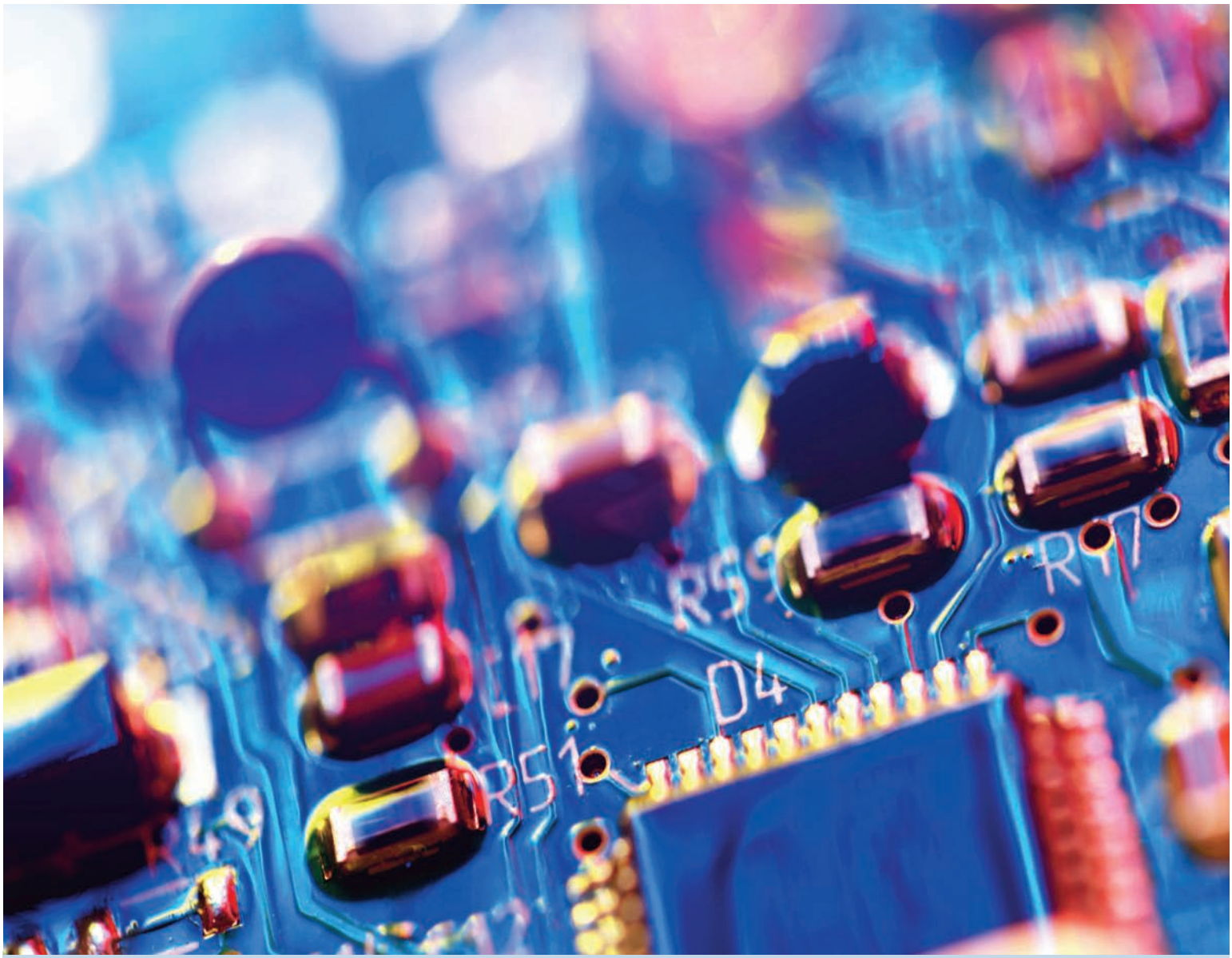

BERGESON & CAMPBELL, P.C.

Forecast for U.S. Federal and International Chemical Regulatory Policy 2023

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Forecast for U.S. Federal and International Chemical Regulatory Policy 2023

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 pleased to offer you our Forecast 2023, our seasoned team's collective take on what to expect regarding global industrial, agricultural, and biocidal chemical initiatives in the New Year. We have worked hard to offer our best-informed judgment on the trends and key developments we expect to see in 2023.

Here at home, most would agree the Biden Administration has made bold and consequential policy shifts in chemical management over the past two years. There is little agreement, however, on the wisdom or success of those initiatives. At a political level, the Republicans' narrow control of the U.S. House of Representatives will almost certainly invite a greater degree of oversight of U.S. Environmental Protection Agency (EPA) actions, particularly with respect to implementation of the 2016 amendments of the Toxic Substances Control Act. As discussed in the pages that follow, concepts core to the Act, including "reasonably foreseen," "to the extent necessary," "systematic review," and "best available science," continue to evolve and not always in predictable, coherent, and consistent ways. Similar policy shifts are seen in the agricultural and biocidal area, with perhaps less dramatic effect. How the **2024** general election will influence EPA's policy choices is unclear. In that the election cycle has already begun, we caution all to buckle up and prepare for what we expect will be an eventful, fascinating year.

Internationally, the European Union's (EU) bold commitment to net-zero global warming emissions by **2050** continues to advance and set the tone and standard for governance programs globally. The EU's Chemicals Strategy for Sustainability and innovative embrace of the principles underlying circularity offer promising approaches to achieving fundamental change without compromising chemical innovation. Watch for more progress in 2023 as the EU and United Kingdom continue to manage the fallout from Brexit and the evolution of chemical governance programs globally pick up steam in a brave new post-pandemic world.

Our unique and exceptionally successful business platform and expanding global team of highly skilled professionals are well-suited to offer this 2023 Forecast. Our core business is laser-focused on the ever-evolving 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 (six Ph.D.s), 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.

I. UNITED STATES: CHEMICAL FORECAST

A. Introduction

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2021 ushered a new Administration into Washington, D.C. 2022 brought the Biden Administration into adolescence, showing more of its approach to governing generally, and how it will approach a broad range of environmental challenges. To predict what is expected for 2023, like any institution, the best predictor of 2023 activity is a careful review of what the Administration emphasized in 2022.

In 2022, the not-so-new Administration continued to focus on its announced plans to emphasize aggressive energy policies to address climate change, continue to "reverse" decisions made by the Trump Administration, integrate environmental justice (EJ) considerations more fully and fundamentally into U.S. Environmental Protection Agency (EPA) policy decisions, rebuild EPA by way of a significant increase in budget (or at least budget requests of Congress), and "follow the science" to justify reevaluating earlier decisions and to improve morale among career employees.

Priorities for the Office of Chemical Safety and Pollution Prevention (OCSPP) tracked these Agency-wide objectives. OCSPP reviewed past decisions made under the Trump Administration, emphasized "science integrity" or "good science" as part of program assessments, reviewed EJ considerations in decision-making, and generally moved aggressively (critics would argue "politically") on a number of regulatory policies and decisions. Regarding climate issues, OCSPP has a less prominent but equally relevant agenda. Pesticide products, as part of agricultural production, have an important role in contributing to positive climate impacts, as do greener, more sustainable industrial chemicals.

2022 saw OCSPP make decisions regarding specific chemicals and pesticides, along with continuing to manage through the COVID-19 pandemic (both in terms of COVID-related pesticide products and office policies). The agenda for the new year will likely see a continuation of these trends, with lower COVID-related impact, as the world continues to adjust to the pandemic. The 2022 election brings a change in party control of the House of Representatives. This change may stymie some of the 2022 trends, but Democrats retain control of the White House and the Senate. The most likely immediate impact will be on the prospects for significant budget increases for EPA and OCSPP. As resource constraints have been repeatedly cited by OCSPP as a major problem, this budget outlook is disappointing and is likely to have a real impact on program activity in the new year and beyond.

The divided government is expected to get off to a rocky start, especially if the debt limit is not addressed by Congress in 2022. Will the House of Representatives, given the narrow majority for Republicans, now join the Senate and become a Dead Sea of deadlock, or will it have any prospect of bipartisan cooperation? The announced agenda for the House presumes many oversight hearings and concerns about all federal agencies, including EPA. Given the controversies about various OCSPP decisions, including those on chlorpyrifos and dicamba pesticides, new chemical review procedures, and assessment assumptions underlying existing chemical reviews, Congressional oversight hearings may tie up significant amounts of senior (political) management time and attention.

Regardless of Congressional interest or interference, OCSPP will have to confront a daily agenda of concerns about the ongoing pandemic, internal budget and spending allocation

between the programs, recruitment and training of any new staff that manages to be hired, ambitious if not impossible deadlines required by both the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), trade policies and decisions of trading partners, and last, but not least, litigation threats and court decisions that may upset any best-laid plans.

And in case it was not noticed, the Presidential election of **2024** has officially begun, with at least one candidate formally announcing his candidacy (as the *New York Post* reported: "Florida Man Makes Announcement").

Expect 2023 to be an impactful year as EPA and OCSPP contend with a new Congress and an even more roiling political climate. EPA will be eager to cement policies and regulations before the **2024** Presidential cycle moves to prime time while contending with a changed operating environment with the new Congress, all of which makes most observers expect even greater partisan division to characterize 2023.

Operating Environment

OCSPP will continue to move ahead with its program priorities as it goes into the third year of the Biden Administration. With the change in the majority in the House of Representatives, however, the operating environment OCSPP will find itself in will be different. With the divided government, as the Senate remains in the control of the Democrats, the Administration will have the ability to guide the agenda and rely on executive actions to press its goals. Decisions about appropriate controls or restrictions on specific chemicals or pesticides will continue, as will developing regulations to lay the groundwork for broader policy approaches or assessment policies.

At the same time, it is unlikely that EPA or OCSPP can expect significant budget increases, a reality that will hinder resources available for new initiatives. Both the pesticide and chemical programs will receive more oversight scrutiny about how the Administration is defining "reliable science" and generally interpreting legislative mandates. Since both programs are woefully behind in meeting current legislative deadlines (among the issues that will be discussed later in this Forecast), Congress will have no trouble in finding issues where there are debates about the most appropriate way to move forward.

For the industrial chemicals programs, the slow pace of reviews for new chemical submissions and the announced inability of the program to meet the legislative deadline for the first round of chemical assessments will be of concern for advocates of both lesser and greater regulatory controls on chemical products. The political leader of OCSPP, Dr. Michal Freedhoff, has been publicly vocal about the urgent need for more resources to attain the policy and legislative goals of the 2016 Frank R. Lautenberg Chemical Safety for the 21st Century Act amendments to TSCA (Lautenberg).

For the pesticide program, the October 2022 deadline for the approximately 1,100 active ingredients to be reviewed will be met by almost no products if the definition of "complete review" includes compliance with the Endangered Species Act (ESA) and the requirement for the assessment of possible endocrine effects from pesticide use. Unfortunately for the way EPA has attempted to define "registration review" in the past, this broader definition of complete review has been the result of recent court decisions. EPA has made significant progress in finally beginning to integrate ESA assessments in pesticide product reviews and has established guidelines for testing for possible endocrine effects, but litigation over what is a completed ESA or endocrine review has been at issue. As a result, the courts have ruled that EPA has completed very few of these pesticide reviews.

For pesticides, 2023 will also be a year where Congress will need to revise (or extend) provisions of the 2018 Farm Bill, which has many moving pieces, mostly not relevant to pesticide use. But provisions authorizing pesticide industry fees to supply approximately 33 percent of program costs are also due to expire at the **end of 2023** — so some kind of reauthorization will be needed to avoid unimaginable program cuts. That will make the Farm Bill and pesticide fee provisions possibly intertwined, which could make for unpredictable Congressional chaos toward the **end of 2023**.

Lastly, it is a cliche to say that the **2024** Presidential election begins now. Pesticide and chemical regulatory issues are not likely to make any candidate's routine stump speech. But as fears of which political party might control both houses of Congress and the White House loom closer, incumbent Administrations begin to triage what "must be done" before they may no longer be in power. And as Congress in more recent years has utilized the Congressional Review Act (CRA) to reverse decisions made by the immediately previous Administration, fears about the need to initiate and complete rulemakings to make effective priority policy objectives will start now, since the rule-writing process, even under an accelerated schedule, can easily take 18-24 months to complete.

Given its experience with test orders issued in 2021 and 2022 on chemicals that are under review, in 2023 EPA may seek to issue orders for substances it is considering for prioritization rather than waiting until risk evaluation is underway to order testing.

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

The Office of Pollution Prevention and Toxics (OPPT) will seek in 2023 to implement revisions to make TSCA more predictable, transparent, and rigorous. It will continue to complete risk evaluations and risk management actions on certain existing chemicals and review and make determinations on new chemical premanufacture notifications (PMN). EPA is planning to complete risk evaluations for formaldehyde and certain chlorinated solvents in 2023. If so, OPPT will be required to initiate the prioritization for risk evaluation of additional chemicals. Given its experience with test orders issued in 2021 and 2022 on chemicals that are under review, EPA may seek to issue orders for substances it is considering for prioritization rather than waiting until risk evaluation is underway to order testing.

EPA met another major milestone in 2022: In May, EPA proposed the first risk management rule based on a risk evaluation under Lautenberg. EPA proposed banning chrysotile asbestos two years after the effective date of the rule. There were extensive comments on the rule, and as of this writing, EPA is considering the additional information it received. A final rule is due to be published in December 2022, but in the Spring 2022 Unified Agenda of Regulatory and Deregulatory Actions (Regulatory Agenda), EPA has indicated that it expects to issue the rule in **November 2023.** It is also possible Congress will supersede EPA's rulemaking with legislation.

In 2022, OPPT completed re-reviewing risk evaluations for three of the "First 10" chemicals designated by EPA for risk evaluation. EPA also implemented its "whole chemical" approach to its risk evaluations and has stated its intent to withdraw all orders it had issued documenting EPA's view that some conditions of use (COU) were not an unreasonable risk. With the reconsideration of the First 10 risk evaluations complete, EPA will begin to propose risk management rules. EPA did not revise the scopes of the "Next 20" chemicals under review, as we expected, but EPA has, presumably, updated its approach to those reviews to reflect EPA's whole chemical and its fenceline analysis approaches. EPA has also, presumably, updated its manufacturer-requested risk evaluations (MRRE) with its updated approaches. Other than EPA's statements, there is little transparency to how EPA is updating its evaluations. The first insight will probably come from the handful of draft risk evaluations that EPA expects to publish in 2023.

For new chemicals, we expect that EPA will improve on its record of completing PMN determinations. EPA has pulled senior scientists from across the Agency to assist with PMN reviews, especially health reviews, while continuing to hire new assessors. The onboarding and training of new assessors will take time, but EPA's performance in reviewing PMNs should improve throughout 2023. Even as EPA expands the number of determinations that it completes, we expect EPA to continue to regulate the majority of those submissions. In 2022, 94 percent of PMN determinations resulted in consent orders. We also expect EPA to try to accelerate promulgating Significant New Use Rules (SNUR) that are derivative of orders.

The fee increase that went into effect in 2022 probably provided limited additional revenue to EPA. For example, fees for PMNs increased 18.9 percent, but PMN submissions decreased 16.1 percent. EPA did collect test order fees for nine test orders, but those fees only amount to a bit over $100,000. EPA initiated no new risk evaluations in 2022, so it collected no additional fees. EPA published a supplemental proposal for its fees rule with comments due **January 17, 2023**. As EPA telegraphed, the proposed fees are surprisingly high. Generally, proposed fees are about double the current fees.

Other major actions that we expect EPA to take near the end of 2022 or in 2023 include the final per- and polyfluo-

ARTICLE

"Toxics Regulation: A Brave New World Catching Many Off Guard," *PLI Current*, Vol. 6 (2022)

roalkyl substance (PFAS) reporting rule and reopening the persistent, bioaccumulative, and toxic (PBT) rules.

1. Section 4(a) — Test Orders

a. High-Priority Substances Undergoing Risk Evaluation

EPA continued to work with recipients of the TSCA Section 4(a)(2) test orders issued in 2021, notably on the protocol for the dermal hand wipe sampling. After extensive discussion, EPA suspended but declined to withdraw in May 2022 that aspect of the test orders but stated that EPA need for data on occupational dermal exposures remains. EPA also struggled to review timely test protocols submitted by order recipients.

In March 2022, EPA issued a second round of TSCA Section 4(a)(2) test orders that were primarily focused on toxicity testing on sediment-dwelling organisms (*i.e.*, chironomids, a.k.a. lake flies) and terrestrial organisms (i.e., earthworms and birds). EPA provided little rationale to support the additional ordered testing, which is notable since EPA had previously concluded that such testing was not required. For example, in the first TSCA Section 4(a)(2) test order on trans-1,2-dichloroethylene (TDCE), EPA stated, "the *Final Risk Evaluation for Trichloroethylene* [the Final TCE RE] has sufficient environmental hazard information for use as analogue data for trans-1,2-dichloroethylene on benthic invertebrate toxicity data due to acute and chronic exposure via sediment." In the second TSCA Section 4(a)(2) test order on TDCE, EPA stated, "No toxicity data for benthic invertebrates exposed for acute or chronic durations were identified." We cannot reconcile these two statements.

Beyond the absence of transparency with EPA's decision-making, another problematic aspect of the second round of test orders is that EPA did not provide an opportunity for companies that had ceased manufacturing, importing, and processing the ordered substance to certify out of the test order pool. As discussed in more detail below, two recipients of the order for testing on *o*-dichlorobenzene (ODCB) sued EPA, as did certain TDCE and 1,1,2-trichloroethane test order recipients.

The chemical substances and associated testing in the first and second round of TSCA Section 4(a)(2) test orders are summarized in Table 1.

Ordered testing for the organic solvents (*e.g.*, TDCE) includes *in vitro* dermal absorption studies and sediment and terrestrial toxicity studies. EPA appears to have ordered these tests to fill apparent data *gaps*, rather than actual data *needs*, for completing its risk evaluations. For example, EPA's own dermal absorption guidance for new chemical substances states that absorption from non-occluded exposures to chemical substances with a vapor pressure > 75 mm Hg is "Nil" (*i.e.*, <0.1%). TDCE has a vapor pressure of 331 mm Hg at 25°, substantially higher than EPA's threshold for nil absorption. Further, EPA's ordered testing on sediment and terrestrial organisms conflicts with the approaches used in the Final TCE [Trichloroethylene] RE, which EPA reaffirmed as "robust and upholding the standards of best available science and weight of the scientific evidence per TSCA sections 26(h) and (i)." In the Final TCE RE, EPA stated that "no ecotoxicity studies were available for sediment-dwelling organisms … [and instead used] aquatic invertebrates … as a surrogate species." EPA did not, however, articulate why surrogate species data were acceptable for assessing potential risks from TCE, but not acceptable for doing so with TDCE. Moreover, EPA concluded that the physicochemical properties of TCE "do not support an exposure pathway through water and soil pathways to terrestrial organisms [*e.g.*, earthworms]." Yet, EPA ordered terrestrial toxicity testing on earthworms for 1,2-dichloroethane (DCE), a chemical substance with comparable physicochemical properties to TCE (*e.g.*, vapor pressure = 73.5 mm Hg for TCE and 76.8 for DCE; water solubility = 1.280 g/L for TCE and 7.9 g/L for DCE) that support that DCE, like TCE, will not remain in the water and soil compartments.

We expect EPA to begin issuing test orders for the remaining "Next 20" high-priority substances and substances that EPA is considering prioritizing for potential risk evaluation. We anticipate that the same issues mentioned above (*e.g.*, ordering testing to fill data gaps, rather than data needs) will be recurring themes in future test orders. We encourage

Table 1. TSCA Section 4(a)(2) Test Orders Issued Since January 2021

Chemical Substance	Required Testing	
	1st TSCA Section 4(a)(2) Test Orders	***2nd TSCA Section 4(a)(2) Test Orders***
1,1,2-Trichloroethane (Chemical Abstracts Service Registry Number® (CAS RN®) 79-00-5)	January 2021: Environmental Hazard Testing (Organization for Economic Cooperation and Development (OECD) Testing Guideline (TG) 233, *Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment*) and facility-specific Occupational Exposure Testing (National Institute for Occupational Safety and Health (NIOSH) Method 1003 [analytical method] for sample matrix reporting on *Occupational Inhalation Exposure*; OECD TG 428, *Skin Absorption: In Vitro Method*; Non-guideline protocol, *Dermal Hand Wipe Sampling — Solvents*)	March 2022: Environmental Hazard Testing (OECD TG 222, *Earthworm Reproduction Test (Eisenia fetida/Eisenia andrei)*; OCSPP 850.2300, *Avian Reproduction Test*)
1,1-Dichloroethane (CAS RN 75-34-3)	January 2021: Environmental Hazard Testing (OECD TG 233, *Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment*) and facility-specific Occupational Exposure Testing (NIOSH Method 1003 [analytical method] for sample matrix reporting on *Occupational Inhalation Exposure*; OECD TG 428, *Skin Absorption: In Vitro Method*; Non-guideline protocol, *Dermal Hand Wipe Sampling — Solvents*)	Not applicable
1,2-Dichloroethane (CAS RN 107-06-2)	January 2021: Facility-specific Occupational Exposure Testing (NIOSH Method 1003 [analytical method] for sample matrix reporting on Occupational Inhalation Exposure; OECD TG 428, *Skin Absorption: In Vitro Method*; Non-guideline protocol, *Dermal Hand Wipe Sampling — Solvents*)	March 2022: Environmental Hazard Testing (OECD TG 222, *Earthworm Reproduction Test (Eisenia fetida/Eisenia andrei)*)
1,2-Dichloropropane (CAS RN 78-87-5)	January 2021: Environmental Hazard Testing (OECD TG 233, *Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment*) and facility-specific Occupational Exposure Testing (NIOSH Method 1013 [analytical method] for sample matrix reporting on *Occupational Inhalation Exposure*; OECD TG 428, *Skin Absorption: In Vitro Method*; Non-guideline protocol, *Dermal Hand Wipe Sampling — Solvents*)	March 2022: Environmental Hazard Testing (OECD TG 222, *Earthworm Reproduction Test (Eisenia fetida/Eisenia andrei)*; OCSPP 850.2200, *Avian Dietary Toxicity Test*; OCSPP 850.2300, *Avian Reproduction Test)*) and Consumer Exposure Testing (Exposure Testing Protocol 3: *Short-Term Emission Testing*)
o-Dichlorobenzene (CAS RN 95-50-1)	January 2021: Environmental Hazard Testing (OCSPP 850.1735, *Spiked Whole Sediment 10-Day Toxicity Test, Freshwater Invertebrates*; OECD TG 233, *Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment*) and facility-specific Occupational Exposure Testing (NIOSH Method 1003 [analytical method] for sample matrix reporting on *Occupational Inhalation Exposure*; OECD TG 428, *Skin Absorption: In Vitro Method*; Non-guideline protocol, *Dermal Hand Wipe Sampling — Solvents*)	March 2022: Environmental Hazard Testing (OECD TG 233, *Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment*; OCSPP 850.1735, *Spiked Whole Sediment 10-Day Toxicity Test, Freshwater Invertebrates*) and Consumer Exposure Testing (Exposure Testing Protocol 2: *Emissions from Water or Aqueous Solutions to Indoor Air*; Exposure Testing Protocol 3: *Short-Term Emission Testing*)

p-Dichlorobenzene (CAS RN 106-46-7)	January 2021: Environmental Hazard Testing (OCSPP 850.1735, *Spiked Whole Sediment 10-Day Toxicity Test, Freshwater Invertebrates*; OECD TG 233, *Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment*) and facility-specific Occupational Exposure Testing (NIOSH Method 1003 [analytical method] for sample matrix reporting on *Occupational Inhalation Exposure*; OECD TG 428, *Skin Absorption: In Vitro Method*; Non-guideline protocol, *Dermal Hand Wipe Sampling-Solvents*)	March 2022: Environmental Hazard Testing (OECD TG 222, *Earthworm Reproduction Test (Eisenia fetida/Eisenia andrei)*)
trans-1,2-Dichloroethylene (CAS RN 156-60-5)	January 2021: Facility-specific Occupational Exposure Testing (NIOSH Method 1003 [analytical method] for sample matrix reporting on *Occupational Inhalation Exposure*; OECD TG 428, *Skin Absorption: In Vitro Method*; Non-guideline protocol, *Dermal Hand Wipe Sampling-Solvents*)	March 2022: Environmental Hazard Testing (OECD TG 219, *Sediment-Water Chironomid Toxicity Using Spiked Water*; OECD TG 233, *Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment*) and Consumer Exposure Testing (Exposure Testing Protocol 3: *Short-Term Emission Testing*; Exposure Testing Protocol 1: *Source Characterization*)
4,4′-(1-Methylethylidene) bis [2,6-dibromophenol] (CAS RN 79-94-7)	January 2021: Environmental Hazard Testing (OCSPP 850.4400, *Aquatic Plant Toxicity Test Using Lemna spp.*; OECD 225, *Sediment-Water Lumbriculus Toxicity Test Using Spiked Sediment*; OECD TG 233, *Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment)*[a] and facility-specific Occupational Exposure Testing (NIOSH Method 1003 [analytical method] for sample matrix reporting on *Occupational Inhalation Exposure*; Non-guideline protocol, *Dermal Hand Wipe Sampling — Flame Retardants*; OECD TG 428, *Skin Absorption: In Vitro Method*)	March 2022: Consumer Exposure Testing (Exposure Testing Protocol 6: *Direct Transfer of Chemicals from Source to Settled Dust*; Exposure Testing Protocol 9: *Migration to Skin (Dermal Exposure)*)
Phosphoric acid, Triphenyl Ester (CAS RN 115-86-6)	January 2021: Environmental Hazard Testing (OCSPP 850.4400, *Aquatic Plant Toxicity Test Using Lemna spp.*; OCSPP 850.4500, Algal Toxicity; OECD 225, *Sediment-Water Lumbriculus Toxicity Test Using Spiked Sediment*; OECD TG 233, *Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment*; OECD TG 222, *Earthworm Reproduction Test (Eisenia fetida/Eisenia andrei)*) and facility-specific Occupational Exposure Testing (NIOSH Method 1003 [analytical method] for sample matrix reporting on *Occupational Inhalation Exposure*; Non-guideline protocol, *Dermal Hand Wipe Sampling — Flame Retardants*; OECD TG 428, *Skin Absorption: In Vitro Method*)	March 2022: Environmental Hazard Testing (OCSPP 850.2200, *Avian Dietary Toxicity Test*; OCSPP 850.2300, *Avian Reproduction Test*)
[a] "EPA received acceptable existing information to fulfill the need for OECD 233 and OECD 225."		

potential test order recipients to be proactive and to evaluate the available data on their chemistries to understand potential data gaps and data needs. Understanding these uncertainties will aid interested parties with actively engaging effectively with EPA to ensure more diligent reviews of reasonably available information and more thoughtful consideration on the need for potential test data generation versus the use of analog read-across or modeling. EPA has expressed 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.

b. National PFAS Testing Strategy

On October 18, 2021, EPA released a national testing strategy on PFAS entitled "National PFAS Testing Strategy: Identification of Candidate Per- and Poly-fluoroalkyl Substances (PFAS) for Testing" (the Strategy). In 2022, EPA issued the first order for testing a PFAS.

EPA intended to issue its first round of test orders on the 24 identified PFAS by the end of 2021. As of November 30, 2022, however, EPA has issued only one TSCA Section 4(a)(1) test order for a PFAS, 6:2 fluorotelomer sulfonamide betaine (6:2 FTSB; CAS RN 34455-29-3), in June 2022. The TSCA Section 4(a)(1) test order was directed to five companies that EPA determined were manufacturers, importers, or processors of the chemical substance. The test order requires testing on physical-chemical properties (OECD TG 109, *Density of Liquids and Solids;* OECD TG 111, *Hydrolysis as a Function of pH;* *NIOSH Manual of Analytical Methods*, 5th Edition, Aerodynamic Particle Size Distribution) and health effects (tier 1: ECETOC Technical Report 122, *Biosolubility Test; tier 2:* OECD TG 417, *Toxicokinetics,* OECD TG 403, *Acute Inhalation Toxicity,* OECD TG 413, *Inhalation Toxicity Range-Finding Study,* OECD TG 412, *Subacute Inhalation Toxicity: 28-Day Study.* One recipient of the test order filed suit, as discussed below. We anticipate that additional test orders covering at least certain of the remaining 23 identified PFAS will be issued in 2023, but the specific substances remain to be seen.

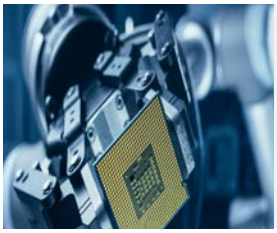
WEBINAR

Register now for B&C's upcoming webinar **PFAS Reporting, PBTs, and other TSCA Hot Topics**, May 17, 2023, 11:00 a.m. (EDT)

As EPA continues to issue test orders on PFAS and other chemical substances, B&C anticipates that questions will continue to arise that call into question the thoroughness of EPA's search for data that may undermine EPA's stated basis for the test orders. TSCA Section 26(h) requires EPA to use the best available science when making decisions based on science under TSCA Sections 4, 5, and 6. For example, the process used in the Strategy identified 24 PFAS that were "lacking toxicity data," yet there are robust summaries of experimental toxicological studies available on many of these PFAS in the European Chemicals Agency (ECHA) database. 2:1 Fluorotelomer alcohol (CAS RN 422-05-9), one of the 24 PFAS, has an acute inhalation toxicity study according to OECD TG 403 and a 28-day inhalation toxicity study according to OECD TG 412, available on the ECHA database. The registrants for this substance completed the ECHA submission in 2018.The fact that EPA did not acknowledge the existence of these data raises questions about EPA's search strategy. EPA will presumably have to address this in any test orders it issues.

Table 2. General Overview of EPA's Proposed Tiered Approach for Testing on 24 PFAS

Tier I	Tier II	Tier III
• Vapor pressure • Water solubility • Log KOW • Particle size • Surface tension • *In vitro* metabolism and protein binding studies • *In vitro* genotoxicity for chromosomal aberrations/gene mutations (*e.g.*, OECD TG 471 and OECD TG 473 or 487) • *In vitro* nuclear receptor/activation assays	• *In vitro* skin absorption testing (*e.g.*, OECD TG 428) • *In vivo* genotoxicity testing (*e.g.*, OECD TG 474) • Acute *in vivo* inhalation toxicity testing (OECD TG 403) • *In vivo* toxicokinetic testing in rats and/or mice (OECD TG 417)	• Cardiac sensitization • 28-day inhalation toxicity test (OECD TG 412) • 28- or 90-day toxicity testing (OECD TG 407 or 408) • Prenatal developmental toxicity testing (OECD TG 414) • Extended one-generation reproductive toxicity testing (OECD TG 443) • Carcinogenicity testing (OECD TG 451)



EPA issued a clarification stating that any company that previously used the cease manufacture option to a 2021 test order will not be listed on any future TSCA Section 4 orders for those same chemical substances subject to the 2021 test orders.

We also note this reoccurring theme of EPA ordering testing on substances when reasonably available information exists that appears to satisfy the ordered testing, in potential conflict with TSCA Section 26(k). For example, in the TSCA Section 4(a)(1) test order on 6:2 FTSB, EPA ordered "Particle Density" testing according to OECD TG 109 and "Hydrolysis as a Function of pH" testing according to OECD TG 111. Yet, the ECHA registrant performed testing on 6:2 FTSB according to OECD test guidelines 109 and 111. EPA did not acknowledge the existence of these data, nor did it offer a reason why these data are inadequate, if that was EPA's position.

ARTICLE

"EPA Targets PFAS Cleanup," *Chemical Processing*, September 23, 2022.

c. New Test Order Policies

In August 2022, EPA posted two new resource documents for recipients of TSCA Section 4 test orders. The August 5, 2022, policy document entitled "Policies Regarding Manufacturers and Processors Subject to TSCA Section 4(a) Testing" provides two policies:

> **Policy 1:** Companies engaged in manufacturing activities for a chemical substance during the five years prior to the projected signature date or effective date of a Section 4(a) action (i.e., a rule, consent agreement, or order) will generally be included in the scope of the action. However, EPA may apply a longer or shorter period of time when appropriate in specific cases.
>
> **Policy 2:** Section 4 actions will not include an option to cease manufacturing as a means to satisfy the requirements of the action. Test orders issued in January 2021 included this option.

Additionally, the policy document states that although EPA's policy is that it will no longer provide a "cease manufacture" response option for a company to cease its manufacture of a chemical substance to satisfy the requirements of an order, EPA recognizes that a company that ceased its manufacture of a chemical substance in response to a 2021 order "forewent a business opportunity in reliance upon EPA's representation that testing on the chemical substance would not be required by the company." EPA states that it will remove from a 2022 order any company that made successful use of the cease manufacture response option for a 2021 order on that same chemical substance, "provided the company has not, and does not, recommence its manufacture of the chemical substance while testing obligations remain in effect for that chemical substance under the applicable 2021 Order and/or 2022 Order."

On September 7, 2022, EPA issued a clarification to a second policy document originally issued on August 5, 2022, titled "Removal of Certain Companies from Seven TSCA Section 4(a)(2) Orders Issued in 2022," stating that any company that previously used the cease manufacture option to a 2021 test order will not be listed on any future TSCA Section 4 orders for those same chemical substances subject to the 2021 test orders.

While we applaud EPA's recognition of the test order recipients that had ceased manufacture, EPA's apparent insistence that it will not offer that option going forward is puzzling. If a company receives a test order to perform workplace exposure testing and that company ceases to manufacture or process that chemical, what exposure will it measure? There is a concern for a company ceasing manufacture or processing only to resume that activity at a later date, but it is also problematic that EPA might force a company to resume manufacture or processing to satisfy a test order or for EPA to enforce a test order at a site that is not manufacturing or processing the substance. If there are no potential targets for a test order because all have ceased that COU, EPA can issue a SNUR under Section 5(a). If any entities comment that the COU that is defined as a Significant New Use (SNU) in the proposed rule, EPA can issue test orders to those entities.

d. Section 4(a) Test Order Litigation

i. 1,1,2-Trichloroethane

On May 23, 2022, the Vinyl Institute, Inc. (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.

On August 26, 2022, the VI filed a motion for leave to make additional submissions to the record, arguing that EPA issued the test order with no opportunity for public review and comment, therefore necessitating an order by the court allowing the VI to supplement the record with additional comments, as well as material information and data. EPA responded on September 16, 2022, that the motion should be denied because such submissions are allowed only when "there were reasonable grounds for … failure to make such submissions … in the proceedings before the Administrator," and the information is "material." According to EPA, the VI "had the opportunity to present to EPA the information it now seeks to add to the record through a process explicitly set forth in the order it is challenging, yet it failed to do so," and the VI's motion "does not demonstrate any reasonable grounds for its failure."

ii. ODCB

Lanxess Corp. filed suit on May 31, 2022, in the U.S. Court of Appeals for the Third Circuit, seeking review of EPA's Section 4(a)(2) test order for *o*-dichlorobenzene. *Lanxess Corp. v. EPA*, No. 22-2036. In 2021, EPA issued a Section 4 test order to Lanxess for five studies of ODCB. Rather than conduct the tests, Lanxess exited the market for ODCB, ceasing all importation, manufacture, and processing of ODCB by April 19, 2021. EPA approved Lanxess's response to the 2021 test order and confirmed that Lanxess had no obligation under the order.

In 2022, EPA issued a second test order to Lanxess for four studies of ODCB, two of which were originally required by the 2021 test order. Lanxess responded by asserting that it was not subject to the 2022 test order under TSCA Section 4(b)(3)(C) as a person who had ceased all importing, manufacturing, and processing of ODCB in 2021. As reported above, EPA clarified its one-time policy for exempting manufacturers from the test order, acknowledging that companies that were offered and exercised the option to cease manufacture should not be subject to the 2022 test orders. On September 15, 2022, the parties filed a motion to dismiss the case, which the court granted on September 16, 2022.

iii. 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, 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.

iv. TDCE

On August 22, 2022, the TDCE Consortium filed suit in the U.S. Court of Appeals for the District of Columbia Circuit seeking review of EPA's Section 4(a)(2) test order for TDCE. *TDCE Consortium v. EPA*, No. 22-1216. In May 2022, the TDCE Consortium submitted information to EPA that supported TDCE is not a hazard concern for sediment-dwelling organisms, thereby precluding the need for sediment-water chironomid toxicity studies. If EPA determines that the submitted information satisfies one or more data needs identified by the test order, EPA will extinguish any associated testing requirement. EPA was not able to evaluate the existing data submission within the 60-day period during which test order recipients may file a petition for judicial review of the test order. EPA declined to rescind and reissue the test order to reset the 60-day clock, as it had done once before in June 2022, pending issuance of its determination.

As a result, the TDCE Consortium filed a lawsuit to protect its legal interests. The TDCE Consortium seeks a determination that the test order is unlawful and therefore must be set aside.

2. Section 4(h) — NAMs

EPA made significant updates to its publicly available resources on new approach methodologies (NAM) in 2022. It launched the "New Approach Methods (NAMs) Training" website, which provides background information and training videos on 84 NAMs. We note that not all of the listed NAMs on the "New Approach Methods (NAMs) Training" website are listed on EPA's "List of Alternative Test Methods and Strategies (or New Approach Methodologies [NAMs])" (List). For example, on February 4, 2021, EPA issued its second update to the List pursuant to TSCA Section 4(h)(2)(C). The List contains NAMs that the EPA Administrator has identified as "scientifically reliable, relevant, and capable of providing information of equivalent or better scientific reliability and quality to that which would be obtained from vertebrate animal testing." The List does not, however, contain the Open (Quantitative) Structure-activity/property Relationship App (OPERA), yet the OPERA models are listed on EPA's "New Approach Methods (NAMs) Training" website with a reference date of 2017. Further, EPA used the OPERA model physicochemical property estimates *in lieu* of measured data, as the basis for concluding that 6:2 FTSB is an "insoluble solid substance" in its TSCA Section 4(a)(1) test order on this substance.

These issues create confusion for the regulated community on the use of NAMs. For example, since OPERA is not included on the List, questions arise as to whether the regulated community should not use this NAM as part of its submissions to EPA. It is unclear if EPA's use of OPERA in a TSCA Section 4(a)(1) test order is an indication that EPA will accept estimates from this NAM submitted by members of the regulated community.

Ultimately, this comes down to transparency. In September 2020, EPA proposed five critical elements for nominating potential NAMs to the List (*i.e.*, 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?]). The critical elements, which have not yet been finalized, were intended to guide members of the regulated community and developers of NAMs, including other federal agencies and private entities. EPA did not, however, reference published information or provide its own evaluation of OPERA in the TSCA Section 4(a)(1) test order to demonstrate that OPERA met these critical elements or other criteria justifying the use of this NAM. We acknowledge that OPERA is supported by a robust publication record in the peer-reviewed literature and do not doubt that its development would satisfy EPA's critical elements. But again, this comes down to transparency in EPA's decision-making, an element that was recently recognized as critical for establishing scientific confidence in NAMs.

In August 2022, van der Zalm *et al.* published an article titled "A framework for establishing scientific confidence in new approach methodologies." The authors included senior members of multiple U.S. federal agencies, the European Commission (EC) Joint Research Centre, OECD, and People for the Ethical Treatment of Animals (PETA) Science Consortium International and proposed a framework consisting of five essential elements to ensure scientific confidence in NAMs, including: fitness for purpose, human biological relevance, technical characterization, data integrity and transparency, and independent review. The framework was focused on NAMs that inform human health, although the applicability of these elements would be expected to overlap with NAMs being developed in other disciplines (*e.g.*, ecotoxicology). With regard to transparency, the authors stated, "Where appropriate, peer reviewed articles and information describing the fitness for purpose, biological relevance, and technical characterization of the NAM should be published in open-access journals and/or *summarized in public-facing regulatory documents*. [emphasis added]"

Collectively, the above information on EPA's proposed critical elements and those proposed by van der Zalm *et al.* (2022) provide readers with insight on the types of information EPA and other regulatory agencies will be looking for when evaluating NAMs. We caution readers, however, to consider scheduling pre-submission meetings with EPA prior to developing NAM data intended for regulatory submission to ensure the proposed work does not overlook any of the above-mentioned critical elements.

WEBINAR ON DEMAND
TSCA New Approach Methodologies

3. Section 6 — Existing Chemical Substances

a. Prioritization

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 (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

Once EPA completes one of these risk evaluations, EPA will be required to initiate prioritization for an additional substance for risk evaluation. While it is not clear, especially considering budget and staffing limitations, it appears that EPA might complete one of the "Next 20" risk evaluations in **mid- to late-2023**. To prepare for that possibility, we expect EPA to review the remaining chemicals on the 2014 update of the TSCA Work Plan for Chemical Assessments and select a number to consider for prioritization. EPA might issue test orders to inform which substances(s) it will select for prioritization.

b. Risk Evaluations

In addition to completing some of the "Next 20" chemicals in 2023, EPA will also continue risk evaluation of the chemicals for which EPA has granted a manufacturer request for a risk evaluation under TSCA Section 6(b)(4)(C)(ii).

Due to its settlement in *Safer Chemicals Healthy Families v. EPA*, 943 F.3d 397 (9th Cir. 2019), 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 because of the settlement. On June 29, 2022, EPA satisfied its obligation pursuant to a settlement agreement in *Asbestos Disease Awareness Organization et al. v. EPA*, to issue its draft scoping document for the Part 2 risk evaluation. 87 Fed. Reg. 38746. Also as part of that settlement, EPA agreed to issue Part 2 of the risk evaluation of asbestos by **December 1, 2024.**

i. Policy Changes

On June 30, 2021, EPA announced several significant policy changes that it intends for chemical risk evaluations performed under TSCA Section 6. The policy changes include considering exposure pathways covered by other EPA-administered statutes, assessing fenceline community exposures, revisiting the assumption that personal protective equipment (PPE) is routinely worn properly, and making risk determinations using a whole chemical approach.

B&C notes that in the Regulatory Agenda issued by the Office of Management and Budget (OMB), there is an action entitled "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act" (2070-AK90), which will likely include proposed changes to the current risk evaluation procedural rule to reflect these policy changes. A notice of proposed rulemaking (NPRM) publication date of September 2022 is included. Given that the proposed rule has not begun Executive Order (EO) 12866 Regulatory Review as of late December 2022, however, we do not expect its publication until **early 2023**. The risk evaluation procedures will be a key regulatory development in 2023; stakeholders should pay careful attention to the proposed revisions to the rule.

For 1,4-dioxane, EPA issued a final risk evaluation in December 2020. EPA intends, however, to reopen and update the risk evaluation to include additional exposure pathways (*e.g.*, drinking water, ambient air, and COUs where 1,4-dioxane is generated as a byproduct). EPA is also planning to take public comments on the update, but EPA has not provided a timeline for these activities.

In 2022, EPA continued to update its approach to assessing fenceline community exposures. It remains to be seen how robust and defensible EPA's approach will be. On January

B&C anticipates legal challenges to the First 10 risk evaluations as EPA moves these documents forward to final risk management rules — the first opportunity for a legal challenge of EPA's risk evaluations.

21, 2022, EPA released the *Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0* (Draft Approach) for public comment and announced that the TSCA Science Advisory Committee on Chemicals (SACC) would review the Draft Approach during a three-day public peer review virtual meeting March 15-17, 2022.

EPA issued the SACC's final report in May 2022. In that report, the SACC provided comments that were both complimentary to EPA's approach and comments that expressed concerns for areas of improvement. For example, the SACC stated that it "agreed that the methodological document was well organized and generally well written [but noted that] "it may not be protective overall because potential key exposure pathways are excluded and because cumulative exposures, multiple source exposures, aggregate exposures, and double/aggregate and occupational exposures from workers living near and working at the facilities were not considered." B&C notes that EPA intends to use the Draft Approach, once issued in final, on six of the First 10 chemicals with final risk evaluations (i.e., methylene chloride (MC), TCE, carbon tetrachloride (CCl_4), perchloroethylene (PCE), N-methylpyrrolidone (NMP), and 1-bromopropane (1-BP)). B&C anticipates that EPA will issue a revised version of the Draft Approach in 2023. We question whether EPA will be able to issue final supplemental analyses for the six risk evaluations before the start of **2024** given the timing required for interagency review, notice and comment, and responding to public comments on the draft and final versions of these documents. Given that accurate risk evaluations are key to EPA proposing risk management rules, it seems that risk management activities for these substances may be delayed substantially.

ii. Systematic Review

In response to the U.S. National Academies of Sciences, Engineering, and Medicine (NASEM) final report on EPA's 2018 *Application of Systematic Review in TSCA Risk Evaluations* (2018 Guidance Document) finding that "the process outlined in the 2018 guidance document, and as elaborated and applied in the example evaluations [*i.e.*, TCE and 1-BP], does not meet the criteria of "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."

On December 20, 2021, EPA issued a *Federal Register* notice regarding review of its "draft TSCA Systematic Review Protocol" (Draft Protocol). EPA stated that the Draft Protocol takes "into account previous peer review comments from SACC reviews of risk evaluations on the First 10 chemical assessments and more recent recommendations from the National Academies of Sciences, Engineering, and Medicine (NASEM)." On April 19-21, 2022, EPA held the SACC public peer-review meeting on the Draft Protocol. EPA subsequently published the SACC meeting minutes and final report in July 2022. The SACC identified multiple aspects of the Draft Document that could be improved. For example, the SACC stated that EPA needed to address the following items that were missing or underdeveloped in the Draft Protocol:

> (1) start with the problem formulation, (2) describe how Populations, Exposures, Comparators, and Outcomes (PECOs) or Receptors, Exposure, Setting or Scenario, and Outcomes (RESOs) statements are developed and refined through the process, (3) describe the process of systematic review, evidence synthesis and integration, and (4) clearly link the steps of the systematic review back to the larger risk evaluation process.

The SACC further stated that "[it] was concerned about the development and application of PECO and Pathways and Processes, Exposure, Setting or Scenario, and Outcomes (PESO) statements to the Next 20 chemicals, noting that they were inconsistent across the first ten chemicals and across time within a single chemical review."

B&C anticipates legal challenges to the First 10 risk evaluations as EPA moves these documents forward to final risk management rules — the first opportunity for a legal challenge of EPA's risk evaluations. NASEM's critical findings

suggest that EPA did not meet its required scientific standards under TSCA Section 26; it is unclear whether EPA's use of the 2018 Guidance Document resulted in substantive errors or significant omissions (as discussed for the test orders) in the risk evaluations that would change EPA's risk determinations.

iii. 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. 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 COUs.

EPA stated in the Final Risk Evaluation for PV29 that it used the [Regional Deposited Dose Ratio (RDDR)] software "for dosimetric adjustment across species instead of the multi-path particle dosimetry (MPPD) model because the MPPD software cannot calculate the DAF [Dosimetric Adjustment Factor] for hamsters tested in the Elder et al., (2005) study." EPA does not explain why it is rejecting a model (*i.e.*, MPPD) that can calculate the appropriate dose metric (*i.e.*, retained mass) for low-solubility particles simply to use hamster data with a model that can only calculate deposited dose (*i.e.*, RDDR). We also note that EPA ultimately rejected using the hamster data for its calculation of a point of departure (POD). EPA appears to prefer RDDR over MPPD "because the particle size data was not robust enough," but EPA does not explain why this limitation would not apply equally to both models. EPA's selection of the RDDR model also conflicts with other recent activities conducted by EPA's Office of Research and Development (ORD), which support the use of MPPD. For example, ORD used MPPD in support of the Integrated Risk Information System (IRIS) derivation of its inhalation reference concentration for benzo[a]pyrene.

On a separate note, EPA also seems to have ignored 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 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 existing chemical exposure limit (ECEL) for PV29. B&C suspects that EPA 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. We expect that EPA may move forward with issuing its draft risk management rule on PV29 in 2023 simply to maintain optics, but we anticipate that EPA will ultimately end up revising the PV29 risk evaluation and re-quantifying risks using the peer-reviewed MPPD model and retained dose.

iv. Exposures from Pathways Regulated by Other Federal Authorities

As readers may recall, in the First 10 risk evaluations, EPA did not evaluate exposures from COUs managed by other environmental statutes implemented by EPA in the risk evaluations. As such, unreasonable risk determinations for the relevant COUs do not account for those exposures to the general population.

The Biden Administration reassessed its conclusions for eight of the First 10 risk evaluations, each to varying degrees. As shown in Table 3, EPA's new policy of assuming that workers will not always appropriately wear PPE resulted in no changes to the number of COUs with unreasonable risk determinations or an increase in the number of COUs with unreasonable risks.

In each case, EPA found that the whole chemical presents an unreasonable risk. There is still ongoing debate about

the whole chemical approach and whether TSCA requires or prohibits it because it implicitly incorporates a hazard-based standard for those COUs where no unreasonable risks were identified. Now that EPA has determined each of the First 10 presents an unreasonable risk, EPA has withdrawn its orders finding no unreasonable risk for certain COUs. It is not clear what the effect of the withdrawn orders will have. The most significant effect is the reversal of the preemptive effect of the orders, although it is not clear that there are any state actions that were preempted by those orders.

PODCAST:
TSCA Regulation of Articles: The Saga Continues

v. "Next 20" Chemical Risk Evaluations

There has been little change in the status of the risk evaluation review of the "Next 20." In late 2021, EPA issued a data call-in under TSCA Section 8(d) with a January 2022 deadline. Shortly thereafter, EPA issued additional test orders on the nine substances for which EPA had already issued orders. Based on anecdotal evidence, risk evaluation work continues on all, but the new policy changes reflected in the First 10 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 are 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 and the final rule promulgated under the Trump Administration at 40 C.F.R. Section 702.33 in nearly identical terms. The differences between the proposed rule and the final rule are shown below; the text in the proposed rule that differs from the final rule is underlined:

> [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].

Importantly, this definition, under both the Obama and Trump Administrations, does not say "for use in risk management." EPA states, however, the following in eight of the First 10 draft or final revised risk determinations:

Table 3. Original and Revised Unreasonable Risk Determinations for Eight of the First 10 Risk Evaluations

High-Priority Substance	Original Unreasonable Risk Determination	Revised Unreasonable Risk Determination
1-Bromopropane (1-BP)	16/25[a]	23/25 (Final)
Carbon Tetrachloride (CCl_4)	13/15	13/15 (Final)
Colour Index Pigment Violet 29 (PV29)	10/14	10/14 (Final)
Cyclic Aliphatic Bromide Cluster (HBCD)	6/12	6/12 (Final)
Methylene Chloride (MC)	47/53	52/53 (Final)
N-Methylpyrrolidone (NMP)	26/37	29/37 (Final)
Perchloroethylene (PCE)	59/61	60/61 (Final)
Trichloroethylene (TCE)	52/54	52/54 (Draft)

[a] Number of COUs with unreasonable risk determinations/total assessed COUs.

> [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-BP, CCl_4, PV29, HBCD, MC, NMP, PCE, and TCE.

It is unclear if EPA will revise the final scope documents for the "Next 20" and provide an opportunity for public comment in 2023. We had expected EPA to do so in 2022, but those updates have not been published. Nevertheless, manufacturers, importers, and processors will continue to engage with EPA on the specific COUs as EPA progresses the risk evaluations. Given that EPA is revisiting the First 10 and EPA has four MRREs under way, B&C expects the risk evaluation work on the "Next 20" to continue through 2023 and possibly through much of **2024.**

vi. 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) Di-isononyl Phthalate (DINP)/Di-isodecyl Phthalate (DIDP)

On December 17, 2021, EPA reopened the docket for comments on DINP, with a comment deadline of June 17, 2022. EPA did receive several comments from the Washington State Department of Ecology and other environmental stakeholders, including Earthjustice and Defend Our Health.

(b) Octamethylcyclotetra-siloxane (D4)

On March 7, 2022, EPA posted to the docket its response to public comments on the scope of the risk evaluation. Then on Oct 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.**

c. Risk Management

i. First 10 Chemicals

The First 10 chemicals selected for risk evaluation are:

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

EPA has now completed its risk evaluations, as well as eight of 10 draft or final revised risk determinations for the First 10. EPA is required to proceed immediately with proposing risk management rules to mitigate unreasonable risks to the "extent necessary."

ii. Asbestos

For asbestos, EPA has moved to risk management, proposing a rule under TSCA Section 6(a) in April 2022 to address the unreasonable risks to human health of activities associated with ongoing uses that EPA identified in its December 2020 Risk Evaluation for Asbestos, Part 1: Chrysotile Asbestos. Additionally, because of the litigation discussed above and more below, EPA is also evaluating 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. A draft risk evaluation will be made available for public comment, although the timing of that release is unclear.

As reflected in the final scope of Part 2 of the asbestos risk evaluation issued in June 2022, this evaluation will consider COUs for which manufacture, import, processing, and distribution in commerce no longer occur, but where use and disposal are still known, intended, or reasonably foreseen to occur, including other asbestos forms in addition to chrysotile, as well as COUs of asbestos containing talc.

ARTICLE

"EPA Targets Asbestos," *Chemical Processing*, May 15, 2022.

EPA still appears to be prepared to revise the PBT regulations with proposed rulemaking in the middle of 2023: June 2023 is included as the planned date for the proposal and September 2024 for the final rule in the Spring 2022 Regulatory Agenda.

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. According to the Spring 2022 Regulatory Agenda (2070-AK86), EPA plans to publish the final rule in **November 2023.**

iii. Other of the First 10 Chemicals

In 2023, EPA will continue to prepare Section 6(a) risk management rules on those of the First 10 for which EPA has completed or will complete 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. It is not clear how this timeline will be affected by EPA reevaluating the First 10 risk evaluations under the whole chemical approach and the withdrawal of the no-unreasonable-risk orders for the First 10.

The Spring 2022 Regulatory Agenda includes EPA's plans to publish proposed Section 6 risk management rules for MC (2070-AK70) and PCE (2070-AK84) in **February 2023, TCE (**2020-AK83) in **March 2023,** CCl_4 (2070-AK82) in **April 2023,** NMP (2070-AK85) and 1-BP (2070-AK73) in **May 2023**, and HBCD (2070-AK71) and PV29 (2070-AK87) in **July 2023**. EPA has not yet published its anticipated date for the risk management rule for 1,4-dioxane. EPA has not explained how this timeline fits with EPA's ongoing assessment of fenceline communities. If EPA is reassessing a risk evaluation, what is EPA's basis for proposing risk management measures that are sufficiently protective of a yet-to-be-identified unreasonable risk? This weakness, along with the open questions about EPA's systematic review (discussed above), may not be addressed in the proposed rule.

iv. PBTs

EPA published the final TSCA Section 6(h) regulations for five PBT chemicals in the *Federal Register* on January 6, 2021, the final rules. Readers may remember the extraordinary concerns related to the nearly immediate ban on processing and distribution of phenol, isopropylated phosphate (3:1) (PIP (3:1)). EPA spent much of 2021 mitigating the potential catastrophic economic effects that the ban might have had. A final rule extending the compliance dates to March 8, 2022, was published in the *Federal Register* on September 17, 2021, and a final rule extending the compliance date further, to **October 31, 2024,** was published in the *Federal Register* on March 8, 2022. In proposing the extended compliance date, EPA stated that the **October 31, 2024**, compliance date was based primarily "on the low end of the timelines provided by commenters and the specific, detailed timeline laid out by the consumer electronics sector."

In the September 3, 2021, announcement, EPA stated that it "is considering revising all five of the final rules to further reduce exposures, promote environmental justice, and better protect human health and the environment." EPA still appears to be prepared to revise the PBT regulations with proposed rulemaking in the **middle of 2023**: **June 2023** is included as the planned date for the proposal and **September 2024** for the final rule in the Spring 2022 Regulatory Agenda (2070-AL02). What EPA may include in the

planned proposed rule remains to be seen. We hope EPA will engage in broad outreach ahead of proposing further restrictions in the final PBT rules. For stakeholders, including article manufacturers, importers, processors, distributors, and commercial users, it will be critically important to comment when EPA reopens all of the PBT rules in 2023.

d. Risk Evaluation Litigation

On June 30, 2021, EPA announced plans to revisit or supplement the risk evaluations for the First 10 chemicals while expeditiously moving to the risk management phase for these substances. Four of the ten final risk evaluations — MC, HBCD, 1-4-dioxane, and asbestos — are the subject of petitions for review challenging EPA's determinations of unreasonable risk for certain COUs. As EPA has decided to supplement its past risk evaluations, EPA has requested, and been granted, voluntary remand in the MC, HBCD, and 1,4-dioxane cases while it revisits the risk evaluation challenges described below. In November 2022, the parties filed a joint motion to dismiss the HBCD case.

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 Environmental 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.

EPA's October 11, 2022, status report to the court states that EPA began to develop a screening-level approach for analysis of ambient air and drinking water chemical exposures to fenceline communities to review exposures previously excluded from the MC risk evaluation. EPA states that it expects to describe its findings regarding the chemical-specific application of this screening-level approach in the proposed TSCA Section 6(a) risk management rule for MC, which EPA expects to publish for public notice and comment in the **first half of 2023**. EPA notes that it published a proposed revised risk determination for MC on July 5, 2022, and is currently reviewing public comment and working on the final revised risk determination. Because EPA proceedings are ongoing, EPA asked that the case stay in abeyance. The next status report is due **January 9, 2023**. More information regarding EPA's proposed revised risk determination is available in our July 12, 2022, memorandum, "EPA Releases Draft Revisions to Risk Determinations for PCE, NMP, Methylene Chloride, and TCE, Finding that Each, as a Whole Chemical Substance, Presents an Unreasonable Risk of Injury to Health."

ii. HBCD

On October 16, 2020, the Alaska Community Action on Toxics (ACAT) filed suit in the U.S. Court of Appeals for the Ninth Circuit, seeking review of EPA's "final risk evaluation and order" determining that HBCD "do[es] not present an unreasonable risk of injury to health or the environment under certain conditions of use and declining to consider certain uses and pathways through which Petitioner's members are exposed and face risks of exposure to HBCD." *Alaska Cmty. Action on Toxics v. EPA* (No. 20-73099); consolidated with *California Professional Firefighters et al. v. EPA* (No. 20-73578). On May 28, 2021, EPA filed a motion for voluntary remand. On August 10, 2021, the court granted EPA's motion for voluntary remand for the limited purpose of permitting it to reconsider the challenged no-unreasonable-risk determinations.

EPA's October 11, 2022, status report notes that EPA published a final revised risk determination for HBCD on June 29, 2022. In the revised risk determination, EPA found that HBCD, as a whole chemical substance, presents an unreasonable risk of injury to health and the environment under the COUs. In addition, the revised risk determination does not reflect an assumption that workers always appropriately

ARTICLE

"Due Diligence in Mergers and Acquisitions Involving Chemical Products," *Financier Worldwide*, October 2022

EPA policies implementing TSCA continue to be in flux, and TSCA stakeholders are expected to seek judicial intervention as they did in 2022, a reflection of the back-and-forth between stakeholders and EPA on the interpretation of the new provisions of TSCA occasioned by Lautenberg.

wear PPE. EPA also withdrew the previously issued TSCA Section 6(i)(1) order for six COUs previously determined not to present unreasonable risk. On November 1, 2022, the parties filed a joint stipulation of dismissal without prejudice. More information regarding EPA's final revised risk evaluation is available in our June 30, 2022, memorandum, "Final Revision to HBCD Risk Determination Finds HBCD, as a Whole Chemical Substance, Presents an Unreasonable Risk."

iii. 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 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 COUs. *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.

EPA filed a status report on November 3, 2022, stating that it began developing an approach for analysis of ambient air and water chemical exposures to fenceline communities. EPA plans to apply elements of the peer-reviewed approach to evaluate potential chemical exposures and associated potential risks to fenceline communities in the supplemental risk evaluation for 1,4-dioxane. Additionally, OPPT is developing an analysis characterizing impacts from down-the-drain releases to the general population, as well as methods to consider aggregate general population exposures from multiple sources of 1,4-dioxane. EPA plans to provide a public notice and comment opportunity on the supplemental risk evaluation for 1,4-dioxane in **early 2023.** Because EPA proceedings are ongoing, EPA asked that the case stay in abeyance. The next status report is due **February 1, 2023**. More information on the final risk evaluation is available in our January 13, 2021, memorandum, "Final Risk Evaluation for 1,4-Dioxane Finds Unreasonable Risk to Workers for Certain Uses."

iv. 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 COUs of chrysotile asbestos fibers but declining to consider the risks of other asbestos fibers, COUs, 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. In the joint motion, EPA estimated that it would publish the final scope document for the Part 2 risk evaluation by June 30, 2022. On October 11, 2022, EPA filed a status report, noting that it had published the final scope document on June 29, 2022. EPA's next status report is due **April 10, 2023.** 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."

e. Risk Management Litigation

We expect that 2023 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. This is entirely predictable and not necessarily an undesirable outcome; rather it is a reflection of the back-and-forth between stakeholders and EPA on the interpretation of the new provisions of TSCA occasioned by Lautenberg.

i. decaBDE

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 was 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. More information on EPA's final rule is available in our December 23, 2020, memorandum, "EPA Releases Final TSCA Section 6(h) Rules for Five PBT Chemicals."

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 recordkeeping 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. The parties are directed to file motions to govern further proceedings by **February 7, 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)."

4. Section 5 — New Chemical Substances

a. Policy Changes

2022 saw the results of the policy changes that EPA announced in 2021: that EPA would no longer use non-order SNURs, and that EPA would no longer assume that worker protections would be used in compliance with OSHA's Worker Protection Standard (WPS).

EPA's review of PMNs has been substantially less efficient in 2022. Although EPA's policy changes are not entirely to blame, both have contributed to delays, as EPA is now issuing orders for nearly every PMN. Whether EPA's actions lead to any additional protective effect is unclear. EPA continues to cite OSHA's top ten violations to support its view, but those violations do not reflect the chemical industry. Why EPA views violations for the construction industry or general industry as representative of the chemical industry is puzzling, and EPA has not explained why it has not focused on violation rates for the chemical industry to support its view.

B&C acknowledges that EPA has authority to impose worker protection under TSCA. Our disagreement stems from EPA's apparent assumption that PPE is "not always" used equates to "never used," which appears to be inconsistent with the legislative history of the TSCA amendments that "the term [conditions of use] is not intended to include "intentional misuse" of chemicals." This begs the question of whether violating another federal law (*e.g.*, the Occupa-

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tional Safety and Health Act (OSH Act)) is reasonably foreseen or a misuse? This is a separate question from whether OSHA standards are sufficiently protective.

b. Scientific Updates

In October 2022, EPA released a summary report submitted to the Board of Scientific Counselors (BOSC) titled *The New Chemicals Collaborative Research Program: Modernizing the Process and Bringing Innovative Science to Evaluate New Chemicals Under TSCA*. The summary report outlined a new joint effort between OPPT and EPA's ORD aimed at advancing the following five key research areas:

- Update and Refine Chemical Categories,
- Develop and Expand Databases Containing TSCA Chemical Information,
- Develop and Refine (Q)SAR and Predictive Models for Physical-Chemical Properties, Environmental Fate/ Transport, Hazard, Exposure, and Toxicokinetics,
- Explore Ways to Integrate and Apply *In Vitro* NAMs in New Chemical Assessments, and
- Develop a TSCA New Chemicals Decision Support Tool to Modernize the Process.

OPPT and ORD identified problem areas that the above key research areas will address. For example, OPPT's TSCA chemical categories document was last revised in 2010. B&C notes, however, that not all of the categories were revised in 2010 and many were last updated in the 1990s (*e.g.*, Alkoxysilanes, revised June 1994). Further, the documentation provided for the categories is sparse and inconsistent with the robust documentation provided in EPA's more recent draft chemical category documents (*e.g.*, general surfactants and poorly soluble, low toxicity [PSLT] polymers).

As another example, OPPT and ORD stated that "Existing TSCA information is not computationally accessible or easily searchable." B&C notes that EPA has an on-site storage area for TSCA confidential business information (CBI), referred to by EPA staff and managers as the "cave," that has decades of hard-copy documents on OPPT's decisions for new chemical substance notifications. Digitizing and curating this information will aid OPPT with informing its decision-making on related chemistries.

OPPT and ORD expect the outcome of these research areas to aid OPPT with improving its timely review of new chemical substance notifications, providing transparency in its decisions, and ensuring compliance with the scientific standards under TSCA Section 26. In the summary report, OPPT and ORD noted that although these research areas overlapped with a draft of ORD's Strategic Research Action Plan (StRAP4) for fiscal years (FY) 2023 to **2026**, "the collaboration needed to support modernization and innovation for new chemicals assessment will likely extend beyond completion of StRAP4."

c. New Chemical Notice Review Case Updates

In 2022, the pace of EPA's review of new chemical notices slowed again. EPA's ability to review cases has been hampered significantly by a lack of human health assessors. As of the December 8, 2022, update on EPA's PMN status website, EPA has made only 74 determinations in calendar year 2022, down from 86 in 2021 and 236 in 2020.

To help address its lack of staffing, EPA has reassigned senior assessors from other parts of OPPT, along with scientists from the Office of Pesticide Programs (OPP) and ORD, to help move cases along. Anecdotally, we have seen some signs of life for cases submitted in FY 2022, but it will take some time for EPA to clear its current backlog of over 400 cases awaiting review. EPA points to the magnitude of the backlog generated in 2016 as being larger than the current backlog. EPA neglects to note that the number of PMNs submitted has gone down significantly and EPA's pace of review has gone down even further. The question is not how many cases EPA has under review. The metric should be the number of cases under review relative to the number of determinations EPA makes in a year. Unfortunately, EPA began the year with 302 cases under review, EPA received 210 cases in calendar year 2022, including 32 in FY 2023. EPA completed only 74 determinations, declared four cases invalid or incomplete, and submitters withdrew 16 cases. This means EPA ends the year with 418 cases under review. Clearly there is a backlog, and the backlog is growing.

Table 4 presents statistics on the number of PMNs submitted annually since 2016 and the outcomes obtained following completion of EPA's review.

Table 5 provides for the length of review for cases reviewed since June 22, 2016, as the average number of days required for EPA to make its final decision on PMN cases, as well as the time trends for different types of outcomes. Table 6 shows the

Table 4. Number of PMNs Submitted in FYs 2016-2023

				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	13 (4%)	351 (96%)	139 (38%)	20 (5%)	11 (3%)	41 (11%)	26 (7%)	114 (31%)
2017	437	7 (2%)	430 (98%)	254 (58%)	12 (3%)	30 (7%)	43 (10%)	24 (5%)	67 (15%)
2018	412	38 (9%)	374 (91%)	83 (20%)	9 (2%)	125 (30%)	73 (18%)	14 (3%)	70 (17%)
2019	187	13 (7%)	174 (93%)	71 (38%)	14 (7%)	32 (17%)	33 (18%)	16 (9%)	8 (4%)
2020	179	31 (17%)	148 (83%)	45 (25%)	2 (1%)	10 (6%)	51 (28%)	15 (8%)	25 (14%)
2021	218	88 (40%)	130 (60%)	77 (35%)	0 (0%)	0 (0%)	23 (11%)	11 (5%)	19 (9%)
2022	195	188 (97%)	6 (3%)	2 (1%)	0 (0%)	0 (0%)	0 (0%)	3 (2%)	1 (1%)
2023	24	32 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Total	2,138	417 (19%)	1,728 (81%)	721 (34%)	58 (3%)	208 (10%)	267 (13%)	106 (5%)	363 (17%)

Statistics based on PMN status posted on EPA's website as of December 19, 2022 (last updated Dec. 8, 2022). 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 COUs that, while not intended, are reasonably foreseeable. EPA's view was that once the SNUR is proposed, those COUs 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 5. 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	557	2,353	436	949	1,082	389	50	515
2017	345	1,991	233	842	820	257	41	461
2018	592	1,625	602	634	418	416	19	636
2019	256	1,262	222	281	111	130	57	404
2020	366	904	344	233	131	203	53	387
2021	404	571	387	—	—	160	39	289
2022	197	219	172	—	—	—	19	217
2023	38	49						

[1] As of December 19, 2022.

determinations made in each *calendar year* (rather than FY of the submission). We discuss below the results shown.

d. Discussion of Table 4

i. Total PMNs Submitted

Total PMNs submitted declined again to just 195 submitted in FY 2022. Unfortunately, other than three cases declared invalid, all of those cases await a determination by EPA. As discussed in more detail below, EPA clearly focused its effort on completing older cases in 2022. EPA completed 61 determinations for FY 2021 cases and an additional eight determinations for cases submitted in FYs 2018-2020, for a total of 69 determinations in 2022 (through December 8, 2022). Clearly, EPA continues to struggle to review PMNs timely.

ii. PMN Outcomes

The vast majority of determinations made in 2022 led to consent orders. Of the 69 total determinations, 65 (94%) were consent orders. Only four were "not likely" determinations. This means that EPA is imposing restrictions on nearly every substance it reviews. As we have written in the past, B&C's view is that EPA is taking 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. EPA has, effectively, rendered meaningless the term "not likely to present unreasonable risk under the reasonably foreseen conditions of use." In EPA's view, any exposure level is foreseeable. Some have hailed this as an achievement, but in our view, it is a gross misinterpretation of the statute. If Congress had intended for EPA to regulate all cases in which EPA identifies a hazard other than low hazard, it would have so stated.

In 2022, EPA launched an effort to help explain the level and quality of information that it expects in a PMN. What is not clear is whether more high-quality information will change EPA's approach to what it reasonably foresees. In B&C's experience, regardless of the data provided, whether toxicity or exposure data, EPA issues an order if it identifies hazard other than low/low hazard.

e. Discussion of Table 5

i. Length of Review Period

Table 5 shows the mean number of days between "Day 1" and the final disposition of cases in each FY. Not surprisingly given the delays discussed above, PMN cases languish under review for years. Even with the reassignment of assessors from other parts of EPA, it will take months, if not years, for EPA to clear its backlog. Even if EPA can increase its throughput to 20 PMN determinations per month, about quadruple its current rate, but below EPA's average of 29 per month during 2017-2020, it will take 21 months, or nearly two years, to address the 417 cases currently waiting for review. This also ignores the cases that have and will be submitted in FYs 2023 and **2024.** As of December 19, 2022, 32 cases have been submitted in 2023, or about four per week. EPA clearly has a high hill to climb in 2023. It is not merely a matter of additional staff. EPA needs to become more efficient in its reviews.

Table 6. 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			285	285	324	88
2018	24	13	19	150	182	206	88
2019	57	27	155	54	236	293	81
2020	78	17	34	107	158	236	67
2021	36	1	N/A	49	50	86	58
2022	4	N/A	N/A	70	70	73	96

N/A – Not Available. OCSPP ceased using non-order SNURs in 2021.

As of December 19, 2022, EPA proposed SNURs on 54 recent PMNs in two batches in 2022. All these SNURs are derivative of orders, consistent with EPA's cessation of the non-order SNUR construct.

EPA continues to propose SNURs for new chemicals. As of December 19, 2022, EPA proposed SNURs on 54 recent PMNs in two batches in 2022. All these SNURs are derivative of orders, consistent with EPA's cessation of the non-order SNUR construct. EPA proposed a batch of SNURs related to PMNs with consent orders dating from before Lautenberg. These cases all appear to be related to PFAS. EPA also published 73 SNURs in final in 2022, including both non-order SNURs and orders conforming with consent orders. Even so, there are still 93 PMNs with consent orders, for which EPA has yet to propose a SNUR and another 55 that await a final SNUR. As we have discussed in years past, substances subject to orders without final SNURs may not be distributed past an immediate customer, so these 148 substances without final SNURs may be in commercial limbo awaiting EPA to promulgate those SNURs. As with PMN reviews, EPA needs to be more diligent and efficient in proposing and promulgating SNURs.

In 2020, a coalition of non-governmental organizations (NGO), including EDF and the Natural Resources Defense Council (NRDC), filed a lawsuit regarding "EPA's repeated and ongoing failures to comply with TSCA's nondiscretionary mandates to disclose to the public information about new chemical substances reviewed by EPA" in the U.S. District Court for the District of Columbia, claiming that EPA fails to disclose required information about new chemical substances under TSCA. *EDF v. Regan* (No. 1:20-cv-762). The parties have been in discussions since 2020, seeking to reach an agreement on some or all of the potential procedural issues in dispute.

Initially, the parties indicated that the issues in the case can be resolved by motions for summary judgment. In particular, the parties discussed options to narrow the scope of factual and legal issues presented to the court. Discussions broke down in 2022, however, and on April 29, 2022, the petitioners filed a motion to compel production of the administrative record. The petitioners refer to their first amended complaint, which presents three distinct categories of claims arising under the public disclosure provisions of TSCA: insufficient notice claims; incomplete application claims; and EPA's failure to place the PMNs in an online docket at www.regulations.gov.

EPA responded on June 14, 2022, that the petitioners' complaint challenges EPA's failure to act, claiming that each time EPA published a notice of receipt of a new chemical submission or disclosed a submission file to petitioners, it took an "agency action" under the Administrative Procedure Act (APA), meaning that their complaint should actually be read to challenge collectively hundreds of these so-called actions. According to EPA, petitioners cannot seek relief under the citizen suit provision of TSCA because that provision only allows suits against parties subject to TSCA's substantive provisions, not administering agencies. Petitioners are also barred from seeking relief for all but two of their claims under the other citizen suit provision, which authorizes suit "to compel the Administrator to perform any act or duty under [TSCA] which is not discretionary," because the cited statutory and regulatory provisions do not impose a date-certain deadline on EPA. For the remaining two counts, petitioners lack standing to raise them. On June 14, 2022, EPA filed a motion for judgment on the pleadings and in opposition of petitioners' motion to compel production of the administrative record.

On October 12, 2022, the court found as moot petitioners' motion to stay briefing on the motion for judgment on the pleadings. The petitioners filed a motion for an oral hearing on October 19, 2022. On November 2, 2022, the court denied the petitioners' motion for hearing, stating that if it should determine a hearing is necessary to rule on the pending motions, it will inform the parties.

On July 5, 2022, EPA issued a final rule it proposed in July 2016 that amends the regulations governing SNUs of chemical substances under TSCA to align with revisions that were made to the OSHA Hazard Communication Standard (HCS) and changes to the OSHA Respiratory Protection Standard and the NIOSH respirator certification requirements for the respiratory protection of workers from exposure to chemicals. In addition, the action clarifies or amends the regulations governing SNURs to address certain issues that have been identified by EPA and raised by stakeholders through public comments. EPA provides clarification of the use of 40 C.F.R. Section 721.80, Indus-

trial, Commercial, and Consumer Activities, and changes to the instructions pertaining to 40 C.F.R. Section 721.91, Computation of Estimated Surface Water Concentrations: Instructions, and 40 C.F.R. Section 721.11, Applicability Determination When the Specific Chemical Identity Is Confidential. EPA also made a minor change to reporting requirements for PMNs and other TSCA notifications to require that any safety data sheet (SDS) already developed, even if in draft form, either to comply with OSHA requirements or for other purposes, must also be submitted as part of any notification or exemption application under Section 5 of TSCA. More information about the rule is available in our August 8, 2022, memorandum, "EPA Amends SNUR Regulations to Protect Workers' Health."

Additionally, as reflected in the Spring 2022 Regulatory Agenda (2070-AK65), EPA plans to propose regulations in **February 2023** that would revise the new chemical regulations at 40 C.F.R. Part 720 to "improve the efficiency of EPA's review process [for new chemicals] and to align its processes and procedures with the new statutory requirements [in the June 2016 Lautenberg Amendments to TSCA]." 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." While it is unclear what, specifically, EPA is planning to propose, EPA has a history of requesting additional information during the new chemicals review process that prolongs reviews. Changing its current guidance (*e.g.*, EPA's current "Points to Consider" guidance) into a regulatory requirement is not likely to improve the quality of information provided in PMNs. Furthermore, as discussed above, even with more, high-quality information, it is not clear that such information will change the outcomes of PMNs.

f. SNURs on Existing Chemicals

EPA proposed no SNURs on existing chemicals in 2022.

In 2023, according to the Spring 2022 Regulatory Agenda, EPA plans to issue SNURs on PFAS substances that are inactive on the TSCA Inventory (2070-AL10) as of September 2022. The Regulatory Agenda entry states that "Persons subject to the Inactive Inventory PFAS SNUR would be required to notify the EPA at least 90 days before commencing manufacture or processing for any use that EPA has determined is a significant new use." We believe EPA will propose a determination that "any use" of these inactive PFAS is a SNU (a "dead chemical SNUR"), given EPA's concerns for these chemical substances. Such SNURs will ensure that EPA has an opportunity to evaluate whether any of those substances is or may present an unreasonable risk prior to a manufacturer beginning to manufacture or import any of those PFAS substances.

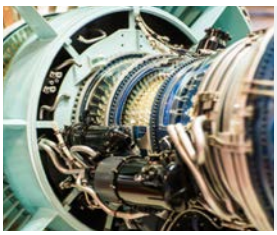
Furthermore, as reflected in the Spring 2022 Regulatory Agenda, in December 2022, EPA is planning to propose SNURs for phthalates (2070-AL06), flame retardants (2070-AL07), certain solvents (2070-AL08), and other high-priority substances undergoing TSCA Section 6 risk evaluations (2070-AL05) that specify as significant new uses COUs identified as not currently ongoing in the final scope documents for the substances. It remains to be seen if and how these actions and any subsequent similar actions will address any COUs that EPA identified in the final scope documents as not currently ongoing but that are intended or reasonably foreseen, which, along with known COUs, can be addressed in risk evaluations and subsequent TSCA Section 6 risk management, as appropriate. The SNURs can be a stop-gap measure pending final Section 6 action, or EPA may view the SNURs as all that is needed to prevent re-introduction of the SNUR substances in those specified COUs. Readers may recall that EPA was resoundingly criticized in a *New York Times* article for its proposal of SNURs for uses of asbestos. It remains to be seen if those same voices will be as critical to the Biden Administration's use of SNURs for existing chemicals.

The proposed SNURs on several groups of existing chemicals, including nonylphenols, nonylphenol ethoxylates, and toluene diisocyanates, remain mired in the proposal stage. Without substantial political pressure, we expect these proposed SNURs to remain in that stage for the **entirety of 2023.**

5. Sections 8 and 14 — Reporting and Confidential Information

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

On November 25, 2022, EPA published in the *Federal Register* an Initial Regulatory Flexibility Analysis (IRFA) and Updated Economic Analysis following the completion of a Small Business Advocacy Review (SBAR) Panel on the PFAS reporting rule it originally proposed in June 2021 to require one-time reporting for PFAS manufactured (including imported) after January 1, 2011. EPA was required to propose this rule under Section 7351 of the National Defense Authorization Act (NDAA) for FY 2020 that amended



We expect EPA will focus the final PFAS reporting rule on those manufacturers most likely to have the requested information and otherwise refine the action to lessen its impact on small manufacturers.

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 information described in TSCA Section 8(a)(2)(A)-(G).

On February 2, 2022, in response to public comments and other information received during the comment period on the proposed rule, EPA announced that it was inviting small businesses, governments, and not-for-profit organizations to participate as Small Entity Representatives (SER) for an SBAR Panel to focus on the development of the PFAS rule. The Panel included federal representatives from the Small Business Administration (SBA), OMB, and EPA. The Panel members asked a selected group of SERs to provide advice and recommendations on behalf of their companies, communities, or organizations to inform the Panel members about the potential impacts of the proposed rule on small entities. The SBAR Panel convened in April 2022 and completed in August 2022.

On November 25, 2022, to facilitate the development of the proposed rule and in light of feedback received from the SBAR Panel — including information that countered EPA's certification that the proposed rule would not have a significant economic impact on a substantial number of small entities (*i.e.*, a "No SISNOSE" certification), EPA developed and released for public comment an IRFA and Updated Economic Analysis. The IRFA reviews the type and number of small entities that may be impacted by the proposed rule, the estimated burden and costs of the proposed rule on small entities, and potential regulatory flexibility alternatives. Included in EPA's IRFA and Updated Economic Analysis are greatly revised estimates of the costs of the proposed rule. Estimated costs grew from approximately $10.8 million to $875 million, with affected small businesses expected to incur approximately $863.5 million of those costs. In the *Federal Register* notice announcing the availability of the IRFA and Updated Economic Analysis, EPA requested comments on specific topics.

In the IRFA, EPA stated it would accept comments on the IRFA and Updated Economic Analysis until December 27, 2022. Given this deadline for comments and the need for EPA to evaluate and respond to those comments, it seems unlikely that EPA will meet the statutory deadline for promulgating the rule.

In accordance with TSCA Section 8(a)(5) and considering the comments received on the proposal, comments from the SBAR Panel, and comments on the IRFA and Updated Economic Analysis, we expect EPA will focus the final rule on those manufacturers most likely to have the requested information and otherwise refine the action to lessen its impact on small manufacturers. We also expect that EPA will define more clearly what it considers to be "known or reasonably ascertainable" for purposes of reporting, particularly regarding reporting by article importers.

Regardless, in its implementation of the final rule, EPA should work with stakeholders to ensure its data gathering efforts are well understood and the information is managed so it can be used efficiently by the federal government and other stakeholders, as appropriate. More information on the November 2022 IRFA is available in our November 29, 2022, memorandum, "EPA Seeks Comment on Initial Regulatory Flexibility Analysis on Proposed PFAS Reporting Rule."

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

EPA published the information from the 2020 CDR reporting cycle on its CDR website. As of November 30, 2022, the updated CDR information was not yet available on EPA's ChemView site. The 2020 CDR data include information on chemicals that lost their confidential status on the TSCA Inventory because manufacturers reported the chemical iden-

ARTICLE
"PFAS: Making Sound Investment Decisions," *Financier Worldwide*, March 2022

tities as non-confidential during the reporting cycles. This information was not included in previous CDR data releases.

EPA is expected to rely heavily on information reported on the 2020 CDR in its next round of Section 6 prioritization. With the December 2019 prioritization process completed, and a three-to-three-and-a-half-year window for completing risk evaluations on the designated high-priority chemicals, the next round of prioritizations would have been expected in late 2022 to **early 2023.** Given the policy changes this Administration is employing in risk evaluation, however, as discussed above, as anticipated, these deadlines were not met and the completion of the risk evaluations for the "Next 20" high-priority chemicals may not occur **until later in 2023.**

c. Procedures for Submitting CBI

On May 12, 2022, EPA proposed new and amended requirements concerning the assertion and treatment of CBI claims for information reported to or otherwise obtained by EPA under TSCA. 87 Fed. Reg. 29078. The proposed rule addresses several issues related to TSCA CBI under Lautenberg and will have significant implications for submitters and their ability and obligations to make and sustain CBI claims across all types of submissions.

EPA proposes procedures for submitting such claims in TSCA submissions and addresses issues such as substantiation requirements, exemptions, electronic reporting enhancements (including expanding electronic reporting requirements), maintenance or withdrawal of confidentiality claims, and provisions in current rules that are inconsistent with amended TSCA. The proposed rule also addresses EPA procedures for reviewing and communicating with TSCA submitters about confidentiality claims and includes provisions requiring the submission of OECD templates, if available, to accompany health and safety studies and information from health and safety studies.

EPA proposes to revise its procedures for reviewing confidentiality claims. The proposed rule would revise the procedures and substantive review criteria to clarify that whether a substance may be readily reverse engineered is among the factors EPA considers as part of the criterion on whether the CBI-claimed information is legitimately and reasonably obtainable without the business's consent. The proposed rule clarifies that EPA requires a certification statement on substantial competitive harm and considers substantial competitive harm as part of its substantive review criteria for TSCA CBI claims.

Among the most significant policies that EPA seeks to embed in the regulations is the ability of study owners to protect the value of study reports without reducing the ability for others to review and understand the study results. The proposed rule would establish a new section of the TSCA regulations to consolidate and standardize how TSCA CBI claims must be asserted and substantiated. EPA is seeking largely to phase out the use of the CBI substantiation templates by incorporating the function into the specific data flows in EPA's Chemical Data Exchange (CDX) so that each data element and attachment in a CDX submission that is claimed as CBI will require substantiation (if not one of the exempt categories of CBI).

Companies are urged to follow the developments regarding this proposed rule in 2023, when it is scheduled to be issued in final in **May**. Industry reactions to the proposed amendments were mixed — positive in aspects including because the rule aims to modernize and bring the TSCA CBI provisions in line with Lautenberg and negative in aspects that could inappropriately compromise legitimate CBI and stifle innovation.

d. CBI Inventory Review Rule

EPA has not published an updated version of the TSCA Inventory that includes the 377 substances that EPA identified for declassification in October 2021. Those substances arose from EPA's review of the confidential listings on the TSCA Inventory required under TSCA Section 8(b) and the TSCA Inventory Notification (Active-Inactive) Requirements Rule. We expect that EPA will continue its efforts in review of the 2016 and 2020 CDR reporting and Form A Notice of Activity reporting and will find additional substances that will be subject to declassification. In particular, stakeholders should carefully monitor the proposed update to the CDR reporting rule that will likely be proposed in **late 2023. The 2024** CDR cycle will be another significant opportunity for declassification.

e. Unique Identifier Implementation

As readers may recall, under TSCA Section 14(g)(4), when EPA approves a CBI claim for 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.

Somewhat surprisingly, EPA's list of UIDs (available here) does not match the most recent copy of the TSCA Inventory (February 2022). The TSCA Inventory file has 680 UIDs, while the list of UIDs has 1,296. EPA may not be providing its list of updated UIDs to the Chemical Abstracts Service for it to incorporate into Inventory listings. Until EPA has developed a method better to integrate its two data sets, stakeholders will have to search for UIDs in the file posted on the CBI review website.

f. Mercury Reporting Rule

The Mercury Reporting Rule, required under TSCA Section 8(b)(10)(D), was published on June 27, 2018. On November 8, 2021, EPA published a final rule revising the regulations associated with persons who must report data to the mercury inventory established under TSCA. 86 Fed. Reg. 61708. The revisions implement an order issued by the U.S. Court of Appeals for the Second Circuit on June 5, 2020, that vacated the exemption at 40 C.F.R. Section 713.7(b)(2) for persons who import pre-assembled products that contain a mercury-added component. As a result, such persons are now required to report pursuant to 40 C.F.R. Section 713.7(b). The final rule was effective on December 8, 2021, and the amended requirements apply to the reporting of 2021 data regarding which the deadline for reporting was July 1, 2022, as well as to subsequent reporting iterations. In February 2022, EPA issued an update to the mercury inventory reporting rule compliance guide to reflect the amended reporting requirements. In 2023, EPA is due to issue the second triennial Mercury Inventory Report based on information submitted to EPA in 2022 for calendar year 2021. It remains to be seen whether EPA will recommend, in this next report, actions to achieve further reductions in mercury use, as contemplated by TSCA Section 8(b)(10)(C). The next reporting cycle will be in **2025** based on mercury information for calendar year **2024.** More information about the rule is available in our June 25, 2018, memorandum, "EPA Publishes Final Reporting Requirements for TSCA Mercury Inventory."

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

On November 21, 2022, EPA improved public access to reports submitted by chemical companies in ChemView, EPA's web application for non-CBI data on chemicals regulated under TSCA, as well as notices of substantial risk. Additionally, EPA has published more than 1,700 health and safety studies received under TSCA Section 8(d) in ChemView, many of which were received in response to EPA's rulemaking with regard to the "Next 20" high-priority substances and 30 organohalogen flame retardants (OFR).

The TSCA Section 8(d) rule requires persons (*i.e.*, manufacturers and importers) who proposed to or have manufactured or imported any of the specified chemical substances in the ten years preceding the effective date of listing (*i.e.*, July 29, 2021) to submit the lists and copies of studies. EPA stated that it intends to use the information obtained on the 20 high-priority substances when informing its risk evaluations under TSCA Section 6.

We expect EPA to continue using the information obtained on the 30 OFR substances to inform prioritization and risk evaluation. EPA will also provide the information received on OFR substances to the Consumer Product Safety Commission (CPSC) to aid CPSC with its evaluation of OFR substances under the Federal Hazardous Substances Act. Additionally, EPA plans to use all the information received with its evaluations of new chemical substances (*e.g.*, analog read-across and category development), under TSCA Section 5.

B&C notes that EPA promulgated the TSCA Section 8(d) rule after issuing TSCA Section 4 test orders on nine of the "Next 20" high-priority substances. While this is arguably an inefficient approach, B&C applauds EPA's efforts to enhance transparency in its scientific and policy-making processes and anticipates that EPA will continue using this approach. Shortly after the reporting deadline, EPA issued additional test orders (as discussed above), but did not explain in those orders if or how EPA evaluated the data received under the Section 8(d) rule.

h. TSCA Section 8 Tiered Data Reporting (TDR) Rule

There has been little visibility into EPA's proposed TDR rule under Section 8(a) to support its evaluation of existing chemicals. The Regulatory Agenda states that EPA expects

The supplemental proposal includes fees for the FYs 2023, 2024, and 2025 that are substantially greater than those in the January 2021 proposed rule. Assistant Administrator Freedhoff forewarned stakeholders of "sticker shock," and the proposal did not disappoint.

to propose the rule in **May 2023**, instead of August 2022, as expected last year.

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

- COU 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 COU stage. For the subset of COU 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 COU 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 COU 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.

EPA has had its hands full with other TSCA requirements, and the PFAS reporting rule clearly was a priority due to its statutory deadline. Once the PFAS reporting rule is published in final, EPA is more likely to return to the TDR rule.

6. Section 26 — Administration of TSCA; Fees Rule

Under TSCA Section 26(b) as amended, EPA has authority to collect fees from chemical manufacturers, including importers, and processors to defray a portion of the EPA costs associated with TSCA Section 4, 5, 6, and 14 implementation efforts. The TSCA Fees Rule (40 C.F.R. Part 700 Subpart C) requires payment of fees from chemical manufacturers for eight categories of fee-triggering events under TSCA, including TSCA Section 4 test orders, test rules, and enforceable consent agreements (ECA); TSCA Section 5 notifications and exemptions; and TSCA Section 6 EPA-initiated risk evaluations, MRREs on chemicals listed on the TSCA Work Plan, and MRREs on chemicals not listed on the TSCA Work Plan.

On January 11, 2021, EPA published proposed amendments to the Fees Rule. The proposed rule describes the proposed modifications to the TSCA fees and fee categories for FYs 2022, 2023, and **2024** and explains the methodology by which these TSCA fees were determined. The incoming Biden Administration reevaluated that proposal with an eye to ensure that it reflected properly the resources needed for EPA to implement TSCA.

On November 16, 2022, EPA published the supplemental proposal. As foreshadowed by Assistant Administrator Freedhoff's June 22, 2022, testimony before the Senate Environment and Public Works Committee regarding EPA's implementation of TSCA and other EPA communications, the supplemental proposal includes fees for the FYs 2023, **2024**, and **2025** that are substantially greater than those in the January 2021 proposed rule based on increased estimates of program costs. Dr. Freedhoff forewarned stakeholders of "sticker shock." The proposal did not disappoint. EPA's proposal approximately doubles the current fees. In addition, the supplemental proposal includes changes that would, if issued in final:

- Narrow certain exemptions proposed in January 2021, including for manufacturers of byproducts, for entities subject to the EPA-initiated risk evaluation fees and include new exemptions for test rule fee activities;

ARTICLE

"Sticker Shock: TSCA Fees Could Soon Be a Lot More Expensive," *Chemical Processing*, December 13, 2022

- Modify the self-identification and reporting requirements for EPA-initiated risk evaluation and test rule fees;
- Provide for a partial refund, *i.e.*, 20 percent, of fees for Section 5 notifications that are withdrawn at any time after the first ten business days during the assessment period of the chemical;
- Modify EPA's proposed methodology for the production volume-based fee allocation for EPA-initiated risk evaluation fees in any scenario where a consortium is not formed;
- Expand the fee requirements to companies required to submit information for test orders — not just those companies required to conduct and submit required testing;
- Modify the fee payment obligations to require payment by processors subject to test orders and ECAs;
- Extend the timeframe provided for test order and test rule payments; and
- Eliminate the three new fee categories proposed in January 2021.

More information on the November 2022 supplemental proposed rule is available in our November 18, 2022, memorandum, "EPA Issues SNPRM Modifying and Supplementing 2021 Proposed TSCA Fees Rule."

7. Section 26 — Scientific Standards

a. Multiple-Path Particle Dosimetry

On March 23, 2021, EPA's 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 the year.

B&C anticipates the new MPPD model will be very helpful to EPA and submitters, since it will represent the best available science for dosimetry modeling under TSCA Section 26(h). The peer-reviewed version of the model will also allow EPA to finalize two of its draft chemical categories. For example, EPA intends to rerun the MPPD model simulations for its draft chemical categories on surfactants and PSLT polymers using the final peer-reviewed version of EPA's version of MPPD and then publish the draft chemical categories in the peer-reviewed scientific literature. Once published, these chemical category documents will aid submitters with evaluating their chemistries that meet the boundaries for these chemical categories.

B&C also anticipates a variety of submitter-prompted activities on new and existing chemical substances once EPA finalizes the MPPD EPA model. For example, persons whose new chemical substances were regulated *via* SNURs based on the 2017 draft chemical categories surfactants and PSLT polymers and that no longer meet the inclusion criteria in the 2021 chemical categories will likely request limitations or revocation of the SNUR requirements under 40 C.F.R. Section 721.185. B&C also 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 using retained dose when quantifying risks for this type of substance.

b. Scientific Challenges

On June 3, 2021, the Semiconductor Industry Association (SIA) submitted a request for correction (RFC) of information to EPA under the Information Quality Act (IQA). SIA's RFC focused on EPA's final risk evaluation on NMP and its use in the semiconductor industry. SIA noted that it had provided EPA with "high quality data on conditions of use, risk management measures, and employee exposure monitoring that demonstrates a high level of worker protection." SIA further noted that EPA's conclusion of unreasonable risk was "based on assumptions and estimates of conditions of use not found in the semiconductor industry in the U.S." Yet EPA did not seem to rely on that information in its risk evaluation; rather EPA relied on its default assumptions.

As of December 2022 (*i.e.*, nearly a year and a half later), EPA has not responded to SIA's RFC. B&C had expected that EPA would deny SIA's RFC using a general justification (*e.g.*, uncertain representativeness of the data). B&C recognizes that EPA's defaults are appropriate when information is lacking to inform specific parameters, however, SIA went to great lengths to educate EPA about its mem-

bers' practices, including providing extensive amounts of information and data, which EPA rated as high quality. Therefore, EPA's decision to use defaults rather than the existing information SIA provided to EPA conflicts with TSCA Section 26(k) and 40 C.F.R. Section 702.33.

Whether there will be further challenges to EPA's conclusions as it moves forward with risk management is not yet clear. If EPA proposes the NMP risk management rule without consideration of the SIA data, EPA may face legal vulnerability for not using the best available science and weight of scientific evidence, as required under TSCA Section 26.

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 judge asked plaintiffs and EPA to consider how to reach an agreement, including plaintiffs submitting a new petition or EPA reconsidering its denial of the petition. On November 4, 2020, plaintiffs filed a supplement to their petition. Based on the scientific evidence that has become available since EPA denied their petition in 2017, plaintiffs requested that EPA reconsider its denial of the petition. EPA responded on January 19, 2021, stating that it declined to exercise its discretion to reopen the administrative record and reconsider its February 17, 2017, denial. On April 22, 2021, the court put the case on hold while waiting for additional scientific data to be released. On September 19, 2022, petitioners moved to list the stay and take the case out of abeyance. The petitioners asked the court to consider supplemental allegations about standing and the scientific developments since the June 2020 trial, including the 2022 National Toxicology Program (NTP) draft and peer reviews. The court held a hearing on October 7, 2022, concerning the motion, and on October 28, 2022, lifted the stay and took the case out of abeyance.

According to the court, the petitioners appear to have cured their standing defects. At the time the court imposed the stay, it stated that the final NTP review was imminent, and its findings were likely to add substantially to the scientific analysis relevant to the questions before the court. As of today, "the final publication is no longer "imminent" because the NTP may never publish the final version," however. Since the case was stayed, two relevant scientific studies have been published in peer-reviewed journals. The court states that it "lifts the stay to permit discovery — focused on obtaining the May 2022 [NTP] draft [review] to share with the parties and the Court so that the Court may assess future scheduling (including whether the next phase of trial should await the final publication of the NTP report)." The court scheduled a status conference on **January 10, 2023**, to discuss future scheduling. A joint status report was scheduled to be filed on January 3, 2023.

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. The petition, filed under TSCA Section 21, seeks issuance of a rule or order under TSCA Section 4 compelling Chemours to fund and carry out testing under the direction of a panel of independent scientists. On January 22, 2021, EPA published the reasons for its denial of the petition, finding that the petitioners have not provided the facts necessary to determine for each of the 54 PFAS that "existing information and experience are insufficient and testing of such substance or mixture with respect to such effects is necessary to develop such information." 86 Fed. Reg. 6602.

In March 2021, the petitioners requested that EPA reconsider its denial, which EPA agreed to do in light of the change in Administration and attendant change in policy priorities concerning PFAS. EPA's National PFAS Testing Strategy identifies priority substances for the first of several described phases of an iterative testing approach based on grouping of chemicals by chemistry features and available toxicity data. EPA states in its December 28, 2021, announcement that it granted the petition that 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. According to EPA, it will use its TSCA Section 4 order authority to require PFAS manufacturers to conduct and fund the following studies that will provide toxicity data and information on categories of PFAS:

- Near-term testing covers 30 of 54 petition chemicals;
- Subsequent testing may cover nine of 54 petition chemicals;

- Testing on the remaining 15 of 54 petition chemicals;
- Testing on mixtures;
- Testing on humans; and
- Develop additional analytical standards.

After their 2020 petition was rejected by EPA, on January 7, 2021, the North Carolina public health and EJ 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. On March 3, 2022, EPA moved to have the case transferred to the U.S. District Court for the Eastern District of North Carolina. The court granted EPA's motion on May 9, 2022. *CEH v. Nishida*, No. 7:22-cv-00073-M. On June 23, 2022, EPA filed a motion to dismiss for lack of subject-matter jurisdiction. According to EPA, Section 21 allows for judicial review only when EPA denies a citizen petition or takes no action on the petition within a certain time. EPA argues that here 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. EPA pointed to previously planned studies on seven other PFAS, but petitioners state that these studies were not selected in response to their petition and would not provide data necessary to understand the effects of the PFAS on Cape Fear populations.

On August 19, 2022, EPA filed a motion to limit the scope of review, stating that if the court denies its motion to dismiss, the court should issue an order "limiting the scope of review to the petition and the facts submitted in support thereof." According to EPA, the petitioners "wish to commence full-on discovery." EPA states that "[t]here is no dispute that the applicable *standard* of review is de novo — in other words, the Court will consider the petition anew. But the text, structure, and legislative history confirm that the *scope* of review is limited to "such petition," which must "set forth the facts" that establish the requested action is necessary." On September 2, 2022, the petitioners filed their opposition to EPA's motion to limit the scope of review. The petitioners argue that the only logical inference from the language of TSCA Section 21(b)(4)(B) is that the district court must conduct a trial at which the plaintiff and defendant present relevant evidence developed during discovery and the court then determines whether the evidence as a whole meets the criteria for testing. The court has not yet ruled on EPA's motions.

EPA received a Section 21 petition on June 16, 2022, from Daniel M. Galpern on behalf of Donn J. Viviani, John Birks, Richard Heede, Lise Van Susteren, James E. Hansen, Climate Science, Awareness and Solutions, and Climate Protection and Restoration Initiative. The petition requests EPA "to phase out the anthropogenic manufacture, processing, distribution, use, and disposal of greenhouse gas (GHG) emissions, fossil fuels, and fossil fuel emissions." On September 21, 2022, EPA announced its decision to deny the petition. 87 Fed. Reg. 57665. EPA "acknowledges both the urgency and uniqueness of the threat presented by climate change," but "even assuming EPA were to determine that the petitioners have adequately demonstrated that the manufacture, processing, distribution in commerce, use, or disposal of at least some of "the subject chemical substances and mixtures" present an unreasonable risk of injury to health or the environment for purposes of TSCA section 6(a), EPA nonetheless finds that the petition is insufficiently specific and fails to establish that it is necessary to issue a rule under TSCA section 6." EPA stated that it makes this latter finding "in light of ongoing and expected federal government actions to address these risks, the relative efficiency of TSCA rulemaking, and lack of TSCA authority to regulate historical GHG emissions."

On October 13, 2022, Earthjustice, on behalf of a coalition of environmental organizations and community advocates, petitioned EPA to revoke the approval of approximately 600 PFAS that were granted through low volume exemptions (LVE) or low release and low exposure exemptions (LoREX) to the PMN requirements of TSCA. In its October 13, 2022, press release, Earthjustice states that these exemptions "allow EPA to approve chemicals through lax safety reviews only if it "will not present an unreasonable risk" to humans or the environment." According to Earthjustice, PFAS do not meet that standard, and EPA must revoke previously granted LVEs and LoREXs for PFAS. The petition follows an April 27, 2021, petition filed by Earthjustice on behalf of many of the same petitioners, and it incorporates the 2021 petition by reference. More information is available in our October 17, 2022, blog item, "Petition Seeks Revocation of Approximately 600 PFAS LVEs and LoREXs."

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." The petitioners request that until such testing is completed, EPA remove PVA/PVOH from its Safer Choice Program "to curb plastic pollution." More information is available in our November 15, 2022, blog item, "Coalition Petitions EPA to Require Health and Environmental Testing and Regulation of Polyvinyl Alcohol."

CONTRIBUTORS

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

For EPA's OPP, 2022 saw the pesticide program staff *finally* move to join the central EPA office in downtown Washington, D.C. This OCSPP office consolidation has been in the planning phase since 1979, so it is a long-awaited goal to see OPP join with OPPT. This may lead to the longstanding goal of closer collaboration among the professional staff. As of Labor Day 2022, OPP staff offices were reopened. This has not ended EPA personnel telecommuting, as there are now a variety of flexible work schedules.

2022 saw a continued march toward meeting the October 1, 2022, deadline for registration review of all pesticides registered as of October 1, 2007; attempting to comply with the requirements of EPA; and meeting Pesticide Registration Improvement Act (PRIA) deadlines for registration applications.

For 2023, the major issues facing OPP are likely to include the topics discussed below.

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1. PRIA 5

The Pesticide Registration Improvement Extension Act of 2018 (PRIA 4) was passed and signed into law on March 8, 2019, reauthorizing PRIA through October 1, 2023. As with preceding reauthorizations, PRIA 4 contained a range of revisions based on OPP's ongoing experience implementing its program. In addition to increasing the number of registration action categories from 189 to 212, PRIA 4 increased the total fee amount that OPP may collect annually in maintenance fees from $27.8 million to $31 million. PRIA 4 explicitly also authorized use of the maintenance fees in the registration review process to offset costs for endangered species assessment. PRIA 4 mandated completion of the registration review cycle by October 1, 2022, for the 726 pesticide cases registered as of October 1, 2007. The October 1, 2022, deadline has passed, but the Consolidated Appropriations Act, 2023 extended the registration review deadline to **October 1, 2026**.

OPP continued its work on PRIA submissions in FY 2022. EPA received over 11,500 submissions through its pesticide registration portal. EPA completed approximately 6,000 PRIA and non-PRIA actions (2,210 PRIA, about 3,700 non-PRIA), registered 13 new active ingredients, approved 38 Section 18 emergency exemption decisions, and collected $31.6 million and $23.95 million in maintenance and PRIA fees.

Most notably, the Pesticide Registration Improvement Extension Act of 2022 (PRIA 5) was signed into law as part of the Consolidated Appropriations Act, 2023 on December 23, 2022. We expect PRIA 5 implementation to be a top priority for EPA, NGOs, and pesticide manufacturers in 2023. Early reauthorization (late 2022 reauthorization versus the **October 1, 2023**, deadline) helped avoid resorting to adding this to the many issues in the 2023 Farm Bill that will be a high priority for Congressional attention.

PRIA 5 reauthorization includes several critical priorities for EPA, industry, and NGOs, including an increase in EPA resources, programmatic process improvements, information technology (IT) modernization, robust reporting requirements, bilingual label changes, and increased program transparency.

PRIA 5 will increase the total registration and maintenance fees paid by industry by 30 percent; increase registration fees by roughly $6 million per year across all fee categories; increase maintenance fees by $11 million per year, from $31 million to $42 million per year; and increase the PRIA appropriations trigger by 30 percent from the current $128 million per year to $140 million per year to reflect an appropriate share of federal appropriations.

Changes to maintenance fees will include creating: (1) new set asides for processing registrant submissions not covered by a PRIA code and to clear the current backlog; (2) a $500,000 set aside for EPA staff education and training to be conducted cooperatively through land grant institutions in partnership with Historically Black Colleges and Universities (HBCU), 1,890 institutions, or other minority-serving institutions; (3) a $500,000 set aside for Vector Expedited Review Vouchers (VERV) to incentivize development of new insect disease vector control methods; (4) a $500,000 set aside for the development of public health pathogen efficacy methods for antimicrobial devices, prioritizing methods for devices used in medical facilities; (5) a $500,000 set aside for education and training of clinicians; and (6) a set aside of $500,000 per year to support the interagen-

PRIA 5 will require EPA to develop a policy for implementing ESA reviews for new use applications and other registration actions and specify that fee-based activities shall continue in the event of a government shutdown.

cy agreement between EPA and the Centers for Disease Control and Prevention (CDC)/NIOSH related to the NIOSH-SENSOR Pesticide Program with a goal of increasing the number of participating states and/or improving the reporting of existing participants. PRIA 5 as envisioned would also create a $350,000 set aside per year for grant writing technical assistance.

PRIA 5 will continue and increase several existing set asides, including increases for worker protection activities to $1.5 million, Pesticide Safety Education Programs (currently funded at $500,000 per year), partnership grants (currently funded at $500,000 per year), and Good Laboratory Practice (GLP) inspections (currently funded at $500,000 per year). PRIA 5 will eliminate several existing set asides, such as the efficacy guidelines for public health pests (previously funded at $500,000 per year) and the fast track and inert review set aside (previously funded at 1/8 to 1/9 of maintenance fees) and move all set asides from maintenance fees (Section 4 funds) to provide greater certainty and transparency of funding.

For process improvements, PRIA 5 will require EPA to issue a competitive bid for an independent third-party audit of EPA's processes and performance and to make recommended process improvements. PRIA 5 will require EPA to address delays in processing registrant submissions not covered by a PRIA code (non-PRIA actions) by establishing a set aside as described above. PRIA 5 will require EPA to develop a policy for implementing ESA reviews for new use applications and other registration actions and specify that fee-based activities shall continue in the event of a government shutdown.

For IT improvements and annual reporting requirements, EPA will streamline the current 67 metrics required in the Annual Report to focus on those that provide insights into processing efficiencies and timelines. EPA also will establish a comprehensive IT system and dashboard that covers all registering divisions and provides real-time access tracking information.

For bilingual labels, all currently registered restricted use pesticides (RUP) must translate the parts of the label contained in the EPA Spanish Translation Guide for Pesticide Labeling and provide the information via scannable technology or other electronic methods readily accessible on the product label **within three years.** Also, all current and newly registered non-RUP products that are designated as Toxicity Category 1 must translate the parts of the label contained in the EPA Spanish Translation Guide for Pesticide Labeling and provide the information via scannable technology or other electronic methods readily accessible on the product label **within three years.**

Registrants of non-agricultural use products may comply with the bilingual labeling requirement by providing the SDS in Spanish via scannable technology or other electronic methods readily accessible on the product label **within four years**. All current and newly registered non-RUP products that are designated as Toxicity Category 2 must translate the parts of the label contained in the EPA Spanish Translation Guide for Pesticide Labeling and provide the information via scannable technology or other electronic methods readily accessible on the product label **within five years**. All other currently and newly registered products must translate the parts of the label contained in the EPA Spanish Translation Guide for Pesticide Labeling and provide the information via scannable technology or other electronic methods readily accessible on the product label **within eight years. Within six months**, EPA must seek stakeholder input on ways to make bilingual labels available to farm workers and begin to implement a plan **within three years**.

Regarding transparency issues, **within six months**, EPA will post on its website "aggregated information." This would include EPA guidance pertaining to risk assessment, risk mitigation, benefits assessments, and cost-benefit balancing, with links to resources, including organic farming

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(the National Organic Program's National List of Allowed and Prohibited Substances); biopesticides and Section 25(b) minimum risk pesticides, and Integrated Pest Management (IPM) principles and technical assistance.

Lastly, in 2023, like many programs in EPA under the Biden Administration, with a new Republican House, look for increased oversight on PRIA 5 implementation.

2. Endangered Species Act

The issue of how EPA should interact with other government agencies to implement ESA provisions has dogged the pesticide program for many years. Litigation challenges were first initiated during the George W. Bush Administration. The pivotal question is how extensive EPA's assessment must be to demonstrate compliance with ESA, how much autonomy EPA needs to make the critical decisions, and the degree to which any EPA assessment must be undertaken in coordination with the other agencies that have responsibility for implementing ESA. Those agencies are the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (Services). 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 more than 15 years and have been and are the subject of extensive litigation.

Earlier lawsuits covered older pesticide products that had been on the market for years; more recent lawsuits have challenged EPA's approvals of new active ingredients. The challenge to new products, many of which include a more attractive environmental and health profile, has led to concerns that these new products would be kept off the market with a prolonged or indefinite review process. This could, ironically, result in greater environmental risks to species compared to the products they would likely replace. Given the enormous costs involved in bringing a new product to the market, registrants also are concerned that unpredictable delays in new product reviews would be a disincentive to continue the process of discovery and development of new products. Industry estimates of the cost of new product discovery and approval are in the range of $150 to $250 million.

Efforts have been made to coordinate more closely information and review procedures, and policies between EPA and the Services, but delays and litigation continue unabated. Efforts to design a process to integrate FIFRA registration actions of EPA in coordination with the ESA reviews of the Services has been an "Administration priority" since the Administration of President George W. Bush. Both Republican and Democratic Administrations have attempted to develop a more efficient, more practical, or at least more predictable, process for ESA compliance.

The Trump Administration established an Interagency Working Group among the Department of the Interior, the Department of Commerce, and EPA to evaluate the current ESA review process, and "to harmonize interagency efforts, and create regulatory certainty for America's farmers and ranchers." To undertake this ambitious goal, the Trump Administration created a "working group" with EPA and the Services along with the U.S. Department of Agriculture (USDA), OMB, and the Council on Environmental Quality (CEQ) acting as chair. This Interagency Working Group helped to organize a senior level effort to coordinate activities of EPA and the Services. As with past efforts, senior management recognizes that a more efficient and predictable process is needed.

Currently, ESA reviews add months or on occasion years to the registration review process. To date, that process is followed by seemingly inevitable litigation challenging EPA's decision as not sufficient to meet ESA requirements. In addition to the Trump Administration efforts, both the George W. Bush Administration and the Obama Administration tried similar efforts with limited success to get the various bureaucracies to understand better the work and mission of the individual agencies.

In 2022, there was renewed focus on ESA in OPP. Importantly, a new political appointee for the Biden Administration, Jake Li, as the Deputy Assistant Administrator for pesticide issues, was tasked *specifically* to focus on the ESA issue. Mr. Li comes to EPA with a wealth of experience about ESA and its requirements and implementation programs of the Services, including senior level experience with an NGO active on ESA matters (Defenders of Wildlife). His background and now senior position in OCSPP reflect the renewed effort by the Biden Administration to achieve the goal of better integrating the work of both EPA and the Services.

EPA has been clear that it will pivot to ways EPA can begin to identify and implement protections for listed species earlier so that they can be more aligned with ESA. To that end, in 2022, EPA released an ESA Workplan Update that attempts to outline major steps to increase protections for wildlife and regulatory certainty for pesticide users. The Workplan, initially released in April 2022 and updated in

November 2022, details how EPA will pursue protections for nontarget species, including federally listed endangered and threatened (*i.e.,* listed) species, earlier in the process for pesticide registration review and other FIFRA actions. These early protections will possibly help EPA comply with ESA, thus reducing EPA's legal vulnerability, providing farmers with more predictable access to pesticides, and simplifying the ESA-FIFRA process that, left unchanged, creates both significant litigation risk and a workload far exceeding what EPA has the resources to handle.

The ESA Workplan addresses the complexity of EPA meeting ESA obligations for thousands of FIFRA actions annually. Among other points, the ESA Workplan prioritizes certain FIFRA actions for ESA compliance, outlines how EPA will pursue early mitigation for listed species under FIFRA, and describes directions for expediting and simplifying the current pesticide consultation process.

EPA also has a responsibility under ESA to ensure certain pesticide registrations do not jeopardize the continued existence of listed species or adversely modify their designated critical habitats. In the past few decades, EPA has seen an increase in litigation due to the failures to meet its ESA obligations when taking FIFRA actions. Over the next six years, existing court-enforceable deadlines will require EPA to complete ESA reviews for 18 pesticides — the most EPA estimates it can handle during this period based on its current capacity and processes.

Ongoing litigation and settlement discussions for other lawsuits cover dozens of additional pesticides and will likely fill EPA's ESA workload well beyond **2030**. If EPA's ESA efforts continue at this pace, a future court may decide to curtail drastically pesticide use until EPA meets its obligations. This unsustainable and legally tenuous situation not only provides inadequate protection for listed species but also creates regulatory uncertainty for farmers and other pesticide users.

In 2023, EPA also will work with registrants to add language on pesticide incident reporting, advisory language to protect insect pollinators, and language to most outdoor-use pesticide labels. In 2023, the Biden Administration may also press in earnest for ESA modernization and reauthorization. Such an effort will heighten public debate around endangered species and put EPA ESA action under the spotlight and microscope.

Lastly, in 2023, implementation of the ESA Workplan will reveal more specificity regarding how EPA intends to impose mitigation measures to meet its ESA obligations when registering a pesticide. The most favorable view of what EPA has presented to date is that it continues to achieve ESA compliance, which is long overdue, as EPA continues to provide more detail about the kinds of mitigation approaches it will place on pesticide labels to meet ESA requirements. The less favorable view is that EPA has outlined several "off the shelf" mitigation options (*e.g.,* buffers to reduce pesticide drift and water runoff), and EPA might impose such conditions even where more careful analysis of usage data and site- or use-specific considerations might lessen the areas where such mitigation measures are needed.

As part of the initial Workplan document, issued in April 2022, EPA stated that by applying present approaches, EPA would complete only five percent of the ESA required reviews in about 18 years — implying that the current approach would take about 360 years to complete. The November 2022 Workplan Update describes "early mitigation" strategies that are designed to reduce this unacceptable timeframe but that may likely lead to fears among some stakeholders that in a "rush" to complete this work, EPA will make overly conservative label restrictions and reduce availability of the pesticide at issue without increased species protections. Such concerns will raise ancillary concerns in 2023 about stakeholder involvement in decision-making, compliance with what might be complicated label requirements, and enforcement of what is already typically a long list of label requirements for many current products. An example of such issues: one mitigation option example discussed is "do not use when rain is expected in the next 48 hours" — which could raise issues concerning what or how compliance might be proven or enforced.

EPA also plans to make significant progress in meeting its ESA obligations as it continues the effort to convince courts that it is meeting its ESA obligations. As such, 2023 may represent a large step forward compared to the past when EPA was left with little progress or plans to present in court as part of ESA compliance litigation. As EPA continues to reveal its plans and options, however, stakeholders will need to follow closely, and consider the possible impacts of, the Workplan and the resulting label proposals to follow.

PODCAST:
Balancing Wildlife Protection and Responsible Pesticide Use — A Conversation with EPA's Jake Li

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. 2023 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 will be replaced by a 2023 Farm Bill on or before **October 1, 2023**. This will likely be the most consequential legislation for agriculture in 2023.

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 2023, look for every major agriculture association and environmental NGO to weigh in with their priorities and expected outcomes, including to some degree pesticide policy. Endangered species may again be a topic of interest, as will climate-smart agriculture and EJ.

4. Environmental Justice and Pesticides

EJ is a high priority issue for the Biden Administration and EPA. In 2023, EJ will continue to be an important theme potentially impacting every decision facing OPP. President Biden's 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 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 goes to overburdened and marginalized neighborhoods.

Of note for pesticides, the Justice40 Initiative includes policy recommendations such as "[f]inalize 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, in its FY 2023 budget request, EPA announced the establishment of a new national EJ program office to be led by a new political appointee. This office is envisioned to include a staff of over 200, and 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."

OPP is committed to making EJ a critical component of its work and is currently carrying out several initiatives. 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. Renewed attention to farmworkers and worker risks from pesticides will be an important consideration for OPP and EJ in 2023.

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 label in Spanish. EPA generally allows pesticide registrants to include on the label other languages optionally in addition to the full English text as long as the translation is true and accurate. Some pesticide registrants already have their product labels fully translated in Spanish. Many product labels are, however, only available in English. With PRIA 5 and its expected mandates for bilingual labels, this will likely be an important EJ area in 2023.

According to the EPA Annual Environmental Justice Progress Report FY 2020, EPA supported several activities over the last few years to implement the 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 2023.

As discussed in the PRIA 5 section above, 2023 will include a new requirement for bilingual labels in the next few years.

Lastly, in November 2022, more than 120 groups urged EPA to put safeguards in place to better protect Black, Indigenous, and other people of color, as well as low-wealth communities, from disproportionate harm from pesticides. The groups asking EPA to fast-track stronger protections from pesticides include public health, EJ, conservation, science, farmworker, grassroots community-based, farmer, and racial justice organizations. The protective actions sought by the groups, which may align with EPA EJ actions, include:

- Increasing monitoring and enforcement of pesticide use and harms;
- 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.

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 expected new PRIA 5 program requirements such as bilingual label requirements, look for EJ to be an important policy area for OPP in 2023.

5. Climate Change and Pesticides

Addressing climate change is a goal of the entire Biden 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 lifespans, 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.

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

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 2023.

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 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 2023.

Extreme heat caused by climate change also will be an important policy consideration in 2023 for OPP as WPSs and other federal worker protection regulations are reviewed and potentially updated. In September 2021, the Biden Administration established an 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 2023.

According to EPA, pesticides can impact climate change throughout their manufacture, transport, and application. Pesticide manufacture emits three main GHGs: 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 2023, 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.

Finally, in 2022, USDA announced the establishment of Partnerships for Climate-Smart Commodities, based on public input received in 2021. Through this new program, USDA will finance 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 will bring the total investment over $3 billion. Look for this work to increase the national discussion around agriculture, pesticides, and climate policy throughout 2023.

6. Import Enforcement

EPA's focus on imported pesticides and devices did not wane in 2022 and can be expected to continue in 2023. The requirements set forth by EPA and the U.S. Customs and Border Protection (CBP) are not new, but there was a noticeable increase in import reviews and enforcement actions following the pandemic. While that initial focus related to pesticide products and devices that were alleged to be marketed with unsubstantiated claims of efficacy against the coronavirus (the cause of COVID-19) and other pathogens, EPA Regions continue to review imported pesticides and devices 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. Without well-established guidance, importers of pesticide devices have been 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. Until more uniform guidance is provided to assist device manufacturers and importers, there is no expectation that such enforcement will diminish in 2023.

7. Chlorpyrifos

Chlorpyrifos was a widely used organophosphate insecticide and has been the target of activist group attention and controversy over many years. In 2007, the Pesticide Action Network North America (PANNA) and NRDC filed a petition to revoke the tolerances and cancel the registrations for chlorpyrifos. After many rounds of legal wrangling, the Ninth Circuit Court of Appeals issued a decision stating unequivocally that EPA's final action on the petition was due no later than March 31, 2017.

In August 2021, complying with the court decision in *League of United Latin Am. Citizens* v. *Regan*, 996 F.3d 673 (9th Cir.2021) to make a final determination about the Food Quality Protection Act (FQPA) safety standard, EPA issued a final rule revoking all "tolerances" for chlorpyrifos (86 Fed. Reg. 48315 (Aug. 30, 2021)). The tolerances for chlorpyrifos were revoked on February 28, 2022, six months after the final rule was published on August 30, 2021, in the *Federal Register*.

Relevant for other pesticides, conclusions about the assessment of chlorpyrifos might have broad implications for the future assessments of other organophosphate insecticides. Revised assessment methods and assumptions for chlorpyrifos would likely apply to EPA assessments of other organophosphates and could lead to further restrictions or prohibitions on the use of other organophosphate products.

Arguments similar to the chlorpyrifos tolerance revocation petition have been made in a petition filed on November 18, 2021, by the United Farm Workers and several other NGOs to revoke all food tolerances and cancel registrations for 15 organophosphate pesticides by the registration review deadline of October 1, 2022. Petitioners filed suit pursuant to FIFRA, the APA, and the First Amendment Constitutional Right to Petition. Petitioners set forth arguments as to why EPA cannot determine that the tolerances in effect are "safe," and claimed that absent such a determination, EPA must revoke the tolerances for these uses. The petition argued that "because a pesticide cannot be registered for a food use if it fails to pass muster under the FFDCA [Federal Food, Drug, and Cosmetic Act] safety standard, EPA must cancel the registrations for these food uses. 7 U.S.C. § 136(bb)." *See* our December 8, 2021, blog, "Petition to Revoke Food Tolerances and Cancel Registrations for Organophosphate Pesticides Filed." On July 12, 2022, EPA issued a *Federal Register notice seeking comments on this petition*. 87 Fed. Reg. 41310. In 2023, EPA will need to assess this petition and comments filed in response to it, as well as address questions surrounding the missed October 1, 2022, registration deadline.

8. Dicamba

Dicamba is a systemic benzoic acid used primarily to control annual, biennial, and perennial broadleaf weeds. First registered in the United States in 1967, it is currently registered for use on a wide variety of agricultural crops, such as soybeans, cotton, corn, grains, and sorghum, as well as for non-agricultural uses, such as rangeland, fallow fields, turf, and residential premises.

Following the widespread use of glyphosate-resistant crops, certain weed species have evolved to withstand treatment with glyphosate, that has induced certain weed species to be resistant and have a significant impact on production yields (up to 100 percent). As a result, new herbicide traits have been developed so that dicamba, an additional herbicide, can be applied "over the top" (OTT) to control the now glyphosate-resistant weeds. Older, more volatile dicamba formulations were considered to present a significant risk of drift to nearby crops, and pesticide registrants developed new formulations designed with low volatility to reduce the risk of off-target movement. This was intended to allow use of the new dicamba formulations around other crops (beside the dicamba-resistant ones) without causing damage to nearby crops.

In August 2022, EPA released its draft ecological risk assessment. The assessment examines the potential ecological risks associated with currently registered uses of dicamba on non-target, non-listed species. Risks to federally listed

threatened and endangered species are not evaluated in the assessment. EPA expects to propose an interim decision regarding the re-registration of dicamba in 2023.

The draft assessment focuses on areas where there have been updates since the most recent national-level risk assessments of dicamba by EPA (2005 and 2020) to examine if the risk picture has changed based on new data and analysis. The 2005 risk assessment was for dicamba's Registration Eligibility Decision (RED) based on use patterns registered at that time, which were applications to non-dicamba-tolerant plants. The 2020 risk assessment was exclusively to evaluate risk associated with relatively new uses of applications to dicamba-tolerant plants (*i.e.*, soybeans and cotton).

Of significance, there have been thousands of reported incidents allegedly caused by dicamba exposure occurring at or near a wide variety of agricultural and non-agricultural use sites and affecting a wide variety of plant species. According to EPA, a pronounced increase in the overall number of reported dicamba incidents associated with damage to non-target plants started around 2016 and appears to link to the introduction of dicamba-tolerant plants and OTT applications to those crops. The combined evidence from field studies and incident data indicates that there may be off-site movement of dicamba via runoff, spray drift, and volatility from the use of dicamba, particularly for OTT application on dicamba-tolerant plants.

Damage to plant species near areas of application presents two separate issues of concern that will have to be addressed in EPA's eventual decisions in 2023. First, does routine OTT use of dicamba cause unacceptable damage to nearby commercial crops, and second, does any tendency to injure nearby plants represent a possible concern about possible impacts on threatened and endangered species when EPA eventually includes ESA assessments as part of its review?

In 2020, EPA concluded that its 2020 label restrictions of dicamba-tolerant plants would significantly reduce incident reports about damage to nearby crops. Despite the new control measures, EPA received nearly 3,500 incident reports for the 2021 growing season of damage to non-dicamba-tolerant soybean, numerous other crops, and a wide variety of non-target plants in non-crop areas, including residences, parks, and wildlife refuges. EPA continues to monitor and evaluate new incident report submissions, and the analysis will be updated as new information becomes available. Dicamba also will continue to be an important issue of discussion at State FIFRA Issues Research and Evaluation Group (SFIREG) meetings in 2023 where data, analysis, and recommendations for dicamba continue to be discussed.

Still, the most significant risk continues to be possible impacts on non-target terrestrial plants from spray drift and volatilization. Almost 3,500 incident reports for a single growing season are hard to ignore. Environmental groups sued EPA to halt the approval, and a federal appeals court ordered EPA in June 2020 to cancel all registrations for use on dicamba-tolerant crops.

This draft ecological risk assessment (ERA) and expected proposed interim decision (PID) puts dicamba under scrutiny once again and may signal important registration challenges for the herbicide in 2023. A PID presents EPA's proposed findings regarding the FIFRA safety standard, proposed modifications to the way the pesticide is used if risk concerns are identified, and any proposed labeling changes.

9. PFAS and Pesticide Containers

EPA continues to make information available about its testing results showing PFAS contamination from fluorinated pesticide containers. While EPA continues to investigate and assess potential impacts on health or the environment, affected pesticide manufacturers have voluntarily stopped shipment of any products in fluorinated high-density polyethylene (HDPE) containers.

This issue dates to September 2020, when EPA became aware of PFAS contamination of a mosquito control product used in Massachusetts. EPA studied the fluorinated HDPE containers used to store and transport the product and determined the fluorination process used may be the source of the contamination.

EPA has since become aware of a second mosquito product used in Maryland 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 be studied and better understood in 2023.

In September 2022, EPA released results from its evaluation on the leaching potential of PFAS from the walls of certain fluorinated HDPE containers into the liquids stored in those containers. According to EPA, results from this study indicate that PFAS present in the inside walls of the fluorinated HDPE containers can be readily leached into formulated liquid products, with higher total amounts seen for products formulated in organic solvents such as methanol compared with water-based products. For both solvents tested (methanol and water), the study also shows continued gradual leaching of PFAS over time. Also in September 2022, EPA issued a notice for public comment that would remove 12 chemicals identified as PFAS from the current list of inert ingredients approved for use in pesticide products. EPA will review comments and continue discussions in 2023.

On December 27, 2022, the Center for Environmental Health and Public Employees for Environmental Responsibility filed suit in the U.S. District Court for the District of Columbia seeking to enjoin and "prevent ongoing violations" of TSCA by Enhance Technologies USA, a company that treats HDPE and other plastic containers by fluorination. (*See Center for Environmental Health v. Enhance Technologies USA*, Docket 2:22-cv-03819.) This TSCA citizen suit case will have implications for HDPE containers used in the agricultural and industrial chemical sectors.

Many experts and law makers 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 2023 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.

10. Rodenticides

Draft risk assessments for the rodenticides were completed in 2020, and in late November 2022, EPA issued its Rodenticide Cluster PIDs. EPA has 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.

This work furthers the goals outlined in EPA's April 2022 Endangered Species Act Workplan and one of the ESA pilots described in its November 2022 Workplan Update to provide practical, timely protections for listed species from pesticides.

Rodents cause significant damage to property, crops, and food supplies across the United States. They also may spread diseases, posing a serious risk to public health. Rodenticides are used in residential, agricultural, and non-agricultural settings to control a variety of pests including house mice, Norway rats, roof rats, moles, voles, pocket gophers, prairie dogs, ground squirrels, feral hogs, and mongooses.

In 2008, EPA issued a risk mitigation decision (RMD) for ten rodenticides that represented its final decision on the re-registration eligibility of rodenticide products at that time and constituted the Agency's final action in response to the remand order in *West Harlem Environmental Action and Natural Resources Defense Council v. U.S. Environmental Protection Agency*. The 2008 RMD included mitigation measures to reduce risks to human health and non-target organisms. For example, EPA implemented minimum packaging size requirements for products on the consumer market (must be in packages one pound or less), prohibited products intended for general consumers (*i.e.*, homeowners or residential consumers) from containing second-generation anticoagulant rodenticides (SGAR), and required tamper- and weather-resistant bait stations for outdoor, above-ground placements where children, pets, and wildlife may be present.

Proposed measures include requiring bait to be placed in tamper-resistant bait boxes to ensure it is contained and requiring users to collect carcasses of rodents that may have consumed rodenticides to prevent further exposures to non-target organisms that could consume the carcasses. EPA also proposes that all products, excluding those registered solely for use by homeowners, include label language directing users to access the web-based Bulletins Live! Two and follow the measures contained in any Endangered Species Protection Bulletin(s) for the area in which the user is applying the product.

The ESA Workplan describes how EPA is developing early mitigation for a subset of species where EPA predicts a like-

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lihood of a jeopardy or adverse modification finding for one or more of the registration review pilot pesticides if mitigation is not undertaken. One of these pilots is for rodenticides, which will focus on addressing effects to mammals and birds that consume rodenticide bait (primary consumers) and to birds, mammals, and reptiles that consume primary consumers (secondary consumers).

As part of its registration review ESA pilot for the rodenticides, EPA evaluated their potential effects on individuals and populations of Stephens' kangaroo rat, Attwater's prairie chicken, and the California condor and its designated critical habitat. EPA's draft evaluation determined that rodenticide use is "likely to adversely affect" these three species but predicted the proposed mitigations will protect them from likely "jeopardy" (*i.e.*, potential impacts to the survival of listed species) and "adverse modification" of critical habitat. A "likely to adversely affect" determination means EPA reasonably expects that at least one individual animal of any of the three species may be exposed to one or more of the rodenticides at a sufficient level to have an adverse effect.

EPA's draft likelihood of jeopardy and adverse modification predictions examine effects of the rodenticides at the species scale (*i.e.*, the population as opposed to an individual of a species). While EPA has made predictions about the likelihood of jeopardy and adverse modification, the U.S. Fish and Wildlife Service (FWS) is responsible for making the actual jeopardy/adverse modification findings for these species and has the sole authority to do so.

EPA chose these three listed species because they represent species that may be affected by rodenticides through different routes of exposure, like primary consumption, for example, by Stephens' kangaroo rat and Attwater's prairie chicken and secondary consumption, for example, by the California condor.

To focus the mitigations where they are most needed while retaining options for rodenticide users, the proposed mitigation measures for the three listed species would be targeted in specific geographic areas most relevant to the species. The PIDs include proposed mitigation measures to be included on the Bulletins Live! Two website for the species and the critical habitat of the California condor.

In addition to describing the pilot and the mitigation measures for the selected species, EPA also has plans for expanding those mitigation measures to the other approximately 90 listed species potentially affected by rodenticides. This plan, when final, will be known as the Rodenticide Strategy EPA described in its November 2022 update to its ESA Workplan.

EPA also intends to make effects determinations for all listed species available in a draft biological evaluation (BE), which the Agency anticipates making available for public comment in **November 2023**. The BEs will contain EPA's draft analysis of the potential effects of the rodenticides on listed species and their designated critical habitats and will identify mitigation measures for these species and critical habitats to avoid or minimize exposure from the rodenticides (Rodenticide Strategy). EPA expects to complete the final BE for the rodenticides in **November 2024**.

2023 is expected to be the year that OPP finally focuses on addressing the "R" in FIFRA, and this will be an important area of focus for the program.

11. Pollinators

2022 was a year of quiet progress on pollinators, and we expect the same for 2023.

Since the January 2017 policy was announced during the last days of the Obama Administration, EPA has not officially changed much of its general guidance about pollinator issues. On the EPA website, "Protecting Bees and Other Pollinators from Pesticides," almost all of the content is the same as it was during the last days of the Obama Administration.

More importantly, behind the scenes is the accumulating data and review experience of both EPA and registrants regarding appropriate pollinator risk assessment requirements. There is some concern among pesticide registrants about how broadly EPA might require certain bee studies

without clear decision rules for which pesticides appropriately need higher tier studies and what questions additional studies might answer, especially if the requirements are cast too broadly or without clear decision criteria. In addition, ESA mitigation may be imposed to protect listed pollinator species as part of the "early mitigation" efforts described earlier.

In June 2022, EPA announced two new pilots to protect pollinators. One was a federal mitigation pilot project to identify and implement earlier mitigation measures for a dozen species that are vulnerable to pesticides, including some pollinators. The second was a vulnerable species pilot to identify and implement mitigation measures across broad groups of pesticides to protect certain species, including pollinators.

In August 2022, EPA underscored again the importance of its Pollinator Protection Strategic Plan, and EPA continues to use the Plan to guide its actions on pollinators. Look for EPA and interaction action to continue to follow this strategy.

Many expect the monarch butterfly to be listed as threatened or endangered. This would likely increase ESA mitigation measures to protect the monarch and other listed species.

12. COVID-19 Pandemic and Antimicrobial Policy

The COVID-19 pandemic was especially impactful on EPA's pesticide program. In 2022, however, the Antimicrobials Division (AD) was able to shift its focus and allocate resources to other non-COVID actions. AD, as part of the Pesticide Program Dialogue Committee's Emerging Pathogen Workgroup, worked on a retrospective analysis, a lessons-learned effort of EPA's COVID-19 response.

EPA's Emerging Viral Pathogen (EVP) Policy, activated for the first time in 2020 for COVID-19, was triggered two times in 2022: Mpox (formerly monkeypox) virus in May and the Ebola virus in October. EPA developed its EVP guidance in 2016 to address emerging pathogens. In the event of an outbreak that meets certain criteria, EPA triggers the EVP guidance for a specific virus. In doing so, EPA authorizes companies whose products have EVP claims to make statements on their websites, social media, and technical literature about their products' expected efficacy against the emerging virus. In 2022, EPA created List Q: Disinfectants for Emerging Viral Pathogens (EVP), providing a comprehensive list of approved disinfectant products sorted by their ability to deactivate viruses. Viruses are divided into three categories, Tier 1 through Tier 3, with Tier 1 being the easiest to inactivate. EPA's List Q currently has 488 disinfectant products for use on Tier 1 viruses.

In October 2022, EPA issued guidance and test methods for registering antimicrobial products with residual efficacy against viruses and bacteria. Throughout the COVID-19 pandemic, EPA received requests from stakeholders regarding a public health need for products with residual efficacy (*i.e.,* ongoing antimicrobial effect beyond the initial time of application, ranging from days to weeks to months). In 2020, EPA issued interim guidance and test methods for public comment as a pathway for companies to add claims of residual efficacy to their products' labels. Revisions to the guidance document and the associated methods were made based on data from EPA laboratory studies and information submitted through public comments. In the final guidance issued in 2022, EPA made minor modifications to represent better the real-world conditions under which products with residual efficacy will be used.

Also in October 2022, EPA announced the registration of the first antimicrobial product that is effective for use in air that can kill both bacteria and viruses. The product is intended to supplement public health guidelines for indoor air regarding filter ratings, heating, ventilation, and air-conditioning (HVAC) system cleaning/maintenance, and ventilation. After the treated room is reopened, the product has no lingering efficacy. The new registered product is approved for use in the air against bacteria and viruses, such as influenza and coronaviruses, and in residential and commercial settings, such as homes, schools, hotels, daycare centers, and office buildings; it contains the active ingredient dipropylene glycol.

On December 21, 2022, EPA announced interim guidance and test methods for products intended to control public health pathogens on the surface of porous materials in clinical and institutional (nonresidential) settings. EPA is seeking public comment on the interim guidance that describes efficacy testing for antimicrobial products to support claims for use on surfaces of certain porous materials in clinical and institutional (non-residential) settings and how to prepare an application for registration, an interim quantitative method for evaluating the efficacy of antimicrobial products on porous surfaces against viruses, and an interim quantitative method for evaluating the efficacy of antimicrobial products on porous surfaces against

bacteria. Comments to EPA are due in **early 2023**. We expect EPA will review comments and continue discussions in 2023.

EPA has requested comments on improving and managing indoor air quality to reduce COVID-19 and other disease transmission, that could involve the use of air sanitization products or pesticidal devices. At this time AD has not issued any final guidance or test methods for air sanitization. AD does intend to develop a Data Call-In (DCI) for air sanitizer data to support public health claims, but due to limited resources, does not expect to complete the DCI until **2024**.

Pesticide devices were never a major focus within EPA until the pandemic, when there was an increase in devices claiming to kill SARS-CoV-2 and other bacteria and viruses. Pesticide devices do not require registration, meaning there is no submission to EPA of any application, label, or data. Pesticide devices are subject to other FIFRA requirements, including, but not limited to, submissions of NOAs for imports, and the prohibition against false or misleading claims. EPA issued some guidance in 2020 through a Compliance Advisory regarding "EPA Regulations About UV Lights that Claim to Kill or Be Effective Against Viruses and Bacteria" but no additional guidance since. Pesticide device manufacturers have faced various actions related to compliance due to lack of EPA guidance and resulting uncertainties and inconsistencies between EPA Regions as to what may be a false or misleading claim. In 2023, unless additional guidance is issued, we expect these issues to continue.

AD completed over 540 PRIA and 740 non-PRIA actions in 2022. AD priorities for 2023 include reducing the large non-PRIA backlog, increasing the number of registration review actions, and developing ESA methods and tools for antimicrobials. AD expects challenges in 2023 to include resource constraints, ESA implementation, electronic labeling implementation, overcoming obstacles associated with a large remote workforce, and an increasing number of device inquiries.

13. Budget, Staffing, Scientific Integrity, and Other Items of Interest

The bulk of OPP's work continues to focus on the thousands of pesticide label amendments, label extensions, me-too registration evaluations, and routine data reviews. The resources necessary to complete this substantial amount of work continues, as it has in the past, to raise issues about EPA staffing and budget. PRIA and FIFRA maintenance fees provide a substantial contribution to support the pesticide review workload. At the same time, EPA- or government-wide policies regarding hiring and spending have hindered full utilization of even the industry-contributed funds. OPP has had a substantial surplus of fees accrue over the years and was authorized to use some of these resources to hire additional staff to meet the program workload. More generally, however, all of EPA has been affected by past hiring freezes and decisions to reduce the number of EPA staff. With the Biden Administration's commitment to increase EPA staff, with a non-controversial PRIA reauthorization, and with the FY 2023 EPA budget authorizing more than $11 million in additional staff and resources for OPP, look for OPP to find some funding and staffing stability in **2023 and the outyears**. The FY 2023 OPP budget is the highest funding level for OPP since 2010.

a. Budget and Staffing

Chronic underfunding of OPP has undermined pesticide registration and policy implementation for years. More than 20 years ago, budget shortfalls resulted in the pesticide community securing passage of PRIA. PRIA created a fee for service program that today provides EPA with more than $50 million in user fees annually to support the staff needed for the pesticide review process. The program is an example of a public-private partnership that works, but more help is needed. EPA needs adequate funding to do its job. Shortfalls in funding have led to staff cuts that are delaying the registration of new pesticide products.

Although we may not agree with all EPA decision, we agree that if EPA is better funded, it is more likely to provide consumers, farmers, and public health officials the tools they need to keep our families safe, grow our food, and protect our communities. In 2023, we are excited to see a level of investment in OPP that has not been seen in decades. This investment will lead to robust hiring, IT modernization, and helping to ensure that OPP meets its pesticide registration schedules. Still, 2023 will be a year of ramping up; it still takes several months to hire a federal employee. Look for resource investments to start paying off in the outyears, **2024-2026**.

b. Certification and Training Requirements

In October 2021, EPA provided information on a March 2022 regulatory deadline in the Certification for Pesticide Applicator Rule. EPA Regional teams continue to coordi-

Enhancing scientific integrity will be an important theme for OPP in 2023. Look for new science policy advisory councils to influence further decision-making processes in OPP, and look for OPP to announce a new senior-level science advisor specific to pesticides in spring 2023.

nate with OPP staff on finalizing Agency review of submitted certification plans.

In August 2022, EPA extended the expiration date for existing plans to **November 4, 2023**. To date, EPA has reviewed and commented on all proposed plan revisions. Of the 56 proposed plan revisions submitted by state and territory certifying authorities, currently four have been approved. EPA is collaborating with certifying authorities to resolve the Agency's comments on remaining plans so that all can be approved by the deadline. In 2023, all plans could be issued in final with additional clarity for worker training and certification.

c. Process Improvements

In 2021, OPP launched a new set of process improvements that the pesticide community hoped to optimize in 2022 in terms of efficiency and effective program management. OPP launched new process improvement efforts and visual management to better track issues with new pesticide active ingredients to address common issues with application packages; converted paper process for Gold Seal Letters to an electronic system for industry exports of pesticides; developed device determination tracking systems; reduced the backlog of ecological incidents in the Incident Data System by more than 60 percent; developed additional, new standard operating procedures (SOP) to gain efficiencies for individual pesticide workflows; and continued to deploy IT Modernization and Digital Transformation work. With PRIA 5, in 2023, look for across-the-board process improvements as previously described as OPP moves toward a more modern, efficient, and effective program.

d. Scientific Integrity

Enhancing scientific integrity will be an important theme for OPP in 2023. In March 2021, Assistant Administrator Michal Freedhoff issued an OSCPP-wide internal memo that affirmed her commitment to scientific integrity as an essential and critical element to EPA work. Following that, in October 2021, Assistant Administrator Freedhoff issued an OCSPP-wide internal memo indicating next steps in her commitment to strong science in the review of chemicals and pesticides. These steps include:

- Establishing two internal science policy advisory councils;
- Creating a new senior-level career position to serve as a science policy advisor in OCSPP; and
- Making further improvements to policies and procedures.

In 2022, these science-based initiatives took root. OCSPP hired a new science advisor and reaffirmed its commitment to pesticide reviews. In 2023, look for these new council and advisor positions to influence further decision-making processes in OPP, and look for OPP to announce a new senior-level science advisor specific to pesticides in **spring 2023**.

e. Registration Review Deadline

EPA missed the October 1, 2022, registration review deadline for the bulk of the program registrations. EPA states the affected universe is 726 "active ingredient cases." Progress has been made, but review of many of the more controversial or widely used active ingredients remains to be completed. In late December 2022, the Consolidated Appropriations Act, 2023 extended the registration review deadline to **October 1, 2026**. Once EPA has issued its conclusions, the more controversial pesticides are likely to face litigation challenges over touchstone disagreements (*e.g.,* ESA assessments, pollinator risks) that have characterized the public debate about numerous active ingredients in recent years. Legal and administrative uncertainty around the missed October 1 deadline and the new **2026** deadline may be an important topic of discussion in 2023.

f. Morale

Under the Biden Administration, EPA budget and staffing increases, and an environmentally focused agenda with EPA at the center of the action, along with generally a more

supportive attitude toward federal workers and workplace conditions, should help bolster OPP morale and program performance. Whether these new atmospherics materially influence morale or the ability to recruit new staff remains uncertain. Significant budget increases and a new Union agreement that allows EPA employees to work in the office only two days per pay period (*i.e.*, two days every two weeks) will help improve staff morale, although the jury is out regarding impact to productivity.

Still, OPP faces generational change and institutional memory challenges as long-time staff step down. The program faces difficulties recruiting and retaining staff, especially when other federal environmental or EPA programs (*e.g.*, climate change, infrastructure, EJ) are ramping up with more prominent program missions or employment opportunities. OCSPP itself often pits TSCA staffing against FIFRA staffing by sharing competing interests, office space, and staff. Look for the program to increase significantly in staff and resources in 2023, but look for that ramp up to impact program output and performance in **2024** and the outyears.

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D. NANOTECHNOLOGY

1. U.S. Environmental Protection Agency

In 2023, EPA will continue reviewing new chemical notices for nanoscale materials under TSCA. According to the 2022 *Developments in Delegations on the Safety of Manufactured Nanomaterials — Tour de Table* published by OECD, since January 2005, EPA has received and reviewed more than 245 new chemical notices for nanoscale materials such as fullerenes, quantum dots, and carbon nanotubes. EPA has issued consent orders and SNURs for these nanoscale materials that permit manufacture under limited conditions. EPA's assessments currently assume that the environmental hazard of a nanomaterial is unknown unless acceptable hazard data are submitted to EPA. Because of limited data to assess nanomaterials, the consent orders and SNURS contain 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. EPA will continue to issue consent orders and SNURs for specific nanomaterials in 2023. More information is available in our January 26, 2022, blog item, "OECD Tour de Table Includes Update on Nano Developments in the United States."

In August 2022, NASEM released a report entitled *Review of Fate, Exposure, and Effects of Sunscreens in Aquatic Environments and Implications for Sunscreen Usage and Human Health*. NASEM was tasked by Congress and funded by EPA to undertake a consensus study of the potential risk of ultraviolet (UV) filters on already threatened aquatic environments and the potential consequence to human health should sunscreen usage or composition be modified. NASEM's report reviews the state of science on the sources and inputs, fate, exposure, and effects of UV filters in aquatic environments, and the availability and applicability of data for conducting ERAs. According to NASEM, given the evidence that aquatic ecosystems in the United States and possibly endangered species are exposed to these UV filters, and given the importance of these ingredients in skin cancer prevention, an ERA is "urgently needed" and should be shared with the U.S. Food and Drug Administration (FDA) for consideration in their oversight of UV filters. More information on NASEM's report is available in our August 16, 2022, blog item.

2. National Institute for Occupational Safety and Health

NIOSH published a program performance one-pager on July 18, 2022, for its Nanotechnology Research Center (NTRC). The one-pager lists the following upcoming activities:

- Publish the document *Occupational Exposure Sampling for Engineered Nanomaterials*;
- Publish the document *Approaches to Safe 3D Printing: A Guide for Makerspace Users, Schools, Libraries and Small Businesses*;
- Conduct an evaluation of biomarkers of engineered nanomaterial exposure and disease;
- Issue in final *Approaches to Developing Occupational Exposure Limits or Bands for Engineered Nanomaterials*; and
- Publish the first two videos in the series of an *Overview of Additive Manufacturing Health and Safety*.

To date, NIOSH has published only the first document, *Technical Report: Occupational Exposure Sampling for Engineered Nanomaterials*. According to NIOSH, occupational health and safety professionals "have expressed a need for one document that explains all of the available nanomaterial sampling techniques, and this document provides a summary of the different sampling techniques." The document includes recommendations addressing exposure monitoring programs, carbon nanotubes and nanofibers, silver, titanium dioxide, use of the nanomaterial exposure assessment technique for other engineered nanomaterials, and optional sampling methods. NIOSH concludes that a comprehensive exposure assessment evaluation for engineered nanomaterials collects information that can be used to identify sources of potential engineered nanomaterial

exposures; establish similar exposure groups by area or job tasks; characterize exposures of all potentially exposed workers; and assess the effectiveness of engineering controls, work practices, PPE, training, and other factors used in reducing exposures. More information is available in our August 1, 2022, blog item, "NIOSH Publishes Technical Report on Occupational Exposure Sampling for Engineered Nanomaterials."

3. American Conference of Governmental Industrial Hygienists

In 2023, the American Conference of Governmental Industrial Hygienists (ACGIH®) Threshold Limit Values for Chemical Substances (TLV®-CS) Committee could include carbon nanotubes on its list of chemical substances and other issues under study. If carbon nanotubes are on the list, then stakeholders will have an opportunity to submit substantive data and comments. The TLV®-CS Committee has included carbon nanotubes on its lists of chemical substances and other issues under study for several years.

In September 2022, ACGIH® updated its development process to meet better the needs of occupational and environmental health professionals. In 2023, it will offer stakeholders the opportunity to provide comments twice per year for draft documentation on the Notice of Intended Changes (NIC) and Notice of Intent to Establish (NIE) lists. The comment periods will run from **January 1 to March 31** and **July 1 to September 30**, with ratification occurring in **May** and **November**, and all changes will be posted online using Data Hub. ACGIH® will continue to publish Threshold Limit Values (TLV®) books at the beginning of every year. ACGIH® states that the under study list will no longer be tiered to allow chemical substances and physical agents to be added throughout the year and worked on immediately. All updates to the under study list will be reflected in ACGIH® communications and on the ACGIH® website.

4. Canada

In 2023, 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 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). Comments on the draft Framework were due August 16, 2022. 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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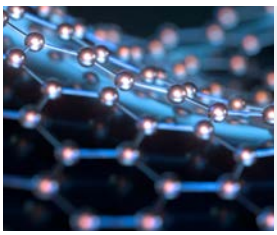

In 2022, there was little to no visible progress on a number of biotechnology initiatives. We expect that 2023 will be very different, however, due to Executive Order 14081 on "Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy."

E. BIOTECHNOLOGY

In 2022, there was little to no visible progress on a number of biotechnology initiatives, including work by FDA and USDA to create a clear regulatory pathway for foods made from cultured cells from animals and a contemplated regulatory framework that would transition portions of FDA's pre-existing animal biotechnology regulatory oversight to USDA. We expect that 2023 will be very different, however, due to EO 14081 on "Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy." 87 Fed. Reg. 56849. Signed by President Joseph Biden on September 12, 2022, the EO acknowledges that advances in biotechnology are rapidly altering the product landscape and that the complexity of the current regulatory system for biotechnology products can be confusing and create challenges for businesses to navigate. To improve the clarity and efficiency of the regulatory process for biotechnology products, and to enable products that further the societal goals identified in the EO, the Secretary of Agriculture, the Administrator of EPA, and the Commissioner of Food and Drugs must take specified actions. Within 180 days of the date of the EO, by **March 2023**, they must identify areas of ambiguity, gaps, or uncertainties in the January 2017 Update to the Coordinated Framework for the Regulation of Biotechnology or in the policy changes made pursuant to EO 13874 ("Modernizing the Regulatory Framework for Agricultural Biotechnology Products"), including by engaging with developers and external stakeholders, and through horizon scanning for novel products of biotechnology. The agencies will then have 100 days to provide to the public plain-language information regarding the regulatory roles, responsibilities, and processes of each agency, including which agency or agencies are responsible for oversight of different types of products developed with biotechnology, with case studies, as appropriate. Within 280 days of the date of the EO, by **June 2023**, USDA, EPA, and FDA will provide a plan with processes and timelines to implement regulatory reform, including identification of the regulations and guidance documents that can be updated, streamlined, or clarified; and identification of potential new guidance or regulations.

In addition, within one year of the date of the EO, by **September 2023**, USDA, EPA, and FDA will build on the Unified Website for Biotechnology Regulation by enabling developers of biotechnology products to submit inquiries about a particular product and promptly receive a single, coordinated response that provides, to the extent practicable, information and, when appropriate, informal guidance regarding the process that the developers must follow for federal regulatory review.

More information on the EO is available in the section on Biobased and Renewable Chemistry, as well as in our September 13, 2022, blog item, "President Biden Launches National Biotechnology and Biomanufacturing Initiative," and October 5, 2022, blog item, "Federal Agencies Announce Investments and Resources to Advance National Biotechnology and Biomanufacturing Initiative."

Under the 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. Prior to the SECURE rule, developers of genetically modified plants could petition APHIS to seek a determination that a modified plant is unlikely to pose a plant pest risk and therefore is no longer subject to APHIS' biotechnology regulations. With the SECURE rule, APHIS made several changes to its procedures, including introducing the RSR process. As reported in our October 11, 2022, blog item, APHIS issued its first RSR response in September 2022, finding the plant unlikely to pose an increased plant pest risk compared to other cultivated tomatoes and not subject to regulation under 7 C.F.R. Part 340. More information on APHIS resources for stakeholders is available in our September 1, 2022, blog item, "USDA's APHIS Announces New Microbes Q&A and Updated Confirmation Request Guidance."

FDA announced on November 16, 2022, that it completed its first pre-market consultation of a human food made from cultured animal cells. FDA evaluated information

submitted by UPSIDE Foods as part of a pre-market consultation for their food made from cultured chicken cells. According to FDA, it has no further questions at this time about the firm's safety conclusion. Before the food can enter the market, the facility in which it is made must meet applicable USDA and FDA requirements, however. 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.

FDA and USDA are working together to create a clear regulatory pathway for foods made from cultured cells from animals. Under a 2019 formal agreement, FDA oversees cell collection, cell banks, and cell growth and differentiation. According to FDA, its approach to regulating products derived from cultured animal cells involves a "thorough pre-market consultation process." Once all questions relevant to the consultation are resolved, the product will transition from FDA to FSIS oversight during the cell harvest stage. FSIS will oversee the post-harvest processing and labeling of human food products derived from the cells of livestock and poultry.

FDA expects food produced using animal cells obtained from livestock, poultry, and seafood to be ready for the U.S. market "in the near future." FDA notes that it is ready to work with additional firms developing cultured animal cell food and production processes to ensure their products are safe and lawful under the FFDCA. FDA plans to issue guidance to assist firms that intend to produce human foods from cultured animal cells to prepare for pre-market consultations. FDA will publish the guidance in draft to provide an opportunity for public comment. As of fall 2022, FDA is "already engaged in discussion with multiple firms about various types of products made from cultured animal cells, including those made from seafood cells," which will be overseen solely by FDA. FDA encourages firms to enter into dialogue with it "often and early" in the product development phase, well ahead of making any submission to FDA.

In 2023, EPA will continue to implement its mature regulatory systems for managing review of biotechnology innovations for pesticides and industrial chemicals. On October 9, 2020, EPA proposed an exemption under FIFRA and the FFDCA for certain Plant-Incorporated Protectants (PIP) that are created in plants using biotechnology. 85 Fed. Reg. 64308. EPA proposed exempt status for select PIPs created through biotechnology if those PIPs could otherwise have been created through conventional breeding and pose no greater risk than PIPs that EPA already had concluded meet the applicable safety standard. Comments were due by December 8, 2020. More than 8,000 comments were received, although only 28 are available in the docket (EPA-HQ-OPP-2019-0508). According to an item in the spring 2022 Unified Agenda, EPA intends to issue a final rule in **January 2023**.

In 2021, EPA continued to work with Oxitec Ltd. and its novel approach to mosquito control. In 2020, EPA approved a 24-month experimental use permit (EUP) to allow Oxitec to field test the use of genetically modified *Aedes aegypti* mosquitoes in Florida to reduce mosquito populations. Oxitec releases genetically modified male mosquitoes that have a gene that makes a specific protein. This protein, as produced in female mosquitoes, prevents female offspring of the modified males from surviving. The absence of female mosquito emergence in the release area results in mosquito population decline and, with it, an expected reduction in the transmission of mosquito-borne disease-causing pathogens. EPA announced on March 7, 2022, that it approved an EUP amendment for Oxitec that expands and extends the testing of genetically engineered *Aedes aegypti* mosquitoes to reduce mosquito populations. The EUP amendment:

- Extends the EUP until **April 30, 2024**, on 5,360 acres of Monroe County, Florida. This extension will generate additional data to evaluate the effectiveness of the mosquitoes at reducing mosquito populations;

- Expands the EUP to four counties in California for the first time, consisting of 29,400 acres in Stanislaus, Fresno, Tulare, and San Bernardino counties. Oxitec may conduct testing in these areas until **April 30, 2024**, to generate efficacy data in different climatic zones; and

- Removes Harris County, Texas, from the approved testing locations because no field tests were conducted in the state during the initial EUP.

EPA continues to review Microbial Commercial Activity Notices (MCAN) under TSCA. EPA received a total of 23 MCANs during FY 2022. Two were submitted in August and determinations are not yet complete. Unlike PMNs, MCANs

were reviewed timely (either within 90 days or close to it) and all determinations were "not likely to present an unreasonable risk." EPA also received two TSCA Environmental Release Applications (TERA). One was withdrawn, and the other, received in February 2022, remains under review. EPA's biotechnology reviews remain a bright spot in EPA's new chemicals review program.

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

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F. 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 research and development (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.

President Joseph Biden's EO 14081 on "Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy," signed on September 12, 2022, launched 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. It will "drive advances in biomanufacturing that substitute fragile supply chains from abroad with strong chains at home, anchored by well-paying jobs in communities all across America." According to the White House fact sheet, the specific goals of the Initiative include:

- Growing domestic biomanufacturing capacity. The Initiative will build, revitalize, and secure national infrastructure for biomanufacturing, including through investments in regional innovation and enhanced bio-education, while strengthening the U.S. supply chain that produces domestic fuels, chemicals, and materials.

- Expanding market opportunities for biobased products. USDA's BioPreferred Program is the standard for sustainable procurement by government agencies. The Initiative will increase mandatory biobased purchasing by federal agencies, including through training and support for contracting officers, and ensure that OMB and USDA are regularly publishing assessments of progress. In so doing, it will provide specific directions to industry about gaps in biobased product options, leading to the creation of new products and new markets. The Initiative will grow and strengthen the BioPreferred Program, increase the use of renewable agricultural materials, and position American companies to continue to lead the world in bio-innovation.

The EO also calls for reports on biotechnology and biomanufacturing from several different agencies. The following reports are due within 180 days of the date of the EO, in **March 2023**:

- A report from the Secretary of Health and Human Services (HHS) assessing how to use biotechnology and biomanufacturing to achieve medical breakthroughs, reduce the overall burden of disease, and improve health outcomes;

- A report from the Secretary of Energy assessing how to use biotechnology, biomanufacturing, bioenergy, and biobased products to address the causes and adapt to and mitigate the impacts of climate change, including by sequestering carbon and reducing GHG emissions;

- A report from the Secretary of Agriculture assessing how to use biotechnology and biomanufacturing for food and agriculture innovation; increasing food quality and nutrition; increasing and protecting agricultural yields; protecting against plant and animal pests and diseases; and cultivating alternative food sources;

ARTICLE

"Optimizing the Toxic Substances Control Act to Achieve Greener Chemicals," *NR&E*, Summer 2022.

Biden's Executive Order calls for the President's Council of Advisors on Science and Technology (PCAST) to prepare a public report on the bioeconomy that provides recommendations on how to maintain U.S. competitiveness in the global bioeconomy.

- A report from the Secretary of Commerce, in consultation with the Secretary of Defense, the Secretary of HHS, and the heads of other appropriate agencies, assessing how to use biotechnology and biomanufacturing to strengthen the resilience of U.S. supply chains; and
- A report from the Director of the National Science Foundation (NSF) identifying high-priority fundamental and use-inspired basic research goals to advance biotechnology and biomanufacturing.

Within 100 days of receiving the reports, the Director of the White House Office of Science and Technology Policy (OSTP) will develop a plan to implement the recommendations in the reports. Within two years of the date of the EO, by **September 2024**, agencies will report on measures taken and resources allocated to enhance biotechnology and biomanufacturing, consistent with the implementation plan.

The EO also calls for the President's Council of Advisors on Science and Technology (PCAST) to prepare a public report on the bioeconomy that provides recommendations on how to maintain U.S. competitiveness in the global bioeconomy. The report is due within 180 days of the date of the EO, by **March 2023**, as is a strategy that identifies policy recommendations to expand domestic biomanufacturing capacity for products spanning the health, energy, agriculture, and industrial sectors. Additionally, the strategy will identify actions to mitigate risks posed by foreign adversary involvement in the biomanufacturing supply chain and to enhance biosafety, biosecurity, and cybersecurity in new and existing infrastructure. More information on the EO is available in our September 13, 2022, blog item, "President Biden Launches National Biotechnology and Biomanufacturing Initiative," and our October 5, 2022, blog item "Federal Agencies Announce Investments and Resources to Advance National Biotechnology and Biomanufacturing Initiative."

In 2023, USDA is likely to propose to codify the BioPreferred Program guidance. According to an item in the spring Unified Agenda, which was published on June 21, 2022, USDA intended to publish the proposed rule in June 2022. USDA expects this action to reduce burden on both it and the applicants by reducing requirements, clarifying requirements, 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.

EPA will continue working in 2023 to expand the Environmentally Preferable Purchasing (EPP) program's Recommendations of Specifications, Standards and Ecolabels for Federal Purchasing (Recommendations). On November 2, 2022, EPA invited managers of standards development organizations, ecolabel programs, and other similar organizations to apply for potential assessment and inclusion in the Recommendations. 87 Fed. Reg. 66176. The EPP program's Recommendations help federal government purchasers use private sector standards and ecolabels to meet sustainable acquisition goals and mandates. The application deadline closed on January 1, 2023. EPA will issue an estimated timeline for full assessments against the Framework by product/service category within 120 days, by the **end of April 2023**. For each category being assessed, EPA will provide further notice and instruction to applicable applicants. More information is available in our November 7, 2022, blog item, "EPA Will Expand Environmental Performance Standard and Ecolabel Recommendations for Federal Purchasing."

WEBINAR ON DEMAND
Domestic Chemical Regulation and Achieving Circularity

PODCAST:
Trends in Product Sustainability and Circularity — A Conversation with Kate Sellers

In 2023, efforts will continue at the federal and state level to define sustainable chemistry. OSTP published on April 4, 2022, a request for information (RFI) from interested parties on federal programs and activities in support of sustainable chemistry. 87 Fed. Reg. 19539. OSTP requested information on the preferred definition for sustainable chemistry and sought comment on how the definition of sustainable chemistry could impact the role of technology, federal policies that may aid or hinder sustainable chemistry initiatives, future research to advance sustainable chemistry, financial and economic considerations, and federal agency efforts. OSTP will use comments provided in response to the RFI to address Subtitle E of Title II of the NDAA for FY 2021 (Subtitle E), which includes the text of the bipartisan Sustainable Chemistry Research and Development Act of 2019. Subtitle E directs OSTP "to identify research questions and priorities to promote transformational progress in improving the sustainability of the chemical sciences." Comments were due June 3, 2022. More information on the RFI is available in our April 6, 2022, memorandum, "OSTP Publishes RFI Regarding Sustainable Chemistry."

In 2022, OSTP's National Science and Technology Council's Strategy Team on Sustainable Chemistry held a series of webinars regarding defining, assessing, and preparing a strategic plan for sustainable chemistry in response to direction in the NDAA. The webinars addressed the science, technology, and innovation needs of the chemical industries, including carbon capture, sustainable process design, and chemical separation technologies; and communicating the use of data and assessments to make decisions for sustainable chemistry choices and to advance the technologies and processes that provide these data and contribute to sustainability. More information about the NDAA is available in B&C's January 19, 2021, memorandum, "Sustainable Chemistry Research and Development Act Passed as Part of National Defense Authorization Act."

At the state level, in November 2022, the California Department of Toxic Substances Control (CDTSC) held two external engagement sessions to share their perspectives on an actionable definition of sustainable chemistry. CDTSC states that stakeholders' participation and expertise can help refine a draft, consensus definition and set of criteria for sustainable chemistry. According to CDTSC, the draft definition and criteria were developed over the past six months by a 20-person Expert Committee on Sustainable Chemistry (ECOSChem) that includes representatives from industry, academia, governmental organizations, and NGOs, including a representative from the Safer Consumer Products Program (SCP). More information is available in our October 28, 2022, blog item, "CDTSC Will Hold Engagement Sessions in November on a Definition of Sustainable Chemistry."

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 2023.

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 Chemicals and Biofuels, Acta Advocating for Biobased Chemicals and Biofuels.**

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G. PROPOSITION 65

On May 20, 2022, the California Office of Environmental Health Hazard Assessment (OEHHA) decided to postpone the significant revisions it proposed to its Proposition 65 (Prop 65) "short-form" warning requirements. These had been in widespread use by industry since it was included as an option in OEHHA's August 31, 2018, amended regulations. If the proposal had been enacted, the opportunities when the short-form warning could be used would have been significantly limited. Even if the conditions to use the short-form warning were satisfied, OEHHA's proposal would change the content of that short-form warning requirement resulting in warning language changes for all companies currently relying upon this option.

Industry was harshly critical of OEHHA's proposal in written comments and during a March 11, 2021, hearing. Industry argued that OEHHA's proposal was unwarranted and its concerns with the current warning requirements unfounded. Industry stakeholders also expressed frustration with the expected significant resources and costs that implementation of these changes would inspire. The timing of these proposed changes was particularly frustrating since the short-form warning has only been an option for a short time (2016-2018). Considering the considerable resources and costs necessary to implement new changes in addition to pandemic recovery costs, industry believed OEHHA's proposal unwarranted and ill-timed.

OEHHA responded to these comments with additional revisions and requests for comments proposed on December 17, 2021, and April 5, 2022. Under California law (Cal. Gov't Code § 11346.4(b), there is a one-year deadline to submit proposed regulations to the California Office of Administrative Law (OAL) for review and approval. Since OEHHA was ultimately unable to complete the rulemaking within prescribed time limits, it instead allowed the rulemaking to lapse. OEHHA stated in its May 20, 2022, notice entitled "May 2022 Status Update for Clear and Reasonable Warnings - Short Form: Completion of Proposed Rulemaking" that it "intends to restart the rulemaking process on the short-form with a new regulatory proposal, informed by comments on the previous proposal." Although OEHHA stated in its May 2022 notice that this new process would take place "in the next several weeks," no new regulatory proposal has yet been released. In October 2022, an OEHHA spokesperson stated that the agency has not abandoned the regulatory proposal, but nor has OEHHA expressed any timeline for when it will be released.

PODCAST:
OEHHA and Prop 65 Update — A Conversation with Lisa R. Burchi

These label changes are expected to impose significant burdens, including how to determine if the short-form warning can be used, and if so, the necessary language changes that must be made to comply. In 2023, stakeholders should monitor these developments closely. If OEHHA proposes new amendments, stakeholders are urged to review and submit comments to OEHHA identifying issues with regard to the need for, and procedural issues with, any such proposal.

The issue of the applicability of Prop 65 warning requirements to pesticide products containing glyphosate continued in 2022 and will extend to 2023. On September 8, 2022, OEHHA adopted a new California Code of Regulations Section 25607.49 to establish tailored safe harbor warning language for consumer product exposures to glyphosate. The final warning language, which OEHHA states will be effective as of January 1, 2023, is as follows:

> **CALIFORNIA PROPOSITION 65 WARNING:** Using this product can expose you to glyphosate. The International Agency for Research on Cancer classified glyphosate as probably carcinogenic to humans. US EPA has determined that glyphosate is not likely to be carcinogenic to humans; other authorities have made similar determinations. A wide variety of factors affect your personal risk, including the level and duration of exposure to the chemical. For more information, including ways to reduce your exposure, go to www.P65Warnings.ca.gov/glyphosate.

The regulations also state that when the warning is provided on the label of a product registered under FIFRA, the word "ATTENTION" or "NOTICE" can be substituted for the words "CALIFORNIA PROPOSITION 65 WARNING." In an April 8, 2022, letter from EPA, EPA confirmed it would allow this warning on labels of registered glyphosate products.

This final rulemaking will be reviewed as part of a legal appeal challenging Prop 65 warnings for glyphosate. The

The issue of the applicability of Prop 65 warning requirements to pesticide products containing glyphosate continued in 2022 and will extend to 2023.

appeal followed a June 22, 2020, decision issued by the U.S. District Court for the Eastern District of California ruling that such warnings could not be justified as a valid restriction on commercial speech and thus violate the First Amendment of the Constitution. The appeal of that decision has been in abeyance while OEHHA proposes a new rulemaking with warning language tailored to glyphosate that was not considered by the District Court. Now that the rulemaking is complete, the parties in *National Association of Wheat Growers et. al. v. Becerra* have prepared supplemental briefings discussing the implications of OEHHA's rulemaking on this case.

A related legal development relates to a March 2021 preliminary injunction enjoining any person from attempting to enforce Prop 65 warning requirements for the presence of acrylamide in food and beverages. In *California Chamber of Commerce v. Becerra*, the U.S. District Court for the Eastern District of California ruled that OEHHA had not demonstrated that the warning is "purely factual and uncontroversial" and thus violated the First Amendment prohibition against compelled commercial speech. The Ninth Circuit on March 17, 2022, affirmed the District Court's order granting 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. A petition was filed by the Council for Education and Research on Toxics (CERT), an intervenor in the case, urging the Ninth Circuit to review *en banc* its decision to uphold the District Court's ruling. The Ninth Circuit on November 4, 2022, issued an opinion upholding its decision that the District Court did not abuse its discretion in granting the preliminary injunction. The case will continue to proceed in the District Court, with various motions and a petition for rehearing pending before a new judge who was appointed on August 24, 2022, after the initial judge recused herself.

Related to this case are two OEHHA regulatory proposals. The first was an OEHHA proposal for a tailored safe harbor warning language in a new subsection to Section 25607.2 for food exposures to acrylamide. The proposed warning language states in part that "Consuming this product can expose you to acrylamide, a probable human carcinogen formed in some foods during cooking or processing at high temperatures. Many factors affect your cancer risk, including the frequency and amount of the chemical consumed." OEHHA states that its proposed language will benefit California residents "by increasing the public's ability to understand the warnings they receive for certain food products they may choose to purchase." Under California law, the regulation should have been submitted to OAL by September 23, 2022. Since this deadline has not been met, it appears OEHHA may be forced to let it lapse.

OEHHA also on October 6, 2022, issued a "Notice of Second Modification of Text of Proposed Regulation and Addition of Documents and Information to Section 25506, Exposures to Acrylamide in Cooked or Heat Processed Foods." OEHHA's first proposal was not approved by OAL, in a rare decision issued on March 11, 2022. OAL states its disapproval was based, in part, on OEHHA's failure to comply with APA requirements and failure to comply with the standards for clarity and necessity as set forth in Government code Section11349.1.

OEHHA has concluded that with its second modified proposed regulation, it has responded to OAL's concerns and modified the regulatory text and its Initial Statement of Reasons to provide further clarity in defining certain terms and to explain the purpose of this proposed regulation. The new proposed Section 25506 is narrowed to refer specifically to acrylamide instead of the prior, broader reference to "listed chemicals." The proposed text continues to set forth safe harbor exemptions when acrylamide concentrations created during cooking or heat processing are reduced to the

ARTICLE
"California Eyes Proposition 65 Modifications," *Chemical Processing*, April 24, 2022

"lowest level currently feasible" and now provides greater specificity to this term by referencing applicable practices recommended in the Codex Alimentarius Code of Practice for the Reduction of Acrylamide in Foods CAC/RCP 67-2009 (2009). The regulations also provide nonmandatory safe harbor "maximum average" and "maximum unit" concentrations for acrylamide in foods that would not constitute an exposure pursuant to Section 25506(a), and therefore would not require a warning. The comment period ended on October 21, 2022, and OEHHA can be expected to respond to comments and proceed with this regulation in 2023.

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H. FDA FOOD AND COSMETICS REGULATIONS

2022 continued to be a challenging year for FDA due to continued efforts with addressing COVID-19, the Mpox (formerly monkeypox) outbreak, and the infant formula recall. FDA progress in promulgating rules proposed in 2019 through 2021 was slow. FDA continues to delay issuing the NPRM for Food Standards Modernization. The NPRM on Food Contact Substance Notification That Is No Longer in Effect, expected in 2021, was issued in 2022. The comment period closed in April, and the final rule is expected in 2023. The 2022 Regulatory Agenda includes proposed rules from 2021, to clarify changes to the Registration of Food Facilities rules, and requirements in hazard analysis and risk-based preventive controls for human and animal food. The Spring 2022 agenda also includes amendments to procedural requirements for Color Additive and Food Additive Petitions, with proposed rules expected in 2023.

In October 2021, FDA withdrew the applicable Emergency Use Authorization that allowed the temporary preparation of certain alcohol-based hand sanitizers. The notice of withdrawal states that firms "...must cease production of these products by December 31, 2021." Firms were to cease, by March 31, 2022, distribution of any remaining hand sanitizer products that were prepared under the temporary policies before or on December 31, 2021. FDA continues to update and issue guidance, as appropriate, to address COVID-19.

PODCAST:
The New Era of Smarter Food Safety — A Conversation with Karin Baron

1. Food and Food Additive Safety

FDA announced "The New Era of Smarter Food Safety" initiative in April 2019. The FDA process eliciting feedback began in 2019 and was open during most of the year. The initiative is said to be Food Safety Modernization Act (FSMA)-based with the inclusion of modern technology and building on the foundational rules issued in 2011 with the enactment of FSMA. FDA advanced its program significantly in 2022. FDA convened several webinars and began a podcast series to address the blueprint it released in 2020. FDA's focus in 2022 was on revising/replacing the pre-harvest microbial quality criteria and testing in the Produce

WEBINAR ON DEMAND
Food Safety Issues in the United States

Safety Rule with its Agricultural Water proposed rule. FDA provided "new user-friendly" tools online to support its efforts. The comment period closed in April of 2022 and a final rule is expected in 2023.

FDA issued the final Food Traceability Rule in November 2022. The final rule includes the food traceability list, critical tracking events, a traceability plan, and recordkeeping requirements. Expect further progress with the New Era initiative in 2023.

2. Food Contact Substances

FDA began seeking information on several food packaging chemicals in 2022. In July, FDA issued an RFI on the food contact uses of fluorinated polyethylene, the use of which is authorized in 21 C.F.R. Section 177.1615. The use includes using fluorine gas in combination with gaseous nitrogen as an inert diluent. This information request was based on concerns raised by EPA when testing confirmed the presence of PFAS in polyethylene containers that hold pesticides. *See* the section on FIFRA: Predictions and Outlook for the OCSPP's Office of Pesticide Programs. FDA issued letters to industry on this topic in 2021 and has initiated a market phaseout on certain PFAS authorized for use by food contact notifications. In September, FDA re-opened the comment period for an RFI on approximately 25 phthalates used as plasticizers in food contact applications. These two requests suggest that FDA in 2023 may begin to amend food additive regulations for substances that are no longer in use or, based on current available information, are no longer considered safe for the intended use. FDA rarely modifies these sections of the C.F.R., so it will be interesting to track what progress is made, if any, on these initiatives in 2023.

3. OTC Reform

In 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), which includes the Over-the-Counter Monograph Safety, Innovation, and Reform Act (OTC Monograph Reform), was enacted. The CARES Act seeks to modernize the over-the-counter (OTC) drug review and the OTC drug monograph development process. It replaces the

rulemaking process with an FDA administrative order process, clarifies the status of existing OTC monograph drugs, and provides FDA with the authority to collect user fees dedicated to OTC monograph drug activities. The CARES Act also amends misbranding provisions to define an OTC monograph drug as misbranded if it does not comply with the requirements of Section 505G of the FFDCA or if user fees have not been paid. Some key elements include mutual agreement between FDA and industry upon timelines and simplification of the entire process.

In September 2021, FDA announced the proposed order "Amending Over-the-Counter (OTC) Monograph M020: Sunscreen Drug Products for OTC Human Use." The proposed order aligns with the 2019 proposed rule apart from the FFDCA Section 505G changes. FDA indicates it is using the proposed order as a vehicle to transition efficiently its ongoing consideration of the appropriate requirements for OTC sunscreens marketed without approved applications from the previous rulemaking process to the order process created by new Section 505G. The original public comment period for the proposed order was scheduled to close on November 12, 2021. FDA announced an extension to the comment period on November 22, 2021. The extended comment period ended December 27, 2021. No progress was made in 2022 to address OTC reform.

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 food contact substances in the U.S., Europe, and Asia. Visit our websites for more information regarding how B&C assists clients with FDA Regulation of Food Contact and Packaging Material and Acta assists with Global Regulation of Food Contact Chemicals.

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II. KEY GLOBAL CHEMICAL MANAGEMENT PREDICTIONS

A. GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELING OF CHEMICALS

1. Overview

2021 ended on a high note with several countries proposing to implement or revise regulations based on the United Nations (UN) Globally Harmonized System of Classification and Labeling of Chemicals (GHS) model. In 2022, many countries began issuing rules updating their standards to a newer revision of GHS or implementing GHS. In late 2022/**early 2023**, we expect that final rules will be issued revising the U.S. and Canadian regulations implementing GHS. 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. In short, buckle up, as 2023 will be a busy year.

PODCAST:
GHS Update — A Conversation with Karin Baron

2. United Nations

The 42nd session of the UN Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals was held in July 2022. 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, classification of skin sensitizers, classification criteria for germ cell mutagenicity, practical classifications issues, nanomaterials, and continued rationalization of precautionary statements). The European Union (EU) at the 42nd session highlighted an informal document about hazards currently not identified at the global level and indicated its intention to submit a proposal for new items for the biennium 2023-**2024**. The 43rd session was held in December 2022, and the agenda items were nearly identical to the 42nd session and include the EU proposal. In addition, the 43rd session included recommendations made by the Sub-Committee at its 40th, 41st, and 42nd sessions. We await a report on significant developments.

The ninth revised edition (Rev 9) of GHS was published in September 2021, and the expectation is that the tenth revised edition (Rev 10) will be published in 2023. While the full content of what is to be added and/or revised in Rev 10 is not known at this time, the expectation is that revisions to Chapter 3.3 on Serious Eye Damage/Eye Irritation to incorporate *in vitro* data criteria will appear. The updated chapter was adopted by the Sub-Committee in 2021. Similar discussions for revisions to Chapter 3.4 on Respiratory or Skin Sensitization are in progress and not expected in Rev 10.

PODCAST:
Keeping up with CLP Changes

3. U.S. OSHA HCS 2012

On May 25, 2012, OSHA revised and updated the HCS. Currently, all substances and mixtures are required to comply with HCS 2012, as the transition period ended in 2015. 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 is expected in **early 2023**. 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 WHMIS 2015

On February 11, 2015, Health Canada published the Hazardous Products Regulation (HPR). The HPR revised and updated the Workplace Hazardous Materials Information System (WHMIS). WHMIS 2015 significantly altered the previous system (WHMIS 1988) and is a modified criteria-based approach following Rev 5 of the UN GHS model. Health Canada worked with the United States to align, as much as possible, each countries' GHS implementation.

On December 9, 2020, Health Canada proposed to update the HPR 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. Health Canada is currently developing a notice to be published in the *Canada Gazette II* and is not proposing to adopt any provisions from Rev 8. The changes throughout the proposed update to the HPR are similar to those in the U.S. HCS where applicable, but variances are still noted.

Both Health Canada 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. Health Canada indicates that the *Canada Gazette II* notice is expected to be published at the same time as the final rule in the United States. The current proposal includes a transition period of two years. The timing for the transition period for implementation could change to align with the United States.

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. The amendments do not automatically apply to all jurisdictions and during the transition period, either Rev 3 or Rev 7 is allowed.

The deadline for compliance was December 31, 2022, with the expectation that in 2023, companies must comply with Rev 7. Guidance on the transition can be found online.

6. Brazil

Brazil first implemented UN GHS in 2009 based on Rev 4. The Brazilian Association of Technical Standards (ABNT) contains the specific details. The Standard, ABNT NBT 14725, contains 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.

ABNT is currently under its first overhaul since implementation. The standard will remain the same but will combine all four parts into one document with seven sections and 17 annexes. The intention of the update is to align with Rev 7 of UN GHS, including concentration limits for classification of mixtures. The public consultation of the draft technical standard ended on November 19, 2020, and all comments and suggestions have been reviewed and analyzed. A revised draft was expected for comment in 2021 but was not released. In September 2022, a third public consultation was posted where companies had the opportunity to review and send comments on the new version of ABNT NBR 14725. The comment period ended October 27, 2022. Expectation is that the publication will occur in **early 2023,** and companies will have a two-year transition period after the standard is published.

7. Chile

The Ministry of Health (MoH) and the Ministry of Environment (MoE) published on February 9, 2021, Decree 57, approving 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

In Colombia's implementation of Rev 6 of UN GHS, the two-year transition period for substances and diluted solutions concludes April 7, 2023, and the transition period for mixtures concludes on April 7, 2024.

substances was February 9, 2022, with an industrial mixtures compliance date of **February 9, 2025**. Non-industrial substances must be implemented by **February 9, 2023**, and non-industrial mixtures by **February 9, 2027**. Companies are able to continue using the Standard NCh 2245:2015 during the implementation period.

There was confusion over the scope of Decree 57 when it was enacted in 2021. This in turn led to many questions pertaining to Material Safety Data Sheet (MSDS) requirements resulting from the fact that both Decree 57 and Decree 43 set out a specific format and criteria, but these are not aligned. To ease the confusion and questions, on August 17, 2022, the MoH published Resolution 60/2022. The Resolution amends Decree 43 and aligns the MSDS requirements with the GHS-based rules of Decree 57.

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 category 2A and 2B, Aspiration category 2, and Hazardous to the aquatic environment acute categories 2 and 3. This approach aligns Chile with the EU Classification, Labeling and Packaging (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, as well as specific concentration limits and multiplying factors for each listed substance. The list is mandatory and considered to be the minimum substance classification. If a manufacturer or importer wishes to apply a less severe classification than what is noted, the classification must be submitted to the MoH for approval and must include the technical background and testing to support the proposed change. The MoH will approve or deny the classification change. If the manufacturer or importer wishes to apply a more severe classification, while maintaining the minimal classification required, the MoH is not required to review and approve the classification update. The list contains approximately 4,500 substances, and updates are expected every two years.

Labeling requirements within the Decree are similar to the requirements in Rev 7. All label elements must be in Spanish. The label must contain a product identifier, CAS RN for all substances contributing to the hazard classification, hazard pictogram(s), a signal word, hazard statement(s), precautionary statement(s), net content, and national supplier name, address, and telephone number. Precautionary statements are not to exceed six, unless additional inclusions are deemed necessary. For consumer products, supplemental information must include instructions on how to use the product and a poison center telephone number. In addition, the Decree establishes minimum dimensions for the label and pictogram depending on the product container for consumer uses.

8. Colombia

The Colombian *Ministerio de 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 is 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.

Labeling information must be in Spanish. Additional languages are allowed on the label but must convey the same information as indicated in Spanish. Labeling requirements are similar to Rev 6 but must include batch number and chemical identities of any component causing acute toxicity, skin corrosion, serious eye damage, mutagenicity, carcinogenicity, reproductive toxicity, skin or respiratory sensitization, or specific toxicity in target organs. There is a mandatory review of the SDS and label content every five years.

9. EU Annex II to REACH and CLP

On August 11, 2020, the 15th Adaptation to Technical Progress (ATP) was published in the EU *Official Journal* and entered into force 20 days after publication. The changes include 37 new entries into Annex VI and 21 new harmonized Acute Toxicity Estimates (ATE). Enforcement of the 15th ATP began March 1, 2022.

On April 20, 2021, the 16th ATP was released. The updates to the 16th ATP are minor with a couple of small phrase changes. As the changes were considered minimal, the 16th ATP was enforced 20 days after its publication on May 10, 2021. This was the first ATP that was not automatically adopted by the United Kingdom (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 back from March 2019 to December 2019. The enforcement of the 17th ATP began on December 17, 2022.

An 18th ATP was published in May 2022 and will enter 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. Expect in 2023 the 19th ATP, once published, to contain clarification from the RAC on 2-ethylhexanoic acid and its salts in the form of a new Note X. In addition, the RAC opinion for boric acid and many boron compounds from 2019 to 2020 is expected. This will include new Notes 11 and 12 on classification of mixtures as reproductive toxicants.

Commission Regulation (EU) 2020/878 of June 18, 2020, amends Annex II to the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation and has applied since January 1, 2021. This amendment includes substantial changes to the required SDS content. Article 2 specifically notes that SDSs not complying were able to continue to be provided until December 31, 2022.

As reported in September 2022, the EC continues to seek comments on proposed changes to CLP to include new hazard classes currently not addressed within the regulation. These changes include the addition of endocrine disruptors and substances that are PBT, very persistent and very bioaccumulative (vPvB), persistent, mobile, and toxic (PMT), or very persistent and very mobile (vPvM). The EU proposed inclusion of these endpoints in its proposal to the UN GHS Sub-Committee for work in 2023-**2024**. The EU suggests an initial focus on PBT/vPvB and PMT/vPvM, as these parameters have existing test guidelines. Endocrine disruptors for both human and environmental species will require extensive discussions on test methods for assessment, as the conceptual framework for testing and assessment is not yet available.

On December 19, 2022, the EC issued its proposal to revise CLP. As noted in the September 2022 report, the EC included the hazard classes discussed in the proposal. The approval process will advance in 2023 to the European Parliament (EP) and Council. Expect also in 2023 continued discussion at the UN GHS Sub-Committee level to address the additional hazard classes included in the proposal.

ARTICLE

"How Might EU Proposals on Harmonised Classification and Prioritisation of Chemicals for Classification Impact Industry?," *Chemical Watch*, April 14, 2022.

2023 will be an active year of transition, with amendments to CLP and the end of the transition period for Annex II to REACH. Enforcement activities in member states will be expected as these changes enter into force and missing content is easily noticed when changes to format and classification are impacted.

10. United Kingdom

January 1, 2021, marked the official end of the transition period for the UK exit from the EU. The Health and Safety Executive (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 Great Britain (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. The 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.

2022 regulatory actions 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. The variations on a substance-by-substance level did result 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 maintains these substance level classifications in an Excel spreadsheet that is updated frequently on its website. These changes require considerable diligence for those navigating trade within the region. 2023 is expected to be similar. It is unclear how the UK will address the Annex II changes to EU REACH that resulted in changes to the SDS in the EU. These would not be addressed within the GB CLP as it is currently written.

11. 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 is 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, the 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 provides details, including that not all categories within Rev 7 are 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.

This update to Rev 7 is a long-anticipated step that will allow for better alignment with other countries that have adopted the UN GHS model into legislation. In 2023, companies will need to consider how these significant changes impact the SDS, labels, and packing provisions now implemented, and 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.

12. 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 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 Only Representative (OR), to submit the MSDS with appropriate documentation to MoEL.

Any new products placed on the market after January 16, 2021, require submission of the MSDS to MoEL and must comply with required content, including being in 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**.

13. Peru

Peru has no chemical management framework in place. A draft bill was circulated in 2020 that proposes a regulation that will 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. Peru will accept a 16-section SDS and label based on the UN GHS as it continues with the development of chemical regulations. Look for the continued progress of this framework in 2023.

14. South Africa

The updates to the South African Occupational Health and Safety Act of 1993 (Regulations for Hazardous Chemical Agents) were issued March 29, 2021. The regulation took effect on September 29, 2022. The update aligns with Rev 8, and not all building blocks were adopted. Explosives and Pyrophoric gas hazard classes are not included. The following physical, health, and environmental hazard categories are also not included: Aerosols category 3, Flammable liquids category 4, Acute toxicity category 5, Skin corrosion/irritation category 3, Eye damage/irritation sub-category 2B, Acute hazardous to the aquatic environment categories 2 and 3, and Chronic hazardous to the aquatic environment categories 3 and 4. The scope includes manufacturers, importers, suppliers, and retailers of hazardous chemicals intended for use in the workplace. The SDS is a standard 16-section format, and the disclosure of ingredients includes provisions for protecting CBI with the use of ranges. The label must include the expected GHS content (*i.e.*, product identifier; chemical identity of hazardous ingredients; name, address, and telephone number of the manufacturer or importer; emergency telephone number; a signal word; hazard statement(s); pictogram(s); and precautionary statement(s)). In addition, the labels must conform to size requirements specified in Annexure 3.

15. Singapore

GHS, first adopted in 2008 under Singapore Standard (SS) 586, 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. The proposed changes by Enterprise Singapore would apply to SS 586 Part 2, "Globally harmonized system of classification and labelling of chemicals — Singapore's adaptation" and SS 586 Part 3, "Preparation of safety data sheets (SDS)." Part 2 amendments include additional labeling and training requirements, the addition of the physical hazard class desensitized explosives, and adding Annex B to provide examples of small container labeling. Part 3 has minor updates but proposes updates to suppliers' and manufacturers' responsibilities in the preparation, review, and updates of an SDS. A new annex, Annex D, is added to provide substance and mixture guidance on determining the physical and chemical properties listed on the SDS. 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. Expect further updates on this proposal in 2023.

B&C and Acta offer a global presence, with offices in North America, Europe, and Asia, 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: GHS Services.

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Both Brazil and Peru are taking steps to implement chemical regulatory schemes as part of their goal of joining OECD.

B. LATIN AMERICA

1. Overview

In 2022, the development of chemical substance legislation remained stalled in several countries. Brazil's draft Industrial Chemicals Regulation failed to progress in the federal legislature. This could change under the leadership of President-elect Luiz Inácio Lula da Silva. Lula's party failed to capture control of the federal legislature, however, so the future is unclear.

Both Brazil and Peru are taking steps to implement chemical regulatory schemes as part of their goal of joining OECD. Perhaps most significantly, Colombia launched an online system to register chemicals for the National Registry of Industrial Chemical Substances in 2022. Companies that manufacture or import industrial chemical substances categorized as hazardous in volumes exceeding 100 kilograms annually are required to report by **May 30, 2025**.

2. Latin American Regulatory Cooperation Forum (LARCF)

The Virtual Working Group for the Sound Management of Chemicals in Latin America published an April 2022 report, *Enfoque de Riesgo En la Gestión De Sustancias y Productos Químicos Industriales: Inventarios*. The report is intended to capture the key elements for the implementation of risk management systems for industrial chemical substances and products, with a focus on compiling national chemical inventories. The goal of the report is to promote discussion between government and industry representatives on the principles and technical concepts related to the development and implementation of a chemical inventory. The report notes that these should not be interpreted as mandatory statutory or regulatory requirements. Annex 4 of the report (on page 40) provides a list of worldwide existing chemical inventories and their main characteristics.

The working group is an initiative of the LARCF with the support of the International Council of Chemical Associations (ICCA). The working group aims to promote the sound management of industrial chemicals and to strengthen regulatory cooperation by reaching a common understanding on the concepts related to sound management of industrial chemicals, in line with the provisions of international conventions and agreements.

The working group is preparing a report on prioritization and risk assessment methodologies. The report will outline a prioritization methodology that considers pre-existing models and the necessary adaptations based on the characteristics of the region. The methodology is expected to include a summary of various approaches, as well as case studies. It is intended to be useful for the development of regulations in Latin America.

3. Brazil

a. Chemical Control

Brazil's draft Industrial Chemicals Regulation (Bill 6120/2019) failed to progress in 2022, in part due to former President Jair Bolsonaro's lack of support for the bill. President-elect Lula narrowly defeated Bolsonaro on October 30, 2022, but it is unclear what the change in leadership means for the legislation. Though Lula was elected President, his party failed to capture control of the federal legislature. Two committees in the lower house of the National Congress have passed the bill, but it must be approved by two additional committees. Once the bill is approved by all committees, it will move to the Senate.

In **early 2023**, a project that will lead to a national chemical inventory is expected to begin. The Ministry of Environment is developing a database that will monitor the quantities, including imports and exports, of hazardous chemicals in Brazil. The project is financed by the UN Environment Programme's (UNEP) Chemicals and Waste Management Programme, and the Brazilian Chemical Industry Association (ABIQUIM) will help manage it. The database is expected to list all industrial chemicals used in quantities greater than one metric ton per year.

OECD approved a roadmap for Brazil's accession in June 2022. The roadmap sets out the terms, conditions, and pro-

cess for accession of Brazil into OECD. In September 2022, Brazil submitted its initial memorandum to OECD. The memorandum, which is more than 1,000 pages, sets out a self-assessment of the alignment of Brazil's legislation, policies, and practices with each OECD legal instrument in force that applies to all OECD members. Membership in OECD requires a national chemical inventory and registration system before accession.

b. Personal Hygiene Products, Cosmetics, and Perfumes

On September 21, 2022, Brazil's National Health Surveillance Agency (Anvisa) repealed Resolution of the Collegiate Board of Directors (RDC) 7/2015, replacing it with RDC 752/2022, which took effect on October 3, 2022. The regulation provides the definition, classification, and requirements for labeling and packaging of personal hygiene products, cosmetics, and perfumes. Under RDC 752/2022, there are only two risk classifications. The first includes personal hygiene products, cosmetics, and perfumes that are characterized as having basic or elementary properties and that do not require detailed information regarding their use due to the intrinsic characteristics of the product. The second classification includes personal hygiene products, cosmetics, and perfumes that have specific indications, including characteristics that require proof of safety and/or efficacy. These products must be registered and include suntan lotion, sunscreen, children's sunscreen, antiseptic hand gel, products to straighten and dye hair, products to curl hair, insect repellent, and children's insect repellent. RDC 752/2022 provides a three-year transition period for manufacturers of products that must be registered or notified. Products manufactured before **October 3, 2025**, and labeled in accordance with the previous requirements may be sold until their expiration dates.

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 establishes a national inventory of industrial chemicals, establishes a method for risk evaluation of priority substances, and implements GHS. Decree No. 57 will be implemented in stages. The government plans to publish the first national inventory by **December 31, 2024**. Notification is required every two years, by August 30. For substances and mixtures for industrial use, the first notifications are due **August 30, 2024**, and **August 30, 2027**, respectively. For substances and mixtures for non-industrial use, the first notifications are due **August 30, 2025**, and **August 30, 2029**, respectively. Chile is developing an online system for the first notifications due in **2024**. In 2022, there were two beta testing periods for industry to use the online system and provide feedback.

In 2022, the Ministry of Environment (MOE) launched a website on chemical substances for industrial use. The website includes information on chemical substances, current regulations in Chile, technical guides to assess the risk of chemical substances and risk studies carried out in the country. MOE and MOH are drafting a regulation on the prioritization and risk assessment of chemical substances.

5. Colombia

a. Chemical Control

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 the following information:

- Identity of the manufacturer/importer;
- Annual production or import quantity of the chemical (the reporting instructions will address reporting mixtures);
- Identification of the chemical substance, including its CAS RN (when applicable);
- Hazard classification, according to the provisions of Decree 1496/2018, which adopted the sixth revision of the GHS; and
- Identified uses.

Under the Decree, exemptions include substances of natural origin without chemical processing, chemical substances that are already regulated by other statutes, arti-

cles, byproducts that have not been imported or traded as such, polymers, and non-isolated intermediates. 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 for the new RSQUI.

b. Pesticides

Resolution 1580/2022, issued on February 9, 2022, took effect on August 1, 2022. The resolution establishes the requirements and procedure for the registration of manufacturers, formulators, packers, distributors, importers, and exporters of chemical pesticides for agricultural use, as well as the requirements for the registration of chemical pesticides for agricultural use.

6. Mexico

a. Chemical Control

After issuing a National Integrated Policy for the Management of Chemical Substances (La Política Nacional Integral para la Gestión de Sustancias Químicas) in November 2019, Mexico's plan to publish a comprehensive chemical law has made no significant progress. According to the policy, the law for the Comprehensive Management of Chemical Substances would include the establishment of an inventory of chemical substances and a subsequent registry.

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 regulation. This is at odds with the USMCA, which backs a risk-based approach for regulating chemicals, similar to TSCA.

b. Cosmetics

On July 5, 2022, Mexico published standard NOM-259-SSA1-2022, concerning Good Manufacturing Practices (GMP) for the cosmetic sector. The standard establishes the minimum necessary requirements of good practices for the processing and importation of cosmetic products.

The standard partially agrees with the International Organization for Standardization (ISO) standard ISO 22716:2007, "Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices."

NOM-259-SSA1-2022 took effect 60 days after its publication date. The documentation requirements took effect 180 days post publication. The requirements concerning facilities and services will take effect 240 days after publication on **March 2, 2023**.

7. Peru

A UNEP project in Peru seeks to implement a regulatory framework for the sound management of chemicals, beginning with a gap analysis and a legal technical evaluation. The project is intended to strengthen the capacities of the public and private sectors to participate in GHS implementation; identify, design, and implement a National Registry of Chemical Substances that are commercialized in Peru; ensure access to updated information; and provide specific measures for the reduction and management of risks to health and the environment from hazardous chemical substances. In addition, technical guidelines for formulating, preparing, and implementing risk assessment will be developed. Risk assessments will then be conducted for chemical substances identified as priorities at the national level. The project outcomes include drafting articles on management mechanisms for chemical substances that will be considered for the draft regulation of the proposed law on the sound management of chemicals.

OECD approved a roadmap for Peru's accession in June 2022. The roadmap sets out the terms, conditions, and process for accession. As noted above, membership in OECD requires a national chemical inventory and registration system before accession.

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Companies outside of Great Britain (GB) holding EU REACH registrations that have not already been grandfathered or are not eligible for grandfathering must register under UK REACH through an OR based in GB to remain in commerce in GB.

C. UNITED KINGDOM/GREAT BRITAIN

1. Overview

Since the UK separated from the EU on December 31, 2020, divergence between the UK and EU regulations pertaining to chemicals has proceeded slowly. Companies worldwide must be aware of the significant implications for chemical regulatory compliance under several regimes, including the UK REACH regulation and the Biocidal Products Regulation (BPR), as divergence between the UK and EU regulations, while slow in 2022, continues in **2023 and beyond**. The number of chemical substances that will be available on the UK market is unlikely to be known by the **end of 2023**, as the regulations, processes, and procedures continue to evolve, and associated costs for access to the market in 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 2023.

2. UK REACH

The EU REACH regulation was adopted into UK law as UK REACH according to the Withdrawal Agreement, with the necessary changes to adjust from the EU to the GB context. EU REACH registrations that existed on December 31, 2020, or were held at any point since March 29, 2017, by GB-based legal entities, including manufacturers, importers, and ORs, had the option to be "grandfathered" under UK REACH until April 30, 2021. The combined total of substances that have been grandfathered or covered by downstream user import notifications (DUIN) still falls well short of the 22,500 substances registered under EU REACH. As noted above, the number of substances registered under EU REACH that will ultimately be placed on the market and remain available in GB is likely to remain unknown in 2023.

Eligible companies that missed the April 30, 2021, deadline have had opportunities to grandfather their EU REACH registrations in 2022, as GB's HSE has reactivated the grandfathering option in the Comply with UK REACH system for limited time periods; whether this will continue into 2023 is unknown. Companies outside of GB holding EU REACH registrations that have not already been grandfathered or are not eligible for grandfathering must register under UK REACH through an OR based in GB to remain in commerce in GB.

GB-based businesses procuring chemical substances directly from EU REACH-registered suppliers are considered importers under UK REACH. The GB-based company must obtain a UK REACH registration to continue importing from EU REACH-registered suppliers unless its supplier appoints a GB-based OR to register under UK REACH on the importer's behalf. To maintain supply chains and ensure continued access to the GB market, GB importers that were formerly downstream users of EU REACH-registered suppliers were offered the option of submitting a DUIN in the UK REACH IT system by the October 27, 2021, deadline. As with grandfathering, the HSE left the DUIN process open past the deadline, but it is unclear as of this writing whether the opportunity to submit a DUIN will be reopened in 2023.

The current registration deadlines for grandfathered substances were the subject of a public consultation launched by the Secretary of State for Environment, Food and Rural Affairs (DEFRA) that closed on September 1, 2022. DEFRA released a summary of the results on November 29, 2022, which included its intention, subject to agreement by Scotland and Wales, to extend the deadlines for three years each, as noted below:

- **October 27, 2026**, for substances at 1,000 metric tons or more per year; carcinogenic, mutagenic, or toxic for reproduction substances (CMR) 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, 2020;

- **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.

DEFRA also proposes to extend the timelines for completion of its compliance checks on registration dossiers. DEFRA did not propose dates for completing these compliance checks but stated that the new dates would align with the revised registration dates as well as with the provisions of REACH Article 41 with respect to the minimum number of dossiers to be reviewed according to the tonnage band and hazard profile.

Since REACH's inception, Acta science, legal, and regulatory professionals have actively assessed the legislation and its implications and have prepared clients for its requirements. Acta launched REACHblog™ in 2022 to assist clients to track news and developments under EU and UK REACH. All companies doing business in Great Britain (GB) and the EU will benefit from the timely and thoughtful analysis of the REACHblog, available at www.REACHblog.com.

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 is considering legislation proposed on November 14, 2022, to extend the transition period for implementing the UK Conformity Assessment (UKCA; the counterpart of EU 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.

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 is expected as regulatory changes occur in GB and the EU. The UK Government is currently updating the technical annexes to the UK Cosmetics Regulation to either prohibit the use of specific chemicals or reduce the permitted levels of specific chemicals. These chemicals are assessed by the Scientific Advisory Group on the Chemical Safety of non-food and non-medicinal consumer products (SAG-CS), which advises the UK Government on amendments to the annexes to the Cosmetics Regulation.

Companies are advised to consult the guidance to ensure that they understand the different nuances of placing on the market cosmetics in GB, NI, and the EU.

4. Biocides

As of January 1, 2021, GB has its own framework for Biocidal Products Regulation (UK BPR), with the HSE replacing ECHA for active substance evaluations and approvals as well as biocidal product authorizations. Divergence between the EU and UK regulations is ongoing, increasing regulatory compliance complexity and costs.

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 has been introduced. The law would extend the timeframes for processing product applications under the UK BPR. The new law, which came into force on December 31, 2022, extends the timeframes for the 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, the HSE NI.

5. PPP

The regulation of Plant Protection Products (PPP) in GB has begun to diverge as existing Maximum Residue Levels (MRL), approvals of active substances, and product authorizations are amended by HSE or expire (active substances and products). The HSE will not issue new parallel trade permits in GB and has withdrawn such permits in GB with a final sale date of **June 30, 2023**, and final use date of **June 30, 2024**. Special rules apply for PPP in NI.

Active substances that are approved by the HSE will be included in the GB Pesticides Approval Register and published on the HSE website. Active substance approvals that expire before **December 2023** will receive a three-year extension to provide enough time for the necessary HSE risk assessment and evaluation work.

Seed that has been treated with a product authorized for that purpose in an EU member state can continue to be traded and used in Great Britain until **December 31, 2023**. After that date, treated seed can only be traded and used in Great Britain if it has been treated with a PPP authorized for that purpose in Great Britain. Applicants should submit any new GB PPP authorizations without delay.

Two years after Brexit, pesticide regulation in GB remains mostly unchanged from the EU regulation it copied into its law, Regulation (EC) 1107/2009. Industry is expressing concern about HSE's extended deadlines for active substance approvals and the divergence from EU regulations that this delay causes. Because of the delayed deadline, pesticide companies must plan for different timelines in GB and the EU, followed by potentially different requirements, which in turn translates to more cost. Some concern was voiced about the HSE taking too long to get its bearings following Brexit and lagging behind essential pesticide developments in the EU, such as the obligation adopted in March 2021 for pesticide companies to publish scientific studies used to support successful pesticide license applications. Companies are advised to stay informed about regulatory developments in 2023. After a slow start, GB might make amendments that diverge from pesticide regulation in the EU.

From offices in Manchester, UK, and Brussels, Belgium, Acta provides local expertise and boots-on-the-ground representation to assist clients in gaining and maintaining compliance in both jurisdictions. Acta's Manchester office can be reached at +44 (0) 161 240 3840.

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D. EUROPEAN UNION

1. Overview

Amending the EU's chemicals regulatory frameworks for better alignment with the Green Deal targets of climate neutrality and circularity 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 **2023 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.

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** in its 2023 Work Programme. This postponement of REACH revision proposals has raised concerns that consideration of revisions will be deferred until after the EP elections in **2024**, which could delay entry into force of REACH amendments and would open the possibility that the next EC could modify or withdraw the current EC's revision proposals. The EC has attempted to ease these concerns by stating that it will attempt to publish the REACH revision proposal prior to the **fourth quarter of 2023** and will forward it to the EP for review as soon as practicable.

Several significant aspects of the Strategy are shaping 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.

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, including the essential use concept in risk management, which was the subject of a stakeholder workshop held in March 2022.

The overall objective of the essential use concept is to facilitate systematic decision-making and allow continued use of the most harmful substances only when their use is demonstrated to be essential for society and there are no acceptable alternatives from the perspective of human health and the environment. It could also provide justification for continuing the use of hazardous substances that are well characterized and for which effective risk mitigation measures exist instead of replacing them with substances that are less data rich.

The Strategy proposes to address the risks of exposure to mixtures of substances (*i.e.*, combination effects) by introducing MAF into REACH, as additional risks that may arise from exposure to mixtures of chemicals are not generally part of the REACH GRA paradigm. Introducing MAFs into REACH raises the possibility that thousands of registrations would have to be updated, would likely cause risk values to increase, and would also likely impact regulatory processes under other regulations in accordance with the "one substance, one assessment" objective of the Strategy. Systematic procedures for assigning MAF would also need to be developed, including consideration of how such assignments should be made for additional hazard classes, such as endocrine disruptors, immunotoxicants, neurotoxicants, respiratory sensitizers, and substances that affect specific organs.

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.

Following the update of the definition of nanomaterials, the EC may opt to include provisions regarding nanomaterials in the body of the revised REACH Regulation.

During the 45th Meeting of Competent Authorities for REACH and CLP (CARACAL), updates were proposed to the definition of "intermediates" as part of the forthcoming revision of REACH. The suggested updates aim to ensure an unambiguous and consistent application of the definition of intermediates and to clarify the uses that benefit from the special regime. The initial proposals for updating the definition of intermediates have been met by industry with concerns, including fears that intermediates could become subject to authorization under the updated definition.

Achieving the ambitious goals of the Strategy timely is expected to place heightened emphasis on REACH compliance and enforcement in **2023 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 Community Rolling Action Plan (CoRAP) update for the years 2022 - **2024** lists 27 substances suspected of posing a risk to human health or the environment, all for evaluation by 10 MS competent authorities. The plan contains two newly allocated substances and 25 substances already included in the previous CoRAP 2021 - 2023 update. Out of the 27 substances to be evaluated, four were to be evaluated in 2022, 14 in 2023, and nine in **2024**. Changes may be introduced for substances listed for years 2023 and **2024** in the next CoRAP update in 2023. The remaining 25 of the 50 substances listed in the previous update are withdrawn from CoRAP, because for six of these, the data were considered sufficient to clarify the initial concerns, while for 19, relevant information is or will be requested under the dossier evaluation processes. These substances may be put on CoRAP again if after the conclusion of these processes, concerns remain beyond what can be clarified through dossier evaluation.

With the REACH revision under way, and several REACH-related initiatives under the Strategy already well advanced in their implementation, the European chemicals legislation will continue to diverge in 2023 from that of GB, as these EU initiatives do not have counterparts in GB. Only two years after Brexit, companies doing business in both markets have already begun to feel the differences in requirements. This sense is only expected to heighten in the upcoming years.

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 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. On September 15, 2022, the EC added 14 CMR chemicals to the Cosmetics Regulation Annex II list of chemicals banned in cosmetic products. The ban includes tetrafluoroethylene, 4-methylpentan-2-one oxime, and methyl isobutyl ketone, and it entered into force on December 17, 2022.

The EC published a draft amendment of the Cosmetics Regulation that would set a labeling requirement for an additional 56 fragrance allergens if they are present at greater than 0.001 percent for leave-on products or 0.01 percent for rinse-off products. The targeted substances include menthol, camphor, vanillin, and essential oils like lavender or cinnamon oil. The proposed amendment is expected to be adopted in the **first half of 2023**.

While significant amendments of the Cosmetics Regulation have been delayed and the sense of urgency has diminished, companies are nevertheless advised in 2023 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 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

As of April 15, 2022, applicants for active substance approvals or biocidal product applications must comply with stricter data requirements regarding reproductive toxicity, developmental neurotoxicity, and developmental immunotoxicity, following the amendment of BPR Annexes II and III by Commission Delegated Regulation (EU) 2021/525.

The biocides Review Programme continues to evolve, though at a slower pace than anticipated and with skepticism about meeting the **December 31, 2024**, BPR deadline for completing the evaluation of existing biocidal active substances contained in biocidal products. 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. Even if the Review Programme falls short of the deadline, the gap between the target and the actual numbers will be smaller than feared in previous years.

With the aim to harmonize biocidal product authorizations across MSs, the competent authorities agreed in June 2022 on a guidance on biocidal carriers, which are borderline cases between treated articles and biocidal products. The guidance offers details regarding the definition and handling of biocidal carriers and outlines the information that must be provided regarding a carrier's composition, physical-chemical properties, and dimensions.

During its September 2022 meeting, the BPC concluded that iodine and polyvinylpyrrolidone (PVP) iodine (PVP-iodine) meet the criteria to be classified as endocrine disruptors. As a consequence, these biocides would require a derogation to be approved for use in the EU. The EC has yet to decide what measures to take following BPC's opinion, but the requirements for these products will likely become stricter over the upcoming years. Iodine and PVP-iodine are currently approved under BPR, principally for use as veterinary hygiene products (Biocidal product type 3, or PT 3), but they underwent an early review after a 2016 screening study identified them as possible endocrine disruptors.

While 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 2023 until the 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. PPP

In light of the EU's ambitious goals for a toxic-free environment, Regulation (EC) No 1107/2009 concerning PPPs (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 to achieve these goals. Initiatives will continue in 2023 to reduce the use of synthetic pesticides and promote their replacement by biopesticides.

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.

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. At least part of this process could take place in 2023, introducing stricter requirements for synthetic pesticides.

The ambitious proposal was received with certain skepticism, due to the large scale of the planned measures, the short timeframe for implementation, and the lack of viable, sustainable pesticide alternatives. Industry also expressed concerns that the EU's outdated regulatory framework for biotechnology solutions for agricultural use cannot support the ambitious goals that the EC has set for the F2F.

One step toward reaching the **2030** goals is the adoption by the EC, within the F2F, on August 31, 2022, of new rules to increase the availability of and access to biological PPPs. The rules, set to become effective in November 2022, list specific approval criteria for microbial active substances in Annex II of the PPPR to reflect the particularities of these substances, which are different from chemical substances.

The goal of these provisions is to speed up approval and authorization of biopesticides, to offer viable safer alternatives to synthetic pesticides. If implemented as planned, the authorization and placing on the market of a biopesticide in an MS would take place one to three years from initial submission. The EC hopes that by revising the data requirements and speeding up the approval process for biopesticides, the goal of cutting the use of synthetic pesticides in half by **2030** will become more achievable.

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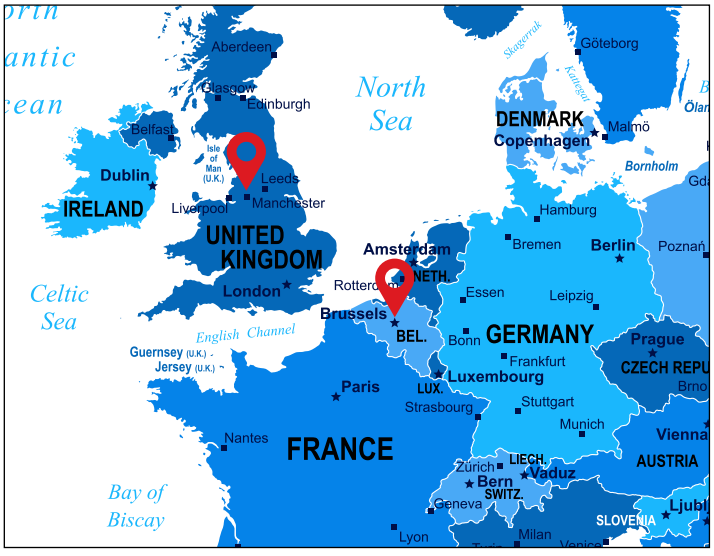

The deadline was extended for applicants to submit information to the authorities without a notification procedure until November 1, 2024, if the applicant can confirm the circulation of the substance in the EAEU customs territory prior to the date TR EAEU 041/2017 entered into force.

E. EURASIA/RUSSIA

In 2017, the Eurasian Economic Union (EAEU) member countries issued a regional chemical framework, Technical Regulation (TR) EAEU 041/2017 on safety of chemical products. Member countries of the EAEU include the Republic of Armenia, the Republic of Belarus, the Republic of Kazakhstan, the Republic of Kyrgyzstan, and the Russian Federation. This regional chemical framework, also referred to as EAEU REACH, includes elements from the EU REACH and the U.S. TSCA.

Two draft implementing sub-regulations, one proposing procedures for creating and maintaining a register of substances and mixtures, and the second proposing procedures to notify and register new substances, were expected to enter into force sometime in 2021. After the first round of discussions on the draft implementing sub-regulations ended inconclusively, the Eurasian Economic Commission (EEC) started a second round of public discussions on February 18, 2021.

The latest drafts contain a revised timeline for adopting the EAEU register of substances. Most notably, the deadline was extended for applicants to submit information to the authorities without a notification procedure until **November 1, 2024**, if the applicant can confirm the circulation of the substance in the EAEU customs territory prior to the date TR EAEU 041/2017 entered into force.

All deadlines established for 2022 lapsed, and there appears to be no progress on the proposed legislation. EAEU member states did not complete their national lists of chemicals by September 1, 2022, and did not meet the October 1, 2022, deadline to issue in final the centralized EAEU list of chemicals. It is unclear whether or how this legislation will progress in 2023.

Parallel to the discussions regarding implementing the sub-regulations for TR EAEU 041/2017, and the corresponding delayed deadlines, EAEU was expected to adopt three classification and labeling standards in 2021. The Commonwealth of Independent States Coordinating Information Center (CIS Center) developed the final draft versions of the following classification and labeling standards:

- GOST 30333: Chemical Safety Passport;
- GOST 32419: Classification of Chemical Products; and
- GOST 31340: Warning Labeling of Chemical Products.

These standards have been expected to enter into force once TR EAEU 041/2017 becomes effective and would apply to the classification and labeling of chemical products placed on the EAEU market. No further progress regarding the draft standards was made in 2021 or 2022, most likely because of the delays to TR EAEU 041/2017. Russia intends to implement all three standards effective January 1, 2023. Industry concerns about the chemical safety passport (CSP) aspect of these standards, including how this requirement would be implemented in practice and whether CBI will be protected, remains a question, especially if registrants are required to disclose the composition of their mixtures to the authorities.

1. Russian Federation

The Russian Federation continues to develop its own chemical regulatory framework. Progress in 2022 was notably delayed due to the ongoing conflict in Ukraine. In January 2021, the Russian Ministry of Industry and Trade (Minpromtorg) published its final chemicals inventory on the Governmental Industry Information Exchange Platform (GISP). The final inventory, like the transitional inventory, contains just over 80,000 substances. Companies had until August 1, 2020, to submit notifications for existing substances to the authorities. The final inventory contains all notifications. Substances not on the inventory will require registration as new substances. Companies that did not meet the August 1, 2020, deadline, but that can prove that the substance was used or produced on the EAEU market before then, have until **June 2, 2023**, to submit a notification of an existing substance.

In 2023, it is likely that Russia will continue the development of its framework independently and in advance of the EAEU. By establishing its final inventory of existing substances, Russia has met the EAEU July 2022 deadline for implementing sub-regulations.

2. Ukraine

In response to the invasion by Russia in February 2022, Ukraine has reacted resiliently and offensively from a regulatory advocacy standpoint. During the armed conflict, Ukraine submitted its candidature to join the EU, and as of June 2022, Ukraine is officially a candidate. To achieve the goal of becoming an EU MS, Ukraine must align its legislation with key legislation of the EU. The main pillars of European chemicals regulation are part of that key legislation: the EU REACH and CLP regulations.

On September 13, 2022, Ukraine's Cabinet of Ministers approved a draft law that would create the country's first comprehensive chemicals regulation framework. The proposal is unsurprisingly based on the EU regulations. Among other provisions, the proposal requires mandatory registration of all chemicals, offers a system for classifying hazardous substances, restricts and bans certain hazardous substances, and requires chemical safety assessments. The proposal would also implement the provisions of the Basel Convention, Rotterdam Convention, and Stockholm Convention on persistent organic pollutants (POP). Following approval by the Cabinet of Ministers, the proposed law must be considered by Parliament.

Also in September 2022, Ukraine's Parliament passed law No. 4142, banning the production and use of asbestos and asbestos-containing products and materials. Ukraine's first attempt to ban asbestos was in 2017, when legislation passed but was repealed only months later. The reintroduction of this ban brings Ukrainian legislation in line with the EU and one step further from Russia, one of the main producers and exporters of asbestos in the world.

Expect further progress on these drafts and similar legislative proposals in the field of chemical regulation in 2023. After years in which it was not always clear which direction Ukraine's legislation would follow, either harmonizing with Russia's law or the EU's, it has become clear that Ukraine is committed to following the EU path. This includes, as an apparent priority, harmonizing its chemical regulations.

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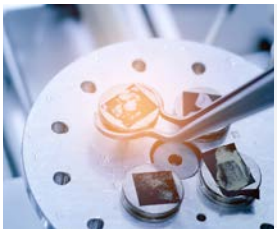

Unlike EU REACH, the KKDIK registration timeline is not staggered according to tonnage band; registrations for all tonnage bands must be submitted by December 31, 2023.

F. TURKEY

1. Overview

With the broader goal of harmonization with the EU's body of law in anticipation of EU membership, Turkey continued in 2022 to align its chemicals legislation framework with the EU's chemicals regulations. By far, the most significant activity in 2022 was the ongoing implementation of the KKDIK regulation (Kimyasalların Kaydı, Değerlendirilmesi, İzni ve Kısıtlanması) that entered into force on December 23, 2017. Amendments to Turkey's 2009 BPR entered into force on January 1, 2022. The requirements of both KKDIK and BPR will drive major chemical regulatory activities in Turkey in 2023.

2. KKDIK

Implementation of the KKDIK regulation continued in 2022 with initiation of the registration phase, formation of Substance Information Exchange Forums (SIEF), and designation of lead registrants (LR) following the conclusion of the pre-registration phase on December 31, 2021. 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 the EU REACH. Unlike EU REACH, the registration timeline is not staggered according to tonnage band; registrations for all tonnage bands must be submitted by **December 31, 2023**.

Although the pre-registration phase ended on December 31, 2020, companies may submit late pre-registrations until **December 31, 2023**. Beginning **January 1, 2024**, a full registration is required for substances that have not yet been registered and are expected to be imported into or manufactured within Turkey in quantities of one metric ton per year or greater.

Companies that pre-registered substances began forming SIEFs, are negotiating the nomination of LRs, and are navigating substance registration. At the end of 2022, fewer LR registration dossiers were submitted than anticipated. Over 18,000 pre-registered substances were counted at the end of the pre-registration phase, yet, as of October 2022, the registration process was complete for only 500 LR dossiers. There are many reasons for the delay, but negotiation for data access appears to be the most common reason cited.

The Turkish Ministry of Environment and Urbanization (MoEU), after a meeting with industry in October 2022, indicated that it would issue specific guidance to help increase the number of registrations. As of November 2022, that guidance was still forthcoming.

As dossier development continues into 2023, a few notable requirements include: translation of the entire dossier into Turkish with minor exceptions for analytical data (*e.g.*, tables on the endpoint of study reports), entry of details on the identity of importers that are to be covered under KKDIK as downstream users, and submission of the entire registration dossier using Turkey's KKS platform.

2023 will continue to see the implementation of the KKDIK registration phase, and the MoEU will likely issue guidance documents, similar to those issued by ECHA in the EU, to assist companies. In 2023, registration of LR dossiers will continue, as well as progress with co-registrant dossiers. Due to the modest number of registrations completed to date, a significant surge in registrations is expected during 2023. The MoEU remains firm on its position of not extending the **December 31, 2023**, registration deadline. As 2023 begins, numerous substances remain without an LR, and in those cases, data needs are not yet clear. Failure of data negotiations and lack of access to required data will lead to eventual market disruption if the process is not completed within the specified timeframe.

3. Biocidal Products

In 2021, Turkey's Ministry of Health proposed several amendments to the BPR, in force since its original publication in *Official Gazette* No. 27449 of December 31, 2009. The goal of the proposed amendments is to harmonize Turkey's laws with the provisions of the EU BPR. The amendments of several articles include the terms and conditions

for placing biocidal products into 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. The amendments entered into force on January 1, 2022. Notified products can be placed on the Turkish market until **December 31, 2023**. To ensure that products can be placed on the Turkish market without interruption, companies must obtain licenses for their biocidal products and start the full registration process in 2023. Expect additional activity associated with this regulation in 2023 as companies prepare registrations.

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G. MIDDLE EAST AND AFRICA

1. Overview

2022 has seen few significant developments in this area of the world. Several of the initiatives that were expected to progress during 2022, such as the publication of Israel's draft chemicals management law, did not. COVID-19's lingering influence continues to delay these and other initiatives.

During the Africa regional meeting convened by the UN's Strategic Approach to International Chemicals Management (SAICM) in July 2022 in Accra, Ghana, countries exchanged information and provided updates regarding the progress toward SAICM objectives in the region. The meeting was followed by the fourth meeting of the intersessional process considering the Strategic Approach and sound management of chemicals and waste beyond 2020 in late August 2022, where the Africa Group proposed the development of an international code of conduct on chemicals and waste management.

These meetings and discussions, and continued UN involvement in the region, indicate that the sound management of chemicals and hazardous waste is becoming a priority, and legislative proposals could be forthcoming as early as 2023. Several African countries, such as Ghana and Kenya, have indicated plans to publish draft chemical regulation laws in recent years. While these drafts have not materialized to date, due to the continued engagement and international assistance in the region, 2023 could see the publication of such draft laws in African countries.

2. Israel

Israel's Ministry of Environmental Protection first published the draft Industrial Chemicals Registration Law in October 2020. The Industrial Chemicals Registration Law aims to take inventory of all chemicals used in Israel, create a risk assessment process for certain chemicals, and establish chemicals risk management measures.

The inventory of existing chemical substances would be created through a mandatory registration process. Once the registration periods end, all non-registered substances will be considered "new chemicals." Manufacturers and importers of chemicals will be required to report information such as chemical properties, risk characteristics, and quantities produced or imported for various uses. Israel has not announced a volume-based threshold for reporting but has projected a range of one to ten metric tons, depending on the risk assessment of the substance. Israel is still surveying other international chemical management regimes to determine how it will implement risk management measures based on chemical assessments. As proposed, manufacturers and importers would have **until September 1, 2024**, to register chemicals. Israel expected the law to be approved in late 2021 and to take effect on **March 1, 2023**, but 2022 passed without Israel publishing an official draft. It is unclear when this legislation will progress toward becoming final. The next steps could be taken in 2023, but likely with an updated timeline for implementation to take into account the delay in adoption.

3. Malawi

In February 2022, Malawi launched the UNEP's chemicals and waste management program. This three-year initiative is intended to develop an information management system to improve the tracking of the presence of chemicals in the market. Local authorities will gather relevant data and plan to make it accessible through an online platform. This database will serve as a tool for the government and environmental stakeholders effectively to monitor the life cycle of chemicals and waste and to ensure their safe management.

4. Pakistan

In January 2022, the Pakistan Environmental Protection Agency (Pakistan EPA) published draft regulations on the handling, manufacture, storage, and import of hazardous substances and wastes, and solicited comments. The draft contains provisions for industrial activities relating to hazardous chemicals and for isolated storage of hazardous chemicals. If adopted, the regulations would impose obligations, including obtaining environmental permits, submitting safety reports and safety and environmental audit reports, preparing emergency response plans, and reporting serious accidents.

Further developments regarding this legislative initiative could be forthcoming during 2023. There have been several proposals and drafts in the field of chemical regulations in recent years, indicating that Pakistan is prioritizing the adoption of a comprehensive regulatory framework and can be expected to adopt legislation in the upcoming years.

5. Saudi Arabia

On July 9, 2021, the Saudi Standards, Metrology and Quality Organisation (SASO) published a technical regula-

tion requiring companies to meet electrical and electronic equipment (EEE) restriction levels for six hazardous substances — lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB), and polybrominated diphenyl ethers (PBDE). This technical regulation moves Saudi Arabia closer to alignment with the EU's Restriction of Hazardous Substances (RoHS) directive, but unlike in the EU, this regulation requires both domestic manufacturers and importers to obtain a certificate that proves the product conforms with the regulation. The regulation also omits four phthalates — DEHP, BBP, DBP, and DIBP.

Before entering the Saudi market, all products will be required to undergo a conformity assessment and prove conformity requirements have been met. Products that will be subject to the regulation include household appliances; information and communication technology equipment; lighting equipment; electrical and electrical tools and equipment; leisure, recreation, and sports equipment; and monitoring and control equipment. The regulation was scheduled to take effect on January 5, 2022, but the date was pushed back to July 5, 2022, with the plan to implement it in stages from that date. The enforcement dates are provided according to product category, ranging from July 4, 2022, for small electrical home appliances, to **December 26, 2023**, for monitoring and control tools.

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H. 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. The transition period for introducing substances under NICNAS ended on August 31, 2022. To ease supply chain issues, provisional measures are in place for specific circumstances. Written confirmation from a supplier may be allowed until **November 30, 2023**. If these circumstances impact importers and formulators, efforts should be made in 2023 to ensure compliance with AICIS.

In 2021, AICIS set a goal of evaluating approximately 20 percent of the 39,422 chemicals currently listed on the inventory by **2024**, prioritizing those that pose high risk and do not have assessments. AICIS intends to assess the remaining chemicals on the inventory that present a high safety risk by the **end of 2030**. As of October 2022, 18 draft evaluation statements on 187 industrial chemicals had been published. Recommendations include regulatory management for workers and public health, in addition to removals from the inventory. Expect significant progress on this item in 2023.

2. China

a. Chemical Substances

Many of the regulatory developments that China initiated in 2020 will continue to evolve in upcoming years. China's new overarching Law on Safety of Hazardous Chemicals, with the latest changes made in February 2021, continues progress toward final form.

In July 2022, The State Council of China proposed 16 draft laws to be deliberated by the National People's Congress (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.

There were many legislative updates on regulations and standards in 2022 related to the Law on Safety of Hazardous Chemicals in China. These include preparation of the Regulation on Environmental Management of Toxic and Hazardous Chemical Substances (drafted in 2019 as Regulations on Environmental Risk Assessment and Control of Chemical Substances), revision and a request for comments on four regulations concerning safety management of hazardous chemicals (*i.e.*, Measures for the Administration of Hazardous Chemicals Safe Production Permit, Measures for the Administration of Hazardous Chemicals Safe Use Permit, Provisions on the Safety Management of Hazardous Chemical Transmission Pipelines, and Measures for the Safety Supervision and Administration of Hazardous Chemicals Construction Project), a plan to revise Measures for the Administration of Hazardous Chemicals Operation Permit, and a plan to incorporate Quick Response (QR) code requirements for GB 15258-2009, General Rules for Preparation of Precautionary Label for Chemicals.

China's Ministry of Ecology and Environment (MEE) announced a draft action plan that aims to phase out priority chemicals by **2025**. MEE identified 28 substances, or substance groups, that it considers "new pollutants." Priority chemicals subject to a ban on the production, use, and import, include decabromodiphenyl ether (decaBDE), pentachlorophenol (PCP), perfluorohexanesulfonic acid (PFHxS), short-chain chlorinated paraffins (SCCP), hexachlorobutadiene (HCBD), dechlorane plus (DCC-CO), and nonylphenol in pesticide formulation. Production and use of perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS) are scheduled to be subject to severe restrictions by **2025**. On May 4, 2022, the State Council of China issued an Action Plan on New Pollutants Governance (Plan), which establishes a framework for an environmental risk management system for chemicals, and integration and expansion of China's existing regulatory programs on chemicals.

On July 20, 2022, the MEE issued a notice to solicit public proposals for the first batch of priority chemical substances, including three POPs (*i.e.,* DCC-CO, UV-328, and methoxychlor), subject to environmental risk assessment as part of the country's efforts to promote the control of new pollutants in China. Under the Plan, MEE intends to continue issuing new guidelines, regulations, restrictions, and bans on new pollutants, following its **2035** timeline to achieve a new pollutant control system and to strengthen new pollutant governance.

Beginning January 1, 2023, all ingredients in cosmetics products in China must include verified safety-related information for registration or notification.

MEE published final technical guidelines to assist industry with MEE Order 12 compliance. These include the Technical Guidelines for Environmental and Health Hazard Assessment of Chemical Substances (Trial), the Technical Guidelines for Environmental and Health Exposure Assessment of Chemical Substances (Trial), and the Technical Guidelines for Environmental and Health Risk Characterization of Chemical Substances (Trial). While it is expected that additional guidelines and regulations will be developed under the Plan in 2023, these technical guidelines will remain in effect to assist industry in risk evaluations and testing.

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b. Cosmetics and Cosmetic Ingredients

China's Cosmetics Supervision and Administration Regulation (CSAR), also referred to as State Council Decree No. 727, came into effect on January 1, 2021. CSAR reclassifies cosmetics products into special-use cosmetics and general-use cosmetics. Special-use cosmetics require registration with CSAR, and general-use cosmetics require notification through the National Medical Products Administration (NMPA) website.

CSAR requires new cosmetic registration or notification depending on whether the products are exclusively made for the Chinese market, are imported, or contain a blend of imported and domestic ingredients. CSAR includes additional regulatory requirements, such as labeling, cosmetic product classification, and new cosmetics ingredients registration. CSAR allows for exemptions on animal testing toxicology for general-use cosmetics, except for products used on children, or products containing ingredients not listed on the Inventory of Existing Cosmetic Ingredients in China (IECIC).

In 2022, China continued to make progress on Cosmetic Supervision and CSAR subsidiary regulations. On January 7, 2022, China's NMPA published the final Good Manufacturing Practices for Cosmetics, which covers the basic requirements for cosmetic production quality management and all aspects of cosmetic output and quality control. On May 1, 2022, China implemented the final Administrative Measures on Cosmetics Labeling, which unifies the contents of the previously released labeling regulations and further standardizes the requirements for cosmetics labeling. On August 17, 2022, CSAR released Subsidiary Regulations, Draft Regulations on the Supervision for Cosmetics' Online Operation, for public comments. Starting October 1, 2022, NMPA only issues registration certificates for special-use cosmetics and new ingredients electronically. This includes existing certificates with extensions or approved changes.

CSAR shifted the burden of safety and efficacy requirements to industry. Beginning January 1, 2023, all ingredients in cosmetics products must include verified safety-related information for registration or notification. Labeling under CSAR requires that all product ingredients be listed on the label, including trace ingredients. Full ingredient listing promotes NMPA's safety and efficacy standards by aiming to prevent false advertising in cosmetics products when chemical concentrations are only used in trace amounts. Products registered or notified before May 1, 2022, have until **May 1, 2023**, to update labeling under CSAR.

NMPA's regulations on the Supervision and Administration of Children's Cosmetics went into effect on January 1, 2022. Children's cosmetics products must include a special child-specific label mark; contain the warning statement "shall be used under adult guidance"; cannot include words such as "edible" or "food grade"; cannot display images of food products; and must be designed in a way that would not lead to consumer confusion with food or pharmaceutical products.

New children's cosmetics products were required to adhere to the labeling requirements by May 1, 2022. Existing products have until **May 1, 2023**, to update product labels. To be registered or notified, all children's cosmetics require animal toxicological testing data. This NMPA policy of requiring animal testing has received an influx of nega-

tive feedback from the international community wishing to participate in the Chinese market.

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. Expect further development of systems and guidance on these aspects of cosmetic legislation in 2023.

c. Food Contact Substances

China continued its work on assessing and regulating food contact materials (FCM) during 2022. As of September 2022, The National Health Commission (NHC) had added 38 new food contact substances, including 11 new food contact additives/substances, 12 food contact additives with expanded scope, 13 new food contact resins, one food contact resin with expanded scope, and one new food contact disinfectant raw material, to the food positive list (GB 9685-2016). In addition, NHC has opened consultation on the addition of eight other FCM substances. If approved and added to the positive list, substances must continue to adhere to GB 4806.1-2016 before being used in FCMs. China expects to continue assessing FCMs in the coming year and updating its food positive list.

The NHC published its revised standard for overall migration testing in FCMs, the National Food Safety Standard for Food Contact Materials and Articles — Determination of Overall Migration (GB 31604.8-2021). The changes outlined in GB 31604.8-2021 include requirements on precise testing methods for FCM migration, reclassification of vegetable oils as food simulants, and expanded testing conditions for FCMs that come in contact with high oil foods. GB 31604.8-2021 replaces GB 31604.8-2016 and took effect on March 7, 2022. On July 28, 2022, the NHC released two major standards for FCMs, GB 4806.8-2022, Paper and Paperboard in Contact with Foodstuffs, and GB 4806.12-2022, Bamboo and Wood in Contact with Foodstuffs. Expect the development of additional use-specific standards in 2023.

d. Hazard Communication/GHS

On September 22, 2022, China's Ministry of Industry and Information Technology (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.

China continues to update its Inventory of Existing Chemical Substances Produced or Imported in China (IECSC). As of March 2022, MEE had released 15 supplemental notices, with a total of 1,222 substances, added to its IECSC.

China launched the Comprehensive Service System for Registration of Hazardous Chemicals on February 16, 2022, promoting the implementation of "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, the Comprehensive Service System for Registration of Hazardous Chemicals, or hazardous chemicals registrations.

3. India

India had been expected to finalize the fifth draft version of its Chemicals (Management and Safety) Rules (Rules) in 2021, often referred to as India REACH. Considering feedback received from select industry stakeholders, India instead began working on a sixth revised draft version of the Rules. The sixth draft retains a registration process for priority substances, the possibility of adopting Rev 8 of the GHS, and restrictions on hazardous and prohibited substances. India's Department of Chemicals and Fertilizers announced intentions to circulate the sixth draft version by the end of 2021, but that draft had yet to be published as of November 2022. Companies operating in India should watch for the sixth draft in 2023 to be issued in final and be aware of its expected regulatory impacts.

India's Ministry of Health and Family Welfare (MHFW) published a draft bill to introduce the new Drugs, Medical Devices, and Cosmetics Act 2022 (2022 Act) in July 2022. If approved, this act would repeal and replace the Drugs and Cosmetics Rules, on the books since the 1940s, including all rules notified thereunder. Accordingly, the Cosmetics Act 2020 would also be repealed, although it came into effect only two years prior.

The proposed 2022 Act would contain provisions regarding cosmetics and their ingredients, would introduce changes to the regulation of online pharmacies, would tighten restrictions for clinical trials, and would separate provisions for medical devices from pharmaceuticals. Progress in 2023 is expected to be slow for the draft 2022 Act to become

effective. The bill must pass through both houses of the Indian Parliament.

4. Indonesia

To meet Stockholm Convention requirements, Indonesia's environment ministry has passed regulations to manage and phase out the use of polychlorinated biphenyls (PCB). The regulations took effect for manufacturers, importers, and distributors of transformers, dielectric oils, and capacitors on December 30, 2020, with some exemptions and an elongated transition period. The regulations allowed for exempt products to come into labeling compliance by December 31, 2022. Non-exempt products containing PCBs must be completely removed from the market by **December 31, 2028**.

5. Japan

Japan's Ministry of Economy, Trade, and Industry (METI) announced last year that as of September 2022, PFOA related substances would be banned from manufacture, import, and use. Current enforcement efforts continue, and Japanese companies must obtain permission prior to exporting. Further to these efforts, Japan intends to ban PFHxS by 2023. These substances will be classified under Japan's Chemical Substances Control Law (CSCL) as Class I substances. These efforts are ongoing by Japan as a signatory to the Stockholm Convention. Expect further actions in 2023 as Japan continues review of POPs.

In 2022, METI released guidance on SDSs and labels that includes specific pollutant release and transfer register (PRTR) requirements. Companies should review the PRTR list to ensure compliance with the requirements. The PRTR is an annual reporting requirement for environmental releases (air and water). The guidance includes how to address this content on the SDS and provides details on substances falling under PRTR. Additional SDS and label requirements were introduced by the Ministry of Health, Labour and Welfare (MHLW) under the Industrial Safety and Health Act (ISHA). These requirements aim to improve worker safety with the implementation within two years. Included are details on risk assessments and chemical handling in the workplace.

6. New Zealand and the Philippines

The New Zealand government is working to ratify the Minamata Convention. The Ministry for the Environment (MfE) had initially projected ratification in 2021 but is now projecting a timeline of **early 2023**. The current regulatory plan aims to ban the manufacture, import, and export of certain products that contain mercury while allowing for a permit-based system for the import and export of the substance.

The New Zealand MfE passed, in 2022, amendments to the Hazardous Substances and New Organisms (HSNO) Act. The amendments to the HSNO Act aim to update the New Zealand EPA's role in chemical assessment and reassessment. Amendments to the HSNO Act include: granting New Zealand EPA the ability to restrict temporarily the use of hazardous substances while reassessment occurs; allowing New Zealand EPA to rely on international regulatory bodies; a New Zealand EPA reassessment work plan; the development of specific criteria for rapid assessment of manufactured and imported hazardous substances; notification and classification for hazardous substances applications; streamlining processing and decision-making for related applications; and changing the reassessment process of hazardous substances to align with classifications. New Zealand EPA aims to investigate improvements with its existing chemical management program in 2023 and suggests that it will include data collection activities for chemical manufacturers and importers.

The Philippines continues its efforts with focused control of specific chemicals. The Department of Environment and Natural Resources (DENR) published Chemical Control Orders (CCO) in 2021 for chromium VI compounds and cadmium and cadmium compounds. In 2022, draft CCOs for vinyl chloride and benzene were issued. Each CCO contains scope and exemptions. The current drafts include importers and laboratories. Expect further progress in 2023.

In implementing the Minamata Convention on mercury, the Philippines has been working on banning mercury in certain medical devices and electronic products. The DENR has been working to reduce mercury limits in products since the Philippines ratified the Minamata Convention in 2020. A revised CCO was issued in 2019. The Department of Trade and Industry is currently proposing limits to mercury content in electrical and electronic products.

7. South Korea

a. New Legislative Developments

Two new Acts took effect in South Korea during 2022 that place additional responsibilities on industry participating in the South Korean market for **2023 and beyond**.

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.

First, the Ministries of Justice; Environment; Employment and Labour; Trade, Industry and Energy; Land, Infrastructure, and Transport; and the Fair Trade Commission have jointly worked to produce a new and final piece of chemical safety legislation, that took effect on January 27, 2022. South Korea's Serious Accidents Punishment Act (SAPA) requires large companies to inspect and report on the substances and products within their facilities at least twice per year.

Second, the Act on Risk Assessment of Products for the Human Body, administered by the Ministry of Food and Drug Safety (MFDS), came into effect on January 28, 2022. The Act aims to establish a comprehensive risk assessment system for all products and substances that come in contact with the human body. The Act operates in conjunction with 11 other pieces of legislation which govern substances that are ingested, administered, inhaled, or otherwise come into contact with the human body. The Act allows the MFDS to conduct site visits, request data and information, and potentially stop production at facilities if there are health risk concerns.

Additionally, South Korea revised portions of its Cosmetics Act. Under the revisions that became effective on February 18, 2022, the sale of cosmetics products or cosmetics ingredients that use animal testing is banned, with limited exceptions. Companies that combine, modify, and repackage existing cosmetics, often referred to as customized cosmetics, are now subject to the Act.

b. 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 response to the initial deadlines imposed by K-REACH, South Korea's Ministry of Environment (MoE) has adjusted the program. MoE has extended deadlines, expanded the definition of what constitutes an existing substance, identified new substances as hazardous or harmful to workers, and initiated a government-funded registration support program.

In March 2021, MoE announced that it would conditionally extend the pre-registration deadline **by two years**. Through 2021, until the first quarter of 2022, close to 200 additional substances were pre-registered. The late pre-registration extension deadline will apply to those companies that are importing or manufacturing substances over one metric ton per year for the first time; companies that manufacture or import substances that MoE has recently added to the existing substances list after a hazard assessment; and companies that have notified a substance but are relying upon an OR for full registration, or the inverse.

South Korea has also expanded the definition of existing substances under K-REACH through a partial amendment. Existing substances now include isomers, hydrates or anhydrides of existing substances, and reaction products consisting of two or more existing substances.

In fall 2022, MoE indicated that it is preparing a significant overhaul of the management of hazardous substances in South Korea, with a draft to be published by the end of the year. This reform would include amendments to K-REACH and the Chemical Control Act (CCA) and is expected to be rolled out through amendments, decrees, and rules that would be published beginning in 2023. This planned reform is meant to create a more differentiated treatment of chemicals based on types of hazard and toxicity levels.

This planned reform likely comes in response to concerns expressed by industry over the recent years regarding the stringent hazard assessments that significantly increased the number of substances designated as toxic under K-REACH. Companies have criticized the rules as being uniformly applied to facilities handling hazardous substances regardless of the characteristics of those substances and the level of risk. According to the planned reform, MoE set out the characteristics that would be used to differentiate regulation, such as substances acutely or chronically hazardous to humans or hazardous to the environment. There would also be further differentiation, based on toxicity levels, according to various criteria.

Several amendments to K-REACH were published and became effective in 2022. These amendments impact the requirements for companies doing business in South Korea in **2023 and beyond**. Some of these amendments, like MoE's March 15, 2022, amendment to ease K-REACH exemption rules for non-hazardous R&D substances, are meant to facilitate compliance with K-REACH. Under this amendment, companies applying for an R&D exemption for a non-hazardous substance in volumes below 0.1 metric ton/year may omit the substance name and CAS RN from the application and submit an SDS. MoE also removed certain test data requirements for substances with a limited risk of environmental contamination.

On August 25, 2022, the National Institute of Environmental Research (NIER) published an amendment to K-REACH meant to reduce vertebrate animal testing for registration and hazard assessments. According to the amendment, non-testing data (such as quantitative structure-activity relationship (QSAR), read-across, and weight of evidence (WOE)) can be added to a registration dossier. The amendment also adds exemption criteria for testing items and provides for companies to give feedback to the authorities on hazard assessment results.

On October 18, 2022, MoE issued a draft to amend the CBI exemption rules under K-REACH, allowing CBI protection under K-REACH for information that has been approved as CBI under other legislation (*e.g.*, CCA or the Occupational Safety and Health Act). The update also allows for CBI protection of the K-REACH pre-registration or registration identity numbers.

On August 25, 2022, MoE enacted a selection system for designating substances that require ministry permission before they can be manufactured, imported, or used under K-REACH. The regulation became effective October 15, 2022. The regulation establishes methods for designating permitted substances, selecting candidate permitted substances through a points-based system, and gathering public opinion on candidate substances. When the regulation was enacted, there were no substances in the category of candidate permitted substances. The first list of substances was published in MoE Notice No. 2022-671 on November 23, 2022. The comment period is open until **February 2, 2023**. Expect further actions on this in 2023.

South Korea also issued and updated certain K-REACH-related guidelines during 2022, aiming to assist companies maintain compliance with K-REACH. On June 30, 2022, NIER published an extensive guideline on classifying hazardous substances in mixtures, covering marking and labeling methods under K-REACH and CCA. Separately, NIER published a leaflet outlining classification and marking methods for hazardous substances. On October 21, 2022, MoE issued updated guidelines regarding K-REACH registration and pre-registration procedures for reaction products consisting of two or more existing substances.

c. K-BPR

South Korea's Consumer Chemical Products and Biocides Safety Act (K-BPR), which regulates consumer chemical products, biocidal products, and biocide-treated articles, has seen refinements this year. Under K-BPR, manufacturers and importers of existing biocides must obtain substance approval within a specified grace period. Grace periods vary by product type. 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.

The grace period for disinfectants, algicides, rodenticides, insecticides, and repellents expired on December 31, 2022.

On August 12, 2022, NIER announced, in a letter to companies manufacturing or importing products subject to safety checks under K-BPR, that they may be eligible to make a new approval application before the **end of January 2023**. Under K-BPR, commonly used substances in households and public places are subject to safety checks. These products must be pre-registered and approved to satisfy safety and labeling standards every three years. There are currently 39 product types included in the list. Many of these products are not biocidal products but may contain biocides. Ten out of the 39 product types are designated as biocidal products.

Companies must apply for both product and substance approval by the **end of January 2023** to meet a new approval deadline of the **end of 2023**. This may also apply to companies manufacturing or importing products with

unapproved substances and that are using a temporary "letter of explanation" stating that the company will replace the unapproved substance by the **end of 2023**. NIER notes that approvals for products with approved substances must be completed by the regular deadline at the **end of 2024**.

On May 27, 2022, NIER launched a new approval process, and a corresponding guideline, for biocidal products that contain multiple similar substances. The biocidal product families (BPF) system, similar to the BPF system under EU BPR, aims to speed up approvals and to reduce unnecessary duplication of data. To qualify in the same product family, a product must have the same core composition: at least one key biocidal substance within the product and at least one common "co-formulant." The composition, use, risk, and effects must also be accepted as similar. Companies intending to manufacture or import product families can use the BPF system for approval, once implemented. Implementation is expected in **early 2023**, after publication of further guidance in December 2022.

On August 1, 2022, NIER published guidelines for companies submitting test data used to determine the shelf life of biocidal products when applying for product approval. According to the guidelines, existing data can be provided for products where stability test data has already been submitted and approved under K-BPR's 39 product types subject to safety checks. Where a product's shelf life is two years or less, either long-term storage test data or accelerated storage stability test data can be submitted. If the shelf life is more than two years, the guidelines require both.

As of August 11, 2022, manufacturers, and importers of newly or recently reported biocidal products must provide their reporting or approval numbers on advertising and packaging. Where the products were reported to MoE before July 1, 2021, the requirement applies as of January 1, 2023. MoE will enable consumers to search the Ministry website using the reporting or approval numbers to find out more information about the biocidal products.

8. Taiwan

In late 2021, Taiwan postponed the issuance of a firm standard registration deadline for priority existing chemicals (PEC) to **December 31, 2024**. In 2019, Taiwan Environmental Protection Administration (Taiwan EPA) amended the Regulation of New and Existing Chemical Substances Registration, requiring a standard registration for 106 PECs. The review and approval process for registration is reportedly backlogged, leaving Taiwan EPA still assessing the first 106 PECs and unable to shift focus to a second batch of PECs. Taiwan EPA had intended to issue the second batch in 2021. In 2022, Taiwan EPA proposed restructure of the organization and possible revisions to registrations activities that could include an OR option. Taiwan's Toxic and Chemical Substances of Concern Control Act (TCSCCA) does not allow for, or consider currently, the ability for foreign manufacturers to register using an OR.

Taiwan EPA has added hydrofluoric acid and ammonium nitrate to its List of Concerned Chemical Substances (CCS). The first chemical Taiwan added to the CCS List was nitrous oxide, in 2020, but additional chemical listings were delayed due to COVID-19. Companies had until August 1, 2022, to attain approval from Taiwan EPA for the manufacture, import, sales, and storage of ammonium nitrate. For hydrofluoric acid, the deadline is **February 1, 2023**. Beginning October 1, 2021, businesses are required to record daily operational volumes for ammonium nitrate and report these values monthly to Taiwan EPA. For hydrofluoric acid, the same recording and reporting requirements began on February 1, 2022. Taiwan EPA reports that non-compliance with CCS regulations will be met with heavy penalties, including fines and potential imprisonment.

In September 2022, Taiwan EPA added 15 chemical substances to the CCS List, including two new psychoactive substances, five chemicals of food safety concern, and eight precursors for blasting explosives, to seek public comments.

On July 21, 2022, Taiwan EPA released the amendments to articles of the Regulation for the Labeling and Material Safety Data Sheets for Toxic and Concerned Chemical Substances. The amendments align with the EU CLP regulations. The final amendments for chemical labels were published in November and entered into force the same day. The implementation of certain articles relating to labels was delayed **until October 31, 2023**.

Taiwan announced a ban on the manufacture, import, and sales of certain products with packaging containing polyvinyl chloride (PVC) starting **July 1, 2023**.

9. Vietnam

In early 2021, Vietnam's chemical agency, Vinachemia, announced that it would focus on amending Vietnam's

chemical regulatory framework. Vinachemia set a goal of publishing revised technical standards and hazardous chemicals regulations **within two years**. The agency also aims to complete a ten-year chemical industry development strategy for **2030 to 2040**. In furtherance of these goals, Vinachemia issued five mandatory national technical regulations (NTR). Three that took effect on January 1, 2022, require limitations on and technical specifications for polyaluminum chloride (PAC), sodium hydroxide, and ammonia. Since July 1, 2022, all paints and varnishes must not contain more than 500 ppm of lead. On **July 1, 2027**, this limit will be reduced to 90 parts per million (ppm). On July 1, 2022, new limits on the quantities of mercury permissible in fluorescent lamps took effect. The NTRs apply to all manufacturers, importers, and distributors in 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.

On April 15, 2021, the second nomination period for adding substances to the draft chemical inventory closed. The Vietnamese Centre for Emergency Response to Chemicals (VCERC) continues to verify the nominated substances. Any substance not verified and included on the national chemical inventory will be treated as a new substance and subject to risk assessment. While originally expected to be published between 2021 and 2022, VCERC has yet to release the inventory of existing chemicals with the inclusion of the newly nominated substances.

CONTRIBUTORS

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III. APPENDIX A: B&C SPEECHES AND WRITINGS

BOOKS

Lynn L. Bergeson, Bethami Auerbach, Lisa R. Burchi, and Carla N. Hutton, co-authors, "Chemical Risk Governance," *Elgar Encyclopedia of Environmental Law*, edited by Adam D.K. Abelkop, Lucas Bergkamp, Lynn L. Bergeson, and Bethami Auerbach, Edward Elgar Publishing Limited (2023).

Lynn L. Bergeson, Christopher R. Blunck, Richard E. Engler, Ph.D., Kelly N. Garson, Edith G. Nagy, and Todd J. Stedeford, co-authors, "Pesticides, Chemical Regulation, and Right-to-Know, 2021 Annual Report," in *Environment, Energy, and Resources Law: The Year in Review 2021*, American Bar Association (2022).

ARTICLES

Recent articles on critical issues:

Lynn L. Bergeson, "Sticker Shock: TSCA Fees Could Soon Be a Lot More Expensive," *Chemical Processing*, December 13, 2022.

Lynn L. Bergeson, "OSHA Considers Revisions to Process Safety Management Standard," *Chemical Processing*, October 25, 2022.

Lynn L. Bergeson, "Toxics Regulation: A Brave New World Catching Many Off Guard," *PLI Current*, Vol. 6 (2022).

Lynn L. Bergeson, "Due Diligence in Mergers and Acquisitions Involving Chemical Products," *Financier Worldwide*, October 2022.

Lynn L. Bergeson, "EPA Targets PFAS Cleanup," *Chemical Processing*, September 23, 2022.

Lynn L. Bergeson, "EPA Holds Webinar on PFAS Strategic Roadmap: Research Tools and Resources," *Finishing & Coating*, August 22, 2022.

Lynn L. Bergeson, "EPA Eases TSCA Testing Demands," *Chemical Processing*, August 15, 2022.

Lynn L. Bergeson, "Compliance: EPA Seeks Input From Small Businesses," *Chemical Processing*, August 1, 2022.

Lynn L. Bergeson, "How Does a Recent Supreme Court Ruling Apply to the EPA's Implementation of TSCA?," *Chemical Watch*, July 27, 2022.

Lynn L. Bergeson, "Environmental Justice and Enforcement in America: What Investors Need to Know," *Financier Worldwide*, July 2022.

Lynn L. Bergeson, "Chemical Compliance: Get Ready For Superfund Excise Tax," *Chemical Processing*, June 22, 2022.

Lynn L. Bergeson and Richard E. Engler, Ph.D., "Optimizing the Toxic Substances Control Act to Achieve Greener Chemicals," *NR&E*, Summer 2022.

Lynn L. Bergeson, "EPA Targets Asbestos," *Chemical Processing*, May 15, 2022.

Lynn L. Bergeson, "California Eyes Proposition 65 Modifications," *Chemical Processing*, April 24, 2022.

Carla N. Hutton and Karin F Baron, MSPH, "How Might EU Proposals on Harmonised Classification and Prioritisation of Chemicals for Classification Impact Industry?," *Chemical Watch*, April 14, 2022.

Lynn L. Bergeson, Richard E. Engler, Ph.D., et al., "Compilation Memorandum Regarding the GCSE Plastics Reports: France and the United States: Comparative Law Analysis and Recommendations Regarding Plastic Waste," *Global Council for Science and the Environment*, March 15, 2022.

Lynn L. Bergeson, "PFAS: Making Sound Investment Decisions," *Financier Worldwide*, March 2022.

Lynn L. Bergeson, "Per- And Polyfluoroalkyl Substances (PFAS): One Size Does Not Fit All," *Chemical Processing*, February 27, 2022.

Lynn L. Bergeson, "Isn't It Ironic?," *American College of Environmental Lawyers (ACOEL) Blog*, January 25, 2022.

Lynn L. Bergeson, "Toxic Substances: EPA Targets Asbestos," *Chemical Processing*, January 23, 2022.

Lynn L. Bergeson, "Straddling Digital and Environmental Goals: Tips for Investors," *Financier Worldwide*, January 2022.

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

"USA EPA and TSCA updates for the electronics sector," Lynn L. Bergeson, Chemicals Management for Electronics (December 13, 2022).

"TSCA Section 18 — Preemption," Richard E. Engler, Ph.D., HCPA XPAND2022 (December 6, 2022).

"Biobased Chemicals under TSCA," Richard E. Engler, Ph.D., HCPA XPAND2022 (December 5, 2022).

"Living in a Circular World: The Challenges of Complying with TSCA," Lynn L. Bergeson and Richard E. Engler, Ph.D., Product Sustainability Summit USA 2022 (November 16, 2022).

"Initial 10 High Priority TSCA Risk Evaluations," Lynn L. Bergeson, Chemical Watch Regulatory Summit USA (October 5, 2022).

"Updates on TSCA," Lynn L. Bergeson, Chemical Watch Regulatory Summit Europe 2022 (September 27, 2022).

"Periodic Review: Reinvigorated Chemical Product Regulation under FIFRA and TSCA," Lynn L. Bergeson, ABA Section of Environment, Energy, and Resources, 30th Fall Conference (September 23, 2022).

"Toxics Regulations," Lynn L. Bergeson, Environmental Regulation in Practice 2022: New Challenges and Priorities (September 16, 2022).

"TSCA Fundamentals," Richard E. Engler, Ph.D., Chemical Watch Training Course (September 1, 2, 7, and 8, 2022).

"Situational Regulatory Awareness — What to Do When a Single Chemical Product Is Subject to Three Major Regulations — TSCA, FIFRA, and FFDCA," Karin F. Baron, MSPH, and Richard E. Engler, Ph.D., NACD Pre-Conference Regulatory Workshop (August 17, 2022).

"Law and Policy of Products Regulation," Lynn L. Bergeson, ELI Summer School Series 2022: Law & Policy of Products Regulation (July 14, 2022).

"New Chemical Review," Richard E. Engler, Ph.D., TSCA Reform – Six Years Later (June 29, 2022).

"TSCA Regulation of Articles," Lynn L. Bergeson, TSCA Reform – Six Years Later (June 29, 2022).

"The Role of Sustainable Thinking in New Chemical Reviews," Richard E. Engler, Ph.D., ACS 26th Annual Green Chemistry & Engineering Conference (June 6, 2022).

"TSCA New Chemicals in 2022," Richard E. Engler, Ph.D., HCPA IMPACT2022 (May 11, 2022).

"Toxic Substances Control Act and Federal Insecticide, Fungicide, and Rodenticide Act," Lynn L. Bergeson, Avoid the Audit: Best Practices for Staying in Compliance (March 8, 2022).

"Sustainable Cleaning Chemistries for a Healthier World," Richard E. Engler, Ph.D., Case Medical (February 23, 2022).

"Chemical Regulation and Emerging Contaminants: Update and What to Expect in 2022," Lynn L. Bergeson, Environmental Law 2022 (February 11, 2022).

IV. APPENDIX B: WEBINARS AND PODCASTS

2023 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)
Two Years Later: How Has the Chemicals Strategy for Sustainability Changed REACH and CLP Regulation?	January 17, 2023 10:00 a.m. – 11:00 a.m. (EST) Register Now.
What to Expect in Chemicals Policy and Regulation and on Capitol Hill in 2023	January 31, 2023 11:00 a.m. – 12:00 p.m. (EST) Register Now.
Extended Producer Responsibility	March 22, 2023 12:00 p.m. – 1:00 p.m. (EDT) Register Now.
PFAS Reporting, PBTs, and other TSCA Hot Topics	May 17, 2023 11:00 a.m. – 12:00 p.m. (EDT) Register Now.
Farm Bill, PRIA, and other FIFRA Hot Topics	September 13, 2023 11:00 a.m. – 12:00 p.m. (EDT)
It's Not as Easy as It May Appear: Bringing Sustainable Chemistry to Market in the U.S.	November 15, 2023 11:00 a.m. – 12:00 p.m. (EST)

WEBINARS AVAILABLE ON DEMAND

Articles under TSCA

When TSCA was enacted in 1976, EPA focused its attention on chemical substances and chemical mixtures, while largely exempting the regulation of chemicals in "articles," generally meaning finished products or manufactured goods. EPA's more recent announcement of its intent to regulate chemicals in articles to a much greater extent has caught many in the regulated industries off guard and reflects a significant shift in U.S. chemical regulation policy. Richard E. Engler, Ph.D., Eve Gartner, and Lynn L. Bergeson discuss the policy changes that led to the regulation of articles under TSCA, the EPA authority to regulate these articles, and what companies need to know to stay in compliance. A recording of this webinar is available now.

Food Safety Issues in the United States

The FSMA is a comprehensive law intended to shift the focus of foodborne illness management from responding to outbreaks to preventing them by improving the safety and sustainability of the nation's food supply, regardless of its country of origin, and identifying clear, specific actions for companies to follow to achieve enhanced food safety. During this webinar, Thomas J. Dunn, Karin F. Baron, and Lynn L. Bergeson review the seven major rules of the FSMA, discuss food safety over the past decade, and explore what the New Era of Smarter Food Safety means for businesses. A recording of this webinar is available now.

Environmental, Social, and Governance Issues: A Business Imperative

Environmental, social, and governance (ESG) performance is more than an aspiration, and realizing it in real time is

not easy. A well-designed ESG strategy can achieve meaningful improvements in corporate performance and provide real value to stakeholders through specific commitments to corporate responsibility. Any such approach, however, must be measurable, transparent, and accountable. During this webinar, Christine DiBartolo, Ken Ditzel, and Lynn L. Bergeson discuss how to conduct an ESG assessment, what makes an ESG program successful, and risks and opportunities that must be considered when undertaking this significant task. A recording of this webinar is available now.

TSCA New Approach Methodologies

The 2016 amendments to TSCA require EPA "to reduce and replace" testing of vertebrate animals to the extent practicable, scientifically justified, and consistent with TSCA policies. EPA is also required to "develop a strategic plan to promote the development and implementation of alternative test methods and strategies to reduce, refine, or replace vertebrate animal testing and provide information of equivalent or better scientific quality and relevance for assessing risks of injury to health or the environment of chemical substances or mixtures." This webinar features Lynn L. Bergeson, Richard E. Engler, Ph.D., James W. Cox, M.S., and Kristie Sullivan, MPH discussing how EPA is fulfilling Congress's expectations. A recording of this webinar is available now.

TSCA Reform — Six Years Later

The Environmental Law Institute (ELI), the George Washington University Milken Institute School of Public Health, and B&C hosted the sixth annual TSCA Reform conference providing updates and insights regarding the current state of TSCA implementation, ongoing and emerging issues, and related developments. Topics included how the potential use of NAMs, new chemical review, the whole chemical approach, and regulation of articles, among other topics. A full recording of the event is available now. Additional suggested readings and other resources are available on the ELI website for members of ELI.

Domestic Chemical Regulation and Achieving Circularity

A circular economy requires new thinking about what products we make, from which materials we make them, and where products go at the end of their useful lives. An important but often overlooked aspect of new product development is an understanding of the consequences of the product's chemical composition and the end-of-life implications of the decisions made at the front end of the process. Lynn L. Bergeson, Kate Sellers, Mathy Stanislaus, and Richard E. Engler, Ph.D. discuss working within this framework to build a resilient, dependable, and sustainable system that fosters innovation and develops a circular economy. A recording of this webinar is available now.

FIFRA Hot Topics

With year one of the Biden Administration's term in the history books, EPA OPP is focusing on long-standing challenges, especially EPA-wide efforts to implement EJ work and determining how best to meet core pesticide registration review obligations in 2022. During this webinar, Lisa M. Campbell, Edward Messina, and James V. Aidala spoke about the recently released ESA Workplan, chlorpyrifos and dicamba developments, pesticide product performance data requirements, and PFAS issues. A recording of this webinar is available now.

What to Expect in Chemicals in 2022

Momentous changes initiated in 2021 continued to influence policy development and rulemakings in 2022. During this webinar, Lynn L. Bergeson, Richard E. Engler, Ph.D., and James V. Aidala offered their best informed judgment as to the trends and key developments chemical industry stakeholders should expect to see from EPA in 2022. These included consequential policy shifts reflecting the Biden Administration's "all of government" commitment to EJ and continuing evolution of EPA's implementation of TSCA under Dr. Michal I. Freedhoff's leadership. A recording of this webinar is available now.

Details regarding all upcoming presentations and past presentations are available on our website.

PODCASTS AVAILABLE ON DEMAND

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, Spotify, and Stitcher, 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.

TSCA Regulation of Articles: The Saga Continues — A Conversation with Richard E. Engler, Ph.D. — *transcript available*

Lynn L. Bergeson and Richard E. Engler, Ph.D. discuss the stubbornly vexatious problem of TSCA's regulation of articles, a fancy name for products or finished goods. Rich Engler explains why the policy shift by EPA to apply TSCA regulations to articles far more than in decades past occurred and suggests some steps regulated entities may wish to consider to comply with current regulations and prepare for the future.

Keeping up with CLP Changes — A Conversation with Karin F. Baron – *transcript available*

Lynn L. Bergeson and Karin F. Baron discuss the controversial changes proposed by the EC to the CLP regulation. Baron explains why the proposed changes are likely to inject even greater dis-harmonization in the area of the global harmonization of packaging and labeling at a time when global commerce can least afford it.

Biotech's Emergence in the EU and Globally — A Conversation with Dr. Claire Skentelbery – *transcript available*

Lynn L. Bergeson and Claire Skentelbery, Ph.D., Director General, EuropaBio — The European Association for Bioindustries, discuss evolving perceptions of biotechnology in the EU, how biotechnology is advancing the EU's commitment to sustainability and circularity, and what's next for biotech advocacy in the EU.

Misunderstood: The Excise Tax No One Likes or Understands — A Conversation with Douglas Charnas and Richard E. Engler, Ph.D. – *transcript available*

Lynn L. Bergeson, Richard E. Engler, Ph.D., and Doug Charnas, a nationally recognized corporate and tax attorney and partner at McGlinchey, discuss the recently reinstated Superfund tax, which entities the tax applies to, what exactly is a taxable chemical and how to distinguish between taxable chemicals and taxable substances, and why just about everyone is really grumpy about this newly reinstated tax.

The New Era of Smarter Food Safety — A Conversation with Karin Baron – *transcript available*

Lynn L. Bergeson and Karin F. Baron, MSPH discuss the FDA initiative called the New Era of Smarter Food Safety, intended to diminish the number of foodborne illnesses. This conversation covers the use of emerging technologies to achieve FDA's goal and how FDA is trying to change the culture of food safety in the United States.

TSCA New Approach Methodologies — A Conversation with James W. Cox – *transcript available*

Lynn L. Bergeson and James W. Cox, M.S. discuss NAMs, their significance in chemical risk assessment under TSCA, how NAMs will enable diminished reliance on animal testing, and some of the challenges facing chemical stakeholders in moving away from animal testing.

Do We Need an Animal Protection Agency? — A Conversation with Professor Delcianna J. Winders – *transcript available*

Lynn L. Bergeson and Delcianna J. Winders, Professor and Animal Law and Policy Institute Director at the Vermont Law School, discuss just a few of the many fascinating issues included under the broad umbrella of animal law, including Professor Winders' judicial successes involving the Animal Welfare Act, her thoughts on alternatives to animal testing, how the concept of one health intersects with animal law, the role of restorative justice in animal and chemical law, and much more.

Is There a New Chemical Bias? — A Conversation with Richard E. Engler, Ph.D. – *transcript available*

Lynn L. Bergeson and Richard E. Engler, Ph.D. discuss what has changed in terms of the new chemical review process since Congress revised TSCA six years ago and one thing that has not changed: the new chemical bias. They explain why it continues to confound chemical innovators and what is being done to eliminate the bias and level the playing field.

The National Tribal Toxics Council — A Conversation with Dianne Barton, Ph.D. – *transcript available*

Lynn L. Bergeson and Dianne Barton, Ph.D., Water Quality Coordinator at the Columbia River Inter-Tribal Fish Commission in Portland, Oregon, and Chair of the National Tribal Toxics Council (NTTC), discuss toxics issues and how the NTTC is engaged with EPA on a wide variety of Lautenberg implementation issues, particularly those affecting tribal communities.

Tips for Working with Foreign Regulators in China — A Conversation with David Cragin, Ph.D. – *transcript available*

Lynn L. Bergeson and David Cragin, Ph.D., DABT®, Quality Assurance and External Affairs Director with a large multinational pharmaceutical company, discuss working with foreign regulators with the additional challenge of language barriers, cultural differences, and differing regulatory standards.

Food Pesticide Residues — A Conversation with Sheryl Dolan and Meibao Zhuang, Ph.D. – *transcript available*

Lynn L. Bergeson, Sheryl Lindros Dolan, and Meibao Zhuang, Ph.D. discuss pesticide tolerances, what they are, how EPA develops them, and how well government and industry stakeholders communicate their utility in ensuring a safe and reliable food supply.

Balancing Wildlife Protection and Responsible Pesticide Use — A Conversation with EPA's Jake Li – *transcript available*

Lynn L. Bergeson, Jake Li, Deputy Assistant Administrator for Pesticide Programs, OCSPP, EPA, and James V. Aidala discuss what the Administration is doing to balance wildlife protection and responsible pesticide use, what the federal Interagency Working Group is doing in this regard, and how the ESA Workplan is helping EPA's Pesticide Program meet its ESA obligations.

OEHHA and Prop 65 Update — A Conversation with Lisa R. Burchi – *transcript available*

Lynn L. Bergeson and Lisa R. Burchi discuss new Prop 65 developments, the law's successes and misses, and a few important judicial rulings about which our listeners will want to know.

GHS Update — A Conversation with Karin Baron – *transcript available*

Lynn L. Bergeson and Karin F. Baron, MSPH discuss the truly seismic changes underway in South and Central America, in the EU and United Kingdom, and in Asia with regard to adoption of GHS and the SDS implications of these actions. These initiatives have a profound impact on the movement of goods and materials internationally, and the unwary can find themselves in a world of trouble by not keeping up.

Trends in Product Sustainability and Circularity — A Conversation with Kate Sellers – *transcript available*

Lynn L. Bergeson and Kate Sellers, Technical Fellow at ERM, discuss the business value of product stewardship, including implementation of TSCA, life-cycle assessment, circular economy programs, and sustainability initiatives.

A Look into the Household & Commercial Products Association — A Conversation with Steven Bennett, Ph.D. – *transcript available*

Lynn L. Bergeson and Dr. Steven Bennett, Executive Vice President, Scientific & Regulatory Affairs, Household & Commercial Products Association (HCPA), discuss a diverse and challenging range of scientific, regulatory, and science policy issues, from consumer exposures, to chemicals used in cleaning products, to the role HCPA members play in addressing COVID-19 and related public health issues.

FIFRA Hot Topics — A Conversation with Jim Aidala – *transcript available*

Lynn L. Bergeson and James V. Aidala discuss EPA and Congressional initiatives involving FIFRA. This episode covers pollinators, PRIA 4 renewal, ESA, and a host of other FIFRA hot topics.

Reflections on TSCA Implementation — A Conversation with Alexandra Dunn – *transcript available*

Lynn L. Bergeson and Alexandra Dunn, immediate past Assistant Administrator of the EPA OCSPP, discuss Dunn's transition back into the private law sector and reflect on current EPA policies under TSCA and FIFRA to understand what has changed since Alex left EPA.

The "PIPing" Point — A Conversation with Kelly Scanlon, DrPH, Director of EHS at IPC – *transcript available*

Lynn L. Bergeson and Kelly Scanlon, DrPH, CIH, Director of Environmental Policy & Research, Global Government Relations, at IPC discuss IPC's work on environment, health, and safety (EHS) policy, enhanced regulation of articles under TSCA, and other challenges the electronics industry faces.

Toxics and Human Rights — A Conversation with Baskut Tuncak, Director of TURI – *transcript available*

Lynn L. Bergeson and Baskut Tuncak discuss Tuncak's goals as Director of the Toxics Use Reduction Institute (TURI) at the University of Massachusetts, Lowell, one of three agencies implementing the Massachusetts Toxics Use Reduction Act, and his prior role of UN Special Rapporteur on toxics and human rights.

Bergeson & Campbell, P.C.'s 2022 Forecast – *transcript available*

Lynn L. Bergeson, James V. Aidala, and Richard E. Engler, Ph.D. discuss what to expect in 2022 with regard to industrial and agricultural chemical regulation.

How Can Battery Production Be Greener? — A Conversation with Mathy Stanislaus – *transcript available*

Lynn L. Bergeson and Mathy Stanislaus cover a broad range of issues, including the mission of the Global Battery Alliance (GBA), Stanislaus's new role as Vice Provost and Executive Director of Drexel University's Environmental Collaboratory, GBA's fascinating and potentially transformational Battery Passport project, and other interesting topics.

The Delicate Balance between Food and Climate — A Conversation with Katherine Meighan of IFAD – *transcript available*

Lynn L. Bergeson and Katherine Meighan, Associate Vice-President and General Counsel of the International Fund for Agricultural Development (IFAD), a UN agency headquartered in Rome, Italy, discuss the delicate balance between food and climate, and the essential role IFAD plays in addressing this challenge.

APPENDIX C: GLOSSARY

6:2 FTSB — 6:2 Fluorotelomer Sulfonamide Betaine
ABIQUIM — Brazilian Chemical Industry Association
ABNT — Brazilian Association of Technical Standards
ACAT — Alaska Community Action on Toxics
ACGIH® — American Conference of Governmental Industrial Hygienists
Acta® — The Acta Group
AD — Antimicrobials Division
ADAO — Asbestos Disease Awareness Organization
AICIS — Australian Industrial Chemicals Introduction Scheme
Anvisa — National Health Surveillance Agency (Brazil)
APA — Administrative Procedure Act
APHIS — Animal and Plant Health Inspection Service
ATE — Acute Toxicity Estimate
ATP — Adaptation to Technical Progress
B&C® — Bergeson & Campbell, P.C.
BBP — Butyl Benzyl Phthalate
BCCM — B&C® Consortia Management, L.L.C.
BE — Biological Evaluation
BOSC — Board of Scientific Counselors
1-BP — 1-Bromopropane
BPC — Biocidal Products Committee
BPF — Biocidal Product Families
BPR — Biocidal Products Regulation
CARACAL — Competent Authorities for REACH and CLP
CARES Act — Coronavirus Aid, Relief, and Economic Security Act
CAS RN® — Chemical Abstracts Service Registry Number®
CBI — Confidential Business Information
CBP — U.S. Customs and Border Protection
CCA — Chemical Control Act (South Korea)
CCl_4 — Carbon Tetrachloride
CCO — Chemical Control Order
CCS — Concerned Chemical Substances
CDC — Centers for Disease Control and Prevention
CDR — Chemical Data Reporting
CDTSC — California Department of Toxic Substances Control
CDX — Chemical Data Exchange
CEH — Center for Environmental Health
CEPA — Canadian Environmental Protection Act, 1999
CEQ — Council on Environmental Quality
CERT — Council for Education and Research on Toxics
CIS Center — Commonwealth of Independent States Coordinating Information Center
CLP — Classification, Labeling and Packaging
CMR — Carcinogenic, Mutagenic, or Toxic to Reproduction
CoRAP — Community Rolling Action Plan
COU — Condition of Use
CPNP — Cosmetic Product Notification Portal
CPSC — Consumer Product Safety Commission
CRA — Congressional Review Act
CSAR — Cosmetics Supervision and Administration Regulation
CSCL — Chemical Substances Control Law (Japan)
CSP — Chemical Safety Passport
D4 — Octamethylcyclotetra-siloxane
DAF — Dosimetric Adjustment Factor
DBP — Dibutyl Phthalate
DCC-CO — Dechlorane Plus
DCE — 1,2-Dichloroethane
DCI — Data Call-In
decaBDE — Decabromodiphenyl Ether
DEFRA — Department of Environment, Food and Rural Affairs (UK)
DEHP — Di-ethylhexyl Phthalate
DENR — Department of Environment and Natural Resources (Philippines)
DIBP — Di-isobutyl Phthalate
DIDP — Di-isodecyl Phthalate
DINP — Di-isononyl Phthalate
DSL — Domestic Substances List (Canada)
DUIN — Downstream User Import Notification
EAEU — Eurasian Economic Union
EC — European Commission
ECA — Enforceable Consent Agreement
ECCC — Environment and Climate Change Canada
ECEL — Existing Chemical Exposure Limit
ECHA — European Chemicals Agency
ECOSChem — Expert Committee on Sustainable Chemistry
EDF — Environmental Defense Fund
EEA — European Economic Area
EEC — Eurasian Economic Commission
EEE — Electrical and Electronic Equipment
EHS — Environment, Health, and Safety
EJ — Environmental Justice
EO — Executive Order
EP — European Parliament
EPA — U.S. Environmental Protection Agency
EPP — Environmentally Preferable Purchasing
ERA — Ecological Risk Assessment
ESA — Endangered Species Act
ESG — Environmental, Social, and Governance
EU — European Union

EUP — Experimental Use Permit
EVP — Emerging Viral Pathogen
F2F — Farm to Fork Strategy
FCM — Food Contact Material
FDA — U.S. Food and Drug Administration
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
FWS — U.S. Fish and Wildlife Service
FY — Fiscal Year
GB — Great Britain
GBA — Global Battery Alliance
GHG — Greenhouse Gas
GHS — Globally Harmonized System of Classification and Labeling of Chemicals
GISP — Governmental Industry Information Exchange Platform
GLP — Good Laboratory Practice
GMO — Genetically Modified Organism
GMP — Good Manufacturing Practices
GRA — Generic Risk Approach
HBCD — Hexabromocyclododecane, Cyclic Aliphatic Bromide Cluster
HBCU — Historically Black Colleges and Universities
HCBD — Hexachlorobutadiene
HCPA — Household & Commercial Products Association
HCS — Hazard Communication Standard
HDPE — High-density Polyethylene
HHCB — 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[γ]-2-benzopyran
HHS — Health and Human Services
HPR — Hazardous Products Regulation
HSE — Health and Safety Executive
HSNO — Hazardous Substances and New Organisms
HVAC — Heating, Ventilation, and Air-Conditioning
HVACR — Heating, Ventilation, Air-Conditioning, and Refrigeration
ICCA — International Council of Chemical Associations
IE/NI Protocol — Ireland/Northern Ireland Protocol
IECIC — Inventory of Existing Cosmetic Ingredients in China
IECSC — Inventory of Existing Chemical Substances Produced or Imported in China
IFAD — International Fund for Agricultural Development
IIA — Inception Impact Assessment
IPM — Integrated Pest Management
IQA — Information Quality Act
IRFA — Initial Regulatory Flexibility Analysis
IRIS — Integrated Risk Information System
ISHA — Industrial Safety and Health Act (Japan)
ISO — International Organization for Standardization
IT — Information Technology
K-BPR — Consumer Chemical Products and Biocides Safety Act (South Korea)
K-OSHA — Occupational Safety and Health Act (South Korea, United States)
K-REACH — Act on the Registration and Evaluation of Chemicals (South Korea)
kg — Kilogram
KKDIK — Kimyasalların Kaydı, Değerlendirilmesi, İzni ve Kısıtlanması
LARCF — Latin American Regulatory Cooperation Forum
Lautenberg — Frank R. Lautenberg Chemical Safety for the 21st Century Act
LoREX — Low Release and Low Exposure Exemption
LR — Lead Registrant
LVE — Low Volume Exemption
MAF — Mixture Assessment Factor (EU)
MC — Methylene Chloride
MCAN — Microbial Commercial Activity Notice
MEE — Ministry of Ecology and Environment
METI — Ministry of Economy, Trade and Industry
MFDS — Ministry of Food and Drug Safety (South Korea)
MfE — Ministry for the Environment (New Zealand)
MHFW — Ministry of Health and Family Welfare
MHLW — Ministry of Health, Labour and Welfare (Japan)
MIIT — Ministry of Industry and Information Technology (China)
MINCIT — Ministry of Commerce (Colombia)
Minpromtorg — Ministry of Industry and Trade (Russia)
MoE — Ministry of Environment (Chile, South Korea)
MoEL — Ministry of Employment and Labor (South Korea)
MoEU — Ministry of Environment and Urbanization (Turkey)
MOH — Ministry of Health (Chile)
MOIT — Ministry of Industry and Trade (Vietnam)
MPA — Medical Products Administration (China)
MPPD — Multiple-Path Particle Dosimetry
MRL — Maximum Residue Level
MRRE — Manufacturer-Requested Risk Evaluation
MS — Member State
MSDS — Material Safety Data Sheet
NAA — No Action Assurance
NAM — New Approach Methodology
NASEM — National Academies of Sciences, Engineering, and Medicine
NDAA — National Defense Authorization Act

New Zealand EPA — New Zealand Environmental Protection Authority
NGO — Non-governmental Organization
NHC — National Health Commission
NI — Northern Ireland
NIC — Notice of Intended Changes
NICNAS — National Industrial Chemicals Notification and Assessment Scheme
NIE — Notice of Intent to Establish
NIER — National Institute of Environmental Research (South Korea)
NIOSH — National Institute for Occupational Safety and Health
NMP — N-Methylpyrrolidone
NMPA — National Medical Products Administration (China)
NOA — Notice of Arrival
NPC — National People's Congress (China)
NPRM — Notice of Proposed Rulemaking
NRDC — Natural Resources Defense Council
NSF — National Science Foundation
NTP — National Toxicology Program
NTR — National Technical Regulation
NTRC — Nanotechnology Research Center
NTTC — National Tribal Toxics Council
OAL — Office of Administrative Law
OCSPP — Office of Chemical Safety and Pollution Prevention
ODCB — *o*-Dichlorobenzene
OECD — Organization for Economic Cooperation and Development
OEHHA — Office of Environmental Health Hazard Assessment
OEM — Original Equipment Manufacturer
OFR — Organohalogen Flame Retardant
OMB — Office of Management and Budget
ONU — Occupational Non-user
OPERA — Open (Quantitative) Structure-Activity Property Relationship App
OPP — Office of Pesticide Programs
OPPT — Office of Pollution Prevention and Toxics
OR — Only Representative
ORD —Office of Research and Development
OSH Act — Occupational Safety and Health Act (South Korea, United States)
OSHA — U.S. Occupational Safety and Health Administration
OSTP — Office of Science and Technology Policy
OTC — Over-the-Counter
OTC Monograph Reform — Over-the-Counter Monograph Safety, Innovation, and Reform Act
OTT — Over the Top
PAC — Polyaluminum Chloride
Pakistan EPA — Pakistan Environmental Protection Agency
PANNA — Pesticide Action Network North America
PBB — Polybrominated Biphenyl
PBDE — Polybrominated Diphenyl Ether
PBT — Persistent, Bioaccumulative, and Toxic
PCAST — President's Council of Advisors on Science and Technology
PCB — Polychlorinated Biphenyl
PCE — Perchloroethylene
PCP — Pentachlorophenol
PEC — Priority Existing Chemical
PECO — Populations, Exposures, Comparators, and Outcomes
PESO — Pathways and Processes, Exposure, Setting or Scenario, and Outcomes
PETA — People for the Ethical Treatment of Animals
PFAS — Per- and Polyfluoroalkyl Substances
PFHxS — Perfluorohexanesulfonic 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
POP — Persistent Organic Pollutant
PPE — Personal Protective Equipment
ppm — Parts Per Million
PPP — Plant Protection Product
PPPR — Plant Protection Product Regulation
PRIA — Pesticide Registration Improvement Act
PRIA 4 — Pesticide Registration Improvement Extension Act of 2018
PRIA 5 — Pesticide Registration Improvement Extension Act of 2022
Prop 65 — Proposition 65
PRTR — Pollutant Release and Transfer Register
PSLT — Poorly Soluble, Low Toxicity
PT 3 — Biocidal Product Type 3
PV29 — Colour Index Pigment Violet 29
PVA — Polyvinyl Alcohol
PVC — Polyvinyl Chloride
PVOH — Polyvinyl Alcohol
PVP — Polyvinylpyrrolidone
QR Code — Quick Response Code

QSAR — Quantitative Structure-Activity Relationship
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
RED — Registration Eligibility Decision
RESO — Receptors, Exposure, Setting or Scenario, and Outcomes
Rev — Revised Edition
RFC — Request for Correction
RFCU — Reasonably Foreseeable Condition of Use
RFI — Request for Information
RMD — Risk Mitigation Decision
RoHS — Restriction of Hazardous Substances Directive
RP — Responsible Person
RSQUI — National Registry of Industrial Chemical Substances (Colombia)
RSR — Regulatory Status Review
RUP — Restricted Use Pesticide
SACC — Science Advisory Committee on Chemicals
SAG-CS — Scientific Advisory Group on the Chemical Safety of Non-food and Non-medicinal Consumer Products
SAICM — Strategic Approach to International Chemicals Management (UN)
SAPA — Serious Accidents Punishment Act (South Korea)
SASO — Saudi Standards, Metrology and Quality Organisation
SBA — Small Business Administration
SBAR — Small Business Advocacy Review
SCCP — Short-chain Chlorinated Paraffin
SCCS — Scientific Committee for Consumer Safety
SCP — Safer Consumer Products Program
SCPN — Submit Cosmetic Product Notification
SDS — Safety Data Sheet
SECURE — Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient
SER — Small Entity Representative
Services — U.S. Fish and Wildlife Service and National Marine Fisheries Service
SFIREG — State FIFRA Issues Research and Evaluation Group
SGAR — Second-Generation Anticoagulant Rodenticide
SIA — Semiconductor Industry Association
SIEF — Substance Information Exchange Forum
SNU — Significant New Use
SNUR — Significant New Use Rule
SOP — Standard Operating Procedure
SS — Singapore Standard
StRAP — Strategic Research Action Plan
Taiwan EPA — Taiwan Environmental Protection Administration
TBBPA — 4,4'-(1-Methylethylidene)bis[2,6-dibromophenol]
TCE — Trichloroethylene
TCEP — Tris(2-chloroethyl) Phosphate
TCSCCA — Toxic and Chemical Substances of Concern Control Act (Taiwan)
TDCE — *trans*-1,2-Dichloroethylene
TDR — Tiered Data Reporting
TERA — TSCA Environmental Release Application
TG — Testing Guideline
TLV® — Threshold Limit Values
TLV®-CS — Threshold Limit Values for Chemical Substances
TPP — Phosphoric Acid, Triphenyl Ester
TR — Technical Regulation
TSCA — Toxic Substances Control Act
TURI — Toxics Use Reduction Institute
UID — Unique Identifier
UK — United Kingdom
UK BPR — United Kingdom Biocidal Products Regulation
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
UV — Ultraviolet
VCERC — Vietnamese Centre for Emergency Response to Chemicals
VERV — Vector Expedited Review Voucher
VI — Vinyl Institute
vPvB — Very Persistent and Very Bioaccumulative
vPvM — Very Persistent and Very Mobile
WHMIS — Workplace Hazardous Materials Information System
WHS — Work Health and Safety Laws (Australia)
WOE — Weight of Evidence
WPS — Worker Protection Standard

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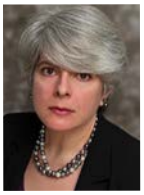

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