21 of the C.F.R. and/or via the FCN process).

3. Modernization of Cosmetics Regulation Act of 2022

On December 29, 2022, Congress passed and President Biden signed MoCRA into law. MoCRA is the first major amendment to FDA's cosmetics authorities since President Franklin Delano Roosevelt signed FFDCA into law in 1938. MoCRA seeks to ensure that cosmetic products are safe for their intended use and provides FDA more enforcement authority. This authority includes mandatory recall, if it determines there is a reasonable probability that a cosmetic is adulterated or misbranded, as this would result in a serious adverse event. MoCRA introduces mandatory facility and product registration, a process that has, until now, been entirely voluntary. MoCRA seeks, through rulemaking, to establish Good Manufacturing Practices (GMP), another process that has, until now, been entirely voluntary. MoCRA also introduces changes to the labeling, and mandates actions on specific ingredients.

FDA hosted a webinar in April to provide an overview of MoCRA and its provisions. FDA held in June a public listening session with stakeholders on the GMPs provisions for cosmetic product manufacturers. MoCRA stipulates that FDA is required to issue an NPRM to address GMPs **no later than two years from enactment** and publish a final rule **no later than three years from enactment**. Another key aspect of MoCRA is facility registration and cosmetic product listing. FDA began posting information for facility registration and cosmetic product listing in August to address these two elements, both of which are noted as requirements that must be met **no later than one year after enactment**. FDA requested comment on draft guidance and newly developed Forms 5066 and 5067, and initiated a pilot program for user acceptance testing. The last update to this aspect was noted in October that included Structured Product Labeling (SPL) Implementation Guide with Validation Procedures for utilization of FDA platforms for submission through the Electronic Submissions Gateway (ESG). Currently, facility registration portals are not available, and the Forms and guidance remain in draft. Late in 2023, FDA indicated in guidance that it intends to delay enforcement on the cosmetic product facility registration and cosmetic product listing requirements **for six months** to "ensure that industry has sufficient time to submit such facility registration and product listing information."

MoCRA imposes labeling obligations to address fragrance allergens. These provisions require the responsible party to identify each fragrance allergen included in the cosmetic product on the product label. The NPRM was expected **18 months after enactment** and a final rule within **two years of enactment**. FDA has not yet implemented this requirement.

Two other provisions of MoCRA address specific ingredients. The first provision relates to talc and stipulates that FDA must propose regulations establishing testing with standardized methods for detecting asbestos in talc-contacting products. The other is PFAS. FDA must, **no later than three years after enactment**, publish on its web-

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Modernization of Cosmetic Regulations Act of 2022 — A Conversation with Karin F. Baron

site a summary of an assessment of the uses and safety of uses, including risks for PFAS in cosmetics.

Expect 2024 to be a busy year for FDA in implementing MoCRA, especially since facility registration and cosmetic product listing was not completed in 2023. If FDA is to meet other mandatory deadlines, expect NPRMs for changes to labeling to address fragrance allergens, GMPs, and possibly action related to talc-containing asbestos in 2024.

B&C and Acta professionals, who include attorneys, regulatory specialists, and in-house polymer chemists and other scientists, have extensive experience assisting clients in obtaining appropriate authority to market FCSs in the United States, Europe, and Asia. Visit our websites for more information regarding how B&C assists clients with FDA Regulation of Food Contact and Additives and Acta assists with Global Regulation of Food Contact Chemicals.

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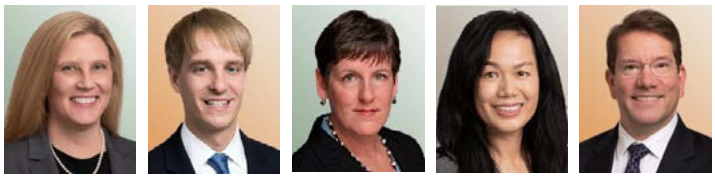


E. PFAS

PFAS are attracting global legal, regulatory, commercial, and litigation attention as no other "emerging contaminant" has, and this attention will only increase in 2024. The regulatory activities are global, from states within the United States to the European Union (EU) and the United Kingdom (UK). Where we have reported on PFAS developments within another chapter, we have provided a link below for readers to follow to obtain more information.

1. United States

a. Federal

i. TSCA

Visit our PFAS News and Information site for a comprehensive and constantly updated library of PFAS resources, including our 23-page booklet PFAS — Bans, Restrictions, Reporting, and Minimizing Liability. B&C has prepared these resources to help those in the chemical and chemical products industry understand what they need to know and what it means to their business.

In 2023, EPA used its authority under Section 4 of TSCA to issue two test orders for PFAS identified through the PFAS National Testing Strategy. (*See* Section I. B. TSCA, 1. Section 4(a) — Test Orders b. National PFAS Testing Strategy.) EPA's use of its TSCA Section 4 testing authority has led to several challenges to specific orders. (*See* Section I. B. TSCA, 1. Section 4(a) — Test Orders c. Section 4(a) Test Order Litigation, ii. 6:2 FTSB, iii. HFPO.)

EPA took several steps in 2023 under TSCA Section 5 to limit the introduction of new PFAS and reintroduction of existing PFAS. Under EPA's May 2023 proposed rule updating the New Chemicals Regulations, EPA would make PFAS ineligible for exemption notices and proposed to void categorically all previous LVEs and LoREXs for PFAS. (*See* Section I. B. TSCA, 4. Section 5 — New Chemical Substances, a. Proposed New Chemicals Procedure Rule.) EPA issued a proposed SNUR in January 2023 for PFAS that are currently on the TSCA Inventory but that have not been actively manufactured (including imported) or processed in the United States since 2006 and are consequently designated as inactive on the TSCA Inventory. A final SNUR would provide EPA an opportunity to determine whether the reintroduction of these PFAS presents an unreasonable risk to health or the environment before manufacture (including import) or processing can commence. (*See* Section I. B. TSCA, Section 5 – New Chemical Substances, h. SNURs on Existing Chemicals.). In June 2023, EPA announced a framework to address new PFAS and new uses of existing PFAS. According to EPA, the framework is intended to ensure that, before the PFAS are allowed to enter commerce, EPA undertakes an "extensive evaluation to ensure they pose no harm to human health and the environment." More information on the framework is available in our July 14, 2023, memorandum, "EPA Announces New Framework Intended to Prevent Unsafe New and New Uses of PFAS from Entering the Market."

In October 2023, under TSCA Section 8(a)(7), EPA issued a final reporting and recordkeeping rule on PFAS. The rule requires all manufacturers (including importers) of PFAS and PFAS-containing articles in any year since 2011 to report information related to chemical identity, uses, volumes made and processed, byproducts, environmental and health effects, worker exposure, and disposal to EPA. (*See* Section I. B. TSCA, 5. Sections 8 and 14 — Reporting and Confidential Information, a. TSCA Section 8(a)(7) Rule on PFAS.)

ii. Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)

On December 6, 2023, EPA submitted to OMB a final rule designating perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS) as hazardous substances under CERCLA. EPA's 2022 proposed rule included the salts and structural isomers of PFOA and PFOS and would require entities to report immediately releases of PFOA and PFOS that meet or exceed the reportable quantity (RQ) of one pound or more in a 24-hour period. OMB has up to 90 days, which can be extended, to review a rule, and should complete its review in **early 2024**. More information on EPA's proposed rule is available in our August 29, 2022, memorandum, "EPA Will Propose to Designate PFOA and PFOS as CERCLA Hazardous Substances."

EPA has indicated that it intends to expand its CERCLA authority beyond regulating PFOA and PFOS, but it is unlikely to issue a proposed rule in 2024. EPA published an ANPRM in April 2023 seeking information to assist in the consideration of potential development of future regulations pertaining to PFAS under CERCLA. EPA requested public input on the possible designation of seven PFAS besides PFOA and PFOS (perfluorobutanesulfonic acid (PFBS), perfluorohexanesulfonic acid (PFHxS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA) (sometimes called GenX), perfluorobutanoic acid (PFBA), perfluorohexanoic acid (PFHxA), and perfluorodecanoic acid (PFDA)); precursors to PFOA, PFOS, and the seven PFAS; and categories of PFAS. Implementation of the proposed rule is expected to jump-start extraordinary remediation activities resulting in significant CERCLA-related cleanups, demands for cost recovery, re-opening of "cleaned-up" sites, and private litigation. According to an item in EPA's fall 2023 Unified Agenda, EPA intends to issue a proposed rule in **August 2025**. More information is available in our April 13, 2023, memorandum, "EPA Publishes ANPRM Seeking Information to Assist in Consideration of Future CERCLA Regulations Regarding PFAS."

iii. Emergency Planning and Community Right-to-Know Act

The NDAA for FY 2020 requires EPA to update annually the list of chemicals covered by the Toxics Release Inventory (TRI) with additional PFAS. EPA issued a final rule in June 2023 identifying nine additional PFAS for TRI Reporting Year 2023 (reporting forms due by **July 1, 2024**). In October 2023, EPA promulgated a final rule adding PFAS subject to reporting under the Emergency Planning and Community Right-to-Know Act (EPCRA) and the Pollution Prevention Act (PPA) pursuant to the NDAA to the list of Lower Thresholds for Chemicals of Special Concern (chemicals of special concern). The addition of these PFAS to the list of chemicals of special concern means such PFAS are subject to the same reporting requirements as other chemicals of special concern (*i.e.*, it eliminates the use of the *de minimis* exemption and the option to use Form A and limits the use of range reporting for PFAS). The final rule removed the availability of the *de minimis* exemption for purposes of the Supplier Notification Requirements for all chemicals on the list of chemicals of special concern, "help[ing] ensure that purchasers of mixtures and trade name products containing such chemicals are informed of their presence in mixtures and products they purchase to better inform any TRI reporting obligations." The final rule applies for the reporting year beginning January 1, 2024 (reports due **July 1, 2025**). More information is available in our October 24, 2023, blog item, "EPA Will Add PFAS Subject to TRI Reporting to List of Chemicals of Special Concern."

ARTICLE

"EPA Issues Final Rule on TSCA PFAS Reporting Requirements," *Chemical Processing*, October 16, 2023.

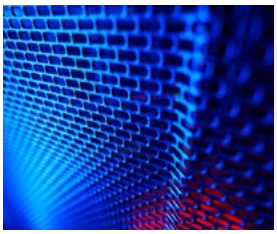
iv. Clean Water Act (CWA)

In March 2023, EPA announced the first-ever national drinking water standard for six PFAS. The proposed National Primary Drinking Water Regulation (NPDWR) would regulate PFOA and PFOS as individual contaminants and will regulate four other PFAS — PFNA, PFHxS, PFBS, and GenX chemicals — as a mixture.

The proposal requires monitoring of the six PFAS consistent with EPA's long-established monitoring frameworks where monitoring frequency depends on previous results. Public notification would be required if monitoring detects these PFAS at levels exceeding the standard.

Public water systems would be required to take actions to reduce the levels of these PFAS if they exceed the regulatory standards by:

- Removing these chemicals through various types of treatment; or



State PFAS regulations are increasing at a rapid pace, and the scope of PFAS reporting and/or bans is extensive. Many of these state regulations involve reporting requirements for PFAS and apply to companies marketing products in a state.

- Switching to an alternative water supply that meets the standard.

An item in EPA's fall 2023 Unified Agenda indicates that EPA intends to issue a final rule by **September 2024**. More information on EPA's proposed NPDWR is available in our March 16, 2023, memorandum.

v. PFAS and HDPE Containers

Since EPA announced in March 2021 that PFAS can leach from fluorinated containers, EPA has taken steps to prevent unintended PFAS contamination. In December 2022, EPA brought suit against Inhance Technologies, claiming that Inhance is generating PFAS when fluorinating plastic containers, in violation of the 2020 SNUR on long-chain perfluoroalkyl carboxylates. In December 2023, following a risk assessment concluding that unreasonable risks cannot be prevented other than through prohibiting manufacture, EPA issued orders to Inhance prohibiting the continued manufacture of three PFAS produced from the fluorination of HDPE. (*See* Section I. B. TSCA, 9. Other Litigation.) Since the PFAS contamination was first noted in HDPE containers used to store and transport a pesticide product, EPA's OPP is also taking steps to address the issue of PFAS contamination in pesticide products. (*See* Section I. C. FIFRA.)

vi. Legislation

To improve the mitigation and remediation of PFAS contamination, Senators Tom Carper (D-DE), Chair of the Senate Committee on Environment and Public Works, and Shelley Moore Capito (R-WV), Ranking Member of the Committee, released draft PFAS legislation for stakeholder comment. Unlike other PFAS legislation introduced in 2023, the draft bill had a much broader scope. Its goals ranged from supporting the ability of states to inventory industrial PFAS users to establishing a consistent definition of PFAS. The Committee sought stakeholder comments on the draft legislation by July 3, 2023. Although the bill was never introduced in the Senate in 2023, similar legislation is likely to be introduced in 2024. More information is available in our June 22, 2023, blog item, "Senate Committee Seeks Stakeholder Comment on Draft PFAS Legislation by July 3, 2023."

ARTICLE

"Reporting PFAS: Reporting Burden Is the Least of Businesses' Worries," *Financier Worldwide,* December 2023

b. States

Most frequently, states restrict or ban the use of PFAS in firefighting foams, food contact materials, pesticides, and consumer products. Some of these state bans are now in effect, while others will become effective in the upcoming years. Many of these state regulations involve reporting requirements for PFAS and apply to companies marketing products in a state. These regulations are increasing at a rapid pace, and the scope of PFAS reporting and/or bans is extensive.

Maine's reporting requirement took effect January 1, 2023, even though the Maine Department of Environmental Protection (MDEP) did not issue until February 2023 a proposed rule intended to provide additional guidance on the notification requirements and sales prohibitions for products and product components containing intentionally added PFAS. To clarify reporting requirements and provide MDEP time to develop guidance, in June 2023, Maine enacted a law postponing the reporting requirement to **January 1, 2025**, and making other clarifications to the reporting requirements. More information regarding MDEP's proposed rule is available in our February 17, 2023, memorandum, "Maine Proposes Rule to Clarify Reporting Requirements for PFAS in Products." More information regarding the law postponing the reporting requirement is available in our June 9, 2023, blog item, "Maine Governor Signs Bill Postponing PFAS Reporting Requirement."

In May 2023, Minnesota enacted legislation that will require on or before **January 1, 2026**, a manufacturer of a product sold, offered for sale, or distributed in Minnesota that

contains intentionally added PFAS to submit certain information. Beginning **January 1, 2025**, a person may not sell, offer for sale, or distribute for sale in Minnesota the following products if the product contains intentionally added PFAS:

- Carpets or rugs;
- Cleaning products;
- Cookware;
- Cosmetics;
- Dental floss;
- Fabric treatments;
- Juvenile products;
- Menstruation products;
- Textile furnishings;
- Ski wax; or
- Upholstered furniture.

The Minnesota Pollution Control Agency (MPCA) published two Requests for Comment (RFC) on planned PFAS rulemakings in the September 25, 2023, *State Register*, the PFAS in Products Reporting Rule (Revisor ID No. R-4828) and the PFAS in Products Fees Rule (Revisor ID No. R-4827). The main purpose of the PFAS in Products Reporting Rule is to establish a program for MPCA to collect information about products containing PFAS intentionally added to products sold, offered for sale, or distributed in Minnesota. The main purpose of the PFAS in Products Fees Rule is to establish PFAS in products reporting fees. MPCA intends to recoup the costs it incurs to create a reporting process and review PFAS compounds and concentrations for each manufacturer. Comments on the RFCs were due November 28, 2023. More information on Minnesota's law is available in our June 14, 2023, blog item, "Minnesota Will Require Manufacturers to Report Intentionally Added PFAS and Will Ban Intentionally Added PFAS in Certain Product Categories Beginning January 1, 2025."

The Washington State Department of Ecology published a draft report in December 2023 that reveals plans to restrict PFAS in cleaners, automotive washes, and clothing. It proposes PFAS disclosure for:

- Shoes, high-performance outdoor sportswear, and recreational gear;
- Firefighting PPE;
- Floor waxes and polishes, automotive waxes, and ski waxes;
- Hard surface sealants; and
- Cookware.

In related state activity, Vermont prohibits PFAS presence in ski wax. Prohibitions starting in **2025** apply to clothing in California and New York, and cleaners in Minnesota. A plan to phase out all non-essential uses in the future is under consideration in Minnesota and Maine.

2. Canada

In May 2023, Canada published for a 60-day public comment period a Draft State of PFAS Report and risk management scope for PFAS. The Draft State of PFAS Report provides the basis for a class-based approach to inform decision-making on PFAS in Canada and proposes to conclude that PFAS as a class are harmful to human health and the environment. (*See* Section II. D. The Americas, 2. Canada, b. PFAS.)

3. EU

On February 7, 2023, the European Chemicals Agency (ECHA) announced the availability of a detailed proposal to restrict more than 10,000 PFAS under the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation. The Annex XV restriction proposal concludes that a REACH restriction is the preferred risk

management option. According to the restriction proposal, the best option to avoid PFAS emissions to the environment during manufacture, production, and use of PFAS-containing articles and at the waste stage is to prohibit the manufacture and use of PFAS to the largest extent possible. ECHA is preparing a plan to evaluate 5,600 comments from stakeholders in a sector-by-sector approach to analyze both comments and attachments to comments. The European Commission (EC) has also proposed lowering the unintentional trace contaminant (UTC) limit for PFOS and its derivatives and remove an existing exemption for mist suppression in non-decorative hard chromium plating by **September 7, 2025**. EU proposed a ten-fold reduction in PFOS limits. (*See* Section II. B. European Union.)

4. UK

In 2023, the UK's Health and Safety Executive (HSE) published a regulatory management option analysis (RMOA) for PFAS. The RMOA is a preliminary step used within the UK REACH framework. The RMOA states that based on initial considerations of likely effectiveness and efficiency of options — and considering the Precautionary Principle — HSE concludes that it would be appropriate to consider initiating risk management measures with regard to certain uses of PFAS, including preparing background dossiers to support UK REACH restrictions of PFAS. (*See* Section II. C. United Kingdom/Great Britain.)

On November 16, 2023, the UK statutory instrument (SI) amending the already banned PFHxS came into force in line with the Stockholm Convention. The ban applies under its persistent organic pollutant (POP) regulation and applies to the use, manufacture, and placing on the market of the substance in England, Wales, and Scotland. The SI includes UTC limits for the substance and its salts and related compounds.

B&C professionals have been deeply engaged in the science, law, and policy of PFAS for years. We assist clients with evaluating potential liabilities in chemical product life cycles and supply chains. Our professionals develop innovative and resilient product stewardship and compliance strategies to help identify and manage risk and thus minimize potential liability. Find out more about our PFAS compliance services on our website: https://www.lawbc.com/practices/pfas-compliance-guidance.

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F. NANOTECHNOLOGY

1. U.S. Environmental Protection Agency

In 2024, manufacturers and importers of new nanoscale materials should expect to be subject to a consent order or SNUR, particularly in the absence of data concerning human health and environmental hazards and occupational exposure. As reported in the 2023 *Developments in Delegations on the Safety of Manufactured Nanomaterials and Advanced Materials — Tour de Table* published by OECD, EPA continues to use consent orders and SNURs to regulate new nanoscale materials under TSCA. Between July 2021 and June 2022, EPA reviewed five LVEs that included modified graphene materials and multi-walled carbon nanotubes (MWCNT). EPA granted one exemption under conditions that limited human and environmental exposures to prevent unreasonable risks, while the other four exemptions were denied or withdrawn before being denied. Additionally, EPA reviewed and completed six PMNs for MWCNTs, regulating all six MWCNTs with a consent order "due to limited available data on nanomaterials." The consent order limited the uses of the MWCNTs and human and environmental exposure to prevent unreasonable risks. EPA's assessments currently assume that the environmental hazard of a nanomaterial is unknown unless acceptable hazard data are submitted to EPA.

Since January 2005, EPA has received and reviewed more than 255 new chemical notices for nanoscale materials, such as fullerenes, quantum dots, and carbon nanotubes. Because of limited data to assess nanomaterials, EPA has issued consent orders and SNURS containing requirements to limit exposure to workers via PPE, limit environmental exposure by not allowing releases to surface waters or direct releases to air, and limit the specific applications/uses to those described in the new chemical notification.

More information is available in our May 1, 2023, blog item, "OECD Tour de Table Includes Information on U.S. Developments on Human Health and Environmental Safety of Nanomaterials."

EPA OPP has formed a work group to review data and information related to whether the current 100-nanometer (nm) threshold for determining whether a substance is a nanomaterial should be reviewed. According to a May 2022 news item published by EPA, "Advancing EPA's Understanding of the Next Generation of Pesticides," 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. More information is available in our October 10, 2023, blog item, "EPA OPP Work Group Reconsidering 100-nm Threshold for Nanomaterials."

2. U.S. Food and Drug Administration

FDA announced on May 3, 2023, that it has filed a color additive petition (CAP 3C0325), submitted by EDF, CEH, the Center for Food Safety (CFS), the Center for Science in the Public Interest (CSPI), and the Environmental Working Group (EWG). 88 Fed. Reg. 27818. The petition proposes that FDA repeal the color additive regulation for titanium dioxide in 21 C.F.R. Section 73.575, which permits the use of titanium dioxide in foods. The petitioners asserted that the intended use of titanium dioxide no longer meets the safety standard under 21 C.F.R. Section 70.3(i) and included the 2021 opinion by the European Food Safety Authority (EFSA) in their citations. Comments were due September 1, 2023. More information is available in our May 4, 2023, blog item, "FDA Seeks Comment on Request to Revoke the Color Additive Listing for Use of Titanium Dioxide in Food."

3. National Nanotechnology Initiative Environmental, Health, and Safety Research Strategy

The National Nanotechnology Coordination Office (NNCO) published a request for information (RFI) on April 5, 2023, seeking public input in updating the National Nanotechnology Initiative (NNI) Environmental, Health, and Safety (EHS) Research Strategy. 88 Fed. Reg. 20194. NNCO solicited input from a wide variety of stakeholders, including individuals, industry, academia, research laboratories, nonprofits, and think tanks. NNCO stated that it is interested in public input to inform an updated nanotechnology EHS research strategy, "specifically a strategy that focuses on the use of science-based risk analysis and risk management to protect public health and the environment while also fostering the technological advancements that benefit society."

Federal agencies participating in the Nanotechnology Environmental and Health Implications Working Group of the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the Committee on Technology, National Science and Technology Council (NSTC) have begun to review the 2011 NNI EHS Research Strategy and will use responses to the RFI to help inform a revised and updated EHS strategy. More information on the RFI is available in our April 6, 2023, blog item.

4. Canada

In 2024, Canada could publish a final Framework for the Risk Assessment of Manufactured Nanomaterials under the Canadian Environmental Protection Act, 1999 (CEPA) (Framework). In June 2022, Canada published its draft Framework for a 60-day public comment period. The plain language summary states that the Framework describes how scientists at Environment and Climate Change Canada (ECCC) and Health Canada (HC) conduct risk assessments on nanomaterials. The draft Framework outlines approaches and considerations for informing the risk assessment of nanomaterials under CEPA, including both existing nanomaterials on the Domestic Substances List (DSL) and new nanomaterials notified under the New Substances Notification Regulations (Chemicals and Polymers). More information on the draft Framework is available in our June 21, 2022, blog item, "Canada Publishes Draft Framework for the Risk Assessment of Manufactured Nanomaterials under CEPA."

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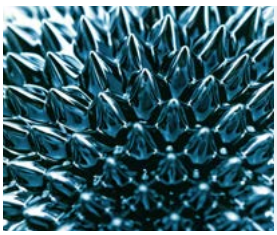

To help developers and the public better understand U.S. regulatory processes for biotechnology products, the Plain Language Document provides a high-level overview of the roles and responsibilities of U.S. regulatory agencies under the Coordinated Framework.

G. BIOTECHNOLOGY

1. White House Office of Science and Technology Policy

After issuing EO 14081 on "Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy" (87 Fed. Reg. 56849) in September 2022, the Biden-Harris Administration began work to meet the EO's ambitious milestones. On December 20, 2022, the White House Office of Science and Technology Policy (OSTP) published an RFI on behalf of the primary agencies that regulate the products of biotechnology — USDA, EPA, and FDA — requesting relevant data and information, including case studies, that may assist in identifying any regulatory ambiguities, gaps, inefficiencies, or uncertainties in the Coordinated Framework for the Regulation of Biotechnology, particularly with regard to new and emerging biotechnology products. 87 Fed. Reg. 77900. On November 13, 2023, USDA, EPA, and FDA posted the following documents on the Unified Website for Biotechnology Regulation:

- *Report on Stakeholder Outreach Related to Ambiguities, Gaps, Uncertainties in Regulation of Biotechnology Under the Coordinated Framework* (Report on Stakeholder Outreach) (Mar. 11, 2023); and
- *The Coordinated Framework for the Regulation of Biotechnology: Plain language information on the biotechnology regulatory system* (Plain Language Document) (Nov. 2023).

The Report on Stakeholder Outreach summarizes the comments received, which concern requests for greater regulatory clarity; requests for greater regulatory coordination and harmonization; requests for regulatory reform or revision; and comments on regulatory resources. representing each area. While OSTP's December 2022 RFI and the Report on Stakeholder Outreach offer starting points to clarify how biotechnology products are regulated in the United States, it is unlikely that there will be significant changes in 2024.

To help developers and the public better understand U.S. regulatory processes for biotechnology products, the Plain Language Document provides a high-level overview of the roles and responsibilities of U.S. regulatory agencies under the Coordinated Framework. It includes examples of case studies describing how specific product types would be regulated by each agency for plants, plant cells, and plant products of biotechnology in Table 3; for animals, animal cells, and animal products produced with biotechnology in Table 4; and for microorganisms produced with biotechnology, microbial cells, and microbial products produced with biotechnology in Table 5. Developers of new products should review the case studies to understand better how their products will be regulated.

Continuing its work to meet EO 14081's milestones, on March 22, 2023, OSTP published a fact sheet announcing "new bold goals and priorities that will catalyze action inside and outside of government to advance American biotechnology and biomanufacturing," including a report entitled *Bold Goals for U.S. Biotechnology and Biomanufacturing: Harnessing Research and Development to Further Societal Goals* highlighting what could be possible with the power of biology. The report set national targets for the next two decades to help establish research and development (R&D) priorities that will be critical to advance the bioeconomy. The report notes that achieving these goals will require significant prioritization of R&D investments and other efforts across the U.S. government, as well as actions from the private sector; state, local, and Tribal governments; and international partners. OSTP will lead the development of a strategy and implementation plan to execute the R&D priorities and other actions identified in the report. More information on the report is available in our April 3, 2023, blog item, "White House OSTP Outlines Goals for U.S. Biotechnology and Manufacturing."

2. U.S. Department of Agriculture

Under the USDA's Animal and Plant Health Inspection Service's (APHIS) final Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient (SECURE) rule, developers of certain genetically modified organisms (GMO) may use

the Regulatory Status Review (RSR) process to determine the regulatory status of the organisms. Under the revised regulations, developers can also request a confirmation from APHIS that a modified plant qualifies for an exemption and is not subject to the regulations in 7 C.F.R. Part 340. As part of the revised regulations, the former notification process was discontinued on April 5, 2021. All applications to move organisms subject to the regulations must now be submitted through the permitting process.

On October 13, 2023, APHIS published a revised draft of the Guide for Submitting Permit Applications for Microorganisms Developed Using Genetic Engineering under 7 CFR Part 340 and a Response to Comments on the first draft of the Guide, published on March 23, 2023. The revised draft includes questions intended to assist developers in evaluating their planned research and developing complete Standard Operating Procedures (SOP) to support research activities and containment and/or confinement of modified microbes, as well as a checklist to assist developers when preparing for a facility inspection. In the Response to Comments document, APHIS's Biotechnology Regulatory Services (BRS) states that it plans to implement a partnership with subject matter experts to develop, maintain, and update a plant pest list in FY 2024 to provide clarity on BRS's regulatory scope and permitting requirements.

According to APHIS's strategic plan for 2023-**2027**, APHIS will continue working to ensure the development of safe agricultural biotechnology products using a science-based regulatory framework. This includes conducting risk-based permit review and issuance for organisms developed using genetic engineering to ensure they are safely contained or confined during movement or release and working with EPA and FDA to increase coordination and harmonization of regulatory oversight for biotechnology products within each agency's existing statutory framework. APHIS will also work to maintain and expand its leadership role through international standard setting and collaboration. To create safe export opportunities, APHIS plans to communicate to international stakeholders about its processes and share outcomes of biotechnology product evaluations, including working with the regulatory authorities of U.S. trading partners to harmonize further regulatory frameworks for biotechnology products. More information is available in our May 3, 2023, blog item, "APHIS Releases New Strategic Plan for 2023-2027, Includes Biotechnology Objectives." The Congressional Research Service (CRS) published a report on the regulation of gene-edited plants and issues for Congress. Given the complex issues concerning gene editing in agriculture and the more pressing issues that Congress will be facing in 2024, it is unlikely to take up the issue. More information on the CRS report is available in our October 6, 2023, blog item, "CRS Report on Gene-Edited Plants Includes Issues Facing Congress."

3. U.S. Food and Drug Administration

After completing its first pre-market consultation of a human food made from cultured chicken cell material in 2022, FDA completed a pre-market consultation of a similar food product, submitted by GOOD Meat, Inc., on March 20, 2023. FDA provides an inventory of completed pre-market consultations for human food made with cultured cells on its website. Before the food can enter the market, however, the facility in which it is made must meet applicable USDA and FDA requirements. In addition to FDA's requirements, including facility registration for the cell culture portion, the manufacturing establishment needs a grant of inspection from USDA's Food Safety and Inspection Service (FSIS) for the harvest and post-harvest portions, and the product itself requires a USDA mark of inspection.

Although FDA has yet to issue guidance on the pre-market consultation process, it encourages firms to enter into dialogue with it "often and early" in the product development phase, well ahead of making any submission to FDA. FDA intends to issue the guidance in draft and provide an opportunity for public comment.

Given the many issues facing Congress, it is unlikely there will be any legislation in 2024 concerning cell-cultivated meat products. Should Congress take up the issue, CRS issued a September 2023 report providing an overview of cell-cultivated meat. CRS outlined policy issues for Congressional consideration, including guidance on how state laws impact labels issued at the federal level, funding for research, encouraging the development of voluntary international food standards, guidelines, and codes of practice for cell-cultivated meat products. More information is available in our October 5, 2023, blog item, "CRS Overview of Cell-Cultivated Meat Includes Policy Considerations for Congress."

4. U.S. Environmental Protection Agency

On May 31, 2023, EPA issued a final rule exempting two groups of plant-incorporated protectants (PIP) created using genetic engineering from registration requirements under FIFRA and from the food or feed residue tolerance requirements under FFDCA. 88 Fed. Reg. 34756. The final

rule provides criteria and definitions that identify "PIPs created through genetic engineering from a sexually compatible plant" and "loss-of-function PIPs" and codifies the process through which the Agency determines their eligibility for exemption. "PIPs created through genetic engineering from a sexually compatible plant" require EPA confirmation of eligibility for the exemption. For "loss-of-function PIPs," biotechnology developers can make a self-determination that their PIP meets the exemption criteria, which requires notification but no EPA review, or request EPA confirmation of eligibility for the exemption. The final rule also codifies the recordkeeping requirements for exempted PIPs.

According to EPA, the exemptions reflect biotechnological advances made since 2001, when EPA first exempted PIPs derived through conventional breeding and excluded from the exemptions those PIPs created through biotechnology. EPA notes that it anticipates that the exemptions will benefit the public by ensuring that human health and the environment are adequately protected while also reducing the regulatory burden for the regulated community. These exemptions may also result in increased R&D activities, commercialization of new pest control options for farmers, particularly in minor crops, and increase the diversity of options for pest and disease management, which could provide environmental benefits. The final rule was effective July 31, 2023. More information on the final rule is available in our June 2, 2023, memorandum. Information on resources intended to help biotechnology developers exercise the full benefits of the exemptions available under the rule is available in our September 7, 2023, blog item, "EPA Posts Resources on Rule to Accelerate Use of PIPs."

As biotechnology advances further, EPA intends to consider exempting additional categories of PIPs from both FIFRA registration and FFDCA tolerance requirements, as well as by adding categories of exempted PIPs to the list of categories that do not require EPA confirmation of eligibility.

On September 29, 2023, EPA announced the proposed registration of pesticide products containing the new active ingredient ledprona, a new type of pesticide that relies on a natural mechanism, RNA interference (RNAi), used by plants and insects to protect against disease. The proposed new biopesticide involves a sprayable double-stranded ribonucleic acid (dsRNA) product that targets the Colorado potato beetle (CPB), "by 'silencing' the CPB gene needed to produce the *PSMB5* protein, whose role is essential to keeping the CPB alive, without resulting in a genetically modified organism." If approved, the RNAi-based pesticide "would be the first sprayable dsRNA pesticide in the world allowed to be used commercially and sprayed on plants." Comments were initially due October 13, 2023, but EPA extended the comment period to October 30, 2023. More information is available in our October 12, 2023, blog item, "Comments Due October 13, 2023, on EPA's Proposal to Register Novel Pesticide Technology for Potato Crops."

EPA's biotechnology reviews were again a bright spot in EPA's New Chemicals Review program. EPA continues to review TSCA biotechnology notices timely, probably helped by the fact that few were submitted. EPA received only four MCANs during FY 2023, and EPA completed review of all of them fairly promptly (two were within 90 days, two were within 180 days). Again, all determinations were "not likely to present an unreasonable risk." EPA also received one TSCA Environmental Release Application (TERA) in January 2023, and EPA granted it in March.

B&C professionals are highly experienced in legal and regulatory issues impacting biotechnology products. We assist clients on product registration, approval, and compliance. Discover how we can assist industrial and agricultural biotechnology stakeholders: **B&C's Biotechnology Services**.

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H. BIOBASED AND RENEWABLE CHEMISTRY

The biobased chemicals and renewable products industry plays a critical role in building a resilient, dependable, and sustainable system that fosters innovation to develop a circular economy. A circular economy requires new thinking about what we make, what we make it from, and where it goes at the end of its useful life. An important but often overlooked aspect of new product development is an understanding of the regulatory framework and landscape that will govern the commercialization of the new product.

Progress in this industrial sector is key to achieving energy efficiency and the conservation of non-renewable resources. To achieve the larger sustainability and circular economy promise, biobased chemicals must progress quickly from R&D platforms into the market. Therefore, it is essential to eliminate or alleviate the regulatory landscape and its challenges to chemical innovation globally. The next generation of biobased and renewable products may be on the line if a modernized and more efficient regulatory system is not developed.

Recognizing these challenges, on September 12, 2022, President Joseph Biden signed EO 14081 on "Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy," launching a National Biotechnology and Biomanufacturing Initiative intended to grow the U.S. bioeconomy across multiple sectors in industries such as health, agriculture, and energy. 87 Fed. Reg. 56849. In 2023, agencies throughout the Biden Administration took steps to ensure that the federal government is meeting its goal to procure sustainable products and services to the maximum extent possible.

On August 3, 2023, the Joint Subcommittee on Environment, Innovation, and Public Health Sustainable Chemistry Strategy Team (Sustainable Chemistry ST) of NSTC published a report entitled Sustainable Chemistry Report: Framing the Federal Landscape. As reported in our January 19, 2021, memorandum, the FY 2021 NDAA included the text of the bipartisan Sustainable Chemistry Research and Development Act of 2019. It established an interagency working group led by OSTP to coordinate federal programs and activities in support of sustainable chemistry. The Sustainable Chemistry ST's report describes the state of federal sustainable chemistry activities and the scientific challenges, roadblocks, and hurdles to transformational progress in improving the sustainability of chemistry. In service of this goal and to reach the mandates of the NDAA, the report:

- Proposes a consensus definition of sustainable chemistry;
- Proposes a working framework of attributes characterizing and considerations for evaluating sustainable chemistry;
- Assesses the status of sustainable chemistry in the United States, including its applicability and utility in key sectors of the economy, key technological platforms, commercial priorities, global priorities, workforce development and education, current innovative trends, and barriers to innovation; and
- Summarizes the federal regulations relevant to sustainable chemistry.

The report states that over the next year, the Sustainable Chemistry ST "will operationalize a strategic plan and implementation framework that organizes and coordinates activities in these strategic areas by harnessing existing research and accelerating transformative advancements." The information generated will inform sustainable chemistry standards and metrics, decarbonization, circularity, and the use of novel methods for assessing sustainable chemistry. More information is available in our August 28, 2023, memorandum, "NSTC's Sustainable Chemistry Strategy Team Releases Sustainable Chemistry Report."

In 2024, USDA could at long last propose to codify the BioPreferred Program guidance. According to an item in the spring 2023 Unified Agenda, published on June 13, 2023, USDA intended to publish the proposed rule in June 2023. USDA expects this action to reduce burden on both it and the applicants by reducing and clarifying requirements,

EPA will continue working in 2024 to expand the Environmentally Preferable Purchasing (EPP) program's Recommendations of Specifications, Standards, and Ecolabels for Federal Purchasing.

streamlining the application and certification process, and increasing efficiencies in program delivery. Improvements will also "facilitate the sales of the business using the labeling program." The two major components of the BioPreferred Program are:

- Mandatory purchasing requirements for federal agencies and their contractors; and
- A voluntary labeling initiative for biobased products.

ARTICLE

"National Science and Technology Council Releases Sustainable Chemistry Report," *Chemical Processing*, September 15, 2023

On August 3, 2023, the U.S. Department of Defense (DOD), the General Services Administration (GSA), and the National Aeronautics and Space Administration (NASA) proposed to amend the Federal Acquisition Regulation (FAR) to restructure and update the regulations to focus on current environmental and sustainability matters and to implement a requirement for agencies to procure sustainable products and services to the maximum extent practicable. 88 Fed. Reg. 51672. The proposed rule is intended to streamline and standardize the policy and procedures for purchasing sustainable products and services, helping federal agencies and industry better understand and comply with the purchasing program requirements already implemented in the FAR. The proposed rule would define "sustainable products and services" as products and services that are subject to and meet statutory purchasing program requirements or other EPA purchasing program requirements. Under the proposed rule, "biobased product" would be defined as "a product determined by [USDA] to be a commercial product or industrial product (other than food or feed) that is composed, in whole or in significant part, of biological products, including renewable domestic agricultural materials and forestry materials, or that is an intermediate ingredient or feedstock. The term includes, with respect to forestry materials, forest products that meet biobased content requirements, notwithstanding the market share the product holds, the age of the product, or whether the market for the product is new or emerging." More information is available in our September 5, 2023, blog item, "DOD, GSA, and NASA Propose to Require Agencies to Procure Sustainable Products and Services to the Maximum Extent Practicable."

EPA will continue working in 2024 to expand the Environmentally Preferable Purchasing (EPP) program's Recommendations of Specifications, Standards, and Ecolabels for Federal Purchasing (Recommendations). The EPP program's Recommendations help federal government purchasers use private sector standards and ecolabels to meet sustainable acquisition goals and mandates. On August 1, 2023, EPA announced the first five product and service categories chosen for the expansion of the Recommendations. The five product and service categories are:

- Food Service Ware (*e.g.*, containers, cutlery, and dishware);
- Healthcare;
- Laboratories;
- Professional Services; and
- Uniforms and Clothing.

EPA anticipated announcing later in 2023 the standards and ecolabels that pass the assessment and will be included in the Recommendations. EPA plans to consider additional

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product and service categories as resources allow. More information is available in our August 7, 2023, blog item, "EPA Announces First Product Categories for Expansion of Ecolabel Recommendations for Federal Purchasing."

B&C and Acta professionals assist clients on a wide range of biobased chemicals, biofuels, and green chemistry matters, from legislative authorization and rulemaking to TSCA naming conventions, TSCA Inventory identification, and general compliance measures. Visit our websites for more information: B&C Biobased and Sustainable Chemicals, Acta Biobased Chemicals and Biofuels.

These types of government coordination, policy reform, and dialogue with industry stakeholders will continue to be vital to move the biobased chemicals and renewable products markets forward in 2024.

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I. PROPOSITION 65

The California Office of Environmental Health Hazard Assessment (OEHHA) has made good on its intentions to re-propose changes to the short-form warning requirements under Proposition 65 (Prop 65). These changes were first proposed changes on January 8, 2021, with modifications proposed on December 13, 2021, and April 5, 2022. Industry was harshly critical of OEHHA's proposal in written comments and during a March 11, 2021, hearing. In light of the considerable resources and costs necessary to implement the changes in addition to pandemic recovery costs, industry believed OEHHA's proposal was unwarranted and ill-timed.

On May 20, 2022, OEHHA announced that it was unable to complete the rulemaking process within the one-year deadline required under California law (Cal. Gov't Code § 11346.4(b)), and thus the rulemaking would lapse. OEHHA at that time stated it would restart this effort. On October 27, 2023, OEHHA issued a notice proposing changes to its Prop 65 Article 6 "clear and reasonable warnings" regulations for "short-form" warnings (Notice).

OEHHA's proposal is similar to its predecessor and would change virtually all aspects of the short-form warning. OEHHA is proposing clarifications on the circumstances when the short-form warning can be used, and proposing requirements for when a short-form warning is permissible for Internet and catalog purchases. OEHHA is proposing modifications to the current regulation for Food Exposure Warnings at Section 25607.2 to clarify that short-form warnings are permissible for food products and the required language for such warnings. OEHHA also proposes four new sections to provide tailored safe harbor warnings for passenger or off-highway motor vehicle parts exposures and recreational marine vessel parts exposures. More information on the changes to the short-form warning requirements is available in our November 2, 2023, memorandum.

The most significant and potentially impactful change relates to the language of the short-form warning and the proposed requirement to list a Prop 65 substance(s). OEHHA states several times in its Initial Statement of Reasons (ISOR) that this revision is needed to be "more informative" and because "many businesses are using the short-form warning prophylactically because it protects from potential litigation." Industry stakeholders have rallied and challenged OEHHA's basis and rationale for its proposed changes, as evidenced in a public hearing held on December 13, 2023, and in written comments submitted by December 20, 2023.

These proposed changes to the short-form warning will be a major issue in 2024. If enacted, the current proposal would make the regulations operative two years from the effective date, with an unlimited sell-through period for products manufactured and labeled prior to the effective date of the amendments.

Legal challenges to Prop 65 warning requirements as invalid restrictions on commercial speech in violation of the First Amendment of the Constitution continued in 2023 and will remain an issue in 2024. On November 7, 2023, the Ninth Circuit affirmed the District Court for the Eastern District of California's June 22, 2020, decision that granted summary judgment in favor of plaintiffs and entered a permanent injunction enjoining the California Attorney General from enforcing Proposition 65's carcinogen warning requirement for the herbicide glyphosate. *National Ass'n of Wheat Growers et al. v. Bonta* (Opinion). The Ninth Circuit affirmed the District Court's determination that the level of its review was higher than it would be if the compelled commercial speech was "purely factual and uncontroversial." Even after considering a glyphosate-specific safe harbor Prop 65 warning that OEHHA issued in September 2022 in an attempt to address the District Court's concerns, the Ninth Circuit found the warning remained false and misleading and controversial.

Under the higher "intermediate" level of scrutiny standard, the Ninth Circuit stated that the government may compel a disclosure of commercial speech "only if (1) it directly advances a substantial governmental interest, and (2) the restriction is not more extensive than necessary to serve that interest." Opinion at 42. In its Opinion, the Ninth Circuit found that the warning did not directly advance OEHHA's interest and that there were other means for OEHHA to promote its views such as "post[ing] information about glyphosate on its own website or conduct[ing] an advertising campaign." *Id.* at 42. The Ninth Circuit also denied OEHHA's request for a remand to the District Court for consideration of the adequacy of its Prop 65 warning, finding remand unnecessary since the Ninth Circuit was able to review the entire record and the issues had been fully briefed and understood. *Id.* at 40. More information on the Ninth Circuit's Opinion is available in our November 14, 2023, memorandum.

A related legal development relates to preliminary injunctions enjoining any person from attempting to enforce Prop 65 warning requirements for the presence of acrylamide in food

and beverages. The U.S. District Court for the Eastern District of California and the Ninth Circuit issued rulings granting and upholding a preliminary injunction that prohibited the Attorney General and his officers, employees, or agents, and all those in privity or acting in concert with those entities or individuals, including private enforcers, from filing or prosecuting new lawsuits to enforce the Prop 65 warning requirement for cancer as applied to acrylamide in food and beverage products because OEHHA had not demonstrated that the warning is "purely factual and uncontroversial" and thus violated the First Amendment prohibition against compelled commercial speech. *See California Chamber of Commerce v. Becerra*, 529 F. Supp.3d 1099 (E.D. Cal. 2021), *aff'd sub nom California Chamber of Commerce v. Council for Education and Research on Toxics*, No. 21-15745 (9th Cir. 2022).

This case has been proceeding on the merits in 2023 in the District Court, with two orders rejecting motions to vacate orders issued by the judge that initially presided over the case (*i.e.*, an order denying the intervenor's motion for summary judgment against the plaintiff and an order granting the plaintiff's motion for a preliminary injunction) and denying a motion by the defendant-intervenor to dismiss this matter for lack of subject matter jurisdiction. Based on the current stipulated scheduling order, if approved by the court, fact and expert discovery should end in **early 2024** with motions and any eventual hearing to be scheduled in 2024. This case will need to consider a December 23, 2022, final rule providing a new regulatory section to address warning language for acrylamide in food formed by cooking or heat processing.

B&C attorneys have substantial experience in Prop 65 compliance and enforcement matters. Our team includes attorneys living in and licensed in California. We help clients develop strategies to provide warnings when required, or support determinations that jurisdictional triggers are not satisfied or that exemption criteria have been met. Contact Lynn L. Bergeson, lbergeson@lawbc.com, if you would like to discuss how our team can assist you with Proposition 65 and other U.S. state regulatory compliance measures.

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Globally, the evolution of chemical governance programs generally will continue to pick up steam, making up for lost time due to the pandemic.

II. GLOBAL CHEMICAL MANAGEMENT FORECAST

A. INTRODUCTION

Internationally, 2024 will be eventful for chemical management stakeholders. The EU's commitment to net-zero global warming emissions by **2050** will continue to drive aggressive regulatory and policy initiatives in the new year. The EU's own election cycle, however, invites significant uncertainty on the policy trajectory in **2024 and beyond**. The EU's proposed PFAS regulation has captured the world's attention. If implemented as proposed, it will be exceedingly consequential far beyond its jurisdictional borders. Further progress will be made in 2024 as the EU and the UK continue to manage Brexit. And globally, the evolution of chemical governance programs generally will continue to pick up steam, making up for lost time due to the pandemic. Federal elections in the fall in Canada also invite an element of added uncertainty.

1. EU

The EC's 2024 Work Programme suggests that in 2024, ecodesign requirements will progress, as will waste requirements for electrical and electronic equipment. More fundamental policy initiatives pertinent to EU REACH revisions are expected to be deferred until after the 2024 EU elections. Similarly, PFAS restrictions will be the subject of significant review in the EU in 2024, with an uncertain outcome, given the complexity of the issue and the overwhelming negative comments received on the proposal.

2. UK

The UK Department for Environment, Food and Rural Affairs (DEFRA) will continue to build the UK's UK REACH program, and divergence from EU REACH is expected to continue. UK REACH compliance checks may pick up, given the maturation of the program and need for additional guidance on areas to improve.

Unsurprisingly, PFAS are listed as a priority in the UK Reach 2023 - 2025 Work Programmes. Expect to see DEFRA developments in this regard in 2024.

3. Asia/Pacific Rim

Incremental evolution in chemical inventory, reporting, and recordkeeping in Asia continues regarding industrial chemicals and cosmetics regulation. In China, this evolution extends to food contact materials, as China expects to continue to address food contact materials (FCM) in the new year. The trajectory in India is less certain, given the general elections scheduled for **May 2024**. The rollout of India's Chemicals (Management and Safety) Rules has been delayed repeatedly, and the election cycle will continue that pattern.

Important changes to K-REACH in South Korea will affect companies that do business there, including new rules that apply starting **January 2024** to changes in ownership or

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company succession. These and other regulatory measures are all consequential and are discussed below, as are the United Nations (UN) Globally Harmonized System of Classification and Labeling of Chemicals (GHS) implementation in countries in this region.

4. South and Central America

The Central and South American chemical regulatory environment continues to evolve, albeit relatively inconsistently and unpredictably. Most Central and South American countries do not currently possess formal chemical inventories and generally have not adopted GHS for their respective safety data sheet (SDS) programs, but many continue to make significant progress in developing regulations that are like those in the United States, the EU, and Canada. This will continue in the new year, particularly in Brazil, Chile, and Colombia. Other Central and South American countries are developing regulatory programs that are expected to have a significant impact on entities doing business in the region, and stakeholders will need to pay much closer attention to chemical management developments in this region.

On the whole, chemical management initiatives outside of the United States are on the move, driven by popular demand, the imperative of climate change, and the forward momentum derivative of evolution and information, limited chiefly by the uncertainty of election outcomes and unshackled by pandemic slowdowns. 2024 will be eventful, at home and abroad.

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B. EUROPEAN UNION

1. Overview

Amending the EU's chemicals regulatory frameworks for better alignment with the Green Deal targets of climate neutrality and a circular net-zero economy by **2050** is key to achieving its goals. Significant innovation in the chemicals sector driven by the EC's 2020 EU Chemicals Strategy for Sustainability (Strategy), to be implemented through amendments to EU chemicals regulations, is foreseen in **2024 and beyond** to achieve the goals of the Green Deal. The amendments will focus on simplifying regulatory processes, improving transparency, and reducing the burden on both the regulators and the regulated community while maintaining a level of human health and environmental protection that is, in the EC's view, second to none and the leading global model for chemical regulation.

According to the EC's 2024 Work Programme, "The majority of initiatives set out in the 2019 Communication on the European Green Deal have been delivered, and many already agreed into law." Goals for the achievement of zero pollution, and protection and restoration of nature will require the EU to legislate proposals on nature restoration, air quality, urban wastewater treatment, and protection of surface and groundwaters. "Swift agreement" on a number of issues, including ecodesign requirements for sustainable products, waste (particularly waste from electrical and electronic equipment) and packaging, shipment of waste, and the repair of goods are deemed necessary by the EC for advancement toward the Green Deal's circular economy goals.

2. EU REACH

As announced in the Strategy, the EC began working on a revision of the REACH Regulation, and in October 2022, published its intention to propose revisions to REACH by the last quarter of 2023. The EC announced on October 17, 2023, in its 2024 Work Programme further postponement of REACH Regulation revisions to align with the EC's Better Regulation provisions. This postponement of REACH revision proposals also acknowledges that consideration of revisions should be deferred until after the European Parliament (EP) elections in 2024.

Several significant aspects of the Strategy will shape the REACH revision proposal, including incorporation of a framework for polymer registration; expansion of the hazard classes that could drive authorization and restriction of substances; revision of the Generic Approach to Risk Management, or Generic Risk Approach (GRA), to include Mixture Assessment Factors (MAF) and incorporate additional designations of substances of very high concern (*e.g.*, endocrine disruptors, immunotoxicants, neurotoxicants, respiratory sensitizers, or substances that affect specific organs); and improving the effectiveness, efficiency, and transparency of the authorization and restriction processes.

Stay up to date with EU REACH and UK REACH regulatory, policy, and business developments with Acta's REACHblog®, www.REACHblog.com.

Development and implementation of a workable and proportionate scheme for registration of polymers that aligns with globally accepted approaches and focuses on polymers with a higher likelihood of affecting human health or the environment adversely has been a long-standing priority for REACH revision. It challenges the EC to propose amendments that will align with the Green Deal without forcing manufacture of desirable polymers and articles containing those polymers to locations outside of the European Economic Area (EEA), which could be problematic for the EU economically as well as politically. Any amendments to REACH that address evaluation of polymers would also need to align with modifications to the authorization and restriction processes.

ECHA announced on February 21, 2023, that it has revised its *Guidance for monomers and polymers* to align with ECHA's Board of Appeal (BoA) June 2021 decision on a compliance check case (A-001-2020) regarding registration obligations for polymer importers. The revised guidance includes changes to the description of REACH registration obligations for those importing and manufacturing polymers and monomers that registrants are advised to consider as they update REACH registration dossiers for monomers in polymers in 2024.

While the publication of the REACH revision proposal was delayed, allowing for additional time to clarify all the necessary details, several aspects of the Strategy continue to move ahead independently of the REACH revision. For example, the Restrictions Roadmap aims to prioritize substances of very high concern and authorized substances for group restrictions for all uses. ECHA's February 2023

detailed proposal to restrict more than 10,000 PFAS under REACH is the most far-reaching and notable deployment of the Restrictions Roadmap. The PFAS proposal suggests two restriction options — a full ban and a ban with use-specific derogations — to address the identified risks associated with PFAS substances. Acta and B&C prepared a detailed memorandum that offers a high-level outline of issues, focusing on the most significant bans and restrictions, the most impactful potential legal developments regarding PFAS, and the most important steps chemical product manufacturers should be taking now to identify, diminish, and supplant, as appropriate, PFAS in their supply chains.

Achieving the ambitious goals of the Strategy timely is expected to place heightened emphasis on REACH compliance and enforcement in **2024 and beyond**. In addition to the existing enforcement authority under REACH, which is granted principally to member states (MS), ECHA will continue to seek changes that give it the authority to address non-compliance by registrants with respect to decisions on compliance checks, conditions of restrictions, and authorizations.

The proposed Community Rolling Action Plan (CoRAP) update for the years **2024 - 2026** lists 28 substances suspected of posing a risk to human health or the environment for evaluation by MS competent authorities. Of the 28 substances proposed for evaluation, ten are proposed to be evaluated in **2024** and 18 in **2025 - 2026**. ECHA urges registrants to review the list and update their registration dossiers to include all available and relevant information prior to publication of the **2024 - 2026** CoRAP in **March 2024**.

3. Cosmetics

Amendment of Regulation (EC) No 1223/2009 of the EP and of the Council of 30 November 2009 on cosmetic products (Cosmetics Regulation) is underway to accommodate the EC's vision of sustainability by promoting uniform risk management across various chemical sectors, centralizing chemical reviews, and addressing environmental concerns. After publishing an inception impact assessment (IIA) in October 2021, the EC launched a public consultation on the revision of the Cosmetics Regulation on March 28, 2022. Based upon the number and complexity of issues that a revision must address and the comments from stakeholders, a draft proposal is not expected before the 2024 EP elections and is unlikely to be published before **2025**.

Under the EC's initial proposal, the scope of the Cosmetics Regulation would be expanded to address environmental endpoints; incorporate the REACH Regulation's generic approach to risk management, which is hazard based; and move the assessment of cosmetic ingredient safety from the Scientific Committee for Consumer Safety (SCCS) to ECHA. These changes represent a major paradigm shift away from the current approach for evaluation of cosmetic ingredients, which considers exposure to a substance as well as its intrinsic hazard. Expansion of the categories of substances to be regulated in addition to Carcinogenic, Mutagenic, or Toxic to Reproduction (CMR) Category 1 substances has, as with REACH, also been controversial. How to assign MAFs and incorporate them into the assessment of cosmetic product safety is also a subject of debate. Application of the REACH essential use concept could be challenging, as cosmetic products are generally considered to be non-essential products. The EC is also considering amending the manner in which cosmetic product information is provided by simplifying certain information or providing it through digital means.

While major revisions to the Cosmetics Regulation remain under discussion, amendments to the Cosmetics Regulation Annexes continue to move forward. An amendment to Annex III of the Cosmetics Regulation entered into force on August 15, 2023, adding 56 fragrance allergens to the list of restricted substances and requiring that these substances appear individually on cosmetic product labels when present at greater than 0.001 percent for leave-on products or 0.01 percent for rinse-off products. The listed substances include menthol, camphor, vanillin, and essential oils like lavender or cinnamon oil. Additional details, including the deadlines for implementing the new labeling requirements and market withdrawal, are provided in the amendment.

While significant amendments of the Cosmetics Regulation have been delayed and the sense of urgency has diminished, companies are nevertheless advised in 2024 to follow developments in the legislative process closely. The changes to the Cosmetics Regulation that are currently under discussion would make fundamental and significant changes to

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PFAS under REACH — A Conversation with Jane S. Vergnes, Ph.D.

the way in which cosmetics are regulated in the EU that will have impacts well beyond EU borders and will affect the cosmetic products market globally.

4. Biocides

The biocides Review Programme continues to evolve, though at a slower pace than anticipated. The consultation on the draft act to extend the Biocidal Products Regulation (BPR) deadline for completing the evaluation of existing biocidal active substances contained in biocidal products until **December 31, 2030**, closed on December 21, 2023. While ECHA and the MSs have increased the pace for reviewing active substances, the number of opinions published by the Biocidal Products Committee (BPC) still falls short of the 50 active substance approvals per year needed to meet the **December 31, 2024**, deadline.

Progress under BPR is comparatively slow, and no major amendments should be expected until **2025**. ECHA has clear intentions to devote more energy and resources to working with MSs to support efficient implementation of BPR. Biocidal products are a high priority in EU chemicals regulation, especially in the context of the Strategy. The pressure to move forward at a faster pace is expected to intensify in 2024 until BPR is revised, as industry concerns become louder regarding the overall functionality of the law in its current form. Industry points to the unpredictability of how BPR, related guidance, and procedures are applied, the lack of harmonization, and delays in dossier evaluations all hamper innovation regarding more sustainable chemicals.

5. Plant Protection Products

In light of the EU's ambitious goals for a toxic-free environment, Regulation (EC) No 1107/2009 concerning plant protection products (PPP) (Plant Protection Product Regulation, or PPPR) is one of the chemical regulations that is being reviewed for efficiency and effectiveness in promoting the Strategy's goals. While it is a high priority in the coming years to tackle "pesticide dependency" and to "significantly reduce the use and risk of chemical pesticides," it appears that an overhaul of the PPPR is not among the priorities singled out by the EC in 2024 to achieve these goals. Initiatives will continue in 2024 to support sustainable farming, shore up food security, reduce the use of synthetic pesticides, and promote their replacement by biopesticides. Agreement on "the proposals on plants obtained by certain new genomic techniques," was cited in the EC 2024 Work Programme.

The EU food policy, the Farm to Fork Strategy (F2F), aims to increase the sustainability of the entire food chain from production to consumption and to neutralize its impact on the environment. Within F2F, the EC proposed in June 2022 the ambitious target to cut synthetic pesticide use in the EU in half by **2030** and tasked the MSs with introducing strategies for meeting reduction targets.

From our offices in England and Belgium, Acta's scientific, regulatory, and stewardship professionals have been, are, and will remain extensively involved in all aspects of REACH and UK REACH and can assist clients in complying with the frameworks today — and also in foreseeing future developments under REACH and UK REACH. Contact Lynn Bergeson at lbergeson@actagroup.com if you would like to discuss how our team can assist with representative services, supply chain communication, testing strategy and management, compliance reviews, and other compliance assistance.

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A new enforcement framework would be created to ensure that all farmers use synthetic pesticides as a last resort measure. Synthetic pesticides would be banned in sensitive areas, such as parks, playgrounds, or sports grounds. The EC published the proposed Regulation on the sustainable use of plant protection products and amending Regulation (EU) 2021/2115 that captures all these objectives. The proposal must pass the European Council and the EP before becoming law, but faces an uphill climb in light of the economic and security concerns that have surfaced since the COVID-19 pandemic and Russia's invasion of Ukraine. Progress is likely to be slow in 2024, even after the 2024 EP elections. In light of these economic and political challenges, the goal of cutting the use of synthetic pesticides in half by **2030** will be challenging.

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Regardless of one's role, whether manufacturer, importer, non-GB supplier, downstream user, or distributor, all companies doing business as or with a GB-based company are advised to follow the developments in GB closely in 2024.

C. UNITED KINGDOM/GREAT BRITAIN

1. Overview

Divergence between the UK and EU regulations pertaining to chemicals will continue in **2024 and beyond**. Companies worldwide must be aware of the significant implications for chemical regulatory compliance under several regimes, including the UK REACH regulation, the Cosmetics Products Regulation, the BPR, and the PPPR. The number of chemical substances that will be available on the UK market is unlikely to be known by the end of 2024, as the regulations, processes, and procedures continue to evolve, and associated costs for access to the market in Great Britain (GB) are likely to remain unclear. Regardless of one's role, whether manufacturer, importer, non-GB supplier, downstream user, or distributor, all companies doing business as or with a GB-based company are advised to follow the developments in GB closely in 2024.

2. UK REACH

The REACH (Amendment) Regulations 2023, extending the UK REACH registration deadlines for transitional (*i.e.*, grandfathered) substances, took effect July 19, 2023. The amendment also extends the period during which downstream users and distributors who were importing before the end of the EU Exit Implementation Period can continue to import chemicals from the EU without submitting a full registration if they have submitted a downstream user import notification (DUIN). In addition to providing additional time for the government to develop and introduce a new transitional registration model, this amendment also extends the dates by which HSE is required to carry out compliance checks so that these dates now align with the extended submission deadlines.

The legislation amends the current UK REACH information submission deadlines by three years to:

- **October 27, 2026**, for substances at 1,000 metric tons or more per year; CMR substances at 1 metric ton or more per year; very toxic to aquatic substances (acute or chronic) at 100 metric tons or more per year; and substances on the candidate list as of December 31, 2023;
- **October 27, 2028**, for substances at 100 metric tons or more per year and substances added to the UK REACH candidate list as of that date; and
- **October 27, 2030**, for substances at one metric ton or more per year.

The dates by which HSE must carry out 20 percent of compliance checks move to **October 27, 2027**, **October 27, 2030**, and **October 27, 2035**, *i.e.*, one, two, and five years after the respective submission deadlines above.

DEFRA published a policy paper on a UK REACH alternative transitional registration model (ATRm) in November 2023, in response to chemicals industry concerns about the significant cost to businesses of accessing EU data packages to support UK REACH transitional registrations.

DEFRA will tailor GB chemical registration requirements to focus on gathering information on the uses of and exposures to the chemicals, in particular those of higher concern. It will reduce to the essential minimum the "hazard" information required for transitional registrations and intermediates and augment this by requiring any further data in a targeted way, as new or emerging risks are identified, either by the UK or other global sources. DEFRA also proposes to revise the UK REACH restriction processes to ensure that DEFRA has the flexibility to act as quickly as possible where risks have been identified, drawing on work performed by UK regulators and other sources.

DEFRA states that it is also looking at how it might improve the working of REACH in the medium to long term. DEFRA intends to consult on more details of the policy in **early 2024**.

On April 4, 2023, HSE published an RMOA for PFAS, and DEFRA ministers have accepted the RMOA's recommen-

dations, which include reducing PFAS emissions by developing UK REACH restrictions, beginning with a restriction on PFAS in firefighting foams and exploring further restrictions covering a wide range of industrial and consumer uses. The RMOA applied a grouping approach to avoid substitution of existing PFAS substances with new substances that are not as well characterized but are regarded as having similar potential to harm human health or the environment. PFAS are listed as a 2024 priority in the UK REACH 2023 - 2025 Work Programmes. DEFRA will continue to work with stakeholders as this work develops and build on the constructive dialogue initiated through the PFAS UK Chemicals Stakeholder Forum (CSF) Working Group.

3. Cosmetics

As with UK REACH, the UK cosmetics legislation adopts and adapts many of the provisions in Regulation (EC) No 1223/2009 of the EP and of the Council on cosmetic products (Cosmetics Regulation), including the designation of a "responsible person" (RP) in GB to assume responsibility for GB Product Information Files (PIF) and other aspects of GB regulatory compliance, and the establishment of the UK Submit Cosmetic Product Notification (SCPN) system to replace the EU Cosmetic Product Notification Portal (CPNP). New cosmetic products must be notified via the SCPN prior to placement on the GB market. GB-based distributors of cosmetic products from the EU will now be considered importers and will be required to undertake the duties of a UK RP, or to appoint an agent in GB to undertake these obligations. The UK Parliament passed legislation to extend the transition period for implementing the UK Conformity Assessment (UKCA; the counterpart of the EU *conformité européenne* (CE)) marking requirement until **December 31, 2024**, and the UKCA labeling, importer information, and RP requirements until **December 31, 2027**, to soften the impact of the transition on the GB market and align with typical product shelf life in the supply chain.

The provisions of the Ireland/Northern Ireland Protocol (IE/NI Protocol) stipulate that a cosmetic product placed on the market in Northern Ireland (NI) must comply with the EU Cosmetics Regulation, and its supply into the EU is not regarded as an import, while a cosmetic product supplied from GB to NI is regarded as an importation into the EU.

Divergence between the EU and the UK cosmetic regulations will present additional challenges in 2024 to purveyors of cosmetic products, as evidenced by the 2023 update to the technical annexes to the UK Cosmetics Regulation. Companies are advised to consult the applicable guidance to ensure that they understand the different nuances of placing on the market cosmetics in GB, NI, and the EU.

4. Biocides

Divergence between the regulation of biocidal products in the EU and the UK is ongoing, increasing regulatory compliance complexity and costs in 2024 and beyond.

A biocidal product authorization valid in GB at the end of the transition period remains valid until its expiry date, but the authorization holder was required to be established in the UK (including NI) by January 1, 2022. Active substance approvals also remain valid in GB until their normal expiry date, but companies must ensure that they are established in the UK.

Due to the large number of resubmissions received, and to ensure that biocidal products can remain on the market legally, a new law, The Biocidal Products (Health and Safety) (Amendment) Regulations 2022 No. 1291, came into force on December 31, 2022. The law extends the timeframes for HSE to complete its review of resubmitted applications, notify the applicant of the appropriate fees associated with the application, and complete the evaluations of new product applications made over the next five years until **December 31, 2027**.

As with other chemical regulations, EU BPR continues to apply in NI. Companies that seek an authorization in NI will apply in a similar way as in an EU MS but to the NI competent authority, HSE NI.

5. PPP

The PPP Amendments, which took effect in GB on December 31, 2023, provide additional relief to the regulated community by extending the timeframe until **July 1, 2027**, for placement on the GB market of treated seed that has not been authorized for use by GB. The PPP Amendments also reinstate parallel trade permits that expired on January

1, 2023, under Article 52. Applications for reinstatement must be filed by **April 1, 2024**, and must include substantiation that the product remains the same. The permit will be valid for two years from the date of issue, as long as authorization of the reference product does not expire in the interim. It is important to note that special rules apply for PPP in NI.

From Acta's offices in the heart of Manchester, our professionals deliver local expertise and boots-on-the-ground representation to assist clients in gaining and maintaining compliance in the UK. Call Acta's Manchester office at +44 (0) 161 240 3840, or contact Lynn Bergeson, lbergeson@actagroup.com.

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D. THE AMERICAS

1. Overview

Canada experienced major changes in all major chemical markets, including changes to chemical control regulations, proposed changes to consumer product regulations, and amendments to hazardous product regulations. Canada is considering regulatory actions on substances of concern, similar to other countries, to address PFAS and plastics. Expect continued regulatory evolution in 2024, as these legislative and regulatory initiatives will have a significant impact on all business sectors.

There was progress in 2023 with the development and/or implementation of chemical substance legislation in several Latin America countries. Brazil's draft Industrial Chemicals Regulation was approved by the final committee in the Chamber of Deputies in September and is now being reviewed by the Senate. Chile and Colombia continued to implement regulatory provisions on the chemical control area. With issuance of Decree 1570/2023 in May, Peru commenced a legislative process for implementing a chemicals management framework. All such efforts are heavily influenced by two factors: trading partners and a desire for membership within OECD. All countries are opting for a notification and/or registration framework like EU REACH.

In 2024, expect this region to be busy, as these countries will continue to implement their legislative approaches and address program nuances that are expected to have significant impact on the regulatory obligations to which stakeholders will be subject.

This region operates under key trade blocs, including The Andean Community (Bolivia, Colombia, Ecuador, and Peru) and Mercosur (Argentina, Brazil, Paraguay, and Uruguay). The EU is the third-largest trade partner with the Andean Community. The Andean Community generates resolutions that establish common approaches to regulated products. In late 2022, Resolution № 2310 was issued, which established new cosmetic labeling standards, including elements of trade (*i.e.*, harmonized tariff codes). The standards will enter into force in **December 2024**. Stakeholders may wish to consider these approaches when shipping impacted products into the region.

2. Canada

a. Chemical Control

In 2023, Canada enacted legislation modernizing CEPA, representing the first significant reform to CEPA in more than 20 years. CEPA uses a risk-based chemical regulatory scheme, similar to TSCA, and the Act maintains this approach. The Act is ambitious, giving the ministers two years to develop and publish a Plan of Chemicals Management Priorities that sets out a multi-year, integrated plan for the assessment of substances. Canada will create a publicly available "Watch List" of substances determined to be capable of becoming toxic under CEPA to inform Canadians and businesses of substances that they may wish to avoid.

Over the next two years, the government intends to develop an implementation framework setting out how the right to a healthy environment will be considered in administering the Act. The Act creates a stronger regime for controlling the subset of substances considered toxic that pose the highest risk to human health or the environment. For substances that are determined to be toxic under CEPA and that meet the new additional criteria of posing the highest risk, the Act requires that the Minister of Environment and Climate Change and the Minister of Health give priority to prohibiting activities involving these substances. The criteria for these substances will be set out in regulations and will include persistence, bioaccumulation, carcinogenicity, mutagenicity, and reproductive toxicity. Canada will develop these regulations in consultation with stakeholders. More information on the bill is available in our June 23, 2023, memorandum, "Bill to Modernize CEPA Receives Royal Assent."

Following enactment of the Act, in June 2023, Canada requested information on 850 substances for the purpose of prioritization, risk assessment, and risk management. Canada is gathering information from Canadian manufacturers, importers, and users on the commercial status, facility information, and uses of these substances in Canada, pursuant to CEPA Section 71. The Minister of the Environment requires the information to assess whether the listed substances are toxic or are capable of becoming toxic, or to assess whether to control, or the manner in which to control, the listed substances. Responses are due **January 17, 2024**.

This is a sweeping, significant initiative, the implications of which will influence commercial transactions for years to come. ECCC and HC will use submitted information to prioritize chemical review and regulation. Persons are required to provide information that they possess or to which they may be reasonably expected to have access. Manufacturers are "reasonably expected" to have access to their formulations; importers are "reasonably expected" to have access to import records and relevant SDSs; and users and importers are "reasonably expected" to contact their suppliers to obtain information on their substances. More information is available in our August 2, 2023, memorandum, "Canada Issues Mandatory Information Request for 850 Chemical Substances."

In July 2023, HC started a public consultation on a proposal to introduce new requirements for consumer chemical products under the Canada Consumer Product Safety Act (CCPSA). HC states that many substances found in consumer chemical products, like household cleaning products, have been linked to human health hazards of concern (HHHOC) such as carcinogens, mutagens, and reproductive toxicants. The proposed new requirements include the introduction of classification criteria for HHHOCs, information disclosure requirements, and additional protections for the health and safety of people in Canada. HC will use the public comments to inform next steps, which may include a cost-benefit analysis of the proposal and future consultations. HC notes that any future regulatory proposal would be pre-published in the *Canada Gazette* for further stakeholder consultation. Comments were due October 9, 2023.

HC is considering additional mechanisms to engage stakeholders on this initiative, including possible engagement sessions following analysis of the comments received during the consultation. HC may use feedback collected through this consultation to inform the development of a broader strategy to outline measures to support supply chain transparency and consumer product labeling.

If these changes are adopted, stakeholders should consider the current mechanisms for classification and labeling under the Consumer Chemicals and Containers Regulations, 2001 (CCCR, 2001) against the criteria and content currently recognized in the UN GHS model, as these changes are significant. CCCR, 2001 uses entirely different criteria and symbols to describe acute hazards. Consumer labels, amended to comply with any variation of UN GHS, would need to be relabeled and reevaluated. This update would also align better with industrial chemicals, as the current approach, under the Hazardous Products Act, is aligned with UN GHS Revision 7 (Rev 7) and certain elements of Rev 8. Consumer products and products in the workplace could essentially use similar processes for addressing hazards, making it easier to train workers on potential hazards associated with consumer products used in the workplace. More information is available in our August 17, 2023, memorandum, "Health Canada Begins Consultation on Proposed New Requirements for Consumer Chemical Products under the CCPSA."

b. PFAS

On May 20, 2023, Canada published a *Canada Gazette* notice announcing the availability of its *Draft State of Per- and Polyfluoroalkyl Substances (PFAS) Report* (Draft Report). According to the notice, the Minister of the Environment and the Minister of Health (the ministers) propose to recommend that the class of PFAS be added to the CEPA Schedule 1 List of Toxic Substances. The Draft Report provides a qualitative assessment of the fate, sources, occurrence, and potential impacts of PFAS on the environment and human health to inform decision-making on PFAS in Canada. The ministers released a risk management scope document for PFAS to initiate discussions with stakeholders on the development of risk management options.

As with any new and ambitious PFAS regulatory initiative, this proposal merits a close read and active engagement. Its scope is broad. The Government of Canada estimates that more than 4,700 substances are implicated, no surprise given the alignment with OECD's definition of PFAS. No list of substances is available, consistent with other regulatory programs keying off structural definitions of PFAS. Comments on the Draft Report and risk management scope document were due July 19, 2023. More information is available in our May 25, 2023, memorandum, "Canada Begins Public Consultation on Draft State of PFAS Report, Proposes to Recommend Adding PFAS to CEPA Schedule 1."

c. Plastics

Canada announced in February 2023 the release of a report summarizing responses to two public consultations focused on developing rules for recyclability and compostability labeling and on establishing a federal plastics registry for the plastic products industry. Canada is developing new labeling rules to prohibit the use of the circular three-arrow symbol (often referred to as the chasing-arrows symbol) and other recyclability claims on plastic packaging and single-use plastics

unless specific conditions are met. In addition, Canada is considering new rules to control the use of terms such as "compostable," "degradable," or "biodegradable" in the labeling of plastic packaging and single-use plastic items. The labeling rules would be part of new regulations that would also require minimum levels of recycled plastic in certain products.

In April 2023, Canada released two papers for a 30-day comment period:

- Technical paper: Federal Plastics Registry: The paper outlines the technical details and reporting requirements being considered for the Federal Plastics Registry. A draft CEPA Section 46 notice was targeted for publication in the *Canada Gazette* before the end of 2023, which will be followed by a further consultation period before the instrument is prepared in final; and

- Recycled content and labelling rules for plastics: Regulatory Framework Paper: The paper outlines a regulatory framework for plastic packaging and certain single-use plastics that includes recycled content requirements and labeling rules for recyclability and compostability. Canada intends it to provide an updated and more detailed overview of the regulatory approach it is proposing for the draft regulations currently under development. The draft regulations were targeted for publication in the *Canada Gazette* before the end of 2023, which will be followed by a further consultation period before the final regulations are issued.

3. Brazil

a. Chemical Control

On September 26, 2023, the Constitution, Justice, and Citizenship Committee in the Chamber of Deputies approved a draft chemicals law (PL 6120/2019) that includes provisions for the creation of a national inventory of existing chemical substances, a prioritization scheme for risk assessment, and options for risk management. The Senate will also consider the bill. If the Senate amends the bill, the bill will be sent back to the Chamber of Deputies; the Chamber could accept the Senate's revisions or reinstate the text it approved on September 26, 2023. The draft bill includes a robust approach for chemical management in Brazil and manages foreign manufacturers in the supply chain by allowing representation, like the Only Representative (OR) in the EU.

PODCAST
Health Canada's Update to Rev 7/8 of GHS — A Conversation with Karin F. Baron

b. Personal Hygiene Products, Cosmetics, and Perfumes

The three-year transition period continues for Brazil's National Health Surveillance Agency (Anvisa) *Resolução da Diretoria Colegiada* (RDC) 752/2022, which took effect on October 3, 2022. The regulation provides the definition, classification, technical requirements for labeling and packaging, and parameters for microbiological control of personal hygiene products, cosmetics, and perfumes. Products manufactured before **October 3, 2025**, and labeled in accordance with the previous requirements may be sold until their expiration dates.

In February, Anvisa issued RDC 774, which replaces RDC 585/2021 and provides the definitions, conditions for registration, and labeling of sanitizing products with antimicrobial action. The Resolution includes sanitizing products intended to be used on surfaces and objects in homes, in industry, in hospitals, and healthcare facilities. The Resolution also specifies that only substances accepted by the U.S. EPA, U.S. FDA, or the EU community are allowed as active ingredients in sanitizing products with antimicrobial action.

4. Chile

On February 9, 2021, the Ministry of Health (MoH) published Decree No. 57 on the Classification, Labeling and Notification of Hazardous Chemicals and Mixtures (*Reglamento de Clasificación, Etiquetado y Notificación de Sustancias Químicas y Mezclas Peligrosas*) (Decree No. 57). Decree No. 57 established a national inventory of industrial chemicals, established a method for risk evaluation of priority substances, and implemented GHS. Decree No. 57 implementation is occurring in stages, with the first notification requirement for industrial substances by **August 30, 2024**. The government plans to publish the first national inventory by **December 31, 2024**. Notifications for industrial substances contained in mixtures are due **August 30, 2027**. For substances and mixtures for non-industrial use, the first notifications are due **August 30, 2025**, and **August 30, 2029**, respectively. In June, Chilean officials provided indus-

try with details of its online system notifications. Foreign manufacturers, under the Decree, are unable to participate in the notification process. In 2024, expect additional progress and potential issues as importers attempt to complete the required notifications. These notifications are tied directly to the hazard classification of the substances, meaning only hazardous substances imported or manufactured at or above 1 metric ton for the preceding two-year period require notification (*i.e.*, annual volumes for 2022 and 2023). Notification includes chemical identity, hazard classification, an SDS, uses, and importation/manufacturing volumes.

5. Colombia

On November 30, 2021, the Ministry of the Environment and Sustainable Development published Decree 1630/2021 regarding the comprehensive management of chemicals for industrial use, including risk management. The Decree established the National Registry of Industrial Chemical Substances (*Registro Nacional de Sustancias Químicas de Uso Industrial* (RSQUI)). Companies that manufacture or import industrial chemical substances categorized as hazardous in volumes exceeding 100 kilograms (kg) annually are required to report information including the identity of the manufacturer/importer, annual quantities produced or imported, substance identification, hazard classification according to Decree 1496/2018, and uses. Manufacturers and importers have until **May 30, 2025**, to report the required information. On **May 31, 2025**, Colombia will create the National Inventory of Industrial Chemical Substances (Inventario Nacional de Sustancias Químicas de Uso Industrial) based on chemicals registered.

On May 31, 2022, the Ministry of Commerce (MINCIT) issued Circular 18, announcing the launch of the online system to register chemicals. In 2023, Colombia updated its instructions for foreign manufacturers and importers to register substances to provide new guidance on confidentiality claims, substance identity, and clarification on obligations for information being provided in the system.

6. Mexico

Mexico's approach to the management of chemicals continues to be use specific. This is curious since Mexico issued a National Integrated Policy for the Management of Chemical Substances (*La Política Nacional Integral para la Gestión de Sustancias Químicas*) in November 2019. Mexico has made no significant progress in implementing a comprehensive chemical law. In developing a comprehensive law for managing chemical substances, Mexico is unique among the Latin American countries in that it is part of the United States-Mexico-Canada Agreement (USMCA) that entered into force in July 2020. The Mexican government's 2019 proposal for chemicals regulation would adopt a hazard-based approach, similar to the EU REACH. This is at odds with the USMCA, which supports a risk-based approach for regulating chemicals, similar to TSCA. There was nothing officially presented to Congress in 2023 that would signal the initiation of a legislative initiative. It is unclear what, if anything, is expected in 2024.

7. Peru

On May 28, 2023, the Ministry of the Environment published Decree No. 1570. The Decree establishes the legal framework for the comprehensive management of chemicals and provides for the standardization of information on hazard classification, labeling, and SDSs; the traceability of information through the creation of a national registry of chemical substances; and the adoption of risk management measures and the evaluation of their impact on health and the environment. The Decree enables Peru to comply with 12 of the 20 legally binding OECD instruments regarding chemicals. Peru will implement the framework in a future regulation, expected to be published in 2024. The regulation will include classifications for hazardous substances; the scope, implementation, and operation of the national registry; technical conditions under which certain activities are exempted from the national registry; a procedure for risk assessment approvals; and risk management measures. The Decree language includes similar exemptions to those that are part of EU REACH.

With the ambitious implementation timeframe of one year, expect 2024 to be active with the establishment of a new online system from the Ministry. The publication of the list of classifications will provide more insight into additional regulatory obligations under this Decree. The ability for foreign manufacturers to participate remains unclear. Guidance is expected as the online systems are deployed.

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Expect 2024 to be a busy time for GHS implementation and revisions. Revisions to existing GHS implementations will require review of hazard communication tools to ensure continued compliance within regulated timeframes.

E. GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELING OF CHEMICALS

1. Overview

2023 began with several countries implementing or revising regulations based on the UN GHS model. Most countries are opting to align with the 7th revised edition of the UN GHS (Rev 7). Canada, early in 2023, issued its update to its existing regulations, followed by continued efforts in a busy Latin American region. April brought major changes, although not aligned with UN GHS, to the European Union (EU) Classification, Labeling and Packaging regulation (*i.e.*, Regulation (EC) 1272/2008 or CLP). The UN published its 10th revised edition (Rev 10) in July 2023. The anticipated update to the U.S. regulation did not make an appearance in 2023 but is expected in **early 2024**. Expect 2024 to be a busy time for GHS implementation and revisions. Companies will be challenged to consider which revision a country adopts, the scope of the legislation (*i.e.*, worker, consumer, or both), additional elements to the legislation (*e.g.*, additional hazard elements, language requirements), and how those elements influence the content of communication tools (*i.e.*, SDSs and labels). Revisions to existing GHS implementations will require review of hazard communication tools to ensure continued compliance within regulated timeframes.

2. United Nations

The 44th session of the UN Sub-Committee of Experts on the Globally Harmonized System of Classification and Labeling of Chemicals convened in early July 2023. The agenda included implementation of GHS with the possible development of a list of classified chemicals, development of guidance on practical issues with classification and labeling, in addition to work that is of interest to the sub-committee (*e.g.*, simultaneous classification in physical hazard classes, use of non-animal testing methods for classification of health hazards and environmental hazards, classification criteria for germ cell mutagenicity, and nanomaterials). The EU, at the 43rd session, submitted a proposal for new items that prompted discussions at the 44th session on capacity building. The 44th session included an agenda item to address capacity-building activities and amendments to Chapter 4 specific to atmospheric systems. The provisional agenda for the 45th session includes nearly identical items to the 44th. The 45th session, held in December 2023, included discussion on incorporation of hazardous material to the atmospheric system that is meant to clarify the classification of substances and mixtures while generating greater alignment with other global initiatives like the Montreal Protocol.

Rev 10 was published as expected in late July 2023. Rev 10 includes the classification procedure for desensitized explosives (Chapter 2.17); the use of non-animal testing methods for classification of health hazards, in particular: skin corrosion/irritation (Chapter 3.2), serious eye damage/eye irritation (Chapter 3.3), and respiratory or skin sensitization (Chapter 3.4); further rationalization of precautionary statements to improve users' comprehensibility while taking into account usability for labeling practitioners; and review of Annexes 9 and 10 to ensure alignment of the classification strategy, guidance, and tools on metals and metal compounds with the provisions for long-term aquatic classification toxicity in Chapter 4.1. For more information on this order, *see* our memorandum on the topic. The next update, Rev 11, is not expected **until 2025**.

PODCAST
Rev 10 GHS — A Conversation with Karin F. Baron

3. U.S. OSHA, HCS 2012

On May 25, 2012, OSHA revised and updated the Hazard Communication Standard (HCS). Currently, all substances and mixtures are required to comply with HCS 2012. On February 5, 2021, OSHA issued an NPRM to amend HCS 2012 to align with Rev 7 of GHS. The NPRM included many

other elements and incorporated some aspects of Rev 8 of GHS. The comment period for the NPRM was approximately 60 days, concluding on April 19, 2021, and it was extended to May 19, 2021.

In September 2021, OSHA convened an informal public hearing to allow interested parties to participate in further dialogue on the NPRM. OSHA notes that it received over 171 comments on the NPRM and reportedly spent most of 2022 reviewing the comments. The final rule, expected in early 2023, never materialized. Indications, at the end of 2023, were that the final rule might appear in **early 2024**. Transition periods were included in the proposed rule. Based on the number of comments received, it is difficult to predict if those implementation dates will remain as proposed.

4. Canada, Health Canada HPR

On December 9, 2020, HC proposed to update the Hazardous Products Regulation (HPR) from its current approach based on Rev 5 to Rev 7 of GHS in the *Canada Gazette I*. The comment period was to end on February 27, 2021, but was extended to May 19, 2021, to allow all comments to be captured and to align with the U.S. NPRM deadline. HC, on January 4, 2023, published in the *Canada Gazette II* the revisions to the HPR. The changes include updates to the HPR to align with Rev 7 of GHS as expected, but also include elements from Rev 8 to align with the NPRM from the United States. The transition period is **three years**, but rumors in 2023 were that a possible extension might be proposed if the United States is further delayed in issuing its final rule. Updates to guidance documents were published in October 2023.

Both HC and OSHA continue to provide guidance to industry that addresses the few variances that do currently exist between the two systems. Comparison documents on labeling and regulatory processes are available based on the older version of the HPR and on HCS 2012. If the OSHA final rule is issued in 2024, expect updates to assist in management of the two systems during the transition period.

5. Australia

Australia implemented Rev 3 of the UN GHS model into its Work Health and Safety Laws (WHS) on January 1, 2012. The transition period ended in January 2017. In July 2019, Safe Work Australia began seeking comments on a consultation to update to Rev 7 of the UN GHS model to "ensure Australia's requirements for workplace hazardous chemicals reflect the most up to date approach and remain aligned with our key chemicals trading partners." The revisions to the regulation were published on August 28, 2020, and reissued with minor amendments on November 5, 2020. The updates were inserted into the model WHS Regulations starting January 1, 2021, with a two-year transition period. As of January 1, 2023, adoption of Rev 7 is required for all classification and labeling of chemicals. No further updates are expected in 2024 as companies ensure compliance with the adopted revisions.

6. Brazil

Brazil first implemented UN GHS in 2009 based on Rev 4. The Brazilian Association of Technical Standards (ABNT) contained the specific details in four parts.

- Part 1: Terminology, Chemicals — Information about safety, health, and the environment;
- Part 2: Hazard Classification;
- Part 3: Labeling; and
- Part 4: Safety Data Sheet.

On July 3, 2023, ABNT adopted Rev 7 and merged the four-part standard into the "new" NBR 14725:2023. Major revisions include the change in the SDS name to "*Ficha com Dados de Segurança* (FDS)," the allowance of a QR code on the label to access FDS content, and the requirement that Section 1 of the FDS must include a 24-hour local phone number for emergencies. The remaining changes follow the adoption of Rev 7 and include amendments and/or additions of physical hazard categories, changes to classification criteria for the health hazard categories, the addition of the environmental classification "Hazardous to the Ozone Layer," revisions and additions to hazard and precautionary phrases, and updates on provisions for the labeling of small packages. A two-year transition period to adopt the changes started in 2023, with the expectation that impacted parties must follow new changes before **July 3, 2025.**

7. Chile

The MoH and the Ministry of Environment (MoE) published on February 9, 2021, Decree 57, which approved the Regulation on the Classification, Labelling, and Notification

of Chemical Substances and Mixtures. The regulation aligns with Rev 7 of GHS and provides transition periods for substances and mixtures for industrial and non-industrial uses. The implementation date for industrial substances was February 9, 2022, and industrial mixtures must comply by **February 9, 2025**. Non-industrial substances had until February 9, 2023, and non-industrial mixtures must comply by **February 9, 2027**. Companies are allowed to continue using the Standard NCh 2245:2015 during the implementation period.

Chile did not adopt all building blocks of Rev 7 and excluded the following Rev 7 classifications: Pyrophoric gas, Desensitized explosives, and Chemicals under pressure. In addition, Chile excluded the following physical, health, and environmental hazard categories: Flammable liquids category 4, Skin corrosion/irritation category 3, Serious eye damage/eye irritation categories 2A and 2B, Aspiration category 2, and Hazardous to the aquatic environment acute categories 2 and 3. This approach aligns Chile with the EU CLP regulation.

Chile identified a list of substances, approved by the MoH in Resolution 777, with required classifications to assist with the classification and labeling of products. The list includes the chemical name, CAS RN, hazard classes and categories, and concentration limits and multiplying factors for each listed substance. The list is mandatory and considered to be the minimum substance classification. The list contains approximately 4,500 substances, and updates are expected every two years. Expect an expanded list in 2024. Also note that the classification and labeling does impose chemical notification obligations. Stakeholders are urged to consult this list prior to developing the SDS, label, and/or verification of compliance with newly enacted notification requirements.

8. China

China's Ministry of Industry and Information Technology (MIIT) is responsible for industrial development, policy, and standards, and it oversees industry operations monitoring, innovation, and information technology.

On September 22, 2022, MIIT announced the plan to revise the national mandatory standard GB 15258-2009, General Rules for Preparation of Precautionary Label for Chemicals, within the next 16 months, or by **March 2024**.

On June 14, 2023, MIIT released GB 30000.1, Rules for Classification and Labeling of Chemicals — Part I: General Specifications for public consultation. GB 30000.1 will replace GB 13690-2009, General Rule for Classification and Hazard Communication of Chemicals. The intent is to align 30000.1 with GHS Rev 8. The newly added Desensitized Explosive (GB 30000.30) was also released on August 15, 2023, for public consultation. 30000.1 and 30000.30 are expected to be implemented within the **next six to 12 months**. Also, expect in 2024 future revisions to each corresponding GB Standard (*i.e.*, 30000.2-30000.29) to align with GHS Rev 8, as these are currently aligned with Rev 4.

China launched the Comprehensive Service System for Registration of Hazardous Chemicals on February 16, 2022, promoting the implementation of the "one enterprise, one chemical product with one code" rule for hazardous chemicals, under which a unique QR code will be automatically generated through the new online system or through hazardous chemicals registrations.

9. Colombia

The Colombian *Ministerio del Trabajo* (Ministry of Labor) implemented Rev 6 of UN GHS through Decree 1496 on August 6, 2018. On April 7, 2021, Resolution 773 was issued to implement Decree 1496. The transition period for substances and diluted solutions was two years, concluding on April 7, 2023. The transition period for mixtures is three years and concludes on **April 7, 2024**. All hazard classes and categories were adopted in accordance with Rev 6. There is a mandatory review of the SDS and label content every five years.

10. CLP

On April 20, 2021, the 16th adaptation to technical progress (ATP) was released. The minor updates were enforced 20 days after its publication on May 10, 2021. This was the first ATP that was not automatically adopted by the UK.

The 17th ATP was published in the EU *Official Journal* on May 28, 2021. This update includes Risk Assessment Committee (RAC) adopted opinions on roughly 50 substances dating from March 2019 to December 2019. The enforcement of the 17th ATP began on December 17, 2022.

An 18th ATP, published in May 2022, entered into force November 23, 2023. Included in the 18th ATP are 39 new entries and 17 amended entries to Annex VI of CLP. These

are the result of the RAC adopted opinions from late 2019 to 2020.

Consultation on the draft of the 19th ATP closed in August 2022. In April 2023, the 19th ATP was published and contains clarification from RAC on 2-ethylhexanoic acid and its salts in the form of a new Note X and Note 12 to address classification of mixtures as reproductive toxicants. In addition, Note 11 was added to address reproductive toxicant classifications for mixtures containing boric acid and its salts, as well as other boric compounds releasing boric acid/borates. Additional clarification was issued in May 2023, assumed to be the 20th ATP, which includes the 19th ATP changes now incorporated into Table 3 of Annex VI to CLP, which are expected to go into force by **February 1, 2025**. Details on the 21st ATP are expected in 2024.

The EC advanced changes to CLP to include new hazard classes currently not addressed within the regulation. These changes entered into force as of April 20, 2023, and include the addition of endocrine disruptors for human health; endocrine disruptors for the environment; PBT; very persistent and very bioaccumulative (vPvB); persistent, mobile, and toxic (PMT); and very persistent and very mobile (vPvM). The transitional periods are divided between substances and mixtures. The transition periods include consideration for existing products on the market. "For new substances on the market, companies need to comply with the new rules from **1 May 2025**, whereas substances that have already been on the EU market, companies have until **1 November 2026** to comply. Separate transition times apply for mixtures. New hazard classes apply from **1 May 2026** to new mixtures, whereas companies have until **1 May 2028** to update the classification and labelling for existing mixtures." All manufacturers, importers, downstream users, and distributors are expected to comply within the specific transition periods. Expect new guidance from ECHA on how to address these endpoints in 2024, and expect that MSs will continue to propose the addition of these endpoints, on specific substances, through harmonized classification and labeling procedures.

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The EU proposed inclusion of these endpoints in a proposal to the UN GHS Sub-Committee for work in 2023. The UN GHS Sub-Committee continues discussions on how best to approach these complex endpoints, with very little movement expected in 2024 due to a myriad of reasons, most importantly resources.

11. United Kingdom

January 1, 2021, marked the official end of the transition period for the UK exit from the EU. HSE is the agency responsible for the UK equivalent to the EU CLP and certain aspects of REACH that impact CLP (*e.g.*, SDS content). The original intent was to incorporate the EU CLP into a GB CLP Regulation, where GB includes England, Scotland, and Wales. The GB CLP Regulation does include all existing EU harmonized classification and labeling in force on December 31, 2020, but was not intended to include provisions for Poison Center Notifications. HSE, in 2022, clarified that it did adopt Poison Center Notifications and refers to the UK National Poisons Information Service for further guidance, which remains under review at this time.

2023 regulatory actions predictably resulted in variations between the EU and the UK, as the UK considered ATPs that were not within the scope of the current GB CLP Regulation (*i.e.*, 16th - 20th). The variations on a substance-by-substance level resulted in the UK aligning with the EU approach for some substances while adopting alternative approaches to classification and labeling for other substances. The HSE currently captures these substance-level classifications in an Excel spreadsheet that is updated frequently on its website, known as the GB mandatory classification and labeling list (GB MCL list). These changes continue to require considerable diligence for those navigating trade within the region. In October, the GB MCL list was amended to adopt 98 substances with a compliance date of **April 20, 2025**.

The UK approach for how it intends to address the addition of new hazard classes is not clear. Expect further progress with the GB MCL list in 2024, but it is unclear if HSE will, through its Parliamentary process, opt to alter the GB CLP with the new EU CLP hazard classes.

In 2023, the UK did not address the Annex II changes to EU REACH that resulted in changes to the SDS in the EU at the end of 2022, but noted that these would not be addressed within the GB CLP as it is currently written.

12. New Zealand

New Zealand was the first country to implement GHS in 2001 by modifying its Hazardous Substances and New Organisms (HSNO) Act of 1996. New Zealand's approach was unique and was originally based on Rev 1 of the UN GHS model.

On October 29, 2019, the New Zealand Environmental Protection Authority (New Zealand EPA) proposed an update to the HSNO classification system by adopting Rev 7 of the UN GHS model. The public consultation period for comments closed on January 9, 2020. On October 15, 2020, New Zealand EPA published a notice to implement the proposed changes. The notice came into force on April 30, 2021, with a **four-year transition** date for companies to update hazard communication elements.

The notice reveals that not all categories within Rev 7 have been adopted. Acute toxicity category 5, skin corrosion/irritation category 3, sub-categories 2A and 2B for eye irritation, aspiration hazard category 2, hazardous to the aquatic environment acute categories 2 and 3, and hazardous to the ozone layer are excluded. The most conservative threshold values for mixture principles are applied, and there are specific considerations for agrichemicals and active ingredients used in the manufacture of agrichemicals that are hazardous to the terrestrial environment. Schedule 3 contains correlation tables to assist in the transition from pre-2021 HSNO to the equivalent classification under the notice.

In 2024, companies are urged to consider how these significant changes impact the SDS, labels, and packing provisions that have been implemented and to develop a plan to meet the enforcement date of **April 30, 2025**, for any hazardous substance placed on the market before April 30, 2021. For any substance placed on the market after April 30, 2021, SDS, labels, and packing provisions must comply with Rev 7.

13. South Korea

On January 16, 2021, the amended South Korean Occupational Safety and Health Act (K-OSHA) entered into force. The amendments require that manufacturers or importers into South Korea provide a copy of the material safety data sheet (MSDS) to the Ministry of Employment and Labor (MoEL) and include, as a separate submission, substantiation for any content that companies wish to maintain as CBI for MoEL to review and approve (with limited exceptions). The CBI review and approval process is daunting, and MoEL's expectations on the types of proof that demonstrate disclosing hazardous ingredients would result in commercial harm are substantial. Foreign manufacturers wishing to protect CBI on the MSDS are able, through the appointment of an OR, to submit the MSDS with appropriate documentation to MoEL.

New products placed on the market after January 16, 2021, require submission of the MSDS to MoEL and must comply with required content requirements, including being translated into Korean. Products that were on the market prior to January 16, 2021, are being phased into this process. Deadlines for submission are tonnage-based by year. Products manufactured or imported at 1,000 metric tons or more per year must comply with the amended K-OSHA, which started on January 16, 2022. In 2023, existing products manufactured or imported between 100 and 1,000 metric tons per year must comply starting January 16. The grace period for existing products between 10 and 100 metric tons per year is until **January 16, 2024**, for existing substances between 1 and 10 metric tons per year is until **January 16, 2025**, and for existing substances less than 1 metric ton per year is until **January 16, 2026**.

14. Peru

A draft bill was circulated in 2020 that proposed a regulation that would follow UN GHS for classification and labeling of all substances. The draft bill includes provisions for a national registry within one year of the approval of the regulation. On May 28, 2023, the draft bill proceeded to a decree. The decree process indicates the intention to officially adopt GHS for classification, labeling, and SDSs. The current decree fails to mention which revision of the GHS is being implemented, but we expect further progress and greater clarity in 2024.

15. Singapore

First adopted in 2008 under Singapore Standard (SS) 586, GHS became mandatory for manufacturers in 2015 and for workers in 2016. There have been several updates, including one in 2011 to Rev 2 of GHS and one in 2014 to Rev 4. On June 6, 2022, consultation on a draft update to align with many of the requirements outlined in GHS Rev 7 began. On February 6, 2023, the revised relevant editions of the Singapore Standards were published to align with Rev

7. There is a 24-month transition period to implement the amended standards. The transition period ends **February 6, 2025.** The Rev 7 adoption excludes the following: Flammable liquid category 4, Acute toxicity category 5, Skin corrosion/irritation category 3, Aspiration hazard category 2, Acute hazard to the aquatic environment categories 2 and 3, and Chronic hazards to the aquatic environment categories 3 and 4.

B&C and Acta, with offices in North America, Europe, and Asia, offer a global presence that is key to our ability to advise and guide clients on GHS issues in every territory. Our professionals routinely provide strategic global counseling on rationalizing GHS obligations across jurisdictional boundaries for product lines and businesses, and assess and revise SDSs for products marketed globally. For more information, visit our website: Globally Harmonized System (GHS).

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The requirements of both KKDIK (Kimyasalların Kaydı, Değerlendirilmesi, İzni ve Kısıtlanması) and Turkey's Biocidal Products Regulation (T-BPR) will continue to drive major chemical regulatory activities and chemical commerce in Turkey in 2024.

F. TURKEY

1. Overview

In anticipation of EU membership, Turkey continued in 2023 to align its chemicals legislative framework with the EU's chemicals regulations. Concerns regarding the accession process continue, with no clear movement toward full EU membership for Turkey. Most chemical regulatory activity in 2023 focused on the submission of data by industry to comply with the KKDIK regulation (*Kimyasalların Kaydı, Değerlendirilmesi, İzni ve Kısıtlanması*), which entered into force on December 23, 2017. Compliance by the regulated community has been hindered by major delays and confusion, especially technical glitches with entry by registrants or their ORs of required information into the KKS IT system. Industry stakeholders raised concerns regarding compliance by the December 31, 2023, deadline, particularly in light of the Turkish government's challenges with implementing this new regulation while responding to the urgent humanitarian crisis caused by the February 6, 2023, earthquake. An extension notice was published December 23, 2023, to extend the registration deadline to avoid supply chain issues and internal market disruptions in 2024. Amendments to Turkey's 2009 Biocidal Products Regulation (T-BPR) entered into force on January 1, 2022. The requirements of both KKDIK and T-BPR will continue to drive major chemical regulatory activities and chemical commerce in Turkey in 2024.

2. KKDIK

KKDIK is a hazard-based chemical regulatory framework that requires registration of chemicals manufactured within or imported into Turkey in quantities of one metric ton or more per year. KKDIK data requirements are aligned with those of EU REACH. Unlike the staggered registration deadlines according to tonnage band under EU REACH, KKDIK set a single registration deadline for all tonnage bands of December 31, 2023. Efforts to comply with the KKDIK regulation continued in 2023 with the designation of lead registrants (LR), formation of Substance Information Exchange Forums (SIEF), drafting of data sharing agreements, and clarification of processes for purchase of access to data.

Stakeholders' concerns regarding the registration process led to the release by the Turkish Ministry of Environment, Urbanization and Climate Change (MoEUCC) on February 3, 2023, of new guidance on importer information for new substance registration, importer tracking, and provision of a chemical safety report (CSR).

Changes to the KKS IT system to allow registrants or their ORs to claim, subject to a Ministry fee, a registrant's identity and registration number as CBI were completed. These options were not available prior to the Ministry's February 2023 announcement. The CBI claims must be substantiated in accordance with the template in the KKS system. Companies wishing to claim the registrant's identity and/or registration number as CBI for dossiers that had already been submitted are required to initiate the KKDIK registration dossier update process.

Registrants were previously required to identify at least one importer for every lead or co-registration dossier. The Ministry now encourages a registrant, or its OR, to include importer information where possible, but no longer includes it as a mandatory field in the KKS system. The OR must keep an up-to-date list of the importers and volumes for each of these importers, as well as the information on obtaining the latest update of the SDS.

Industry also expressed concern with the requirement to submit a CSR translated into Turkish for every registration at or more than 10 metric tons per year. The Ministry relented and announced that registrants now have the option of submitting the CSR in English. Registrants have up to one year after December 31, 2023, to submit the Turkish translation. The Ministry does require translation of risk management measures into Turkish. The requirement to submit the information regarding robust study summaries in Turkish remains unchanged.

Due to delays and industry concerns over the deadline, on October 19, 2023, a meeting was held at the MoEUCC,

chaired by General Director Recep Akdeniz. A draft extension was published November 13, 2023, to meet industry stakeholder concerns. A final revision of the KKDIK Regulation Regarding the Extension of Registration Deadlines was published in the *Official Gazette* on December 23, 2023.

The new registration deadlines are:

I. **December 31, 2026**, for substances that meet the following conditions:

   a. Substances manufactured or imported on their own or in mixtures in quantities of 1,000 metric tons or more per year;

   b. Substances manufactured or imported on their own or in mixtures in amounts of 100 metric tons or more per year and classified as Aquatic Acute 1 and Aquatic Chronic 1 (H400, H410); and

   c. Substances manufactured or imported on their own or in mixtures in amounts of 1 metric ton or more per year and classified as carcinogenic, mutagenic, and toxic to the reproductive system, Categories 1A and 1B.

II. **December 31, 2028**, for substances manufactured or imported in quantities of 100 metric tons or more annually, either on their own or in mixtures or in articles.

III. **December 31, 2030**, for substances manufactured or imported in quantities of 1 metric ton or more per year, on their own or in mixtures or in goods.

An extension of the registration deadlines will allow for a more reasonable approach to implementation of KKDIK for manufacturers and importers, as well as downstream users, and submission of the entire registration dossier using Turkey's KKS platform.

Note that no extension applies regarding the SDS-related provisions of KKDIK, and the former SDS Regulation 29204 was repealed as of December 31, 2023. Thus, beginning **January 1, 2024**, SDSs should be prepared in accordance with the provisions of KKDIK Annex II.

3. Biocidal Products

Turkey's Ministry of Health proposed several amendments to the T-BPR, in force since its original publication in *Official Gazette* No. 27449, December 31, 2009. Amendments of several articles entered into force on January 1, 2022, including terms and conditions for placing biocidal products on the market, the testing of active substances, prohibitions for use and sale of biocidal products, the criteria to be used for adding an active substance, and updates or corrections to the biocidal product inventory. Notified products could be placed on the Turkish market until December 31, 2023.

On February 3, 2023, the T-BPR list A (list of active substances permitted for use in biocidal products, due to be evaluated) was updated. Active substance and product types were added and removed from the list, associated with this regulation.

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G. ASIA/PACIFIC RIM

1. Australia

The Australian Industrial Chemicals Introduction Scheme (AICIS) replaced the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) in July 2020, and the transition period for introducing substances under NICNAS ended on August 31, 2022. On September 13, 2023, AICIS announced that the recordkeeping provisions for introducers that transitioned from NICNAS to AICIS, which were set to end on November 30, 2023, will continue to be available until **April 1, 2024**. AICIS notes that these arrangements apply only to "eligible introducers who are still importing or manufacturing chemicals that were previously on the NICNAS Inventory." Introducers must meet certain requirements to be eligible to use the temporary recordkeeping provisions.

AICIS announced on September 15, 2023, a public consultation on a suite of regulatory proposals relating to categorization, reporting, and recordkeeping obligations. According to AICIS, it has explored possible solutions to address stakeholder advice regarding the challenges of compliance with certain requirements of the Industrial Chemicals (General) Rules 2019. AICIS also identified aspects of the Rules that it thinks should be strengthened to ensure protection of human health and the environment or to clarify the intent of certain requirements. The proposals use an evidence- and risk-based approach to regulation that is appropriate to each circumstance. Comments were due November 9, 2023. Expect further clarification on AICIS and additional guidance to support impacted stakeholders in 2024.

2. China

a. Chemical Substances

Many of the regulatory developments initiated in 2020 by the Ministry of Ecology and Environment (MEE) continue to evolve. China's new overarching Law on Safety of Hazardous Chemicals, with the latest changes made in February 2021, continues to progress toward final form.

The draft Law on Safety of Hazardous Chemicals remains Priority 1 on the National People's Congress's (NPC) Five-Year Legislative Plan for its current term (the 14th) ending in **2028**, based on NPC's September 7, 2023, update. In July 2022, the State Council of China proposed 16 draft laws to be deliberated by the NPC Standing Committee. The State Council continues preparation and submission of 26 additional draft laws for such deliberation, including the draft Law on Safety of Hazardous Chemicals. This law will replace the 2011 Regulations on the Control over Safety of Hazardous Chemicals (*i.e.*, Decree 591), which established a hazardous chemicals information management system, implemented electronic identification, and initiated whole life cycle information management of hazardous chemicals.

Even though the Law on Safety of Hazardous Chemicals remains in draft in the NPC, in 2023, MEE issued a number of related legislative updates on regulations and standards. These include implementation of the List of New Pollutants for Priority Management (2023) and publication and enforcement of the Inventory of Severely Restricted Toxic Chemicals (2023). The List of New Pollutants for Priority Management, released on November 29, 2022, includes the POPs specified in the Stockholm Convention, new pollutants that have been included in the list of toxic and harmful air or water pollutants that are subject to key management and control, an environmental endocrine disruptor (nonylphenol) that has attracted great public attention, antibiotic substances of high global concern, and POPs that have been eliminated in China. After issuing this List, MEE announced the Inventory of Severely Restricted Toxic Chemicals (2023) on October 18, 2023. This list revises the 2020 version and intends to align with the Stockholm Convention, the Minamata Convention, and the Rotterdam Convention. A total of nine types of chemical substances such as PFOA, PFOS, polychlorinated terphenyls (PCT), tributyltin compound, and mercury are included in the list. Publication and implementation of these lists align with MEE's **2035** action plan.

MEE issued a Notice on Collecting Public Opinions on the Technical Specification for Nomenclature of Chemicals for Environmental Management (Draft for Comments) on May 5, 2023, to standardize chemical substance nomenclature for new chemical substance environmental management and registration, and for the management of the Inventory of Existing Chemical Substances in China (IECSC). This is the first time a Technical Standard, which regulates the nomenclature of chemical substances for environmental management, has been published. China continues to update its IECSC. As of June 2023, MEE had released 18 supplemental notices, with a total of 1,286 substances, added to the IECSC.

China's National Medical Products Administration (NMPA) continued to make progress in 2023 on Cosmetics Supervision and Administration Regulation (CSAR) subsidiary regulations.

b. Cosmetics and Cosmetic Ingredients

China's National Medical Products Administration (NMPA) continued to make progress in 2023 on Cosmetics Supervision and Administration Regulation (CSAR) subsidiary regulations. On March 31, 2023, NMPA issued the final Measures for the Supervision and Administration of Cosmetics Online Operations, with an effective date of September 1, 2023. This is China's first regulation specifically published for cosmetic online operation and supervision, covering specific measures for management requirements, operations, supervisions, and administrations for cosmetic e-commerce platform.

Beginning January 1, 2023, the CSAR shifted the burden of safety and efficacy requirements to industry. All ingredients in cosmetics products must now include verified safety-related information, including ingredient quality specifications, safety risk substance control, ingredient safety risk assessment conclusions, and other safety-related information, for registration or notification. Labeling under CSAR requires that all product ingredients be listed on the label, including trace ingredients. Products registered or notified before May 1, 2022, had until May 1, 2023, to update labeling. NMPA issued an announcement on Matters Related to Further Optimizing Safety Information Management Measures for Cosmetic Raw Materials on March 22, 2023, to standardize further product quality and safety requirements. Applicants can use the ingredient submission code, if available, and/or fill out the required information and submit it via the NMPA submission platform. NMPA also extended the ingredient submission deadline for registered cosmetics to January 1, 2024.

In a move to align with the cosmetic regulation, the State Administration for Market Regulation (SAMR) announced the release of the Regulations on Supervision and Administration of Toothpaste on March 16, 2023, with an implementation date of December 1, 2023. This Measure explicitly states that toothpaste should be managed in accordance with provisions related to general cosmetics, and it includes specific guidance information, such as efficacy claims, label requirements, safety monitoring for toothpaste raw materials, accountability, compliance, and legal liabilities. Following that, on September 5, 2023, NMPA announced the Implementation of Toothpaste Regulatory Regulations and Implications of the Filing Requirements for Toothpaste on the Market, providing a simplified filing process for those that are already on the market. Labels for these toothpaste products are required to be updated by **July 1, 2024**, and the registrants also need to submit and publish the abstracts regarding the basis for product efficacy claims by **December 1, 2025**, except for those only claiming a cleaning function.

In addition, on May 11, 2022, NMPA issued the "14th Five-Year Plan for Network Security and Information Construction on Medical Products Supervision," which introduces requirements for provincial medical products administrations (MPA) on the supervision of medical products, cosmetics, and medical devices. For cosmetics, this plan requires provincial MPAs to tighten further the supervision of cosmetics, build a nationally integrated monitoring system for cosmetic adverse reactions, and improve the archive management of cosmetics. On August 28, 2023, NMPA published the final Measurement Methods for pH Value of Water-in-Oil Cosmetics and announced the inclusion of a total of 21 revised items into the 2015 edition of the Safety Technical Specifications for Cosmetics, effective immediately or by **March 1, 2024**. Expect further development of systems and guidance on these aspects of cosmetic legislation in 2024.

c. Food Contact Substances

China continued its work on assessing and regulating FCMs during 2023. On February 13, 2023, the National Health Commission (NHC) released the draft No. 1 Amendment to GB 9685-2016, Standard for the Use of Additives in Food Contact Materials and Articles, along with 37 other draft GB food standards. GB 9685-2016 is one of the key standards under China's FCM regulatory system, which provides standards for use of additives in the production of FCMs and articles. According to the draft amendment, additives approved for use in rubber are now also allowed for use in silicone rubber. Corrections to the specific migration limits for 5-Isobenzofurancarbonyl chloride, 1,3-dihydro-1,3-dioxo-, polymer with 4,4′-meth-

ylenebis[benzenamine], and the addition of three new categories of specific migration limits are included in the draft amendment. China expects to continue assessing FCMs in the coming year and updating its food positive list.

The NHC continued its efforts in 2023 to revise food standards. On September 25, 2023, the NHC released a notice of 85 national food safety standards and three amendments (NHC Announcement No. 6 of 2023). Among the standards, 17 are related to FCMs, including five for FCM product standards, two general principles, and ten inspection methods. A new food contact ink standard (GB 4806.14-2023), effective **September 6, 2024**, is included in this announcement. Revisions to food contact plastics (GB 4806.7-2023), metals (GB 4806.9-2023), rubber (GB 4806.11-2023), and composite materials (GB 4806.13-2023) are also provided. In October 2023, the NHC published the consultation drafts of 11 national food safety (GB) standards, including two significant standards related to FCMs, the proposed revised version of GB 4806.1 General Safety Requirements for Food Contact Materials and Articles, and the new GB 4806.XX Silicon Rubber Materials and Articles in Contact with Foodstuffs. Expect the development of additional use-specific standards in 2024.

3. India

On September 30, 2023, the Department of Revenue's Central Board of Indirect Taxes & Customs (CBIC) issued Circular No. 23/2023-Customs regarding mandatory additional qualifiers in import/export declarations in respect of certain products. Beginning October 15, 2023, import declarations for chemicals (bulk and basic chemicals; formulations and mixtures; and proprietary components, R&D substances, or others) must include additional information. For bulk and basic chemicals, the CAS RN and International Union of Pure and Applied Chemistry (IUPAC) name is mandatory. For the other two categories, the CAS RN and IUPAC name of at least one main or active ingredient is mandatory. If the supplier did not share the information because of confidentiality concerns, a declaration on non-availability must be filed. Although the Circular notes that CBIC consulted with the Department of Chemicals and Petrochemicals (DCPC), as well as stakeholders, industry representatives have expressed concern that the protection for CBI is insufficient.

India's Chemicals (Management and Safety) Rules, 20XX (Rules), continues to be delayed and may not progress before India's next general election, which is due to take place by **May 2024**. In September 2020, the government circulated a fifth draft of the Rules to certain industry groups. Under the fifth draft, priority substances are defined as:

- Any substance that falls under any of the following hazard classifications of the eighth revision (Rev 8) of the UN GHS:
  - Carcinogenicity and/or germ cell mutagenicity and/or reproductive toxicity and categorized as Category 1 or 2; or
  - Specific target organ toxicity (repeated exposure or single exposure) Category 1 or 2; or
- Any substance that fulfills the criteria of PBT or vPvB, as set out in Schedule I; or
- Any of the 750 substances listed in Schedule II.

Under the fifth draft, substances listed in Schedule II that are imported in volumes above one metric ton annually would have to be registered within 18 months of the Rules coming into effect unless already registered under another regulation in India. Schedule IV lists substances exempt from Chapters III (notification, registration, and restrictions on use) and V (labeling and packaging). Hazardous chemicals include substances that satisfy any of the criteria laid down in Part I of Schedule X, any substance listed in Part II of Schedule X, any substance listed in column 2 of Schedule XI, and any substance listed in column 2 of Schedule XII. Companies would be required to submit information on the import of priority and hazardous substances at least 30 days before import.

4. New Zealand

The New Zealand Environmental Protection Authority (New Zealand EPA) announced on February 17, 2023, a work plan for all New Zealand EPA-initiated reassessments of hazardous substances over the **next three years**. The plan includes indicative start dates for each reassessment, reasons for reassessing a substance, and the existing hazardous substance approvals that may be affected. According to New Zealand EPA, all hazardous substances must be approved to be used in New Zealand, and it is "constantly reviewing the list of approved chemicals as new information becomes available." New Zealand EPA reassesses approved hazardous substances if there is a risk to human health or the environment. It makes a decision at the end of the process on whether to change the rules for using a substance, further restrict its use, or ban a

substance entirely. New Zealand EPA notes that there are 15 reassessments currently in progress or due to begin in the next three years, including for aquatic herbicides, synthetic pyrethroids used in insecticides, and domestic use of vertebrate toxic agents (used to kill or control pests such as rodents).

On March 2, 2023, New Zealand EPA announced a public consultation on proposed updates to the Cosmetic Products Group Standard. The proposed updates:

- Align the rules for ingredients with the EU;
- Phase out PFAS ingredients by the **end of 2025**;
- Extend the group standard to cover more products; and
- Other updates, including requiring clear recordkeeping for nanomaterials, updating requirements for fragrances, consolidating the main text and Schedules 4 to 8 into one document, and improving the presentation and usability of the group standard.

Comments were due May 31, 2023.

The New Zealand EPA announced on August 16, 2023, the international regulators on which it can draw for information used in some hazardous substance assessments. The regulators are from Australia, Canada, the EU, the UK, and the United States — "all of which regulate hazardous substances in a similar way to our own system." New Zealand EPA will use information from the recognized international regulators to assess and reassess hazardous substances through two new pathways aimed at streamlining the processes:

- Approving a substance via a rapid assessment if the same use has been approved by a recognized international regulator, unless it will have significant cultural, environmental, and/or human health effects; and
- Amending the hazard classifications or rules for use of an existing substance to align with recognized regulators.

The change entered into force on October 1, 2023. New Zealand EPA states that it will work with relevant industries to develop guidance for the new pathways, including the information that will be required.

5. South Korea

a. K-REACH

South Korea's Act on the Registration and Evaluation of Chemicals (K-REACH), which came into effect in 2019, requires in-country manufacturers and importers to register substances in a series of volume-based deadlines through **2030**. In January 2023, K-REACH was amended to add reporting requirements for companies importing or manufacturing products containing priority control substances. Under the amendment, manufacturers and importers of products containing priority control substances must continue to report when the following conditions are met:

- The company is manufacturing or importing products containing more than 0.1 percent (by weight) of priority control substances; and
- The total volume of priority control substances in the products exceeds one metric ton per year.

Effective immediately, the amendment requires companies to report:

- Changes in the exposure to priority control substances in the product;
- Changes in the use of the product;
- Changes in the content levels of priority control substances in the product; or
- Other changes determined by the Ministry of Environment (MoE) in individual cases.

Companies must report the changes by the end of the following January.

Effective **January 3, 2024**, when there is a change in the ownership or succession for companies that import or manufacture priority control substances, the change must be reported within one month of the occurrence.

On August 31, 2023, MoE notified the World Trade Organization (WTO) of partial amendments to the K-REACH enforcement decree and enforcement rule that would implement these amendments. The draft partial amendment of the K-REACH enforcement decree would:

Under South Korea's Consumer Chemical Products and Biocides Safety Act (K-BPR), manufacturers and importers of existing biocides must obtain substance approval within a specified grace period.

- Enable ORs to report changes of priority control substances in products and the newly amended duty;
- Allow the tasks of reporting changes of priority control substances in products and the newly amended duty to be done via the government's online system;
- Specify that reporting changes of priority control substances in products should be submitted to the heads of regional environmental offices; and
- Depending on how many times a person has failed to report the changes of priority control substances in products and the newly amended duty, increase the maximum fine to 10,000,000 South Korean wons (KRW).

The draft partial amendment of the K-REACH enforcement rule would:

- Simplify the provision of information on chemical substances;
- Amend the criteria for reporting changes on priority control substances so that only when the amount contained in a product changes more than 50 percent, the change must be reported;
- Change the reporting fee for the initial notification to 20,000 KRW and change the reporting fee for changes to the notification to 15,000 KRW.

Comments were due October 24, 2023. The WTO notifications state that the proposed date of adoption for each draft partial amendment is **January 4, 2024**.

b. K-BPR

Under South Korea's Consumer Chemical Products and Biocides Safety Act (K-BPR), manufacturers and importers of existing biocides must obtain substance approval within a specified grace period. Currently, the following grace periods remain open:

- **December 31, 2024**, for wood preservatives, vertebrate control substances, and invertebrate control substances;
- **December 31, 2027**, for product, surface, textile, and leather preservatives; and
- **December 31, 2029**, for preservatives for materials, construction, and equipment, and for use in taxidermy and marine antifouling agents.

Although the grace period for disinfectants, algicides, rodenticides, insecticides, and repellents expired on December 31, 2022, because less than half of the submitted substances were approved, South Korea's National Institute of Environmental Research (NIER) allowed more time for some submissions.

Registrants of wood preservatives, vertebrate control substances, and invertebrate control substances have until **December 31, 2024**, to obtain approval. NIER estimates that the approval process takes 18 months, so registrants for these products should have already submitted their approval dossiers. In May 2023, NIER published guidelines that exempted registrants producing wood preservatives that are listed under national standard KSM 1701 from submitting certain data.

6. Taiwan

Because more than a dozen different regulatory agencies regulate chemical substances under 19 different statutes, the Legislative Yuan requested that regulation be simplified and the management of chemicals of concern be enhanced. Under the Organization Act of the Ministry of the Environment, the Taiwan Environmental Protection Administration (Taiwan EPA) has been restructured to create a Ministry of Environment (MOENV) and four tertiary agencies, including the Chemicals Administration. According to a spokesperson for the Toxic and Chemical Substances Bureau (TCSB), now the Taiwan Chemical Administration (TCHA), TCHA will act

as a "single window" to simplify and harmonize chemicals management. The head of TCHA will be a political affairs officer, appointed by the prime minister, rather than a common affairs officer like the head of TCSB.

According to MOENV's website, MOENV's objectives include:

> Expand the targets of chemical substance management to all chemical substances used in Taiwan, follow the principles of "source management extends the border, reduces breakpoints and prevents illegality", "connect and integrate disaster prevention resources, strengthen response and reduce losses from incidents", "transmit complete hazard information, reduce health risk exposure" and "sustainable and non-toxic transformation of resources, in line with international conventions and management", and other goals.

7. Vietnam

On April 28, 2022, based on comments and survey results received in 2021, Vietnam's Ministry of Industry and Trade (MOIT) published draft amendments to Circular No. 32/2017/TT-BCT as implementation guidelines to Decree No. 113/2017 and the Law on Chemicals. This amendment was signed on October 27, 2022, and went into effect on December 22, 2022, with the exception of Clause 6 in Article 1 regarding the annual report process, which was effective in December 2023.

On June 26, 2023, the Ministry of Natural Resources and Environment (MONRE) of Vietnam published Decision 1701/QD-BTNMT on Guidance for Implementation of Administrative Procedures in the Environmental Sector. The Decision, effective the same day, outlines the newly mandated administrative processes for environmental protection as set forth in the Environmental Protection Law (72/2020/QH14), which underwent a complete amendment in 2020. The Decision contains 11 administrative processes and appendices in the field of environmental protection, including comprehensive instructions for issuance of environmental permits, authorization for handover of hazardous waste, registration for the exemption of POPs, and other procedures.

CONTRIBUTORS

CARLA N. HUTTON, MEIBAO ZHUANG, PH.D., KARIN F. BARON, MSPH



APPENDIX A: SPEECHES AND WRITINGS

BOOKS

Lynn Bergeson, Richard E. Engler, Ph.D., Carla N. Hutton, and Todd J. Stedeford, Ph.D., DABT®, ERT, ATS, co-authors, "Pesticides, Chemical Regulation, and Right-to-Know, 2022 Annual Report," in *Environment, Energy, and Resources Law: The Year in Review 2022*, American Bar Association (2023).

ARTICLES

Recent articles on critical issues:

Lynn L. Bergeson, "EPA Proposes Revised PBT Rules for decaBDE and PIP (3:1)," *Chemical Processing,* December 11, 2023.

Lynn L. Bergeson, "Reporting PFAS: Reporting Burden Is the Least of Businesses' Worries," *Financier Worldwide*, December 2023.

Lynn L. Bergeson, "EPA Proposes Ban on Trichloroethylene," *Chemical Processing*, November 17, 2023.

Lynn L. Bergeson, "EPA Issues Final Rule on TSCA PFAS Reporting Requirements," *Chemical Processing*, October 16, 2023.

Lynn L. Bergeson, "National Science and Technology Council Releases Sustainable Chemistry Report," *Chemical Processing*, September 15, 2023.

Lynn L. Bergeson, "EPA Rolls Out New PFAS Framework," *Chemical Processing,* August 16, 2023.

Lynn L. Bergeson, "TSCA, SNURs, and Plastic Waste-Based Feedstocks," *Chemical Processing*, July 18, 2023.

Lynn L. Bergeson, "Expanding PFAS Liability in the US," *Financier Worldwide,* July 2023.

Richard E. Engler, Ph.D., and Todd J. Stedeford, Ph.D., DABT®, ERT, ATS, "What Are the Key Elements and Likely Impact of the EPA's Proposed Rule for Methylene Chloride?," *Chemical Watch,* June 21, 2023.

Lynn L. Bergeson, "Toxics Release Inventory Reporting: What Is New This Year?," *Chemical Processing,* June 9, 2023.

Lynn L. Bergeson, "EPA Proposes to Ban Most Uses of Methylene Chloride," *Chemical Processing*, May 10, 2023.

Lynn L. Bergeson, "TSCA Litigation: The Case to Watch," *Speciality Chemicals Magazine*, May/June 2023.

Lynn L. Bergeson, "EPA Can Lead or Get Out of the Way," *The Environmental Forum*, May/June 2023.

Lynn L. Bergeson, "Congress Strengthens Cosmetics Regulations," *Chemical Processing*, April 12, 2023.

Lynn L. Bergeson, "Maine Clarifies PFAS Product Reporting Requirements," *Chemical Processing*, March 20, 2023.

Lynn L. Bergeson and L. Claire Hansen, "Toxic Substances Law Creating More Confusion for Legal Teams and Public," *Chemical Processing*, February 15, 2023.

Lynn L. Bergeson, "Risky Business: Deciding Whether Chemicals Pose Risk Is Getting Really Confusing," *American College of Environmental Lawyers (ACOEL) Blog*, January 27, 2023.

Lynn L. Bergeson, "Chemical Compliance: FTC To Revise Green Guides, Again," *Chemical Processing,* January 10, 2023.

PRESENTATIONS

Materials from recent presentations are available by request — e-mail hlewis@lawbc.com.

"TSCA Section 6 — Risk Management," Richard E. Engler, Ph.D., HCPA XPAND2023, (December 5, 2023).

"Antimicrobial resistance regulation in the context of one health: how legislation can help reduce AMR," Lynn L. Bergeson (chair), IBA 2023 Annual Conference (October 31, 2023).

"Challenges Facing EPA's Pesticide and Chemical Programs Response to PFAS Issues," James V. Aidala, 2023 Center for PFAS Research Annual Symposium (October 24, 2023).

"Careers in Chemicals," Lynn L. Bergeson, ABA Section of Environment, Energy, and Resources' (SEER) Pesticides and Chemicals Committee (October 20, 2023).

"TSCA Fundamentals," Catherine M. Croke, DBA, and Richard E. Engler, Ph.D., Chemical Watch (October 10-11, 2023).

"The European Commission Chemicals Strategy for Sustainability and Its Impacts on CLP," Karin F. Baron, MSPH SCHC 2023 Annual Meeting (October 4, 2023).

"Regulatory Jurisdiction Workshop," Karin F. Baron, MSPH, and Richard E. Engler, Ph.D., SCHC 2023 Annual Meeting (October 2, 2023).

"Reporting and Restriction at the Federal Level," Lynn L. Bergeson, PFAS Updates USA 2023 (September 27, 2023).

"Legal requirements of the Federal Trade Commission (FTC) Green Guides," Lisa R. Burchi, Regulatory Summit Americas 2023 (September 25, 2023).

"TSCA reporting including PFAS and Asbestos," Lynn L. Bergeson, Regulatory Summit Americas 2023 (September 25, 2023).

"Use and Regulation of Chemicals," Lynn L. Bergeson, Environmental Regulation in Practice 2023: New Challenges and Priorities (August 2, 2023).

"New Chemical Review," Richard E. Engler, Ph.D., TSCA Reform — Seven Years Later (June 29, 2023).

"Special Lunch Discussion with Former Toxics Assistant Administrators," James V. Aidala and Lynn L. Bergeson (moderator), TSCA Reform — Seven Years Later (June 29, 2023).

"Reflections on the Current State of TSCA Implementation," Lynn L. Bergeson, TSCA Reform — Seven Years Later (June 29, 2023).

"Circular Routes and Chemical Nomenclature," Richard E. Engler, Ph.D., 27th Annual Green Chemistry & Engineering Conference (June 14, 2023).

"Navigating Non-Alignment of PFAS Regulation in the EU, UK, and US," Lynn L. Bergeson, Lexology (June 7, 2023).

"TSCA Fundamentals," Catherine M. Croke, DBA, and Richard E. Engler, Ph.D., Chemical Watch (June 6-8, 2023).

"Product Stewardship in a Regulated World," Catherine M. Croke, DBA, HCPA IMPACT2023 (May 5, 2023).

"IRS Issues Proposed Superfund Chemical Excise Tax Regulations — What Now, What is Next?," Richard E. Engler, Ph.D., National Association of Chemical Distributors (NACD, now ACD) Webinar (April 27, 2023).

"CLP/GHS: Effects of New Hazard Classes and Implications for GHS," Karin F. Baron, GlobalChem 2023 (April 5, 2023).

"New Chemicals — Breakout Session," Richard E. Engler, Ph.D., GlobalChem 2023 (April 4, 2023).

"TSCA litigation," Lynn L. Bergeson, TSCA Developments 2023 (March 7, 2023).

"Emerging Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) legal and policy issues and the Congress: Implications for the pesticide community," Dennis R. Deziel and Meibao Zhuang, Ph.D., Biocides North America 2023 (February 28, 2023).

"2023 Chemicals Overview: Trends in Regulation and Emerging Contaminants," Lynn L. Bergeson, Environmental Law 2023 (February 17, 2023).

"Analyzing the EPA's Proposal to List PFAS Chemicals as Hazardous Substances," Lynn L. Bergeson, Environmental Law Institute (January 30, 2023).

APPENDIX B: WEBINARS AND PODCASTS

2024 COMPLIMENTARY WEBINAR SCHEDULE

B&C's complimentary webinars feature leading figures from government, industry, and private practice analyzing and advising on pressing chemical policy issues to equip regulatory professionals to succeed in an ever-changing regulatory environment. More information and registration details are available at www.lawbc.com/seminars-webinars.

Topic	Date and Time (subject to change)
What to Expect in Chemicals Policy and Regulation and on Capitol Hill in 2024 Register now	January 23, 2024 11:00 a.m. - 12:00 p.m. (EST)
FIFRA Hot Topics Register now	March 12, 2024 11:00 a.m. - 12:00 p.m. (EDT)
Harmonizing TSCA Consent Orders with OSHA HCS 2012 Register now	May 14, 2024 11:00 a.m. - 12:00 p.m. (EDT)
PFAS — Determining PFAS Content in Your Organization and Expanding Data Collection Practice	July 23, 2024 11:00 a.m. - 12:00 p.m. (EDT)
An Update on the EU Chemical Strategy for Sustainability with EPPA	September 18, 2024 11:00 a.m. - 12:00 p.m. (EDT)
Consumer Labeling and the Status of GHS	November 12, 2024 11:00 a.m. - 12:00 p.m. (EST)

WEBINARS AVAILABLE ON DEMAND

Watch B&C and Acta webinar recordings on our Vimeo channel: https://vimeo.com/showcase/bergesonandcampbell.

It's Not as Easy as It May Appear: Bringing Sustainable Chemistry to Market in the U.S.
View on demand: https://vimeo.com/884911144.

Increasingly, chemical and product innovators, businesses, and others are more discerning in selecting and using raw materials based on new criteria heavily influenced by sustainability factors. During this webinar Richard E. Engler, Ph.D., Director of Chemistry, B&C; Amir Mahmoudkhani, VP of R&D and Innovation, Locus Fermentation Solutions; Molly Blessing, Director of Sustainability, Household and Commercial Products Association; and Lynn L. Bergeson, Managing Partner, B&C, explore the challenges entities face in making chemical products more sustainable, what the federal government is doing to encourage sustainable chemistry, and how stakeholders can help move the needle to accelerate the pace of sustainable chemistry.

Product Stewardship Practices for Effective Supply Chain Interaction
View on demand: https://vimeo.com/850914224.

International compliance in today's evolving regulatory arena presents challenges to organizations as supply chain networks must support operations with ever-changing regulations and requirements. During this webinar, Catherine M. Croke, DBA, Director of Product Stewardship and Regulatory Affairs, B&C; Lee A. Bowers, Vice President, Environmental Health & Safety, RPM International Inc.; Michael J. Ford, President, Tradebridge Consulting; and Lynn L. Bergeson, Managing Partner, B&C explore current and proposed international regulations and restrictions in developed and emerging legislation and provide examples informing and proactively promoting product stewardship practices and regulatory compliance in supply chains.

Preparing a PFAS Game Plan in the U.S., the UK, and the EU
View on demand: https://vimeo.com/844336624.

PFAS are attracting global legal, regulatory, commercial, and litigation attention as no other "emerging contaminant" has. Companies producing, processing, distributing, and/or using these substances must be aware of these global legal developments and take steps now to minimize legal, regulatory, and commercial risk. During this webinar, co-hosted with EPPA, Meglena Mihova, Managing Partner, EPPA; Richard E. Engler, Ph.D., Director of Chemistry, Acta; and Lynn L. Bergeson, President, Acta, discuss how best to respond to U.S., UK, and EU PFAS developments influencing market access, supplier continuity, product sustainability, and reputation management.

TSCA Reform — Seven Years Later
The Environmental Law Institute (ELI), the George Washington University Milken Institute School of Public Health, and B&C hosted the seventh annual TSCA Reform conference, providing updates and insights regarding the current state of TSCA implementation, ongoing and emerging issues, and related developments. Topics include risk evaluations, risk management, new chemical review, and PFAS.

A full recording of the event, additional suggested readings, and other resources are available on the ELI website for members of ELI. Audio recordings of the panels are available as episodes of the podcast *All Things Chemical*® — *see* Podcasts section below.

TOP TSCA Topics: PFAS, Cumulative Risk, NAMs, Risk Evaluations, CBI, and More!
View on demand: https://vimeo.com/827721391.

As EPA advances NAMs, cumulative risk assessment methodologies, and systematic review procedures, chemical stakeholders must understand directionally how these initiatives are influencing EPA decisions under TSCA Sections 5 and 6. During this webinar, Anna B. Lowit, Ph.D., Senior Science Advisor, EPA, OPPT; Richard E. Engler, Ph.D., Director of Chemistry, B&C; and Lynn L. Bergeson, Managing Partner, B&C, discuss groundbreaking science policy initiatives in furtherance of implementation of TSCA.

Extended Producer Responsibility Regulations
View on demand: https://vimeo.com/810655656.

Rooted in the circular economy concept and the "polluter pays" principle, extended producer responsibility (EPR) laws have a long tradition in Europe for many product categories, including packaging. In the United States, EPR is much newer and is viewed as a funding mechanism to support recycling programs by shifting the responsibility to pay for these programs from municipal, public sources to private, product producer sources. During this webinar, LeRoy (Lee) C. Paddock, Distinguished Professorial Lecturer of Environmental Law at the George Washington University Law School; Edith G. Nagy; and Lynn L. Bergeson, Managing Partner, B&C, explore the history and evolution of EPR legislation, expected developments that will affect the chemical and chemical product industry, and what companies need to know to prepare for these changes.

What to Expect in Chemicals Policy and Regulation and on Capitol Hill in 2023
View on demand: https://vimeo.com/794645051.

In 2023, concepts core to TSCA, including "reasonably foreseen," "to the extent necessary," "systematic review," and "best available science," continued to evolve and not always in predictable, coherent, and consistent ways. Similar policy shifts were seen in the agricultural and biocidal area, with perhaps less dramatic effect. During this forward-looking webinar from January 2023, Lynn L. Bergeson, James V. Aidala, Richard E. Engler, Ph.D., and Dennis R. Deziel offered their best informed judgment as to the trends and key developments chemical industry stakeholders should expect to see from EPA in 2023.

Two Years Later: How Has the Chemicals Strategy for Sustainability Changed REACH and CLP Regulations?
View on demand: https://vimeo.com/811021518.

The EC's Chemicals Strategy for Sustainability set into motion a series of remarkable actions by ECHA intended to transform the EU into a sustainable and carbon neutral economy while improving protection of its people and the environment. During this webinar, Meglena Mihova, Managing Partner, EPPA; Thomas Petry, Ph.D., Managing Director, ToxMinds; Jane S. Vergnes, Ph.D., DABT®, Vice President, Scientific Affairs, Director of Toxicology, Acta; and Lynn L. Bergeson, President, Acta, explore exactly how the Chemicals Strategy for Sustainability is fundamentally reshaping REACH and the CLP regulations in ways that are resetting the global stage in terms of identifying new hazard classes and NAMs for identifying them.

PODCASTS

All Things Chemical® engages listeners in intelligent, insightful conversation about everything related to industrial, pesticidal, and specialty chemicals and the law and business issues surrounding chemicals. B&C's talented team of lawyers, scientists, and consultants keeps listeners abreast of the changing world of both domestic and international chemical regulation and provides analysis of the many intriguing and complicated issues surrounding this space. The issues that B&C pursues in its day-to-day business are unfailingly interesting, and we wish to share our knowledge, our insights, and our enthusiasm for these issues with you through our *All Things Chemical* podcast. *All Things Chemical* is available now on Apple Podcasts, Google Podcasts, and Spotify, with new episodes released approximately every two weeks. Subscribe so you never miss an episode. *All Things Chemical* is recorded and produced by Bierfeldt Audio, LLC.

EPA's Proposed Registration of a Sprayable RNAi Biopesticide — A Conversation with Meibao Zhuang, Ph.D.
Lynn L. Bergeson and Meibao Zhuang, Ph.D. discuss EPA's proposed registration of the first sprayable RNAi biopesticide and the exciting implications of this technology. Double-stranded (ds) RNAi is a technology that allows scientists to silence (or interfere with) a particular gene. In the agricultural sector, this genetic modification can be used to great advantage to control pests of all sorts with extreme precision.

Community Outreach and Environmental Justice — A Conversation with Rachel James of the SELC — *transcript available*
Lynn L. Bergeson and Rachel James, an attorney with the Southern Environmental Law Center (SELC) discuss the Biden-Harris Administration's commitments to environmental justice and accounting for susceptible subpopulations.

Rev 10 GHS — A Conversation with Karin F. Baron — *transcript available*
Lynn L. Bergeson and Karin F. Baron, MSPH discuss Revision 10 of the GHS, including changes to "weight of evidence," the classification of ozone-depleting chemicals, precautionary statements and much more.

Sessions from TSCA Reform — Seven Years Later
On June 29, 2023, B&C, along with ELI and the George Washington University Milken Institute of Public Health, sponsored the all-day virtual conference, TSCA Reform — Seven Years Later. The quality of the discussion, the caliber of the participants, and the timeliness of the content motivated us to repurpose the substantive sessions to enable our podcast audience to listen to the sessions in this venue.

- TSCA Reform — Seven Years Later: Risk Evaluation Session
- TSCA Reform — Seven Years Later: Risk Management Session
- TSCA Reform — Seven Years Later: New Chemicals Review Session
- TSCA Reform — Seven Years Later: Per- and Polyfluoroalkyl Substances (PFAS) Session

Lessons in Effective Government Advocacy — A Conversation with Mark Washko — *transcript available*
Lynn L. Bergeson and Mark Washko, Head of Federal Government Affairs at BASF Corporation, discuss how to advocate on complex science policy and chemical issues clearly and in a way that is relatable and how to remain respectful when addressing issues about which we care deeply.

Section 6 Advocacy and the Importance of Being Early — A Conversation with Richard E. Engler, Ph.D. — *transcript available*
Lynn L. Bergeson and Richard E. Engler, Ph.D. discuss the importance of engaging early and often with the EPA in the TSCA Section 6 risk evaluation process, including conditions of use (COU) of a chemical being evaluated by EPA, the reasons why educating EPA on COUs is critically important to regulated businesses, the relevance of ECELs, and the consequences of a SNUR for use conditions out of scope of a risk evaluation.

Competitive Advantage of Product Stewardship — A Conversation with Catherine M. Croke, DBA — *transcript available*
Lynn L. Bergeson and Catherine M. Croke, DBA explore how employee and management engagement in product stewardship is essential, how products can be brought to market faster, how fulfilling customer expectations is part of the equation, and how to measure the business success of implementing an effective product stewardship program.

The Hazard Communication Standard — A Conversation with Lesa Rice-Jackson, CPPS, Ph.D. — *transcript available*
Lynn L. Bergeson and Dr. Lesa Rice-Jackson, CPPS, Ph.D., Managing Principal Consultant, Rice Jackson Health Safety & Regulatory Compliance Consulting, discuss the pending amendments to the OSHA HCS, key issues likely to complicate compliance, and how best to balance occupational

safety and health compliance with emerging and more rigorous best practice standards.

CLP Changes — A Conversation with Lee Bowers and Karin F. Baron — *transcript available*
Lynn L. Bergeson, Karin F. Baron, MSPH, and Lee Bowers, Vice President — EHS, RPM International, Inc., discuss the consequential changes to the CLP system in the EU and the lack of alignment between CLP and GHS.

A Conversation with Rear Admiral Melissa Bert, Esquire (Ret.) — *transcript available*
Lynn L. Bergeson and Retired Rear Admiral Melissa Bert discuss Coast Guard responsibilities, what the Chief Counsel of the Coast Guard does, some of Admiral Bert's more memorable engagements, and the Admiral's founding of the Coast Guard Women's Leadership Initiative and Leadership Diversity Advisory Council.

A Conversation with Shanisha Y. Smith, Esquire — *transcript available*
Lynn L. Bergeson and Shanisha Smith, Health, Safety, and Environmental (HSE) Counsel for LyondellBasell, discuss Ms. Smith's role as counsel and the rewards and challenges of advising a major chemical producer on HSE legal and product stewardship issues.

PFAS under REACH — A Conversation with Jane S. Vergnes, Ph.D. — *transcript available*
Lynn L. Bergeson and Jane S. Vergnes, Ph.D., DABT® discuss the regulation of PFAS under REACH: the risk options ECHA considered, what it has proposed, some legal vulnerabilities with the approach ECHA has taken that commentators are discussing, and how best to prepare for the final restrictions, whenever they are issued and in whatever form.

PMN Review and Orders — A Conversation with Richard E. Engler, Ph.D. — *transcript available*
Lynn L. Bergeson and Richard E. Engler, Ph.D., discuss a lawsuit challenging EPA's issuance of a Consent Order under Section 5(e) of TSCA, the concept of "chemical categories" under Section 5, concerns with EPA's new chemical review process, and EPA's assessment and communication of risk in the new chemicals it reviews under Section 5.

TSCA: New and Old — A Conversation with the Legendary Robert M. Sussman — *transcript available*
Lynn L. Bergeson and Robert M. Sussman, of Sussman & Associates and frequent senior official at EPA before TSCA was amended in 2016, discuss the implementation of new TSCA and possibilities for the future of chemical management.

Modernization of Cosmetic Regulations Act of 2022 — A Conversation with Karin F. Baron — *transcript available*
Lynn L. Bergeson and Karin F. Baron, MSPH, discuss the most consequential new regulatory provisions MoCRA imposes and explains when they are effective and how they will impact the manufacture and marketing of cosmetic products.

The East Palestine Train Derailment: Behind the Scenes with Three Former Government Officials — *transcript available*
Lynn L. Bergeson and former government representatives, James V. Aidala, Dennis R. Deziel, and Richard E. Engler, Ph.D., discuss what happens when the call comes in reporting on a major incident, how did each plan for the unexpected, what are the key challenges in communicating risk information about chemicals to the public, and their thoughts on restoring trust in what the government reports during major incidents.

What is Product Stewardship's Value to a Company? — A Conversation with Tina N. Armstrong, Ph.D. — *transcript available*
Lynn L. Bergeson and Dr. Tina N. Armstrong, a Vice President with Arcadis U.S., Inc., discuss the role of product stewardship in business organizations today, its origins, its value to companies, particularly those in the chemical and chemical product manufacturing sector, and the essential elements of a stewardship team.

Product Stewardship, Supply Chain, and Downstream User Engagement — A Conversation with Catherine M. Croke, DBA — *transcript available*
Lynn L. Bergeson and Catherine M. Croke, DBA, discuss the expanding role and growing importance of product stewards in corporate America today, what product stewardship is, the value this role offers to companies, and where to begin if your company is without a product steward.

Health Canada's Update to Rev 7/8 of GHS — A Conversation with Karin F. Baron — *transcript available*
Lynn L. Bergeson and Karin F. Baron, MSPH discuss the very important amendments to the Canadian HPR, what listeners need to know regarding the new HPR provisions, when they must be implemented, and how they will impact the classification and labeling of hazardous products in Canada and beyond.

[What to Expect on Capitol Hill and at EPA OCSPP in 2023 — A Conversation with Jim Aidala] — *transcript available*
Lynn L. Bergeson and James V. Aidala discuss what to expect in 2023 from Capitol Hill and EPA's OCSPP when it comes to key chemical matters, including EPA staffing deficits, a divided Congress, and the many daunting legal, science, and policy issues that this OCSPP is tasked with solving, or at least managing.

[What to Expect in Chemicals Policy and Regulation in 2023 — A Conversation with Richard E. Engler, Ph.D.] — *transcript available*
Lynn L. Bergeson and Richard E. Engler, Ph.D. discuss what to expect in TSCA regulation in the New Year, including the first final risk management rule, the final PFAS reporting rule, the final CBI rule, and possible TSCA litigation issues.

[EPA Adds Two New Chemical Categories: What It Means to Chemical Innovators — A Conversation with Richard E. Engler, Ph.D.] — *transcript available*
Lynn L. Bergeson and Richard E. Engler, Ph.D. discuss EPA's bold moves in developing new chemical categories to help streamline the review of new chemicals under TSCA Section 5, including the new category for mixed metal oxides (MMO) and cathode active materials (CAM) and another category for biofuels.

[Environmental Law Series: Inside the Toxic Substances Control Act (TSCA)]
Lynn L. Bergeson joined J. Craig Williams on the Lawyer 2 Lawyer podcast in a spotlight on TSCA, with an overview of the Act, its history, impact, and the forecast for U.S. federal and international chemical regulatory policy.

APPENDIX C: TRAINING COURSES ON DEMAND

B&C is pleased to present our suite of regulatory training courses online and on demand at https://training.lawbc.com/. Professionals seeking expert, efficient, essential training can enroll in on-demand classes to complete at their own pace and timing.

The courses were developed and are presented by members of B&C's renowned TSCA and FIFRA practice groups. Courses can be completed at the learner's own pace, and enrollment is valid for one full year. Interested professionals should visit https://training.lawbc.com/ to view sample course segments and purchase modules.

Online courses are offered at $100 for one-hour modules and $200 for 2-hour modules. Course bundles are available at a reduced cost per course. Volume discounts are available for companies wishing to purchase courses for multiple employees. Contact Emily Scherer, escherer@lawbc.com, for more information on volume discounts.

TSCA Tutor®

T101: An Overview of TSCA
T103: Import Requirements — TSCA Section 13
T104: Export Requirements — TSCA Section 12
T105: Confidential Business Information (CBI)
T106: Reporting and Retention of Information — TSCA Section 8

T201: Inspections and Audits
T202: TSCA Section 5, Part 1 — Chemical Inventory, Exemptions
T203: TSCA Section 5, Part 2 — New Chemicals/New Use
T204: Chemical Data Reporting (2023)
T205: Chemical Testing (Regulatory)/Animal Welfare — TSCA Section 4
T206: Prioritization and Risk Evaluation — TSCA Section 6

T100-series bundle (five modules)
T200-series bundle (six modules)
Complete TSCA Tutor course (11 modules)

FIFRA Tutor®

F101: FIFRA Overview
F102: Import and Export of Pesticides
F103: Managing Effectively Confidential and Proprietary Business Information*
F104: Reporting and Recordkeeping Requirements
F105: Due Diligence and Transferring FIFRA Registrations and/or Data
F106: State Registration Requirements*
F107: Inert Ingredients*
F108: Pest Control Devices
F109: Defining Tolerances and Their Regulation
F110: Adverse Effects Reporting Requirements

F201: Understanding FIFRA-Regulated Products
F202: FIFRA Registration Strategy and Process*
F203: Building a Registration Application
F204: FIFRA Data Production Requirements and Regulatory Risk Assessment*
F205: Developing the Pesticide Label
F206: Antimicrobial Pesticides
F207: Regulation of Biopesticides*
F208: Data Citation, Data Compensation, and Data Sharing

F100-series bundle (currently seven modules)
F200-series bundle (currently five modules)
All currently available FIFRA Tutor modules (12 modules)

*Releasing in 2024

APPENDIX D: GLOSSARY

6:2 FTSB — 6:2 Fluorotelomer Sulfonamide Betaine
6PPD — N-(1,3-Dimethylbutyl)-N′-phenyl-p-phenylenediamine
ABNT — Brazilian Association of Technical Standards
ACAT — Alaska Community Action on Toxics
ACC — American Chemistry Council
ACOEL — American College of Environmental Lawyers
Acta® — The Acta Group
AD — Antimicrobials Division
ADAO — Asbestos Disease Awareness Organization
AFPM — American Fuel and Petrochemical Manufacturers
AICIS — Australian Industrial Chemicals Introduction Scheme
AMR — Antimicrobial Resistance
ANPRM — Advance Notice of Proposed Rulemaking
Anvisa — National Health Surveillance Agency (Brazil)
APHIS — Animal and Plant Health Inspection Service
ATP — Adaptation to Technical Progress
ATRm — Alternative Transitional Registration Model
B&C® — Bergeson & Campbell, P.C.
BBP — Butyl Benzyl Phthalate
BCCM — B&C® Consortia Management, L.L.C.
BE — Biological Evaluation
BoA — Board of Appeal
BOSC — Board of Scientific Counselors
1-BP — 1-Bromopropane
BPA — Bisphenol A
BPC — Biocidal Products Committee
BPR — Biocidal Products Regulation
BRS — Biotechnology Regulatory Services
CAM — Cathode Active Material
CAS RN® — Chemical Abstracts Service Registry Number®
CBD — Center for Biological Diversity
CBI — Confidential Business Information
CBIC — Central Board of Indirect Taxes & Customs (India)
CCCEH — Columbia Center for Children's Environmental Health
CCCR, 2001 — Consumer Chemicals and Containers Regulations, 2001
CCl_4 — Carbon Tetrachloride
CCPSA — Canada Consumer Product Safety Act
CDC — Centers for Disease Control and Prevention
CDR — Chemical Data Reporting
CE — *Conformité Européenne*
CEH — Center for Environmental Health
CEPA — Canadian Environmental Protection Act, 1999
CEQ — Council on Environmental Quality
CERCLA — Comprehensive Environmental Response, Compensation, and Liability Act
C.F.R. — Code of Federal Regulations
CFS — Center for Food Safety
CFSAN — Center for Food Safety and Applied Nutrition
CLP — Classification, Labeling, and Packaging
CMR — Carcinogenic, Mutagenic, or Toxic to Reproduction
CoRAP — Community Rolling Action Plan
COU — Condition of Use
CPB — Colorado Potato Beetle
CPNP — Cosmetic Product Notification Portal
CPSC — Consumer Product Safety Commission
CRS — Congressional Research Service
CSAR — Cosmetics Supervision and Administration Regulation (China)
CSF — Chemicals Stakeholder Forum
CSPI — Center for Science in the Public Interest
CSR — Chemical Safety Report
CTC — Carbon Tetrachloride
CWA — Clean Water Act
D4 — Octamethylcyclotetra-siloxane
DBP — Dibutyl Phthalate
DCI — Data Call-In
DCPC — Department of Chemicals and Petrochemicals (India)
decaBDE — Decabromodiphenyl Ether
DEFRA — Department for Environment, Food and Rural Affairs (UK)
DEHP — Di-ethylhexyl Phthalate
DER — Data Evaluation Record
DfE – Design for the Environment
DIBP — Di-isobutyl Phthalate
DIDP — Diisodecyl Phthalate
DINP — Diisononyl Phthalate
DOD — U.S. Department of Defense
DSL — Domestic Substances List
dsRNA — Double-Stranded Ribonucleic Acid
DUIN — Downstream User Import Notification
EC — European Commission
ECCC — Environment and Climate Change Canada
ECEL — Existing Chemical Exposure Limit
ECHA — European Chemicals Agency
EDF — Environmental Defense Fund
EDSP — Endocrine Disruptor Screening Program
EEA — European Economic Area
EFSA — European Food Safety Authority
EHS — Environmental, Health, and Safety
EJ — Environmental Justice
ELI — Environmental Law Institute
EO — Executive Order
EP — European Parliament

EPA — U.S. Environmental Protection Agency
EPCRA — Emergency Planning and Community Right-to-Know Act
EPP — Environmentally Preferable Purchasing
EPR — Extended Producer Responsibility
ESA — Endangered Species Act
ESG — Electronic Submissions Gateway (FDA)
ETAP — EPA Transcriptomic Assessment Product
EU — European Union
EWG — Environmental Working Group
F2F — Farm to Fork Strategy
FAO — Food and Agriculture Organization of the United Nations
FAR — Federal Acquisition Regulation
FCM — Food Contact Material
FCN — Food Contact Notification
FCS — Food Contact Substance
FDA — U.S. Food and Drug Administration
FDS – *Ficha com Dados de Segurança* (Brazil)
FFDCA — Federal Food, Drug, and Cosmetic Act
FIFRA — Federal Insecticide, Fungicide, and Rodenticide Act
FQPA — Food Quality Protection Act
FSIS — Food Safety and Inspection Service
FSMA — Food Safety Modernization Act
FTC – Federal Trade Commission
FTE – Full-Time Equivalent
FWS — U.S. Fish and Wildlife Service
FY — Fiscal Year
GB — Great Britain
GBMCL List — Great Britain Mandatory Classification and Labeling List
GenX — Hexafluoropropylene Oxide Dimer Acid, also known as HFPO-DA
GHG — Greenhouse Gas
GHS — Globally Harmonized System of Classification and Labeling of Chemicals
GMO — Genetically Modified Organism
GMP — Good Manufacturing Practices
GO — Gene Ontology
GP2W – Great Place to Work
GRA — Generic Approach to Risk Assessment
GRAS — Generally Recognized as Safe
GSA — General Services Administration
HBCD — Hexabromocyclododecane, also known as Cyclic Aliphatic Bromide Cluster
HC — Health Canada
HCS — Hazard Communication Standard
HDPE — High-Density Polyethylene
HFP — Human Foods Program
HFPO – Trifluoro(trifluoromethyl)oxirane
HFPO-DA — Hexafluoropropylene Oxide Dimer Acid, also known as GenX
HFPO-DAF – 2,3,3,3-Tetrafluoro-2-(heptafluoropropoxy)-propanoyl Fluoride
HHCB — 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[γ]-2-benzopyran
HHHOC — Human Health Hazard of Concern
HHS — U.S. Department of Health and Human Services
HPR — Hazardous Products Regulation
HSE — Health and Safety Executive
HSE – Health, Safety, and Environmental
HSIA — Halogenated Solvents Industry Alliance
HSNO — Hazardous Substances and New Organisms
HVACR — Heating, Ventilation, Air-Conditioning, and Refrigeration
IE/NI Protocol — Ireland/Northern Ireland Protocol
IECSC — Inventory of Existing Chemical Substances in China
IIA — Inception Impact Assessment
IQA — Information Quality Act
ISOR — Initial Statement of Reasons
IT — Information Technology
IUPAC — International Union of Pure and Applied Chemistry
K-BPR — Consumer Chemical Products and Biocides Safety Act (South Korea)
K-OSHA — Occupational Safety and Health Act (South Korea)
K-REACH — Act on the Registration and Evaluation of Chemicals (South Korea)
kg — Kilogram
KKDIK — *Kimyasalların Kaydı, Değerlendirilmesi, İzni ve Kısıtlanması*
KRW — South Korean Won
Lautenberg — Frank R. Lautenberg Chemical Safety for the 21st Century Act
LD — Legionnaires' Disease
LoREX — Low Release and Low Exposure Exemption
LR — Lead Registrant
LVE — Low Volume Exemption
MAF — Mixture Assessment Factor
MBOCA — 4,4′-Methylenebis(2-chloroaniline)
MC — Methylene Chloride
MCAN — Microbial Commercial Activity Notice
MCL — Maximum Contaminant Level
MDEP — Maine Department of Environmental Protection
MEE — Ministry of Ecology and Environment (China)
MIIT — Ministry of Industry and Information Technology (China)

MINCIT — Ministry of Commerce (Colombia)
MMO — Mixed Metal Oxide
MoCRA — Modernization of Cosmetics Regulation Act of 2022
MoE — Ministry of Environment (Chile, South Korea)
MoEUCC — Ministry of Environment, Urbanization and Climate Change (Turkey)
MoEL — Ministry of Employment and Labor (South Korea)
MOENV — Ministry of Environment (Taiwan)
MoH — Ministry of Health (Chile)
MOIT — Ministry of Industry and Trade (Vietnam)
MONRE – Ministry of Natural Resources and Environment (Vietnam)
MPA — Medical Products Administration (China)
MPCA — Minnesota Pollution Control Agency
MPPD — Multiple-Path Particle Dosimetry
MRRE — Manufacturer-Requested Risk Evaluation
MS — Member State
MSDS — Material Safety Data Sheet
MWCNT — Multi-Walled Carbon Nanotube
NAA — No Action Assurance
NACD – National Association of Chemical Distributors, now ACD
NAM — New Approach Methodology
NASA — National Aeronautics and Space Administration
NASEM — National Academies of Sciences, Engineering, and Medicine
NCD — New Chemicals Division
NDAA — National Defense Authorization Act
New Zealand EPA — New Zealand Environmental Protection Authority
NGO — Non-governmental Organization
NHC — National Health Commission (China)
NI — Northern Ireland
NICNAS — National Industrial Chemicals Notification and Assessment Scheme
NIER — National Institute of Environmental Research (South Korea)
NIOSH — National Institute for Occupational Safety and Health
nm — Nanometer
NMP — N-Methylpyrrolidone
NMPA — National Medical Products Administration (China)
NNCO — National Nanotechnology Coordination Office
NNI — National Nanotechnology Initiative
NOA — Notice of Arrival
NPC — National People's Congress (China)
NPDES — National Pollutant Discharge Elimination System
NPDWR — National Primary Drinking Water Regulation
NPRM — Notice of Proposed Rulemaking
NRC — Nuclear Regulatory Commission
NSET — Nanoscale Science, Engineering, and Technology
NSTC — National Science and Technology Council
OARM — Office of Administration and Resources Management
OCSPP — Office of Chemical Safety and Pollution Prevention
OECD — Organization for Economic Cooperation and Development
OEHHA — Office of Environmental Health Hazard Assessment
OEM — Original Equipment Manufacturer
OFPR — Office of Food Policy and Response
OFR — Organohalogen Flame Retardant
OHLAT — One Health Legislative Assessment Tool
OIG — Office of Inspector General
OMB — Office of Management and Budget
ONU — Occupational Non-user
OPMP — Office of Pest Management Policy
OPP — Office of Pesticide Programs
OPPT — Office of Pollution Prevention and Toxics
OR — Only Representative
ORA — Office of Regulatory Affairs
ORD — Office of Research and Development
OSHA — U.S. Occupational Safety and Health Administration
OSTP — Office of Science and Technology Policy
PBT — Persistent, Bioaccumulative, and Toxic
PCB — Polychlorinated Biphenyl
PCE — Perchloroethylene, also known as PERC
PCT — Polychlorinated Terphenyl
PEER — Public Employees for Environmental Responsibility
PERC — Perchloroethylene, also known as PCE
PFAS — Per- and Polyfluoroalkyl Substances
PFBA — Perfluorobutanoic Acid
PFBS — Perfluorobutanesulfonic Acid
PFDA — Perfluorodecanoic Acid
PFHxA — Perfluorohexanoic Acid
PFHxS — Perfluorohexanesulfonic Acid
PFNA — Perfluorononanoic Acid
PFOA — Perfluorooctanoic Acid
PFOS — Perfluorooctanesulfonic Acid
PID — Proposed Interim Decision
PIF — Product Information File
PIP — Plant-Incorporated Protectant
PIP (3:1) — Phenol, Isopropylated Phosphate (3:1)
PMN — Premanufacture Notice
PMT — Persistent, Mobile, and Toxic
POD — Point of Departure

POE — Portal of Entry
POP — Persistent Organic Pollutant
PPA — Pollution Prevention Act
PPE — Personal Protective Equipment
PPP — Plant Protection Product
PPPR — Plant Protection Product Regulation
PRIA — Pesticide Registration Improvement Act
PRIA 5 — Pesticide Registration Improvement Extension Act of 2022
Prop 65 — Proposition 65
PSP — Pesticide Submissions Portal
PULA – Pesticide Use Limitation Area
PV29 — Colour Index Pigment Violet 29
PVA — Polyvinyl Alcohol, also known as PVOH
QR Code — Quick Response Code
R&D — Research and Development
RAC — Risk Assessment Committee
RDC — Resolution of the Collegiate Board of Directors (Brazil)
RDDR — Regional Deposited Dose Ratio (software)
REACH — Registration, Evaluation, Authorization and Restriction of Chemicals
Rev — Revised Edition
RFC — Request for Comment (PFAS)
RFC — Request for Correction (TSCA)
RFCU — Reasonably Foreseeable Condition of Use
RFI — Request for Information
RFR — Request for Reconsideration
RHCE — Reconstructed Human Cornea-like Epithelium
RHE — Reconstructed Human Epidermis
RMOA — Regulatory Management Option Analysis
RNA — Ribonucleic Acid
RNAi — RNA Interference
RP — Responsible Person
RQ — Reportable Quantity
RSQUI — National Registry of Industrial Chemical Substances (Colombia)
RSR — Regulatory Status Review
SACC — Science Advisory Committee on Chemicals
SAMR — State Administration for Market Regulation (China)
SCCS — Scientific Committee for Consumer Safety
SCPN — Submit Cosmetic Product Notification
SDS — Safety Data Sheet
SDWA — Safe Drinking Water Act
SECURE — Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient
SELC — Southern Environmental Law Center
Services — U.S. Fish and Wildlife Service and National Marine Fisheries Service
SI – Statutory Instrument
SIA — Semiconductor Industry Association
SIDS — Screening Information Dataset
SIEF — Substance Information Exchange Forum
SNUN — Significant New Use Notice
SNUR — Significant New Use Rule
SOP — Standard Operating Procedure
SPL — Structured Product Labeling
SS — Singapore Standard
Sustainable Chemistry ST — Joint Subcommittee on Environment, Innovation, and Public Health Sustainable Chemistry Strategy Team
T-BPR – Turkey Biocidal Products Regulation
Taiwan EPA — Taiwan Environmental Protection Administration
TBBPA — 4,4'-(1-Methylethylidene)bis[2,6-dibromophenol]
TCE — Trichloroethylene
TCEP — Tris(2-chloroethyl) Phosphate
TCSB — Toxic and Chemical Substances Bureau (Taiwan)
TCHA — Taiwan Chemical Administration
TDCE — *trans*-1,2-Dichloroethylene
TDR — Tiered Data Reporting
TEER — Trans-Epithelial Electrical Resistance
TERA — TSCA Environmental Release Application
TES — Threatened and Endangered Species
TG — Testing Guideline
TPP — Phosphoric Acid, Triphenyl Ester, also known as Triphenyl Phosphate
TRI — Toxics Release Inventory
TRV — Transcriptomic Reference Value
TSCA — Toxic Substances Control Act
UID — Unique Identifier
UK — United Kingdom
UKCA — United Kingdom Conformity Assessment
UN — United Nations
UNEP — United Nations Environment Programme
U.S. — United States
USDA — U.S. Department of Agriculture
USMCA — United States-Mexico-Canada Agreement
UTC — Unintentional Trace Contaminant
VERV — Vector Expedited Review Voucher
VI — Vinyl Institute
vPvB — Very Persistent and Very Bioaccumulative
vPvM — Very Persistent and Very Mobile
VSP — Vulnerable Species Pilot
WCPP — Workplace Chemical Protection Program
WHO — World Health Organization
WHS — Work Health and Safety Laws (Australia)
WOAH — World Organization for Animal Health
WPS — Worker Protection Standard
WTO — World Trade Organization

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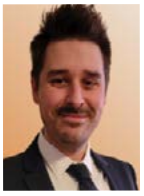

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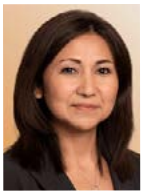

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