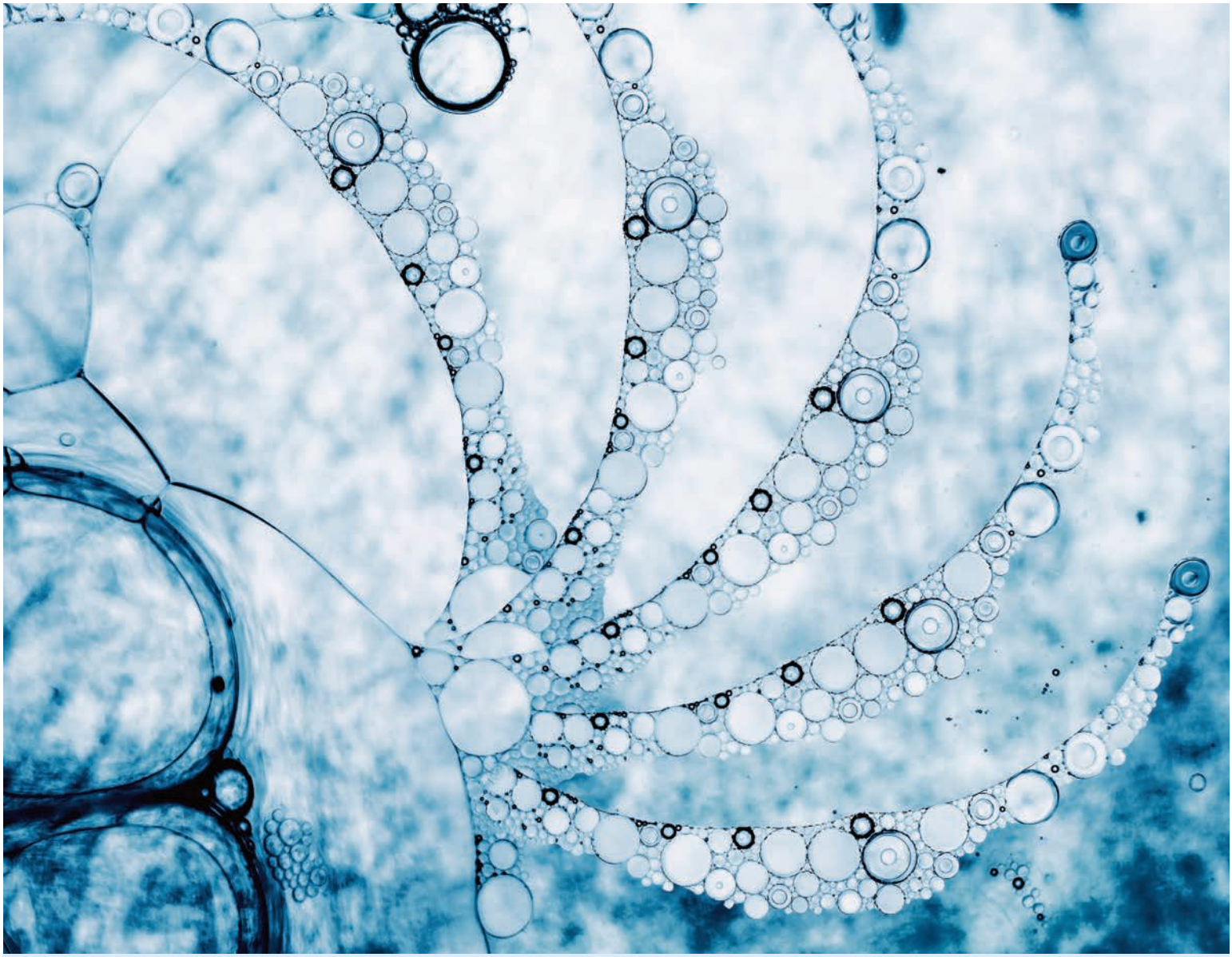

BERGESON & CAMPBELL, P.C.

Forecast for U.S. Federal and International Chemical Regulatory Policy 2022

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Forecast for U.S. Federal and International Chemical Regulatory Policy 2022

Bergeson & Campbell, P.C. (B&C®) and its 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 2022. The extraordinary diversity and complexity of global industrial, agricultural, and biocidal chemical initiatives in which our clients engage are reflected in the detailed summary that follows, prepared by the legal, scientific, and regulatory professionals of B&C, Acta, and BCCM. In this comprehensive overview, we offer our best informed judgment as to the trends and key developments we expect to see in 2022. Domestically, we expect to see more mature and consequential policy shifts reflecting the Biden Administration's "all-of-government" commitment to environmental justice and continuing evolution of the U.S. Environmental Protection Agency's implementation of the Toxic Substances Control Act under Dr. Michal I. Freedhoff's leadership. What role the forthcoming mid-term elections will have on these and other initiatives remains to be seen. Internationally, governance frameworks globally are evolving, becoming more specific in their application to chemicals, and in many cases promoting more specifically efforts to support sustainability and circularity.

Our unique business platform and growing global team of highly skilled professionals around the world are exceptionally well suited to offer this 2022 Forecast. Our core business, about which each of us feels passionately, focuses on the law, science, regulation, and policy of chemicals of all varieties — industrial, agricultural, intermediate, specialty, and biocidal, whether manufactured at the bulk or nano scale, or using conventional or innovative technologies, including nanotechnology, biotechnology, synthetic biology, or biobased technology. Our highly acclaimed team of lawyers; scientists (eight Ph.D.s), including toxicologists, chemists, exposure experts, and geneticists; and regulatory and policy experts is deeply versed in chemical law, science, and policy. We seamlessly leverage and ensure the integration of law, science, and policy to deliver successful outcomes for our clients at every level and in all parts of the globe.

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

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Many professionals at B&C, Acta, and BCCM participated in the preparation of this Forecast. Special thanks to Allison J. MacDougall Davidson and Paula M. Berard for their unrelenting attention to detail and literary excellence, Chad H. Howlin for his meticulous coordination of content, Heidi B. Lewis for her creative direction, Emily A. Scherer for cataloguing firm resources, and Scott Severson of Shelter Studios, Inc. for his extraordinary layout and artistic vision.

I. UNITED STATES: CHEMICAL FORECAST

A. Introduction

2021 brought a new Administration to Washington, D.C., with punditry abounding, including prognostications about the nation's recovery from COVID-19 and an effort in Washington to reestablish bipartisanship with a generally more cooperative tone on Capitol Hill. With the acknowledgment of the immediate need to address climate issues, the importance of science, and the trifecta of partisan control of the White House and both the House and the Senate, significant consensus to address the nation's needs and environmental concerns will be attainable, right? Not long after the New Year began, the attack on the Capitol on January 6, 2021, and the continued stirrings about the 2020 election results, 2021 got off to a rocky start and closes with renewed concerns about whether Washington can again "get things done."

In last year's Forecast, we posed the following questions that remain resonant: Will the Biden Administration be torn apart from internal battles within the Democratic Party (progressives vs. centrists)? Will majority control of the Senate make governing easier or harder for the new Administration? Will the Senate remain a Dead Sea of deadlock or provide hope for bipartisan cooperation?

Although these rhetorical questions remain relevant, fortunately this Forecast is limited in scope and ambition, with a narrower focus on the range of issues surrounding industrial chemical and pesticide regulation in 2022. The past year has seen important changes that will continue to impact 2022: Administration appointments in political leadership positions have been installed, new policies and priorities have been unveiled, and with Democrats in control, a much more encouraging attitude toward regulation and regulatory initiatives has taken root.

The effects of the ongoing COVID-19 pandemic continue to affect the economy and have more local impacts of whether the U.S. Environmental Protection Agency (EPA), or any other organization, actually has staff located in a central office setting. Hearings in Congress are still a hybrid of in-person and remote attendance. Large gatherings and public meetings that were slowly seem now to be returning to being only on Zoom or Teams meeting platforms in light of the onset of the Omicron strain surge. Perhaps budget fights, threats of government debt default, and rancorous partisan bickering are a sign of "normalcy," that might be welcome in an odd way if COVID-19 and its impact eventually fades as the dominant issue confronting the Administration.

The larger dynamic of underlying tension between partisan jockeying and prospects for bipartisan cooperation will nonetheless affect greatly what may happen to EPA Administration or any other Agency initiatives. Notwithstanding the "all-of-government" priority given to climate issues and environmental justice (EJ), the Administration will continue to address many other competing issues of significance. These include the ongoing pandemic, budget and spending priorities, foreign policy, cyber security, and a long list of other priorities needing attention by the Administration. And do not forget that 2022 will see off-year elections where current projections indicate that the Democrats may no longer control both sides of Capitol Hill — but the impact of what that might mean for EPA and chemical and pesticide issues will have to wait for the **2023** Forecast document.

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Priority and emphasis on addressing climate change with significant domestic policy initiatives and reasserting leadership internationally became core components of the Biden Administration's environmental agenda.

1. Biden Administration Priorities

The Biden Administration set to work immediately by issuing a flurry of executive orders (EO) and Presidential directives to make good on campaign promises and to make it clear that the new President will be the "un-Trump." Over the first 100 days, according to CNN, President Biden issued 60 EOs and directives, most in the first few weeks after the Inauguration. This compares to 34 such actions for President Obama and 13 for President Bush in 2001. Most focused on managing COVID-19 and immigration policies, but some were issued, as promised, on "Day One" to stress the importance of addressing climate issues — rejoining the Paris Accord on climate and canceling the Keystone fossil fuel pipeline.

These and other actions taken early in 2021 were consistent with statements and policies described during the campaign about environmental issues. Priority and emphasis on addressing climate change (both with significant domestic policy initiatives and reasserting global leadership internationally), reversing policies and "damage" done by Trump Administration decisions, and emphasis on EJ became the core components of the Biden Administration's environmental agenda. For EPA's Office of Chemical Safety and Pollution Prevention (OCSPP), the role chemical exposures play in disproportionately affecting vulnerable subpopulations and marginalized communities became an elevated priority of concern.

For pesticides and chemicals, these priorities quickly led to consideration of revisions to Trump-era decisions on implementing the 2016 Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg) amendments to the Toxic Substances Control Act (TSCA), and decisions on various specific pesticides, most notably, chlorpyrifos. Rhetoric about the need to reverse previous policies and to be more inclusive was part of decisions announced throughout 2021. These points will continue to be emphasized for the foreseeable future, not just in the work of OCSPP, but throughout all EPA initiatives.

PODCAST
A Conversation with Michal Freedhoff, Ph.D., Assistant Administrator, OCSPP

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2. Priorities for EPA's OCSPP

As expected, EPA priorities for OCSPP were less prominent than the emphasis on climate change, but EPA set to work immediately to change the direction and policies of the toxics program as well as address notable pesticide decisions of the Trump Administration. These will be discussed in more detail in the following sections of the Forecast, but in summary, new appointees were put in place more quickly and had a more significant impact earlier when compared to past Administrations. For OCSPP, the priorities will include EJ, scientific integrity, and reviewing some of the major decisions of the past Administration.

a. New Leadership

The nominee to lead OCSPP, Dr. Michal I. Freedhoff, was brought onboard in January 2021, and her nomination was announced in April 2021. She was confirmed by the Senate in June (*see* Bergeson & Campbell, P.C.'s (B&C®) June 16, 2021, blog). This is in contrast to the Trump Administration, that did not have a confirmed Assistant Administrator for OCSPP until two years after the Inauguration. This gave the new EPA leadership team an early start to review and

implement changes across the OCSPP media programs. Dr. Freedhoff holds a Ph.D. in Chemistry, a credential key to the work of the program she now leads. She has also had extensive Congressional staff experience, having worked for Senator Ed Markey (D-MA), including many years when the now-Senator was a Representative from Massachusetts. Senator Markey has been active in environmental legislation in both the House and Senate, and Dr. Freedhoff was active in Congressional deliberations of the TSCA Amendments — the Lautenberg amendments of 2016. This direct experience will influence decisions about the meaning of various legislative language in the Amendments. Many important definitions remain controversial, and Dr. Freedhoff will bring her own personal experience to the debate regarding some of the pivotal terms.

As Dr. Freedhoff has focused extensively on the implementation of the Lautenberg amendments, the Administration has also recruited Ya-Wei (Jake) Li as Deputy Assistant Administrator for Pesticide Programs. Mr. Li has experience as an environmental lawyer at a prominent Washington, D.C., law firm, Latham & Watkins, and years as a staff professional at the Defenders of Wildlife, an environmental advocacy group especially dedicated to the protection of endangered species. This experience is expected to help him maneuver through the thicket of past failed attempts of previous Administrations to resolve how to integrate the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) program actions at EPA with the requirements of the Endangered Species Act (ESA) implemented by other government agencies. Past cross-agency attempts since 2003, across different Administrations, can be described bluntly as "many have tried, all have failed."

Litigation in this space has continued unabated, and the courts in more recent years have viewed favorably the sanction of vacating pesticide registrations for a variety of reasons. If the courts were to agree with vacating or preventing pesticides from being registered under FIFRA due to ESA implementation concerns, it could paralyze the pesticide registration program for an uncertain and perhaps very long time. Preventing such an outcome will be a priority for the new EPA leadership team and Mr. Li in particular.

b. Environmental Justice

Keeping in mind the priorities articulated by the White House and Administration, OCSPP has announced an emphasis on identifying and giving EJ issues greater consideration as a core part of program decision-making. The toxics and pesticides programs conduct risk assessments of chemicals and pesticides, and exposures to vulnerable and disadvantaged communities, while part of past deliberations, will be more central to decisions about how to protect a community's health and safety. Both the toxics and pesticides programs have pressing deadlines to meet, as described in the following sections — and possible impacts on workers, adjacent communities near exposure sources, farmworkers, children, and other vulnerable subpopulations are likely to get special review.

c. Scientific Integrity — "Follow the Science"

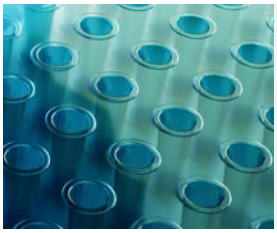
The Administration has emphasized the need to "follow the science" as central to decision-making; this is explicitly described as an intentional contrast with the perceived or alleged practice of "not following science" during the Trump Administration. Political rhetoric aside, this emphasis has been touted as being a core principle to be followed across all of government. For EPA, this has meant not only reassuring the career staff, where EPA is one of the more science-heavy departments, but also reviewing some of the key decisions and policies of the past four years.

For OCSPP, this translates into new reviews of core assumptions regarding various TSCA activities (example: whether wearing personal protective equipment (PPE) to mitigate worker risk is sufficient to control possible chemical exposure risks), along with important pesticide assessment decisions (the assessments done in the past regarding chlorpyrifos or dicamba).

Emphasizing science is non-controversial *per se*; one's definition of how much or how certain supporting scientific information is needed to support a particular regulatory outcome is where many "scientific" disagreements begin. And the forum of least competence for deciding science issues may be Congress itself, given the lack of general expertise among members and staff. This is not helped by the inherent clumsiness of political debate in discussing granular details about scientific issues (*see* the later section about per- and polyfluoroalkyl substances (PFAS)).

ARTICLE

"Environmental Justice: Operationalizing TSCA to Fulfill Its Destiny," *American College of Environmental Lawyers (ACOEL) Blog,* February 4, 2021.



Both EPA and the Office of Chemical Safety and Pollution Prevention are targeted to receive a large budget increase. One of the most important increases would allow a large increase in new personnel to help with the TSCA program.

i. Raised Expectations

While it is not surprising that the new Administration has stressed the role of science and taken pains on occasion to point out how a past policy "was not supported by science," there may be a newly created problem of "raised expectations." In any regulatory program, especially those that are "science-heavy" such as chemical or pesticide review, there can be significant disagreements between and among career scientific staff over interpretation of data or the implications (that is, the appropriate regulatory response) of a science matter. Over the years, as this is not a new issue, EPA, and OCSPP as a whole, have created a number of internal review committees, outside peer-review procedures, and detailed manuals of standard operating procedures (SOP) to resolve questions of scientific interpretation. Still, disagreements do, and will, happen.

For OCSPP, early in 2021 Dr. Freedhoff announced with some fanfare how the Trump Administration had interfered politically and ignored relevant information when making a decision about a specific pesticide (dicamba). Later in 2021, the Office of Pollution Prevention and Toxics (OPPT) was alleged to have muzzled some career scientists inappropriately and did not follow procedures for explaining or resolving internal staff disagreements. Both of these incidents have led to investigations referred to the EPA Office of Inspector General (OIG). Given the loud pronouncements Administration-wide about believing in or following the science, this may encourage continued concerns by internal reviewers when opinions are not uniform and, in the end, a decision needs to be made.

d. Congressional Oversight and Litigation

Given that party control of the House and Senate currently aligns with the party of the President, and in the case of EPA, further aligns with the general support of environmental groups for Democratic party activities, relations with Capitol Hill will be less confrontational compared to times where partisan control is not uniform. Litigation from environmental advocacy groups will also be reduced, or at least less intense; some litigation has been and will be filed to reverse decisions by the previous regime.

At the same time, at Congressional hearings, the minority members have the opportunity to raise concerns or probe difficult issues with Administration witnesses — as well as "friendly" members allied with the Administration wanting to make a point or stress their concerns over certain priorities. And with the off-year elections of 2022 coming "soon" in political terms — where party control in the House and/or Senate may flip — hearings or litigation now may serve as a way of locking in commitments or setting an agenda while more favorable incumbents control the necessary positions.

e. Program Support — Budget and Resources; Retirements and Deadlines

More easily recognized support of career staff and program activities are indicated by the Biden Administration's support for significantly greater budgets for EPA generally and OCSPP in particular. Both EPA and OCSPP are targeted to receive a large budget increase. One of the most important increases would allow a large increase in new personnel to be hired to help with the TSCA program. Authority to increase the number of staff is important as an increase for the next year, and it signals a functional kind of permanent increase, since large swings in staffing levels are less subject to yearly changes.

EPA has plans to hire approximately 90 new positions, almost all of them to support TSCA work, in fiscal year (FY)

WEBINAR

Register now for B&C's upcoming webinar What to Expect in Chemicals in 2022, January 26, 2022, 12:00 p.m. EST

ARTICLE

"Environmental Protection: Infrastructure Law Benefits Chemical Industry," *Chemical Processing*, December 14, 2021.

2022. If granted, it will still take time for EPA to recruit, hire, and train new personnel and eventually meet the program's required workloads. Both the pesticides and toxics programs face daunting legislative deadlines in the immediate future. And, if party control of either the House or Senate flips in 2022, future increases slated in the current budget documents may be even less likely to be achieved.

And last but not least, the EPA workforce is broadly considered to be an aging one, with a significant fraction of the workforce eligible for retirement already or in the next few years. This is due in part to simple demographic mathematics: EPA, the cute, young agency of 1970 that saw a huge increase in hiring, is not so new anymore (perhaps still cute or at least cool to work at). These many years later, the workforce is in the midst of a generational turnover, with broad recruitment and training needs taking place in a pandemic. Along with a tone of anti-government sentiment in some quarters, and some disillusionment about the ability of government to solve big problems, government agencies across the board may find it more difficult to attract new hires.

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B. TSCA: Predictions and Outlook for OCSPP's OPPT

1. Overview

OPPT will continue to focus on TSCA implementation, including the development of required risk evaluations and risk management actions on certain existing chemicals, review of and determinations on new chemical premanufacture notices (PMN), and issuance in final of a rule requiring the reporting of hazard and exposure information on PFAS. In 2022, we also expect OPPT to initiate the prioritization for risk evaluation of certain chemicals to replace in the TSCA risk evaluation pipeline those "high-priority" chemicals for which risk evaluations may be completed in **late 2022 or 2023**.

In early 2021, OPPT completed risk evaluations for the "First 10" chemicals designated by EPA for risk evaluation and initiated the development of some risk management actions where EPA found unreasonable risks. In March 2021, OPPT announced that it was revisiting its approach to risk evaluations and that it intended to withdraw some of the orders in which EPA found no unreasonable risk for some conditions of use. In 2022, EPA will be reexamining many of the risk evaluations for the "First 10" chemicals "to address overlooked and/or inadequately assessed exposure pathways." While EPA works on revising these risk evaluations, work on risk management is expected to continue for several of the "First 10" chemicals for which EPA believes the existing risk evaluations are sufficient to inform risk management, including hexabromocyclododecane (HBCD), C.I. Pigment Violet 29 (PV29), and asbestos. Given the tight statutory deadline for issuing proposed Section 6(a) rules, the complexity of the issues, and the novelty of applying the new regulatory authorities, we continue to expect risk management to present difficult, if not daunting challenges to EPA in 2022 as it works to sort through and satisfy the many legal and policy issues at play. EPA, in 2020 and 2021, directed significant energy to developing risk evaluations for the "Next 20" chemicals designated as high-priority for risk evaluations through the TSCA prioritization process, completing scoping documents in September 2020. In light of the current Administration's revised approach to risk evaluations, however, those scoping documents will need to be revisited and revised as appropriate, and work is expected to continue through 2022 and probably much of **2023**. EPA also now has received four manufacturer-requested risk evaluations (MRRE), three of which have been granted as of mid-December 2021, and one of which is pending, as discussed below.

For the risk evaluations for the "First 10" substances that were completed in 2020 and 2021, and for the ongoing risk evaluations for the "Next 20" substances, the Biden Administration in 2022 will continue to take a hard look at their nature and scope, especially how they address potentially exposed or susceptible subpopulations as required under TSCA. Exposures to workers and populations bordering chemical facilities are receiving increased attention consistent with the Biden Administration's elevated consideration of EJ. Additionally, exposures addressed under other EPA-administered authorities, exposures generally not evaluated under the Trump Administration in the completed risk evaluations, and those ongoing at the time are being reviewed by the Biden Administration for potential inclusion under the TSCA standards. These changes will result in EPA's issuance of revised risk evaluations for those completed under the Trump Administration and presumably a need to supplement or amend the scopes of the risk evaluations now under development. Similarly, and as discussed in more detail below, EPA determinations in certain completed risk evaluations that the chemical substance does not present an unreasonable risk for certain conditions of use are the subjects of litigation; depending on the litigation outcomes, completed risk evaluations and risk evaluations under development may need to be amended/supplemented, substantially impacting timelines for the completion of the risk evaluations and required risk management action addressing unreasonable risks. EPA's ongoing re-work of the completed risk evaluations, as discussed above, may address certain points being litigated, but this remains to be seen.

We also expect continued use of TSCA Section 4 test orders and Section 8 information gathering rules to strengthen the data sets that are available to EPA to support TSCA implementation. In July 2021, EPA announced and solicited comments on a planned Section 8 rule that would include a tiered data collection approach to help inform the Agency's prioritization, risk evaluation, and risk management activities under TSCA. For new chemicals, we expect that the Administration's rejection of the use of non-order Significant New Use Rules (SNUR) *in lieu* of consent orders

and SNURs will result in additional delays in PMN review times. Additionally, we expect EPA's new policy of identifying the absence of worker safeguards as "reasonably foreseen" conditions of use, notwithstanding U.S. Occupational Safety and Health Administration (OSHA) requirements concerning those safeguards, will also delay the PMN review process and add to the number of chemicals covered by consent orders and corresponding SNURs.

New fees authorized under TSCA Section 26 went into effect on January 1, 2022. These new fees, announced in November 2021, are the result of a statutorily required triennial adjustment based on inflation. This fee adjustment is separate from the changes in fees that might arise from a final fees rule amendment expected in **late 2022**. That final rule will be based on a January 2021 proposed rule and a supplemental proposal also expected in 2022.

2. Section 4(a) — Test Orders

a. High-Priority Substances Undergoing Risk Evaluation

On January 15, 2021, EPA issued test orders on nine chemical substances it had identified among the "Next 20" as high-priority substances that are undergoing risk evaluation pursuant to TSCA Section 6(b). The TSCA Section 4(a)(2) test orders require testing in two main areas, environmental hazard testing and/or occupational exposure monitoring. The chemical substances and associated testing are provided below.

EPA used a systematic review method to identify reasonably available information on these chemical substances and used this information for determining data needs. B&C notes, however, that EPA's systematic review method did not capture relevant data in the peer-reviewed literature on at least one chemical substance, nor did it capture relevant data in EPA's possession for at least two chemical substances. EPA released a new systemic review on December 20, 2021, capturing an approach it believes addresses the deficiencies noted earlier this year. Our review of the approach can be found here. While EPA has new, broad authority to order testing, EPA is required to evaluate reasonably available information and explain its need for the ordered testing. At a minimum, order recipients need to be diligent to search for existing information that may be responsive to EPA's orders.

In the test orders, EPA also required that all of the testing, including the occupational exposure (industrial hygiene or IH) monitoring, be performed in accordance with Good Laboratory Practice (GLP) standards as set forth in 40 C.F.R. Part 792, despite the fact that few IH monitoring experiments are performed to the GLP standards. In fact, most IH monitoring is performed to American Industrial Hygiene Association (AIHA) Industrial Hygiene Laboratory

Chemical Substance	Required Testing
1,1,2-Trichloroethane (Chemical Abstracts Service Registry Number (CAS RN) 79-00-5)	Environmental Hazard Testing (Organization for Economic Cooperation and Development (OECD) 233) and facility-specific Occupational Exposure Testing (Inhalation Monitoring; Dermal Hand Wipe Sampling; *in vitro* dermal absorption study OECD 428)
1,1-Dichloroethane (CAS RN 75-34-3)	
1,2-Dichloropropane (CAS RN 78-87-5)	
o-Dichlorobenzene (CAS RN 95-50-1)	
p-Dichlorobenzene (CAS RN 106-46-7)	
4,4'-(1-Methylethylidene)bis[2,6-dibromophenol] (CAS RN 79-94-7)	Environmental Hazard Testing (OCSPP 850.4400; OECD 225; OECD 233) and facility-specific Occupational Exposure Testing (Inhalation Monitoring; Dermal Hand Wipe Sampling; *in vitro* dermal absorption study OECD 428)
Phosphoric acid, Triphenyl Ester (CAS RN 115-86-6)	Environmental Hazard Testing (OCSPP 850.4400; OCSPP 850.4500; OECD 225; OECD 233; OECD 222) and facility-specific Occupational Exposure Testing (Inhalation Monitoring; Dermal Hand Wipe Sampling; *in vitro* dermal absorption study OECD 428)
1,2-Dichloroethane (CAS RN 107-06-2)	Facility-specific Occupational Exposure Testing (Inhalation Monitoring; Dermal Hand Wipe Sampling; *in vitro* dermal absorption study OECD 428)
trans-1,2-Dichloroethylene (CAS RN 156-60-5)	

Accreditation Program (IHLAP) standards. EPA recognizes the validity of IHLAP as an appropriate accreditation standard in EPA's boilerplate language for TSCA Section 5(e) consent orders with new chemical exposure limits (NCEL): "Compliance with TSCA GLPS, however, is not required under this New Chemical Exposure Limit Section where the analytical method is verified by a laboratory accredited by either: the [AIHA IHLAP] or another comparable program approved in advance in writing by EPA."

We expect EPA to issue additional test orders for the remaining "Next 20" substances. Presumably, EPA's test orders will be informed by the TSCA Section 8(d) data call-in for all 20 substances issued in 2021. Recipients (and potential recipients) of test orders should be engaging with EPA on addressing EPA's data needs, whether through modeling, read-across, identifying existing data, or testing, rather than waiting for orders to be issued.

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 Polyfluoroalkyl Substances (PFAS) for Testing" (the Strategy). EPA issued the Strategy to identify candidate PFAS that EPA plans on requiring companies to perform testing on using its TSCA Section 4 test order authority. EPA used a multistep process to identify candidate PFAS, as summarized below.

EPA first divided the starting list of 6,504 PFAS into nine primary categories. EPA then subdivided the PFAS into one of three secondary categories and further subdivided the PFAS based on structural similarity "within" or "between" categories. EPA used this approach to identify 70 terminal categories that consisted of secondary and tertiary PFAS categories.

EPA also identified "all available, human health-related toxicity studies" on the starting list of PFAS using two separate sources (*i.e.*, EPA's Toxicity Value Database (ToxValDB) and EPA's Chemical Information System (CIS)). EPA's ToxValDB is a "compilation of publicly-derived experimental toxicity data on ~34,000 chemicals from 43 distinct sources," including the European Chemicals Agency (ECHA), whereas CIS is an internal platform that EPA uses to manage data submissions under TSCA, such as data included in PMNs and Section 8(e) notices, including studies that contain confidential business information (CBI).

EPA mapped the 70 terminal categories with the toxicity data from ToxValDB and CIS to identify its initial list of PFAS for testing. EPA subsequently identified "a total of 56 terminal categories that lack any data about the toxicity of the PFAS in that category." Within the 56 terminal categories "lacking toxicity data," EPA identified 24 PFAS "with an identifiable manufacturer(s) to whom EPA could issue a test order."

EPA stated that the category approach used in the Strategy, along with the tiered approach for testing shown in Table 1, is consistent with its statutory mandate under TSCA Section 4(h) to reduce and replace the use of vertebrate animals.

Table 1: General overview of EPA's proposed tiered approach for testing on 24 PFAS

Tier I	Tier II	Tier III
• Vapor pressure • Water solubility • Log K_{OW} • Particle size • Surface tension • *In vitro* metabolism and protein binding studies • *In vitro* genotoxicity for chromosomal aberrations/gene mutations (*e.g.*, OECD Test Guidelines (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 testing (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)

Persons potentially subject to EPA test orders should consider their options and the availability of New Approach Methodology (NAM) approved by the EPA Administrator prior to selecting the option to conduct testing, even if EPA does not suggest NAMs in its test orders.

EPA intended on issuing its first round of test orders on the 24 identified PFAS by the end of 2021. As of late-December 2021, however, EPA has not issued any test orders on PFAS. Regardless of the date, B&C anticipates that questions will arise that call into question the thoroughness of EPA's search for data that may undermine EPA's stated basis for the 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. We note that 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 ECHA database. For example, 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.

B&C also notes that the proposed tiered testing approach requires physicochemical property testing (*e.g.*, surface tension) under Tier I, but does not provide any clarity on how Tier I testing will inform further testing. For example, EPA proposes acute inhalation toxicity testing in rodents under Tier II for those PFAS identified with potential surfactant properties under Tier I. If the lethal concentration of the PFAS in 50 percent of the animals (LC_{50}) is less than 2,000 milligrams per cubic meter (mg/m^3), EPA proposes a 28-day inhalation toxicity study in rodents under Tier III. This tiered testing approach is inconsistent with the statutory mandates under TSCA Section 4(h) to reduce testing using vertebrates and the best available science under TSCA Section 26(h). It is not clear why EPA is not using the Integrated Approach to Testing and Assessment (IATA) for surfactants that EPA completed. The IATA for chemical surfactants is an effective substitute for inhumane inhalation testing on vertebrates.

For example, the OECD TG 403 (acute inhalation) states, "Testing corrosive and/or irritating test articles at concentrations that are expected to cause severe pain and/or distress should be avoided to the extent possible." Surfactants are known to be irritating or corrosive to mucous membranes; therefore, requiring acute inhalation toxicity testing on PFAS with potential surfactant properties would lead to inhumane testing on vertebrates. This is especially troubling since the cutoff listed (LC_{50} < 2,000 mg/m^3) in the Strategy would likely lead to most, if not all, PFAS being tested needlessly for both acute and subacute inhalation toxicity.

3. Section 4(h) — New Approach Methodologies (NAM)

On February 4, 2021, EPA issued its second update to the "List of Alternative Test Methods and Strategies (or New Approach Methodologies [NAMs])" (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." TSCA Section 4(h) focuses on the reduction of testing on vertebrates; however, EPA included NAMs on the List that provide estimates for endpoints other than hazard. For example, EPA included the Chemical Screening Tool for Exposures and Environmental Releases (ChemSTEER) and the Exposure and Fate Assessment Screening Tool (E-FAST).

B&C notes that TSCA Section 4(a)(4) requires EPA to "employ a tiered screening and testing process" that would include using an approved NAM prior to requiring animal testing. EPA did not, however, generate ChemSTEER estimates for occupational dermal and inhalation exposures prior to issuing the TSCA Section 4(a)(2) test orders for dermal and inhalation exposure monitoring. EPA did, how-

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ever, provide the option of "submitting an existing study and/or other relevant information" as a means of responding to the test orders. Therefore, persons potentially subject to EPA test orders should consider their options and the availability of NAMs approved by the EPA Administrator prior to selecting the option to conduct testing, even if EPA does not suggest NAMs in its test orders.

In addition, B&C questions whether EPA will incorporate the occupational monitoring data it obtains through test orders into its risk evaluations or revert to its standard models (*e.g.*, ChemSTEER) as a worst case. This has been a point of contention between the regulated community and EPA on at least one completed risk evaluation. For example, the Semiconductor Industry Association (SIA) submitted extensive workplace exposure and activity data to EPA on N-methylpyrrolidone (NMP). EPA rated these data as "high quality" under its systematic review methods, yet EPA ultimately adopted modeling approaches with default, worst-case assumptions *in lieu* of the data to inform its risk determination on NMP.

4. 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 [g]-2-benzopyran (HHCB)
19. Formaldehyde
20. Phthalic anhydride

EPA must designate additional high-priority chemicals upon completion of a risk evaluation. Given EPA's review and revision of the "First 10" risk evaluations (discussed below), it seems likely that EPA will be pressed to complete risk evaluations on the "Next 20" in 2022. On the other hand, TSCA requires that the prioritization process leading to the designation of high- (and low-) priority chemicals for risk evaluation be completed within nine and 12 months of initiation. It appears that EPA might initiate the prioritization process for additional chemicals in 2022 so that those prioritizations will be nearing completion when EPA is close to completing one of the "Next 20." We expect that most, if not all, of the chemicals will be drawn from those yet to be evaluated in the 2014 update of the TSCA Work Plan for Chemical Assessments, the source that is given priority under TSCA Section 6(b).

b. Risk Evaluations

Chemicals that will be undergoing risk evaluation in 2022 include the "First 10" and the "Next 20" high-priority substances, as well as chemicals for which EPA has granted a manufacturer request for a risk evaluation under TSCA Section 6(b)(4)(C)(ii).

The "First 10" chemicals selected for risk evaluation are:

1. 1,4-Dioxane
2. 1-Bromopropane
3. Asbestos
4. Carbon Tetrachloride
5. HBCD (also known as Cyclic Aliphatic Bromide Cluster)
6. Methylene Chloride
7. NMP
8. PV29
9. Tetrachloroethylene, also known as perchloroethylene
10. Trichloroethylene

Under TSCA Section 6(b)(4), EPA has three years to complete a risk evaluation, extendable for an additional six months. The deadline for the issuance of the risk evaluations for these chemicals, as extended by six months, was June 19, 2020. EPA published final risk evaluations for

all ten between June 2020 and January 2021, but because of policy changes and criticism from outside experts (discussed in more detail below), the Biden Administration appears to be revisiting all ten.

EPA is obligated to publish a supplemental risk evaluation (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 in *Safer Chemicals Healthy Families v. EPA*, 943 F.3d 397 (9th Cir. 2019). Additionally, pursuant to a settlement agreement in *Asbestos Disease Awareness Organization, et al. v. EPA*, EPA will issue a draft scoping document for the Part 2 risk evaluation which provides that, based on reasonably available information, the risk evaluation will include consideration of the following elements: the human health hazard endpoints and exposures associated with all six asbestos fiber types; any evidence of associations between exposure to asbestos and cancer; any evidence of non-cancer human health hazard endpoints; risks of human health hazard endpoints resulting from all environmental pathways of exposure and inhalation, dermal, and ingestion routes of exposure to asbestos; the association between exposure to asbestos in talc and talc-containing products and human health hazard endpoints; risks of human health hazard endpoints for potentially exposed or susceptible subpopulations; and any circumstances of known, intended, or reasonably foreseen manufacture, processing, distribution in commerce, use, or disposal not evaluated in Part 1. EPA also agreed to issue Part 2 of the risk evaluation of asbestos by **December 1, 2024**, under the settlement of a separate lawsuit (*Asbestos Disease Awareness Organization et al. v. Regan et al.*).

i. Policy Changes

On June 30, 2021, EPA announced several 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 PPE is routinely worn properly, and making risk determinations using a whole chemical approach. B&C notes that in the Fall 2021 Unified Agenda of Regulatory and Deregulatory Actions (Regulatory Agenda) issued by the Office of Management and Budget (OMB), there is an action entitled "Reconsideration of Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act" (2070-AK90). A notice of proposed rulemaking (NPRM) publication date of **September 2022** is included. In the entry, EPA states "The Agency is now in the process of reconsidering that [risk evaluation] final rule in keeping with new executive orders concerning the advancement of racial equity and support for underserved communities through the Federal government (EO 13985), the protection of public health and the environment and restoring science to tackle the climate crisis (EO 13990), tackling the climate crisis at home and abroad (EO 14008), and other Administration priorities." Whether EPA will pursue this rulemaking, including on the stated timeline, remains to be seen.

EPA reportedly plans to apply its policy changes retroactively to the "First 10" chemical substances that EPA issued as final risk evaluations. For example, EPA issued the final risk evaluation on 1,4-dioxane in December 2020. EPA intends on reopening and updating the 1,4-dioxane risk evaluation to include additional exposure pathways (*e.g.*, drinking water, ambient air, and conditions of use where 1,4-dioxane is generated as a byproduct). EPA is also planning on taking public comments on the update prior to finalizing the document. EPA did not, however, provide a timeline for these activities.

In calendar year 2021, EPA intended on releasing the screening approaches and methods for fenceline community air and water exposures. EPA also stated that it planned on taking public comments on the screening approaches and methods and having them peer reviewed by the Scientific Advisory Committee on Chemicals (SACC). On October 27, 2021, EPA also issued a *Federal Register* notice for nominations to the SACC for serving on the peer review of EPA's fenceline community models. As of late-December 2021, however, EPA has not released these screening approaches and methods for public comment, nor has it scheduled the SACC review. B&C notes that EPA intended on using the screening approaches and methods on six of the "First 10" chemicals with final risk evaluations (*i.e.*, methylene chloride, trichloroethylene, carbon tetrachloride, perchloroethylene, NMP, and 1-bromopropane).

EPA stated, "data on violations of PPE use suggest that the assumptions that PPE is always provided to workers, and worn properly, are not justified." EPA provided no data or references in support of this statement. B&C notes, however, that EPA's position is contradictory to an analysis of 40 years of violations issued by OSHA, which showed that although there have been millions of violations asserted by

B&C anticipates challenges to the "First 10" risk evaluations as EPA moves these documents forward to risk management.

OSHA, PPE violations such as glove and goggle non-use comprise less than one percent of recorded violations.

EPA summarized the whole chemical approach by stating that it "will continue to assess and analyze each condition of use, but then the agency plans to make the determination of unreasonable risk just once for the whole chemical when it is clear the majority of the conditions of use warrant one determination." B&C notes that the TSCA regulations codifying procedures for risk evaluations appear inconsistent with this approach. 40 C.F.R. Section 702.47 states that "EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under *each condition of uses* [sic] within the scope of the risk evaluation" (emphasis added). EPA intends on taking public comment on this after it withdraws previously issued orders of no unreasonable risk for conditions of use from the "First 10" risk evaluations and then issues revised determinations using the whole chemical approach.

ii. Systematic Review

TSCA Section 26(i) requires the Administrator to "make decisions under sections [4, 5, and 6] … based on the weight of the scientific evidence." The statute does not define weight of the scientific evidence; however, EPA defined these terms in its risk evaluation rule as:

> a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.

In support of this, EPA issued internal guidance in 2018 titled "Application of Systematic Review in TSCA Risk Evaluations" (2018 Guidance Document), that served as EPA's basis for meeting the required scientific standards under TSCA Section 26 on the "First 10" risk evaluations.

In December 2019, prior to EPA completing the "First 10" risk evaluations, EPA requested the U.S. National Academy of Sciences, Engineering, and Medicine (NASEM) to evaluate its 2018 Guidance Document to determine whether it met specific criteria for comprehensivity, workability, objectivity, and transparency. In February 2021, after EPA completed the "First 10" risk evaluations, NASEM released its final report on EPA's 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-bromopropane], 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 its revised approach. *See* our summary here.

B&C anticipates challenges to the "First 10" risk evaluations as EPA moves these documents forward to risk management. 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 on 1,2-dichloroethane and *trans*-1,2-dichloroethylene) in the risk evaluations that would change EPA's risk determinations. Regardless, B&C expects procedural challenges that will likely result in significant delays with EPA re-issuing its "First 10" risk evaluations and may delay EPA being able to propose risk management rules that already have the necessary robust scientific support.

B&C also notes that EPA announced a request for nominations on October 27, 2021 for *ad hoc* expert reviewers to participate on the SACC's peer review of the "draft EPA TSCA Systematic Review Protocol" (Draft Protocol) in **early 2022**. 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 December 20, 2021, EPA issued a *Federal Register*

notice regarding review of the Draft Protocol. The notice announces an **April 19-22, 2022**, virtual public meeting of the SACC "to consider and review the draft TSCA Systematic Review Protocol." It also announces the availability of, and solicits public comments on the Draft Protocol, with written comments due by **February 18, 2022**.

iii. PV29 Risk Evaluation

On January 14, 2021, EPA released the Final Risk Evaluation on PV29. EPA determined that four conditions of use did not present an unreasonable risk to workers and that ten conditions of use presented an unreasonable risk to workers during manufacturing (two conditions of use), processing (four conditions of use), use (three conditions of use), and disposal (one condition of use). In comparison, EPA's initial draft risk evaluation on PV29 did not identify unreasonable risks to workers for any conditions of use, whereas EPA's revised risk evaluation on PV29 identified unreasonable risks to workers for eight out of 14 conditions of use.

On June 30, 2021, EPA announced that PV29 was one of three chemicals that it planned to move forward to risk management, although EPA stated that it intended on reissuing "the risk determinations that amend the approach to PPE and include a whole chemical risk determination."

B&C anticipates that some stakeholders may raise issues with the final PV29 risk management rule, based on certain aspects of the final risk evaluation. First, it is not clear how EPA will address NASEM's criticism of the systematic review process that EPA used in the PV29 risk evaluation. In addition, EPA made several assumptions about the hazard and exposure that appear to contradict the best available science, and EPA provided no scientific justification for those assumptions. Interestingly, one assumption would lead to over-protection and one would lead to under-protection. In the end, the two assumptions might cancel each other in terms of the actual level of potential risk, but even if that is the case, the conclusion would not be based on the best available science, as required. Because of these flaws, EPA may face legal challenges under TSCA Section 26 to a PV29 risk management rule.

iv. Exposures from Pathways Regulated by Other Federal Authorities

In the "First 10" risk evaluations, EPA did not evaluate exposures from conditions of use managed by other environmental statutes implemented by EPA in the risk evaluations completed to date, and as such, unreasonable risk determinations for the relevant conditions of use do not account for those exposures to the general population. EPA explained this decision in the risk evaluations by stating in each of the completed risk evaluations that it believes "it is both reasonable and prudent" to tailor TSCA risk evaluations when other EPA offices have expertise and experience to address specific environmental media, rather than attempt to evaluate and regulate potential exposures and risks from those media under TSCA.

EPA explained further that it believes that coordinated action on exposure pathways and risks addressed by other EPA-administered statutes and regulatory programs is consistent with the statutory text and legislative history, particularly as they pertain to TSCA's function as a "gap-filling" statute, and also further explained that EPA aims to use efficiently Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadlines for completing risk evaluations. EPA states it therefore tailored the scope of the risk evaluation for the chemical substances using authorities in TSCA Sections 6(b) and 9(b)(1). EPA has been criticized for this approach and has stated that it will revisit its assumptions as it reviews the "First 10" risk evaluations.

The Biden Administration is reassessing the "First 10" risk evaluations, each to varying degrees. EPA presumably will have to withdraw its orders finding no unreasonable risk for some conditions of use for some chemicals and reissue its "whole chemical" determinations. Given that EPA found some conditions of use that presented unreasonable risk in at least one condition of use for each of the "First 10," EPA will presumably issue ten unreasonable risk determinations. We note, however, that EPA stated as part of its June 30, 2021, announcement on TSCA risk evaluations that "the agency plans to make the determination of unreasonable risk just once for the whole chemical when it is clear *the majority* of the conditions of use warrant one determination" (emphasis added). It is not clear to us how (or if) that policy statement will be implemented.

As of late-December 2021, EPA has yet to propose a risk management rule for asbestos, despite stating that it "is moving immediately to risk management for chrysotile asbestos and will work as quickly as possible to propose and finalize actions to protect against unreasonable risk." According to the Fall 2021 Regulatory Agenda (2070-AK86), however, EPA plans on issuing an NPRM in **April 2022** and a final rule in **November 2023**.

Given that EPA is revisiting the "First 10" and EPA has four Manufacturer-Requested Risk Evaluations under way, B&C expects the risk evaluation work on the "Next 20" to continue through 2022 and possibly through much of 2023.

Although EPA had largely met the deadlines under the Lautenberg amendments to TSCA, EPA's reconsideration of the "First 10" risk evaluations and any related delays to risk management are clearly past the June 2020 extended deadlines. B&C expects the reissuance by EPA of each of the "First 10" risk evaluations to occur in the **first half of 2022**. EPA will presumably follow those actions by proceeding with risk management.

v. "Next 20" Chemical Risk Evaluations

On September 4, 2020, EPA announced the availability of the final scope documents for the ongoing risk evaluations of the 20 chemicals designated as "high-priority." EPA has issued test orders for nine of the chemicals and promulgated Section 8(d) data call-in rules for all 20. Risk evaluation work continues on all, but the change of approach reflected in the "First 10" will need to be incorporated in the scope documents for the "Next 20." In 2022, B&C expects that EPA will revise the final scope documents and presumably provide an opportunity to comment. Manufacturers, importers, and processors will continue to engage with EPA on the specific conditions of use 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 2022 and possibly through much of **2023**.

vi. Manufacturer-Requested Risk Evaluations

MRREs are authorized under TSCA Section 6(b)(4)(C)(ii) and are conducted in the same manner as other risk evaluations conducted under TSCA Section 6(b)(4)(A). Procedures for submitting requests and the process and timelines associated with the review of the requests by EPA are at 40 C.F.R. Section 702.37. As with risk evaluations for "high-priority" chemicals, EPA has three years to complete MRREs, with an extension available for up to six months.

(a) DINP/DIDP

On August 31, 2021, EPA announced the availability of the final scope documents for the MRREs of di-isodecyl phthalate (DIDP) and di-isononyl phthalate (DINP). The risk evaluations are ongoing; EPA posted to the DINP and DIDP dockets notes from two stakeholder meetings in September 2021. B&C expects that the risk evaluations for both substances will continue throughout 2022 as EPA revises its approach based on the new policy decisions discussed above. It is unclear if EPA will post revised final scope documents, post supplemental scope documents, or simply incorporate the scope changes in the draft risk evaluations.

(b) D4

On September 8, 2021, EPA announced the availability of the draft scope document for octamethylcyclotetra-siloxane (D4). The draft scope document includes the conditions of use, hazards, exposures, and the potentially exposed or susceptible subpopulations that EPA plans to consider in conducting the risk evaluations for D4. According to the draft scope document, EPA plans to evaluate manufacturing (including importing), processing, distribution in commerce, and commercial and consumer uses. EPA solicited public comments on the draft scope document over a 45-day period, which ended on October 25, 2021.

In its press releases on the final and draft scope documents, EPA noted that these documents reflect its policy changes on risk evaluations announced in June 2021. This includes plans to consider exposure pathways that may be regulated outside of TSCA, like air and water, and potential for exposures to fenceline communities. In addition, EPA will not assume that PPE will always be provided and properly used in occupational settings as the basis for the risk determination. EPA stated that it will assess use of PPE, and other ways industry protects its workers, during the risk evaluation and will consider these methods as potential ways to address unreasonable risks during the risk management process. Finally, EPA made nearly identical statements in each of the press releases (*i.e.*, DIDP/DINP and D4) that "Going forward, risk evaluations of existing chemicals, including DIDP and DINP, will ensure unreasonable risks from chemicals are assessed in a way that is supported by science and law."

B&C notes that neither the final nor the draft scope documents provided the systematic review approaches EPA intends to use. Rather, the scope documents for DIDP, DINP, and D4 each contained virtually the same statement that "EPA plans to evaluate the epidemiological and toxicological literature for DIDP using revised evaluation strategies. These revised evaluation strategies are described in a draft systematic review protocol that EPA plans to release later this year."

B&C notes that EPA cited environmental monitoring data that were generated and completed on D4 in September 2017 under an enforceable consent agreement (ECA) with five D4 manufacturers. EPA stated that it was intent on considering these data for environmental releases, however, EPA also listed standard modeling approaches (*e.g.*, EPA Generic Scenarios and OECD Emission Scenario Documents) that may also be used. B&C acknowledges the extensive nature of the environmental monitoring data that EPA summarized under the ECA as including the collection and analysis of samples from environmental media around wastewater treatment plants (WWTP) that treat D4 (influent, effluent, and biosolids), downstream surface water, sediment, and biota.

B&C questions, however, whether EPA will rely upon the environmental monitoring data in its risk evaluation on D4 or revert to its standard models and default assumptions. As discussed above for NMP, this practice of EPA acknowledging high-quality data and nevertheless relying upon models has been a point of contention between the regulated community and EPA. It again begs the question of the value of the test data if EPA is going to base its risk evaluations on worst-case assumptions and propose regulations based solely on hazard data.

As announced by EPA on December 8, 2020, EPA received a request from the OTNE Consortium to conduct a risk evaluation for four chemical substances as a category, the octahydro-tetramethyl-naphthalenyl-ethanone (OTNE) chemical category. On December 8, 2020, EPA found the request to be facially complete. EPA opened a docket and took comments in 2021. EPA has not made any further announcements, and there have been no recent postings to the docket.

c. Risk Management

i. "First 10" Chemicals

In 2022, EPA will continue the development of Section 6(a) risk management rules on those of the "First 10." 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 statutory deadline will be affected if and when EPA reissues the "First 10" risk evaluations. This is especially problematic given EPA's intended "whole chemical" approach. If EPA is reassessing the entirety of the risk evaluation, what is EPA's basis for proposing risk management measures that are sufficiently protective of a yet-to-be-identified unreasonable risk? As these rules are expected to be complex, the next several years will be challenging for EPA as existing chemicals risk management activity will proceed at a level unprecedented under TSCA. As stated in the Fall 2021 Regulatory Agenda, EPA plans to publish proposed Section 6 risk management rules for HBCD (2070-AK71) in **September 2022** and for 1-bromopropane (2070-AK73), carbon tetrachloride (2070-AK82), and trichloroethylene (TCE) (2070-AK83) in **October 2022**.

ii. PBTs

EPA met the June 2019 deadline in TSCA Section 6(h) for proposing regulatory action and published in the *Federal Register* on January 6, 2021, the final rules for five PBT chemicals — decabromodiphenyl ether (decaBDE); phenol, isopropylated phosphate (3:1) (PIP (3:1)); 2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP); hexachlorobutadiene (HCBD); and pentachlorothiophenol (PCTP). The chemicals covered and summaries of these final actions are as follows.

- HCBD, used as a solvent and functional fluid:
  - » EPA prohibited the manufacturing (including import), processing, and distribution in commerce of HCBD and HCBD-containing products or articles, except for the unintentional production of HCBD as a byproduct during the production of chlorinated solvents, and the processing and distribution in commerce of HCBD for burning as a waste fuel.

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"EPA Goes Back To The Drawing Board On Toxic Substances," *Chemical Processing*, September 24, 2021.

- PIP (3:1), used as a flame retardant, functional fluid, and in other uses:
  - » EPA prohibited processing and distribution in commerce of PIP (3:1), and products containing the chemical substance, for all uses, except for certain limited uses.
    - EPA required that persons manufacturing, processing, and distributing in commerce PIP (3:1) and products containing PIP (3:1) notify their customers of these restrictions.
    - EPA prohibited releases to water from the remaining manufacturing, processing, and distribution in commerce activities and required commercial users of PIP (3:1) and PIP (3:1)-containing products to follow existing regulations and best practices to prevent releases to water during use.
- 2,4,6-TTBP, antioxidant used as fuel/lubricant additive:
  - » EPA prohibited the distribution in commerce of 2,4,6-TTBP and products containing 2,4,6-TTBP at concentrations above 0.3 percent by weight in any container with a volume of less than 35 gallons in order to prevent effectively the use of 2,4,6-TTBP as a fuel additive or fuel injector cleaner by consumers and small commercial operations.
  - » EPA also prohibited the processing and distribution in commerce of 2,4,6-TTBP, and products containing 2,4,6-TTBP, for use as an oil or lubricant additive in concentrations above 0.3 percent by weight regardless of container size.
- PCTP, used as cross-linking agent in rubber:
  - » EPA prohibited the manufacture (including import), processing, and distribution in commerce of PCTP, and products or articles containing PCTP, unless PCTP concentrations are at or below 1 percent by weight.
- decaBDE, used as a flame retardant:
  - » EPA prohibited the manufacture (including import), processing, and distribution in commerce of decaBDE, and products containing decaBDE, for all uses, except for certain limited uses.

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EPA and PBTs: A New Normal? — A Conversation with Richard E. Engler, Ph.D.

Following the release of the final PIP (3:1) rule on January 6, 2021, stakeholders informed EPA that the prohibition on processing and distribution of PIP (3:1) could impact articles used in a wide variety of electronics, from cell phones, to robotics used to manufacture semiconductors, to equipment used to move COVID-19 vaccines and keep them at the appropriate temperature. EPA stated in its March 8, 2021, announcement that stakeholders "note that the complexity of international supply chains makes locating the presence of, and finding alternatives to, PIP (3:1) in components challenging." Stakeholders asserted that an extension to the compliance deadline was necessary to avoid significant disruption to the supply chain for a wide variety of articles.

In response to this information, EPA issued a No Action Assurance (NAA), effective through September 4, 2021, or until the effective date of a final action addressing the compliance date for the prohibition on processing and distributing in commerce of PIP (3:1), including in PIP (3:1)-containing articles, whichever occurs earlier. In issuing the NAA, EPA stated that it would exercise its enforcement discretion regarding the prohibitions on processing and distribution of PIP (3:1) for use in articles, and the articles to which PIP (3:1) has been added.

In its March 8, 2021, announcement, EPA stated that "in accordance with Biden-Harris Administration executive orders and directives," it was asking for additional public input on the persistent, bioaccumulative, and toxic (PBT) rules. Through a notice published on March 16, 2021, in the *Federal Register*, EPA opened a 60-day comment period for the public to provide input on:

- Whether the rules sufficiently reduce exposure to these chemicals, including exposures to potentially exposed or susceptible subpopulations and the environment;

March 8, 2022, is the newly extended compliance date 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.

- Newly raised compliance issues associated with the final PIP (3:1) rule, including the compliance dates for certain regulated articles; and

- Whether to consider additional or alternative measures or approaches.

EPA has been criticized for providing relief to companies that failed to comment on the proposed rule, and manufacturers and importers of articles definitely bear responsibility for not monitoring carefully TSCA rulemaking. Nevertheless, the Retail Industry Leaders Association (RILA) commented on the proposed rule, stating, among other things, that it is critically important that EPA provide a sell-through provision in the rule to avoid severe economic injury to the retail industry and market disruption to consumers. RILA suggested that the compliance dates should be phased in over a period of three to five years following promulgation of the rule in order to educate foreign supply chains and work to revise product design and help ensure products and articles exported to the United States do not contain banned substances, including PIP (3:1). EPA dismissed the concern and stated that 60 days was sufficient to come into compliance. If EPA had not granted relief to article manufacturers, importers, processors, and distributors, the economic disruption due to the cessation of sale of any electric or electronic article that could not be confidently documented as being PIP (3:1)-free would have been extraordinary. It is likely that *all* wholesale and retail sales (at least of electrical and electronic products) would have had to cease until each supply chain for each product could be queried and documented. To avoid the devastating economic effects that would have resulted, EPA granted the relief in the form of the NAA and proposed extension of the compliance date.

On September 3, 2021, EPA announced an extension of the compliance dates covered by the NAA to **March 8, 2022**, "to address the hardships inadvertently created by the original applicable compliance dates in the January 2021 final rule to ensure that supply chains are not disrupted for key consumer and commercial goods." EPA announced further that it "will also soon issue a notice of proposed rulemaking that, if finalized would further extend the compliance dates." A final rule extending the compliance dates to **March 8, 2022**, was published in the *Federal Register* on September 17, 2021, and a proposed rule that would further extend those compliance dates to **October 31, 2024**, was published in the *Federal Register* on October 28, 2021. 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."

Additionally, in the October 28 proposed rule, while EPA noted that it understands that many industry sectors impacted or potentially impacted by the PIP (3:1) rulemaking "are still attempting to determine exactly where PIP (3:1) is present in their supply chains," EPA stated that "to the extent that any industry sector believes that it needs a compliance date beyond **October 31, 2024**, EPA invites comments providing specific information and documentation supporting a further compliance date extension." EPA intends to issue the October 2021 proposed rule in final before **March 8, 2022**, the newly extended compliance date 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.

While the extension of the compliance dates concerning the prohibitions on processing and distribution of PIP (3:1) for use in articles, and the articles to which PIP (3:1) has been added, to **March 8, 2022**, in the September 2021 final rule was certainly welcome relief to importers, processors, and distributors, including retailers, of articles including electric and electronic devices, especially given the September 4, 2021, expiration of the NAA, we imagine that most were disappointed by the short timeframe (only six months).

As the many comments submitted in response to EPA's March 2021 request for additional comment on the January 2021 final rule demonstrate, most importers and distributors of electric and electronic articles could not determine with confidence whether PIP (3:1) was in any part of any article, whether it could be replaced if it was, and that it would take years to survey the complex global supply

chains that underlie most complex articles. EPA's subsequent proposed rule that would further extend the compliance dates to **October 31, 2024**, should provide some additional level of relief to impacted companies, but does not address adequately issues identified by many companies in their comments. The comment deadline is December 27, 2021, shortly before the publication of this Forecast. We believe that EPA is unlikely to extend the comment deadline because EPA must extend the compliance date prior to **March 8, 2022**, to avoid the disruption averted by the NAA and subsequent rulemaking.

In the September 3, 2021, announcement, EPA stated also 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." In this regard, EPA stated that it plans to propose a new separate rulemaking on all five PBT chemicals in **spring 2023**. This is likely, in part, due to criticism that the other PBT rules are not sufficiently protective, especially of potentially exposed or susceptible subpopulations. What EPA may include in the proposed rule is to be seen, but we hope EPA will engage in broad outreach ahead of proposing further restrictions in the final PBT rules.

iii. Other Section 6 Risk Management

On January 15, 2021, the Trump EPA withdrew the proposed regulatory requirements in three proposed TSCA Section 6(a) rules, stating that it no longer intends to issue these actions in final. EPA officially terminated the ongoing rulemaking activities for the following actions:

- Trichloroethylene (TCE); Regulation of Certain Uses Under TSCA Section 6(a); Proposed Rule (Renewable Identification Number (RIN) 2070-AK03)
- TCE; Regulation of Use in Vapor Degreasing Under TSCA Section 6(a); Proposed Rule (RIN 2070-AK11)
- NMP; Regulation of Certain Uses Under TSCA Section 6(a); Proposed Rule (RIN 2070-AK07)

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- Methylene chloride; Regulation of Certain Uses under TSCA Section 6(a); Proposed Rule (RIN 2070-AK07).

EPA proposed these rules under TSCA Section 6(a), which provides authority for EPA to ban or restrict the manufacture (including import), processing, distribution in commerce, use, and disposal of chemical substances, with certain limitations. TSCA Section 26(l)(4) authorizes EPA to issue rules under TSCA Section 6(a) for chemicals listed in the 2014 Update to the TSCA Work Plan for Chemical Assessments (Work Plan) for which EPA published completed risk assessments prior to June 22, 2016. These three chemicals are listed in the Work Plan and are the subjects of risk assessments completed before June 22, 2016.

The Trump Administration's withdrawal of these proposed rules makes it unlikely that the Biden EPA will use the TSCA Section 26(l)(4) authority to regulate unreasonable risks associated with TCE, NMP, or methylene chloride in 2022 or thereafter. Each of these chemicals is among the "First 10," and presumably these conditions of use will be addressed in the overall risk management rules for each substance. For NMP, the proposed TSCA Section 6(a) rule withdrawal terminated the TSCA Section 12(b) export notification requirements that were triggered by the proposed action, as well as the lower TSCA Section 8(a) Chemical Data Reporting (CDR) rule threshold for this chemical that were associated with the withdrawn rule. (For TCE and methylene chloride, TSCA Section 12(b) requirements and the lower CDR reporting threshold remain in place because of other TSCA actions covering these chemicals that continue in effect.)

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 are the subject of petitions for review challenging EPA's determinations of unreasonable risk for certain conditions of use. As EPA has decided to supplement its past risk evaluations, EPA has requested, and been granted, voluntary remand in the methylene chloride, HBCD, and 1,4-dioxane cases while it revisits the risk evaluation challenges described below.

EPA "currently anticipates that the development and implementation of a screening-level approach document and screening-level analysis of methylene chloride will include intra-agency review, public comment and independent external peer review through EPA's Scientific Advisory Council on Chemicals."

i. Methylene Chloride

Suits challenging EPA's June 2020 final risk evaluation for methylene chloride 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 methylene chloride, 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 methylene chloride.

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. According to EPA's October 12, 2021, status report, EPA "currently anticipates that the development and implementation of a screening-level approach document and screening-level analysis of methylene chloride will include intra-agency review, public comment and independent external peer review through EPA's Scientific Advisory Council on Chemicals (SACC)." OPPT is also collecting and reviewing ambient air and drinking water exposure data for methylene chloride. The next status report is due **January 10, 2022**. Proceedings are being held in abeyance pending completion of EPA's reconsideration proceedings or further order of the court. More information regarding EPA's final risk evaluation is available in our June 25, 2020, memorandum, "Final Risk Evaluation for Methylene Chloride Is First Completed under Lautenberg Act Amendments."

ii. HBCD

On October 16, 2020, the Alaska Community Action on Toxics 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. According to EPA's November 8, 2021, status report, EPA anticipates the proposed revised risk determination will be completed "in the coming weeks." Once completed, EPA states that it plans to open a public comment period on the proposed revised risk determination and will issue a final revised risk determination for HBCD after taking into account public comments. The next status report is due **January 10, 2022**. Proceedings are being held in abeyance pending completion of EPA's reconsideration proceedings or further order of the court. More information regarding EPA's final risk evaluation is available in our September 28, 2020, memorandum, "EPA Publishes Final Risk Evaluation for HBCD."

iii. 1,4-Dioxane

On January 26, 2021, Environmental Defense Fund (EDF), 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 conditions of use. *EDF et al. v. EPA* (No. 21-70162); consolidated with No. 21-70194, No. 21-70727, No. 21-70684, and No. 21-70930. A coalition of 14 states and three municipalities also filed suit, and the court consolidated the cases. On June 8, 2021, EPA requested voluntary remand without vacatur to allow it to revisit the final risk evaluation. The court granted EPA's motion on August 10,

2021, for the limited purpose of permitting EPA to reconsider the challenged no-unreasonable-risk determinations. EPA filed a status report on November 8, 2021, stating that it currently anticipates supplementing the risk evaluation, which will include public comment and independent external peer review through SACC. The next status report is due **February 7, 2022**. Proceedings are being held in abeyance pending completion of EPA's reconsideration proceedings or further order of the court. 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) and a number of scientists and public health groups filed a petition on January 26, 2021, in the U.S. Court of Appeals for the Ninth Circuit challenging Part 1 of the asbestos risk evaluation. *Asbestos Disease Awareness Organization et al. v. EPA* (No. 21-70160). The petitioners seek review of the final risk evaluation determining the risks of certain conditions of use of chrysotile asbestos fibers but declining to consider the risks of other asbestos fibers, conditions of use, health effects, and pathways of exposure that impact public health. The parties filed a joint motion for abeyance on October 13, 2021, pursuant to an agreement with EPA for conducting Part 2 of its risk evaluation of asbestos (Legacy Uses and Associated Disposals of Asbestos). The court granted the parties' motion on October 28, 2021. Appellate proceedings are stayed pending further EPA proceedings or until further order of the court. A status report is due **April 12, 2022**. 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."

A coalition of public health groups and scientists filed a complaint in the U.S. District Court for the Northern District of California on May 18, 2021, alleging that EPA failed to undertake a non-discretionary duty under TSCA Section 6(b) because it did not complete the risk evaluation of asbestos by June 19, 2020, as required by TSCA, because it did not evaluate the risks of legacy uses and associated disposals of asbestos. *ADAO et al. v. Regan* (No. 21-03716). The parties reached agreement on a proposed consent decree that requires EPA to complete Part 2 of its risk evaluation of asbestos by **December 1, 2024**. The consent decree requires EPA to submit status reports every six months on its progress toward completing the Part 2 Risk Evaluation. The court approved the consent decree on October 13, 2021.

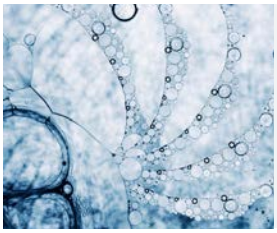
e. Risk Management Litigation

2022 is expected to be a year filled with TSCA-related litigation. There was no small amount of litigation in 2021, and with EPA policies implementing TSCA very much in flux, TSCA stakeholders are expected to seek judicial intervention. This is entirely predictable and not necessarily an undesirable outcome.

i. Ban on Methylene Chloride in Paint and Coating Strippers for Consumer Purchase

Three petitions for review challenging EPA's 2019 TSCA Section 6(a) rule banning methylene chloride in paint and coating strippers for consumer use were filed. The cases were consolidated, and arguments were heard in the U.S. Court of Appeals for the Second Circuit on March 4, 2021. *Labor Council for Latin Am. Advancement v. EPA* (No. 19-1042). Environmental petitioners (Natural Resources Defense Council (NRDC), Earthjustice, and the Labor Council for Latin American Advancement) argued that EPA should have banned the commercial uses of stripping products, in addition to consumer uses, due to fatalities when workers used methylene chloride. According to the Halogenated Solvents Industry Alliance (HSIA), EPA's rule barring retailers that sell any chemical products to consumers from selling methylene chloride paint removers was arbitrary and capricious and would prevent the majority of commercial uses still allowed by EPA. EPA maintained that it was exploring other options to protect workers that may not require a commercial ban of methylene chloride and that it may also regulate methylene chloride based upon unreasonable risk findings in its risk evaluations.

On September 1, 2021, the court denied the petitions for review, stating that HSIA's challenge to the final rule failed because the rule was supported by substantial evidence and that the environmental petitioners' challenge was unripe for review at this time. The court noted that the deadline for a final risk management rule regarding commercial uses of methylene chloride is "rapidly approaching." The court concluded that the extent to which TSCA requires EPA to regulate commercial uses of methylene chloride, and whether the rules EPA promulgates adequately do so, "will be a better fit for judicial review after that rulemaking process is complete and the 'policy in question has sufficiently crystallized'" (citation omitted). More information on the final rule is available in our March 20, 2019, memorandum, "EPA Bans Consumer Sales of Methylene Chloride Paint Removers, Seeks Com-



B&C anticipates that EPA's decision to stop issuing non-Section 5(e) Significant New Use Rules that precede "not likely" determinations will lead to longer delays with completing its evaluations on new chemical substance notifications.

ment on Program for Commercial Uses." Whether EPA proposes risk management rules that address the concerns expressed in the various suits remains to be seen.

ii. 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 of or recycled are unlawful. Briefing will begin in 2022. In addition, as discussed above, EPA intends to take further comment on the PBT rules. As with other pending litigation, EPA may request a voluntary remand to reconsider the final rules. 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."

iii. 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 first issued a temporary NAA, and then in October 2021 proposed to extend further 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.

On April 1, 2021, EPA filed an unopposed motion to hold the case in abeyance, which the court granted on April 6, 2021. On October 7, 2021, EPA filed an unopposed motion to hold the case in abeyance through **April 7, 2022**, and the court granted EPA's motion on October 8, 2021. More information on the status of the PIP (3:1) rule is available in our October 25, 2021, memorandum, "EPA Proposes Further Extension of Compliance Dates for PIP (3:1)-Containing Articles."

5. Section 5 — New Chemical Substances

a. Policy Changes

On March 29, 2021, EPA announced two prospective policy changes to the TSCA New Chemicals Program. First, EPA stated that it will no longer issue non-Section 5(e) SNURs for new chemical substances that precede EPA's determination of "not likely to present an unreasonable risk." Instead, EPA stated that it would issue TSCA Section 5(e) orders to address reasonably foreseeable condition of use (RFCU) that may present an unreasonable risk or for those RFCUs for which EPA lacks sufficient information to make a risk determination. Second, EPA stated that it would no longer assume that worker protections, such as PPE and hazard warnings on safety data sheets (SDS), would be adequate to mitigate potential unreasonable risks, based on the assumption of compliance with OSHA's worker protection standards (WPS). Rather, EPA stated that it would consider non-compliance as an RFCU and would issue TSCA Section 5(e) orders to ensure regulation of worker protections under TSCA.

B&C anticipates that EPA's decision to stop issuing non-Section 5(e) SNURs that precede "not likely" determinations will lead to longer delays with completing its evaluations on new chemical substance notifications. The

non-Section 5(e) SNUR construct provided an efficiency to EPA's under-resourced New Chemicals Program that bypassed the need for issuing a TSCA Section 5(e) order, which only binds the submitter to the restrictions, and then following up with a SNUR, which binds any person to those restrictions, including the submitter. EPA's reliance on orders is also undermined by lengthy delays between when orders are executed and corresponding SNURs are proposed (average 339 days) and promulgated (757 days). That is in addition to 68 cases for which EPA has yet to propose a corresponding SNUR; these cases have been waiting on average 717 days, with some waiting over five years.

B&C acknowledges that EPA's decision to issue TSCA Section 5(e) orders for worker protections in some cases is consistent with how the New Chemicals Program addressed worker protection concerns prior to the 2016 TSCA amendments. We anticipate issues with the implementation of the policy that EPA's assumption that PPE is "not always" used equates to "never used," necessitating a TSCA regulation, because it 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 Occupational Safety and Health Act (OSH Act)) is reasonably foreseen or a misuse.

EPA provided no clarification when it announced this policy change on how it would address potential hazard concerns that it formerly addressed qualitatively in its risk assessments (*e.g.*, skin irritation). For example, it is unclear if EPA will consider the nature and severity of the hazard when making a determination on unreasonable risk or whether EPA will consider any hazard (even skin irritation) as a justification for making a "may present" unreasonable risk determination and issuing a TSCA Section 5(e) order.

Although these policy changes were prospective in nature, any new chemical substance notification that was stalled in the review process, of which there are many, prior to these changes will likely be subjected to them. This will lead to significant and consequential impacts on their review.

b. Scientific Updates

On March 22, 2021, EPA presented the current approaches it uses for determining whether a chemical substance is a respiratory sensitizer under TSCA Section 5 at the Society of Toxicology's Annual Meeting and ToxExpo. EPA acknowledged that given the lack of a validated testing guideline for respiratory sensitization, it uses a weight of evidence (WOE) analysis for making this hazard determination.

EPA stated in the abstract of its presentation that its WOE analysis includes "evaluating the physical/chemical properties, reviewing available skin sensitization data, identifying structural alerts and/or anticipated metabolites, assessing the potential for protein cross-linking, *etc.*" EPA stated that the goal of this evaluation is "to estimate the bioavailability and reactivity of the new chemical substance and potential metabolites." EPA's presentation elaborated on this approach, noting that it also utilizes the OECD Quantitative Structure-Activity Relationship (QSAR) Toolbox for evaluating the new chemical substance and potential metabolites with the OECD QSAR Toolbox profiler for respiratory sensitization.

B&C acknowledges that EPA's current approach represents a significant improvement over its former approach of extrapolating dermal sensitization to respiratory sensitization in all cases. We note, however, that EPA has not consistently applied its current approach to new chemical substance notifications. EPA has not applied the current approach retroactively to those new chemical substances, originally assessed with the former approach, that remain "stuck" in the new chemicals review process.

B&C anticipates that submitters will increasingly evaluate their chemistries that had previously been predicted to be respiratory sensitizers against EPA's current approach and will challenge EPA's risk determinations, or request limitations or revocations on SNUR requirements under 40 C.F.R. Section 721.185, when the WOE analysis does not support a hazard concern for respiratory sensitization.

c. New Chemical Notice Review Case Updates

In 2020, EPA made significant progress in resolving older cases (defined as those more than six months past the submission date). Unfortunately, in 2021, the pace of EPA making final determinations slowed dramatically. After September 1, 2021, EPA has only completed determinations on ten cases, eight submitted prior to FY 2021 and two submitted in FY 2021. New chemical reviews may continue to languish until the Inspector General investigation into alleged scientific integrity complaints is resolved. EPA's announcement on October 14, 2021, that OCSPP will create a new Science Policy Council and a new Science Policy Advisor position may also help some of the scientific gridlock in new chemicals reviews.

Table 2 presents statistics on the number of PMNs submitted annually since 2016 and the outcomes obtained following completion of EPA's review. Table 3 provides trend information over time since 2016 concerning 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. We discuss below the results shown.

d. Discussion of Table 2

i. Total PMNs Submitted

After years of decline in the number of PMN submissions, FY 2021 saw a slight uptick in the number of PMNs submitted. Unfortunately, that increase coincides with a marked decrease in the number of determinations made. EPA has made determinations on only 28 (about 13 percent) of FY 2021 PMNs. EPA has made an additional 40 determinations on older cases. While some slowdown is to be expected after the change of Administration, the pace of determinations has slowed. For cases submitted in all years, EPA made 16, 27, 18, and 7 determinations in each quarter (based on the status on the PMN status page through December 4). EPA is clearly struggling to review PMNs timely.

ii. PMN Outcomes

B&C has taken a different approach in this year's Forecast document. In this version, we consider the number of "not likely" determinations among all determinations and exclude invalid, withdrawn, and cases still under review from the outcome statistics.

Table 2: Number of PMNs submitted in FYs 2016-2021

				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	354	14 (4%)	340 (96%)	139 (39%)	20 (6%)	10 (3%)	42 (12%)	16 (5%)	113 (32%)
2017	437	10 (2%)	427 (98%)	254 (58%)	12 (3%)	25 (6%)	48 (11%)	24 (5%)	64 (15%)
2018	411	46 (11%)	365 (89%)	78 (19%)	9 (2%)	113 (27%)	85 (21%)	14 (3%)	66 (16%)
2019	187	15 (8%)	172 (92%)	70 (37%)	14 (7%)	32 (17%)	33 (18%)	16 (9%)	7 (4%)
2020	177	46 (26%)	131 (74%)	38 (21%)	2 (1%)	9 (5%)	48 (27%)	15 (8%)	19 (11%)
2021	211	163 (77%)	48 (23%)	13 (6%)	0 (0%)	0 (0%)	15 (7%)	11 (5%)	9 (4%)
Total	**1,899**	**301 (16%)**	**1,598 (84%)**	**644 (34%)**	**58 (16%)**	**189 (53%)**	**274 (14%)**	**96 (5%)**	**337 (18%)**

Statistics based on PMN status posted on EPA's website as of December 6, 2021 (last updated Nov. 11, 2021). 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 with Follow-Up SNUR" are all regulated outcomes. "Not Likely Based on SNUR" are decisions in which EPA uses a SNUR to prohibit conditions of use that, while not intended, are reasonably foreseeable. EPA's view is that once the SNUR is proposed, those conditions of use are no longer reasonably foreseeable and EPA can then make a "not likely" determination. "Not Likely with Follow-up SNUR" are decisions in which EPA did not identify unreasonable risk under the RFCUs, 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 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).

There is a popular, but entirely false, narrative that the prior Administration allowed many dangerous chemicals onto the market with no controls. The 17 percent of "not likely" cases in 2019 represents 27 cases. The percentage of "not likely" determinations made in the last half of calendar year 2016 (29 out of 73 total determinations) is higher than the number of "not likely" determinations made in calendar year 2020 (32 out of 259).

The last column shows the number of PMN cases still under review for each FY. Among the cases received between 2016 and 2020, 131 of 1,566, or 8 percent, of the PMNs are yet to be completed, including 26 percent of the cases from 2020. These are in addition to the 163 FY 2021 cases under review. While Congress intended that EPA proceed to complete PMN reviews within the "applicable review period," as defined in TSCA Section 5(i)(3), this statistic shows that meeting this statutory requirement remains elusive for EPA. EPA's statistics website provides some additional insight. According to that site, there are 298 "active" cases (cases that have passed EPA's completeness checks and are in some stage of review) as of November 1, 2021. Of those, 48 are awaiting submitter action, meaning 250 are awaiting EPA action, with the majority (174) of cases in the "risk assessment" stage. The discussion of Table 3 explores this issue from another perspective.

e. Discussion of Table 3

i. Length of Review Period

Table 3 shows the mean number of days between "Day 1" and the final disposition of cases in each FY. For cases still under review, the value represents the number of days through December 7, 2021. Although EPA's record of accomplishments had been improving, there has been a significant back-slide in late 2021. While some of the issues may be related to thinly supported PMNs (*e.g.*, those without robust release and exposure information or without test data on the substance or analogs), the primary hold-up is in EPA's initial review, during which, if there are no data, EPA can and does make worst-case assumptions about releases and exposure and either identifies analogs for read-across or determines that there is insufficient hazard information. Results of that review are then reported to the submitter, after which the submitter may submit additional information to clarify what was submitted or identify errors in EPA's assessment. Once the risk characterization is complete, EPA then makes its preliminary determination, either a "not likely" determination, or an order. For the handful of FY 2021 cases that EPA has completed, the average time to determination is 133 days for "not likely" determinations and 154 days to achieve signed orders. Both of these numbers are heartening because both outcomes are reached in less than 180 days, but are in stark contrast to the average of 219 days for cases still under review.

EPA continues to propose SNURs for new chemicals. As of December 7, 2021, EPA proposed five batches of SNURs in 2021, including SNURs derivative of orders (54 cases), "based on" SNURs (3), and follow-on SNURs (39). Even so, there are still 68 PMNs with consent orders signed as early as August 2021 for which EPA has yet to propose a SNUR and another 96 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 164 substances without final SNURs may be in commercial limbo awaiting EPA to promulgate those SNURs.

Table 3: 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	With-drawal
2016	544	1977	436	949	1065	410	50	501
2017	338	1623	232	842	800	325	41	398
2018	555	1242	553	634	402	437	19	599
2019	224	876	200	281	111	130	57	306
2020	298	561	283	233	136	154	53	330
2021	198	219	154	0	0	133	39	180

[1]As of December 7, 2021.

EPA's assumption is that if there is any hazard other than "low," someone, at some point in the future, "might" exceed EPA's concern level, leading to an unreasonable risk.

One of the reasons that there continue to be substantial delays in PMN review is EPA's return to hazard-based decision-making. As was true in the early days of Lautenberg, EPA was proposing orders for any substance for which EPA identified a hazard other than "low" for health and ecotoxicity ("low/low" cases). EPA's assumption is that if there is any hazard other than "low," someone, at some point in the future, "might" exceed EPA's concern level, leading to an unreasonable risk. EPA has yet to explain how this view meets the statutory requirement for EPA to evaluate RFCUs. This is true regardless of how robust a data set is provided by the submitter. In fact, EPA's practice of insisting on regulation for all substances other than low/lows is a disincentive to developing data — if testing does not demonstrate the substance is low hazard, EPA will issue a regulation. If that is the case, what is the value of the testing other than to refine the concern level?

In 2020, a coalition of non-governmental organizations (NGO), including EDF and 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. Wheeler* (No. 1:20-cv-762). The parties have been engaged in discussions since 2020 and are seeking to reach an agreement on some or all of the potential procedural issues in dispute. According to the parties, the issues in the case can be resolved by motions for summary judgment. In particular, the parties are discussing options to narrow the scope of factual and legal issues presented to the court, which may minimize the potential for future disputes over the availability and scope of discovery. There is little question that EPA has not published the requisite notices timely, but EPA historically has not done so. OPPT has been publishing receipt and status notices in the *Federal Register* on a monthly basis, but full (redacted) low volume exemption (LVE) notices do not seem to be available within the required timeframe. We expect that this issue will continue to bedevil EPA in 2022 while EPA attempts to formalize a process to post cases timely.

We note that, as reflected in the Fall 2021 Regulatory Agenda (2070-AJ94), EPA plans to issue in **February 2022** a final rule it proposed in July 2016 to amend aspects of the SNUR regulations at 40 C.F.R. Part 721 that pertain to new chemicals, including, among others, provisions addressing "Protection in the Workplace" and "Hazard Communication Program." According to EPA, this action will align, where possible, EPA's regulations with OSHA Hazard Communication Standard (HCS) regulations at 29 C.F.R. Section 1910.1200 and make minor amendments to PMN reporting requirements.

Additionally, as reflected in the Fall 2021 Regulatory Agenda (2070-AK65), EPA plans to propose regulations in **September 2022** 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. If EPA can characterize better the information needed in new chemicals submissions to support timely reviews and this, in fact, results in fewer requests for additional information during the submission review process, the rulemaking, if pursued anew by this Administration, would likely be regarded as a significant success by industry. On the other hand, if the regulations would simply convert EPA's current "Points to Consider" guidance into a regulatory requirement, we doubt that such a change will have a significant effect on rework. In our clients'

experience, EPA has difficulty defining up front what information it needs to override its default assumptions about releases and exposures.

EPA reorganized OPPT in 2020. The key functions that support new chemicals review, including chemistry, risk assessment, and risk management, were moved into a single division, reporting to a single division director in the OPPT New Chemicals Division. This reorganization does not seem to have had a material effect on the efficiency of PMN reviews, but there may be other factors at play.

f. SNURs on Existing Chemicals

As we discussed last year, in 2020, EPA announced in the *Federal Register* the availability of a draft compliance guide that outlines which imported articles are covered by EPA's July 2020 long-chain perfluoroalkyl carboxylate (LCPFAC) SNUR. On January 19, 2021, EPA issued the draft in final. On June 10, 2021, EPA announced the withdrawal of the guidance. In withdrawing the guidance, EPA cited to the Biden-Harris Administration's EOs and other directives, including those on EJ, scientific integrity, and regulatory review. As reported in our January 20, 2021, blog item, EPA issued the compliance guide in January 2021 in the last days of the previous Administration and limited what would be considered a "surface coating" subject to the SNUR. EPA stated in the June announcement that "[t]he guide was never deemed necessary by career staff and its development was directed by political officials serving in the last Administration." Additionally, EPA prepared the final guide without considering or addressing comments submitted by the public. After further review, EPA "determined that the guide inappropriately narrowed the scope and weakened the prohibitions included in the SNUR."

EPA previously proposed SNURs on several groups of existing chemicals, including nonylphenols and nonylphenol ethoxylates and toluene diisocyanates. Because of the workload associated with the "First 10," "Next 20," and MRREs, risk management actions on the "First 10" chemicals, and ongoing work on PFAS, we, again, believe it is unlikely that EPA will act further on these and other long-dormant SNURs in 2022.

WEBINAR ON DEMAND

PFAS Reporting Rules — What Every Company Needs to Know

6. Sections 8 and 14 — Reporting and Confidential Information

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

On June 28, 2021, EPA published in the *Federal Register* a proposed rule to require one-time reporting for PFAS manufactured (including imported) after January 1, 2011. This is in furtherance of a requirement under Section 7351 of the National Defense Authorization Act (NDAA) for FY 2020 that amended TSCA Section 8(a) to require EPA to, not later than **January 1, 2023**, promulgate a rule requiring each person who has manufactured a PFAS chemical in any year since January 1, 2011, to submit to EPA a report that includes, for each year since January 1, 2011, the information described in TSCA Section 8(a)(2)(A)-(G).

EPA's proposed PFAS rule would require all manufacturers, including importers, of PFAS in any year since 2011 to report information related to chemical identity, categories of use, volumes manufactured and processed, byproducts, environmental and health effects, worker exposure, and disposal. PFAS is defined in the rule as any substance including at least two fluorine atoms on one saturated carbon and at least one fluorine on an adjacent saturated carbon, with neither carbon bound to a hydrogen. The proposed deadline for reporting PFAS data to EPA is one year following the effective date of the final rule. Manufacturers would need to report information that is "known or reasonably ascertainable," a standard untested and not well defined in the proposed rule where reporting is required for substances that are imported as part of articles. Of particular note, the manufacture of PFAS as a byproduct, impurity, or polymer would not be exempt for the purpose of the proposed rule. Furthermore, there is no *de minimis* threshold either, and articles containing PFAS imported into the United States are not exempt. Additionally, EPA included no exemption or special treatment for small manufacturers.

Although EPA provided no exemptions in the proposed rule, we anticipate that in accordance with TSCA Section 8(a)(5) and taking into account comments received on the proposal, EPA will focus better its final rule on those manufacturers most likely to have the requested information and refine the action to minimize impact on small manufacturers. In developing the rule in final and in its implementation, EPA should work with stakeholders to ensure its data gathering efforts are prioritized and well understood.

The 2024 Chemical Data Reporting cycle might lead to another significant tranche of declassification if numerous reporters decline to maintain the confidentiality of chemical identities.

b. Section 8(a) — CDR Rule

EPA completed the 2020 CDR reporting cycle and has been in the process of data quality checks. It is not clear when EPA will publish the updated CDR information to its Chem-View site.

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 be expected in **late 2022 to early 2023**. Given the policy changes this Administration is employing in risk evaluation, however, as discussed above, it is anticipated that these deadlines will not be met and the completion of the risk evaluations for the "Next 20" high-priority chemicals may not occur until after 2022.

c. Procedures for Submitting CBI

According to the Fall 2021 Regulatory Agenda (2070-AK68), EPA "is considering proposing new and amended rules" on the assertion and maintenance of CBI claims under TSCA. EPA states that it "is considering procedures for submitting and supporting such claims in TSCA submissions, including substantiation requirements, exemptions, electronic reporting enhancements, and maintenance or withdrawal of confidentiality claims." EPA states further that it "is also considering whether the proposed rule should also elaborate on EPA's procedures for reviewing and communicating with TSCA submitters about confidentiality claims." A proposed rule is planned for **April 2022**.

d. CBI Inventory Review Rule

TSCA Section 8(b) requires EPA to issue a rule on CBI claims for specific chemical identities for chemicals reported as "active" in U.S. commerce under the TSCA Inventory Notification (Active-Inactive) Requirements Rule. 82 Fed. Reg. 37520. On March 6, 2020, EPA issued a final rule on the procedures for companies to substantiate their CBI claims for the specific chemical identities of substances on the TSCA Inventory, as well as the plan for how the Agency will review the claims, the timeframes for EPA to complete reviews, and the annual posting of results. 85 Fed. Reg. 13062.

As a result of EPA reviewing 2016 and 2020 CDR reporting, along with the Form A reporting, EPA proposed to declassify 377 substances listed on the confidential portion of the Inventory. EPA will, presumably, continue to declassify substances in the coming years, probably a few at a time, as a result of specific submissions until the **2024** CDR cycle. The **2024** CDR cycle might lead to another significant tranche of declassification if numerous reporters decline to maintain the confidentiality of chemical identities.

e. Unique Identifier Implementation

Under TSCA Section 14(g)(4), when EPA approves a CBI claim for specific chemical identity, EPA is required to:

- Assign a unique identifier to that chemical identity;
- Apply this unique identifier 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 unique identifier while the specific chemical identity of the chemical substance is protected from disclosure.

EPA's approach for assigning and applying unique identifiers can be found here.

Additionally, TSCA Section 14(g)(4) requires EPA to "annually publish and update a list of chemical substances, referred to by their unique identifiers, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim." On December 18, 2019, EPA published a list of unique identifiers assigned to chemical substances for which EPA has approved a confidentiality claim for spe-

cific chemical identity since the enactment of the TSCA amendments. EPA has not published an updated list as of late-December 2021. At that time, EPA had assigned 449 unique identifiers to substances on the confidential portion of the Inventory. This file is, arguably, duplicative of the TSCA Inventory, so EPA may not be keeping it up to date. The most recent copy of the TSCA Inventory (August 2021) has 684 unique identifiers, the most recent of which are dated 2020. There may be an explanation for why unique identifiers were not assigned to additional chemicals, but it may also be the case that EPA has not been keeping up with assigning unique identifiers. EPA is, presumably, assigning unique identifiers to substances as it reviews CBI claims on Notices of Commencement (NOC).

f. Mercury Reporting Rule

As required under TSCA Section 8(b)(10)(D), on June 27, 2018, EPA published a final rule that requires reporting every three years from any person who manufactures (including imports) mercury or mercury-added products, or otherwise intentionally uses mercury in a manufacturing process (including persons traditionally not subject to TSCA, such as persons who process mercury in the manufacture of pharmaceuticals and pesticides). 83 Fed. Reg. 30054. The information collected through the reporting requirements is for use in EPA's development of inventories of mercury supply, use, and trade in the United States, as required under TSCA Section 8(b)(10)(B). On April 2, 2020, EPA announced the availability of the first triennial Mercury Inventory Report based on information submitted under the mercury inventory reporting rule. 85 Fed. Reg. 18574. Based on the information collected, EPA is to identify any manufacturing processes or products that intentionally add mercury and recommend actions to achieve further reductions in mercury use, as required under TSCA Section 8(b)(10)(C).

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). EPA states that the rule is effectuating the vacatur ordered by the Second Circuit by making necessary amendments to the corresponding text in 40 C.F.R. Section 713.7(b). The final rule was effective on December 8, 2021. EPA states in its November 2, 2021, press release that the final rule "offers impacted communities adequate notice of the amended reporting requirements, as the deadline for reporting 2021 data is **July 1, 2022**." EPA states additionally that it will update the mercury inventory reporting rule compliance guide and other supporting materials to reflect these new reporting requirements.

The next reporting cycle will be in 2022 based on mercury information for calendar year 2021. 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 June 29, 2021, EPA issued a final rule under TSCA Section 8(d) that required manufacturers and importers of the "Next 20" high-priority substances and 30 organohalogen flame retardants (OFR) to submit lists and copies of unpublished health and safety studies to EPA. The effective date of the rule was July 29, 2021, and the original sunset date (*i.e.*, list/study submission deadline) was September 27, 2021. EPA subsequently amended the sunset date to December 1, 2021, for the 20 high-priority substances and to **January 25, 2022**, for the 30 OFR substances.

The TSCA Section 8(d) rule requires persons (*i.e.*, manufacturers and importers) who proposed to or have manufactured or imported any of the 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 on using the information obtained on the 20 high-priority substances with informing its risk evaluations under TSCA Section 6.

EPA intends on 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 of the information received with its evaluations of new chemical substances (*e.g.*, analog read-across and category development), under TSCA Section 5.

EPA seeks to build on Chemical Data Reporting (CDR) to develop a pool of chemicals from which it will identify chemicals for prioritization.

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. B&C anticipates that EPA may, in the interim, use this seemingly backward approach, however, B&C expects that EPA will ultimately reach a point where it uses its information gathering authorities, including under its planned tiered data reporting rule, discussed below, under TSCA Sections 8(a) and 8(d) before issuing TSCA Section 4 test orders. After all, this approach would allow EPA to identify the universe of available information on existing chemical substances and to identify data needs, prior to issuing TSCA Section 4 test orders.

EPA worked with the TSCA Section 4 Interagency Testing Committee (ITC), established under TSCA Section 4(e), to facilitate the collection of the information. The ITC discussed and recommended adding these chemicals to the Priority Testing List (PTL) in May 2020 at the request of EPA for the 20 high-priority chemicals and CPSC for the 30 OFR substances to obtain the health and safety information to inform risk evaluations each agency is required to conduct pursuant to its respective statutory programs. When the ITC adds chemicals to the PTL, those chemicals can be added to the Section 8(d) "model" reporting rule at 40 C.F.R. Part 716 via expedited procedures under the rule. (A similar expedited rulemaking procedure exists for requiring the reporting of use and exposure-type information under the TSCA Section 8(a) Preliminary Assessment Information Reporting rule at 40 C.F.R. Part 712.)

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

EPA convened a public webinar on July 27, 2021, to engage with stakeholders on the development of a proposed TSCA Section 8 rule to implement a tiered data collection strategy intended to inform EPA's TSCA Section 6 prioritization, risk evaluation, and risk management activities for chemical substances or mixtures. EPA currently collects certain exposure-related data through the TSCA CDR process, and EPA is exploring a data reporting rule that is tiered to specific stages of the TSCA existing chemicals program: identifying a pool of substances as potential candidates for prioritization; selecting candidate chemicals for and completing the prioritization process; and assessing high-priority substances through a risk evaluation that may be followed by risk management actions (depending on the outcome of the risk evaluation). EPA states that feedback from the public webinar and comments received will help inform its development of a proposed rule.

The slides from EPA's July 27, 2021, webinar are posted online. EPA seeks to build on CDR to develop a pool of chemicals from which it will identify chemicals for prioritization. EPA also seeks to integrate multiple collection authorities in a systematic and comprehensive manner. EPA states that it believes that TDR will reduce reporting of certain data elements under CDR to focus on exposure-related elements.

TSCA Section 8(a) allows EPA to require reporting from manufacturers (including importers) and processors. (CDR is an example of a Section 8(a) rule.) TSCA Section 8(c) requires manufacturers, processors, and distributors to maintain and, upon request, submit to EPA information such as significant adverse health effects, consumer allegations, occupational disease or injury, and complaints of injury to the environment. (EPA's TSCA Section 8(c) implementing regulations apply to manufacturers (including importers) and certain processors.) TSCA Section 8(d) requires manufacturers, processors, and distributors to submit to EPA study information that is known or reasonably ascertainable, including lists of health and safety studies and, upon request, copies of such studies.

According to EPA, TDR would supplement quadrennial CDR. EPA envisions the following stages:

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

reporting. Members of this conditions of use pool would either be taken forward to the Prioritization Data Set stage or returned to the overall CDR pool;

- Prioritization Data Set: EPA would collect additional conditions of use data to determine whether a chemical should be designated as 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 a need for information to support its TSCA prioritization, risk evaluation, and risk management activities and has the authority under TSCA Section 8 to gather much needed information. The tiered reporting framework, if focused well, can support EPA and minimize impacts on industry. According to the Fall 2021 Regulatory Agenda (2070-AK62), EPA plans to issue a proposed TDR rule in **July 2022**.

7. 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 implementation efforts. The TSCA Fees Rule (40 C.F.R. 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 ECAs; 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 proposed updates include:

- Regarding EPA-initiated risk evaluations, narrowing the scope of the TSCA Fees Rule by exempting from the requirement to pay fees importers of articles containing a chemical substance, companies that produce a chemical as a byproduct or manufacture or import as an impurity, companies that manufacture or import a chemical in *de minimis* amounts, companies that manufacture or import chemicals solely for research and development (R&D) purposes, and companies that produce a chemical as a non-isolated intermediate;

- Using cost data gathered over the past two years, instead of estimates, to update the fee calculations;

- A production (and import)-volume based fee allocation and the inclusion of export-only manufacturers for EPA-initiated risk evaluations;

- Allowing for corrections to be made to the list of manufacturers subject to fees for EPA-initiated risk evaluations after the final list is published, ensuring the accuracy of the list;

- Increasing flexibility for companies by extending the amount of time to form consortia to share in fee payments;

- Ensuring that EPA can fully collect fees and enabling companies to prepare better for paying fees by allowing payments in installments for EPA-initiated evaluations and MRREs; and

- Adding three new fee categories; two associated with new chemicals activities and one with test orders.

More information on the January 2021 proposed rule is available in our December 30, 2020, memorandum, "EPA Intends Proposed Rule to Increase Flexibility and Reduce Burdens under TSCA Fees Program."

On November 23, 2021, EPA announced a statutorily required triennial adjustment to fees based on inflation as reflected by the Producer Price Index (PPI). The new fees went into effect on January 1, 2022. This required fee adjustment is independent of the changes in fees that might arise from the final Fees Rule. In the November 23, 2021, announcement, EPA stated also that, "in 2022, EPA plans to propose additional revisions to the 2018 TSCA fees rule to supplement the agency's proposal from January 11, 2021 to ensure that TSCA fee amounts capture up to 25% of the actual costs of TSCA activities, fees are distributed equi-

tably, and fee payers are identified through a transparent process." According to the Fall 2021 Regulatory Agenda (2070-AK64), EPA plans to issue the supplemental proposed rule in **February 2022**.

8. Section 26 — Scientific Standards

a. Multiple-Path Particle Dosimetry

On March 23, 2021, EPA's Office of Research and Development (ORD) announced its plan to convene an external peer-review panel to review the draft Multiple-Path Particle Dosimetry (MPPD) Model Software (MPPD EPA 2021 v.1.01) and Technical Support Documentation and User's Guide (External Review Draft). The MPPD model is a NAM that is used to translate observed effect levels from exposures in experimental animals to human equivalent concentrations. It is widely used for inhalation dosimetry in the peer-reviewed literature and in government assessments.

The draft MPPD EPA model includes more recent features that represent the best available science in dosimetry modeling (*e.g.*, mechanistic descriptions and the ability to predict retained dose). Moreover, EPA's external peer review of this model, which was held in May 2021, will aid with meeting the scientific standards under Section 26(h) of TSCA and facilitate its use in quantitative risk assessments performed under TSCA Sections 5 and 6.

B&C notes that EPA used the public version of the MPPD model for refining its draft chemical categories on surfactants and poorly soluble, low toxicity (PSLT) polymers in 2021. Prior to making these refinements, B&C expressed concerns to EPA when it first issued these draft chemical categories in 2017. Therefore, B&C commends EPA for refining these draft chemical categories and ensuring that they meet the scientific standards under TSCA Section 26.

B&C anticipates a variety of activities on new and existing chemical substances once EPA finalizes the MPPD EPA model and the chemical categories on surfactants and PSLT polymers. For example, persons whose new chemical substances were regulated *via* SNURs based on the 2017 draft chemical categories 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 SIA submitted a request for correction (RFC) of information to EPA under the Information Quality

Table 4. Example of EPA's assumed input parameters versus SIA's proposed input parameters

EPA input parameters			
Work Activity	Scenario	Duration of Liquid Contact (hours)	Skin Surface Area Exposed (cm^2)
Semiconductor manufacturing — Container handling, small containers	Central Tendency	6	445 (female) 535 (male)
	High-end	12	890 (female) 1,070 (male)
SIA proposed input parameters			
Work Activity	Scenario	Duration of Liquid Contact (hours)	Skin Surface Area Exposed (cm^2)
Semiconductor manufacturing — Container handling, small containers	Central Tendency	0.33	20.03 (female) 24.08 (male)
	High-end	1.0	66.75 (female) 80.25 (male)

EPA will promulgate a rule requiring manufacturers, importers, and processors to report on their uses of asbestos and asbestos-containing articles, including as an impurity, under TSCA Section 8(a). The rule is due by December 2022.

Act (IQA). SIA's RFC focused on EPA's final risk evaluation on NMP and its use in the semiconductor industry. EPA concluded that the use of NMP in the semiconductor industry presents an unreasonable risk to workers. 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." For example, EPA made assumptions about the skin surface area exposed to NMP and the dermal contact time that did not comport with the data SIA provided EPA (Table 4).

As of late December, EPA has not provided a response to SIA's RFC. If EPA denies SIA's RFC, it may rely on a general justification (*e.g.*, uncertain representativeness of the data). EPA may also deny a request for reconsideration (RFR) using the same general justification, if SIA chooses to submit an RFR. EPA's continued reliance on default assumptions is troubling. B&C recognizes that EPA's defaults are appropriate when information is lacking to inform specific parameters. SIA, however, went to great lengths to educate EPA about its members' practices, including providing extensive amounts of information and data, which EPA rated as high quality.

9. Section 21 — Litigation and Petitions

In 2021, the parties in a U.S. District Court for the Northern District of California case arising from EPA's dismissal of TSCA Section 21 petitions regarding asbestos agreed to settle. *ADAO et al. v. Wheeler et al.* (No. 3:19-CV-03807-EMC; No. 19-cv-00871-EMC). On December 22, 2020, after full briefing and oral argument, the court granted plaintiffs' motion for summary judgment, directing EPA to address the following loopholes in the CDR scheme that prevent EPA from receiving "reasonably available information" on asbestos: (1) the asbestos-containing articles exemption; (2) the impurities exemption; and (3) the processors exemption. In February 2021, EPA filed a motion to amend the court's order to vacate a specific instruction that EPA amend the CDR rule. The plaintiffs opposed EPA's motion, arguing that TSCA Section 21(b)(4)(A) authorizes the court to direct EPA to initiate a rulemaking. The parties agreed to settle the case on June 7, 2021. Under the settlement agreement, EPA will promulgate a rule requiring manufacturers, importers, and processors to report on their uses of asbestos and asbestos-containing articles, including as an impurity, under TSCA Section 8(a). The rule is due by **December 2022**. According to the Fall 2021 Regulatory Agenda (2070-AK99), EPA plans on publishing a proposed rule in **March 2022** and a final rule in **November 2022**.

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. The September 7, 2021, joint status report states that the National Toxicology Program (NTP) expects the final draft of its systematic review will be published in **early 2022**. A status conference is scheduled to be held **January 18, 2022**.

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 Caro-

lina. 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.

The petitioners filed suit on March 3, 2021, in the U.S. District Court for the Northern District of California, asking the court to reverse EPA's decision. *Center for Environmental Health et al. v. EPA et al.* (No. 4:21-cv-01535). On September 29, 2021, the court ordered the case placed in abeyance for 90 days pending EPA's reconsideration of the TSCA Section 21 petition. More information on the petition is available in our October 29, 2020, memorandum, "TSCA Section 21 Petition Seeks Section 4 Test Rule for 54 PFAS." More information on EPA's denial is available in our January 26, 2021, blog item, "EPA Denies TSCA Section 21 Petition Seeking Section 4 Test Rule for 54 PFAS."

On February 8, 2021, EPA received a petition seeking Resource Conservation and Recovery Act (RCRA) and TSCA regulatory action for phosphogypsum and process wastewater from phosphoric acid production (process wastewater). Under TSCA Section 21, petitioners request that EPA initiate the prioritization process to designate phosphogypsum and process wastewater as high-priority substances for risk evaluation under TSCA Section 6, issue a TSCA Section 4 test rule for disposed phosphogypsum, and issue a SNUR under TSCA Section 5 for phosphogypsum used in road construction. EPA published its response on May 21, 2021, to a portion of the petition.

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

86 Fed. Reg. 27546. While the petition requested three actions related to TSCA, EPA determined that only one of those actions is an appropriate request: a request to issue a test rule under TSCA requiring testing of phosphogypsum and process wastewater from phosphoric acid production. According to the notice, EPA is treating the other portions of the petition involving TSCA as a petition under the Administrative Procedure Act (APA). EPA states that "[a]fter careful consideration," it has denied the TSCA Section 21 portion of the petition, finding that the petitioners have not met their burden as defined in TSCA Sections 4(a)(1)(A) and 21(b)(1) because they have not provided the facts necessary to determine that existing information and experience are insufficient and testing is necessary to develop such information. More information is available in our March 12, 2021, memorandum, "EPA Receives Petition Seeking RCRA and TSCA Regulatory Action for Phosphogypsum and Process Wastewater" and in our May 25, 2021, blog item, "EPA Responds to Petition Seeking RCRA and TSCA Regulatory Action for Phosphogypsum and Process Wastewater."

On August 2, 2021, EPA received a TSCA Section 21 petition seeking a rule requiring cigarette manufacturers to eliminate the hazardous chemicals used and to develop new product designs that eliminate or reduce the cigarette butt disposal risks to the environment. EPA announced its response on October 29, 2021. 86 Fed. Reg. 59931. EPA notes that TSCA Section 3(2)(B), which defines "chemical substance," excludes "tobacco or any tobacco product." EPA states that it finds that the petitioner has not met its burden as defined in TSCA Sections 6(a) and 21(b)(1) "because cigarettes are not a product that can be regulated under TSCA section 6(a)." More information is available in our October 5, 2021, blog item, "EPA Receives TSCA Section 21 Petitions Regarding Chemical Mixtures in Cigarettes and Cosmetics," and in our November 8, 2021, blog item, "EPA Denies TSCA Section 21 Petition Regarding Chemical Mixtures in Cigarettes."

EPA received a TSCA Section 21 petition on August 16, 2021, seeking a determination that the chemical mixtures contained within cosmetics present an unreasonable risk of injury to public health and the environment. The petition asks that EPA order by rule that cosmetic manufacturers eliminate hazardous chemicals used in mixtures, stating that examples include formaldehyde, paraformaldehyde, methylene glycol, quaternium 15, mercury, dibutyl and diethylhexyl phthalates, isobutyl and isopropyl parabens,

long-chain PFAS, and m- and o-phenylenediamine. EPA announced its decision to deny the petition on November 17, 2021. 86 Fed. Reg. 64129. EPA states that to the extent the petition seeks a TSCA Section 6 action on "cosmetics" when manufactured, processed, or distributed in commerce as cosmetics, the requested actions are not within its jurisdiction under TSCA. In addition, according to EPA, to the extent the petition seeks action on "chemical substances" within the TSCA Section 3(2) definition of that term, EPA finds that the petition did not set forth facts establishing that it is necessary for EPA to initiate an appropriate proceeding pursuant to TSCA Section 21. More information is available in our November 19, 2021, blog item, "EPA Denies TSCA Section 21 Petition Seeking the Elimination of Hazardous Chemicals Used in Mixtures in Cosmetics."

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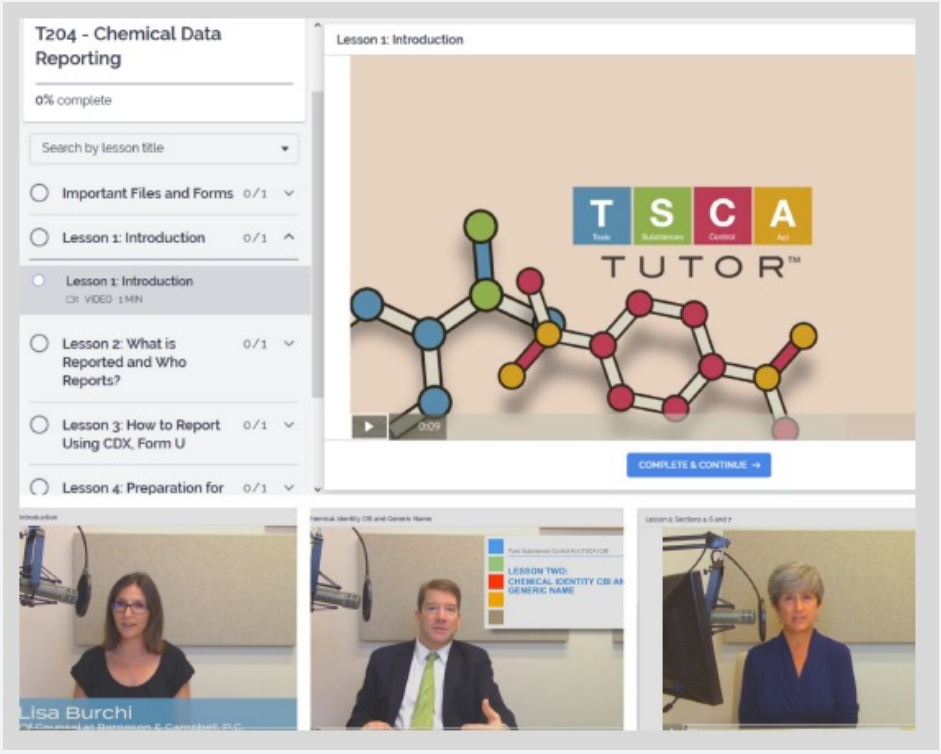

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C. FIFRA: PREDICTIONS AND OUTLOOK FOR OCSPP'S OFFICE OF PESTICIDE PROGRAMS

For EPA's Office of Pesticide Programs (OPP), 2021 was a full year of working from home while addressing ongoing priorities; continuing the march toward meeting the 2022 deadline for registration review of pesticides registered before 2006; attempting to comply with the requirements of ESA; and meeting Pesticide Registration Improvement Act (PRIA) deadlines for registration applications. Under the Biden Administration, OPP renewed its focus on EJ and its commitment to protect pollinators, address chlorpyrifos use on food, and tackle pest management issues exacerbated by climate change.

OPP also continued to focus on responding to the COVID-19 pandemic, since disinfectants against COVID-19 and other coronaviruses are reviewed and approved by EPA under FIFRA. In 2020, the surge in applications for such disinfectant products caused EPA to reallocate resources and personnel to meet the critical need for timely review of products designed to help control pandemic risk. Having met that challenge, OPP has largely resumed its regular operational process that should be the programmatic norm we see in 2022.

With the Biden Administration's first year in office completed, the EPA political leadership team in position, and with its first full budget cycle for FY 2022 in place, look for OCSPP to continue to place a heavy emphasis on TSCA implementation in the New Year. OPP is expected to focus on long-standing challenges, especially a renewed effort to meet ESA consultation requirements and to meet core pesticide registration review obligations.

Other program priorities will include ensuring that regulatory actions include special considerations for EJ and climate change, advancing critical science and policy issues, working toward a fifth PRIA implementation framework, and a renewed commitment to working collaboratively with state partners and other stakeholders to implement the program.

WEBINAR

Register now for B&C's upcoming webinar FIFRA Hot Topics, March 16, 2022, 12:00 p.m. EDT

With budget increases, new hiring authority, and full OCSPP office consolidation in downtown Washington, D.C. (having moved from Crystal City, Virginia), staff morale improvements and system upgrades aim for meaningful program progress. The pesticide program has its own deadlines and controversies, of course, and the major issues facing the program in 2022 are likely to include the topics discussed below.

1. Climate Change and Pesticides

Addressing climate change is an all-of-government goal of the Biden Administration, and especially at EPA. In his first week in office, President Biden 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 will likely result in changes in where crops are grown and in the presence of pests and diseases: "As pests move into new areas, pest management practices and application of pesticides may expand. This may lead to more chemicals present in soil and water. Chemical safety may be affected by changing chemical use patterns resulting from climate change. An increase in the frequency of new pest problems could trigger requests for emergency exemptions under [FIFRA] if currently registered pesticides are ineffective."

According to EPA and the Centers for Disease Control and Prevention (CDC), the development and survival of ticks, their animal hosts (such as deer), and the bacterium that causes Lyme disease are all strongly influenced by climatic factors, especially temperature, precipitation, and humidity. An expansion of the geographic area in which ticks can survive may lead to more people having contact with infected ticks. In regions where Lyme disease already exists, milder winters result in fewer disease-carrying ticks dying during winter. This can increase the tick population, thus increasing the risk of contracting Lyme disease in those areas. West Nile virus is another example of a vector-borne disease influenced by climate change. Preventing people from contracting West Nile virus is important because there are no medications to treat, or vaccines to prevent, this virus in humans, and recovery from severe disease may take several weeks or months. An increase in mosquitoes and ticks is a good example of pests that may thrive with climate change, and OPP may focus on these sorts of climate change public health concerns in 2022.

Extreme heat caused by climate change will also be an important policy consideration in 2022 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 (IWG) on Extreme Heat to develop and coordinate a holistic response on the issue. Recommendations from the Working Group are expected in 2022.

According to EPA, pesticides can impact climate change throughout their manufacture, transport, and application. Pesticide manufacture emits three main greenhouse gases: 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 2022, 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 play 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.

ARTICLE

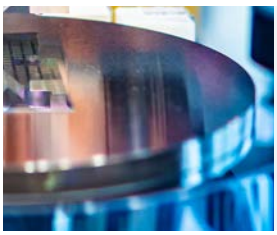
"The essential role of evolving technologies in securing a safe and sustainable food supply," *Agricultural Law Section of the International Bar Association,* June 1, 2021.

2. Environmental Justice and Pesticides

EJ is a much noted priority issue for the Biden Administration and EPA. In 2022, EJ will 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 is that 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, EPA announced the establishment of a new $100 million EJ program office to be led by a new political appointee. With a renewed focus on EJ issues, and an updated EJ strategic plan, each EPA program office plays an integral part in fulfilling the Agency's mission



The Office of Pesticide Programs is committed to making Environmental Justice a critical component of its work and is currently carrying out several initiatives.

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: "Strengthening 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. For example, OPP is researching how to compare shallow private drinking water well locations in high agricultural areas to urban settings, and to understand better pesticide exposure through drinking water for these populations. OPP is also 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 2022.

EPA improved risk communication in 2020 and 2021 by expanding the Agency's 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, and provides a resource for pesticide registrants that choose to display parts of their pesticide product label in Spanish. EPA generally allows pesticide registrants to translate product labels into any language as long as there is an EPA-accepted English version of the label and 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. Look for more initiatives like this in 2022.

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, 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 2022.

3. COVID-19 Pandemic

The COVID-19 pandemic was especially impactful on EPA's pesticide program. Certain disinfectants with pesticide claims (*e.g.,* to kill viruses such as those that cause COVID-19) must be registered with EPA as pesticide products. Other machines that work by physical means (*e.g.,* Ultra Violet C (UVC) light devices and ozone-generating devices) with pesticide claims that do not contain any substances that perform the intended pesticidal purpose of the machine are considered pesticide devices. While these devices do not require registration, EPA regulates them under FIFRA. OPP revised and adapted various policies and accelerated review efforts to help users evaluate and have access to effective products to help control the virus in home and work settings. For 2022, COVID-19 product reviews in OPP are expected to decrease from the large numbers of those reviews, often conducted on an expedited

ARTICLE

"Pesticides, Chemical Regulation, and Right-to-Know, 2020 Annual Report" in The Year in Review 2020: Environment, Energy, and Resources Law, American Bar Association (2021).

basis, in 2020 and early 2021, that will allow OPP to focus on other core program priorities.

Starting in March 2020, OPP received and reviewed applications for hundreds of products and evaluated product claims for products that were registered before COVID-19 was discovered. EPA created and posted online a list of products — List N — that EPA expected, based on available data, to kill the coronavirus SARS-CoV-2 (COVID-19) when used according to the label directions. List N was used as a reference by the CDC and other health agencies. By the fall of 2021, EPA had completed over 300 expedited actions in response to COVID-19. Today, EPA's List N contains over 570 disinfectant products, and the List N website has been viewed tens of millions of times.

Among other COVID-19 activities, EPA completed laboratory efficacy testing of many List N products and other chemistries against human coronavirus strain 229E and SARS-CoV-2; registered copper surfaces for residual long-term effectiveness against coronaviruses on a wide range of surfaces, including doorknobs and handrails; issued emergency exemptions to six states for an indoor air treatment and three states for a product used on airlines; revoked emergency exemptions issued to Texas and Arizona for the product SurfaceWise2 due to alleged company misconduct and scientific concerns regarding product performance; approved the first disinfectant for alpha and beta variants of COVID-19; and hosted a webinar on best practices for disinfecting schools and day care centers.

OPP also updated its disinfectant policy. In April 2021, CDC announced that the risk of being infected with COVID-19 by touching contaminated surfaces is considered low. Based on this announcement, EPA stopped prioritizing public health emergency requests for new products that address surface transmission of SARS-CoV-2. EPA continued to devote resources to expedite applications for products with novel COVID-19 claims, such as killing of airborne SARS-CoV-2.

OPP additionally issued interim guidance and associated test methods for registering products that claim to have "residual" or "long-lasting" efficacy claims against SARS-CoV-2; terminated temporary guidance for protective equipment (*e.g.*, respirators, amendments to Pesticide Registration Notice (PRN) 98-10) due to return to adequate supplies following shortages in FY 2020 because of COVID-19; and initiated American Society for Testing and Materials (ASTM) review processes for a draft method for quantitative testing of antimicrobial products following extensive stakeholder collaborations.

In 2021, pesticide devices have been a focus of EPA's attention, particularly those that make claims regarding SARS-CoV-2. While pesticide devices do not require registration, other FIFRA requirements are applicable, including but not limited to certain label requirements and the requirement to be produced in a FIFRA registered establishment. While pesticide devices have been subject to FIFRA jurisdiction since FIFRA was enacted, EPA has focused intensely on compliance with pesticide device requirements, particularly label and claim requirements, for those devices that claim to kill SARS-CoV-2 and other bacteria and viruses.

In 2020 and 2021, EPA responded and addressed a variety of issues related to device requirements, with particular attention on the types of claims these devices can make and the efficacy data required to support those claims. Actions taken by EPA included the issuance of a Compliance Advisory regarding "UV Lights that Claim to Kill or Be Effective Against Viruses and Bacteria" and the initiation of research efforts to understand how different devices can reduce the amount of SARS-CoV-2 on surfaces. Even if the number of pesticide devices to be sold and distributed may decline in 2022, EPA is likely to continue its efforts to address the issues and uncertainties that have been raised as they relate to compliance with pesticide device requirements.

Putting aside other work, pulling resources from other divisions (disinfectants are reviewed in OPP's Antimicrobials Division (AD)), and working remotely as COVID-19 protective measures were imposed, the program staff was able to respond to the crush of disinfectant applications while generally continuing the bulk of its work for agricultural and other pesticides. Though PRIA deadlines are often renegotiated, the program has been able to keep up with its workload without any significant increase in budget or staff. Unless there is a new variant or outbreak of COVID-19, expect OPP increasingly to shift resources back to core PRIA review and other Biden Administration priorities.

4. Import Enforcement

Importers of pesticides and devices are required to comply with regulations set forth by EPA and the U.S. Customs and Border Protection (CBP). These requirements include providing information set forth in EPA's Notice of Arrival (NOA) form and providing copies of pesticide and device labels. In 2021, EPA Regions across the United States focused

on reviewing import documentation for pesticide products and devices. These reviews resulted in what appears to be an increase in enforcement actions, whether through issuances of Notices of Detention, Notices of Refusal of Admission (NORA), Stop Sale, Use, or Removal Order, and/or penalties. Part of EPA's interest can be traced to the pandemic, as EPA stated in its Compliance Advisory regarding "What You Need to Know Regarding Products Making Claims to Kill the *Coronavirus*[1] Causing COVID-19 (UPDATE)" that it was receiving a "steady stream of tips/complaints concerning potentially false or misleading claims, including efficacy claims, associated with pesticides and devices." EPA Region 2's press release in October 2020, for example, noted it had issued 29 Advisory Letters and eight Notices of Warning, and issued 52 NORAs to address pesticide products and devices that were found to be marketed with unsubstantiated claims of efficacy against the coronavirus that causes COVID-19 and other pathogens.

EPA's review of imported pesticides and devices was not limited to products making claims related to the coronavirus, however. EPA reviewed and compared labels submitted through import procedures with those EPA-approved labels on file. EPA considers label language that does not match with EPA-approved labels as "misbranding" violations of FIFRA Section 12(a)(1)(E), so any discrepancies between label versions could give rise to enforcement action.

EPA is expected in 2022 to continue to focus on imported pesticides and devices.

5. 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, since continual litigation challenges were first initiated during the Administration of George W. Bush. The pivotal question is how extensive EPA's assessment has to be to determine compliance with ESA, and how much autonomy EPA needs to make the critical decisions, and the degree to which any EPA assessment has to 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 have 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, which could ironically result in greater environmental risks to species compared to the products they would likely replace. 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, given the enormous costs involved in bringing a new product to the market. 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. In 2017, arrival of the Republican Administration and with Republican majorities in both the House and Senate, inspired hope that some more practical, or at least predictable, process for ESA compliance could be put into place.

The Trump Administration established an IWG 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 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 IWG helped to organize a senior level effort to coordinate activities of EPA and the Services, and like past efforts, at the senior management level there is a recognition that something needs to be done to fashion a more efficient and predictable process.

Currently, ESA reviews add months and years to the registration review process, and to date, that process is followed by seemingly inevitable litigation challenging EPA's decision as not sufficient to meet ESA requirements. Both the George W. Bush Administration and the Obama Administration tried similar efforts with limited success in getting the bureaucracies to understand better the work and mission of the individual agencies.

During the Trump Administration, there was also an attempt to find a legislation solution as part of the 2018 Farm Bill. The House version of the Farm Bill included amendments that would have incorporated the ESA requirement to prevent harm to threatened or endangered species as part of the definition of what is an "unreasonable adverse effect." This was strong language that was intended by its drafters to be added to FIFRA to protect species and break the gridlock between EPA and the Services. Nonetheless, the reception by environmental advocates was forceful and unequivocal — they would strongly oppose any amendments giving EPA the decision authority in this arena.

Even though these provisions were included in the legislation approved by the full House as part of the Farm Bill, the 2018 Senate-approved Farm Bill contains a much different approach to the issue of pesticides and ESA. The Senate bill received broad bipartisan support as the Senate approved a compromise Farm Bill that did not include the House ESA language and, in fact, did not contain any amendments to FIFRA or ESA. The language approved in the final legislation after the House-Senate legislative conference process essentially codifies the process for agencies better to coordinate and use the expertise of the respective agencies. It further specifies steps and timelines that the agencies must take to implement these goals over the next two to five years with reports submitted to the Agriculture Committees every six months. The bi-annual reports are intended to help keep the process on a "short leash," to prod the respective bureaucracies to find a solution to the problem.

EPA officials report that the interagency process has continued to make progress in improving coordination and designing a more predictable and efficient ESA review process. One product of this interaction was the publication in the *Federal Register* on May 16, 2019 (84 Fed. Reg. 22120) of a "draft revised method for conducting national level threatened and endangered (listed) species biological evaluations (BEs) for pesticides." *See* our May 16, 2019, blog, "EPA Issues Draft Revised Method for ESA Pesticide Assessments." Registrants and pesticide users have generally supported the EPA revised method, while environmental groups have viewed the changed approach as weakening species protections. In 2020, EPA started to use the revised method as part of registration decisions. Litigation continues, however, as environmental groups still view EPA as disregarding ESA requirements.

Expect in 2022 a 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, has been tasked *specifically* to focus on the ESA issue. EPA has stated that it plans to make significant progress on the scientific analysis used to conduct a BE. EPA has been clear that in 2022, EPA will pivot with an eye toward ways EPA can begin to identify and implement protections for listed species earlier so that they can be more aligned with ESA.

EPA will continue to work and consult with the Services and meet litigation-related commitments. EPA has stated that it has created cross-divisional initiatives to meet ESA obligations and intends to focus its efforts in 2022 on working with stakeholders to identify mitigations for protecting species in the short term and not wait for completion of the entire consultation process. EPA believes that there is a shared goal of protecting vulnerable species in a manner that is both effective and practical and ensures the availability and benefits of pesticides. In 2022, negotiations on a new Farm Bill will also begin in earnest; look for ESA process and programs — and progress — again as a possible topic in the legislation.

ESA litigation is ongoing, and the Biden Administration will have to continue efforts to coordinate, integrate, and improve the ESA-FIFRA review process. This will be important, as EPA will have to account for how it plans to incorporate ESA considerations as part of the registration reviews of existing pesticides due in 2022.

6. Trade Issues

An issue of increasing concern relates to international trade issues, often seen as an economic issue of trade deficits or indicators of the economic health of farm communities. Negotiations between the United States and its trading partners have long been concerned with moving toward relatively uniform or at least predictable phytosanitary policies and review procedures.

Of special concern has been the adoption and greater integration of the "precautionary principle" in the regulatory framework of U.S. trading partners, especially with members of the European Union (EU). The simple summary of

PODCAST:
What will the Biden Trade Plan look like? — A Conversation with Daniella Taveau

The concern of many stakeholders in agricultural production is that U.S. farm products could be disadvantaged or prohibited in certain markets for what is seen as little true risk.

this principle is that regulatory decisions should be made on the basis of possible hazards to consumers, with less, little, or no consideration of the estimated exposures to a compound. The explanation for imposing such a "precautionary" approach is based on the uncertainty of certain elements in a product's hazard profile, uncertainty as to who exactly may be exposed to specific levels of a chemical, and thus a decision that such exposures may have an effect that is difficult to estimate reliably. This approach runs counter to the approach traditionally used by EPA that estimates and compares the possible hazards of a product with expected exposures, and then calculates the estimated risk level (summarized as the familiar phrase: risk = hazard x exposure).

This difference in approaches has been an ongoing EU-U.S. trade policy discussion for many years. More recently, countries outside of the EU have moved toward a domestic policy stance similar to the EU. The concern of many stakeholders in agricultural production is that U.S. farm products could be disadvantaged or prohibited in certain markets for what is seen as little true risk.

In 2020, for example, Mexico announced its intention to prohibit residues of glyphosate in its food supply, that after surviving numerous lawsuits, will go into effect in **2024**. This could result in prohibiting a large volume of exports of corn and other crops that use glyphosate as part of their production in the United States. The specter of wider adoption of the precautionary principle among U.S. trading partners threatens a growing proportion of U.S. agricultural exports.

The Biden Administration is facing similar questions of what should be the appropriate policy on these and other issues relating to agricultural exports, and whether or how aggressively to continue U.S. opposition to such policies that may be adopted by other countries. To date, the Administration has raised issues with Mexico on its biotech acceptance actions under the U.S.-Mexico-Canada Agreement (USMCA), and as late as fall 2021 stated: "We will continue to press Mexico for compliance with the terms and conditions of the USMCA whether [it's] GE [genetically engineered] corn or whether it's glyphosate or other issues that separate us." Expect clarity of these trade issues in 2022.

The issue of establishing Maximum Residue Limits (MRL) is another long-standing issue of concern for U.S. growers and will continue to be so in 2022. Finding the resources to pay for the international meetings and international consideration of the scientific assessment of pesticide residues has been a problem in the past. Data generation protocols and evaluation methods have been subject to international coordination that also can be disrupted by lack of resources by the international bodies, leading to delays in the joint evaluations needed to establish international residue limits.

7. Chlorpyrifos

Chlorpyrifos is 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, and 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. EPA's past actions and decisions regarding the petition are described in more detail on B&C's Pesticide Law and Policy Blog® under key word chlorpyrifos. *See also* our March 30, 2017, blog item, "EPA Denies Petition to Ban Chlorpyrifos."

In response to what was described as EPA "inaction," Senator Tom Udall (D-NM) and others introduced legislation in 2017 and 2019 to eliminate chlorpyrifos uses (S. 1624 and S. 921, respectively). S. 1624 and S. 921 were notable as chemical-specific pesticide legislation calling for a ban of a specific pesticide, which Congress has generally been reluctant to do, and that had not occurred in some time. This signaled Congressional concern about a specific pesticide case and was thought by some to portend that chlorpyrifos, and/or potentially other pesticides, could become specific targets of Congressional action, at least if one or both chambers were under Democratic control with a Republi-

can President. It is less likely, but possible, such proposals will continue even with the Biden Administration in office.

The trail of litigation continued over the EPA response to the original petition; on July 19, 2019, the final order denying objections to EPA's 2017 response was signed by then Assistant Administrator Alexandra D. Dunn. In this order, published in the *Federal Register* on July 24, 2019 (84 Fed. Reg. 35555), the arguments denying the challenge to chlorpyrifos tolerances were more fully articulated. *See* our July 19, 2019, blog, "EPA Issues Final Order Denying Objections to EPA's March 2017 Order Denying PANNA's and NRDC's 2007 Petition to Revoke All Tolerances and Cancel All Registrations for Chlorpyrifos." EPA concluded that a renewed determination of the safety standard did not need to be completed until the registration review deadline for the pesticide in 2022. Later, the state of California became more involved in the chlorpyrifos debate by issuing cancellation notices for chlorpyrifos under California state law. *See* our August 16, 2019, blog, "California DPR Issues Cancellation Notices for Chlorpyrifos, and Establishes a Work Group to Recommend and to Develop Alternatives to Chlorpyrifos."

In February 2020, the largest manufacturer of chlorpyrifos, Corteva (formerly DowAgro), announced that it would end production and sale of the insecticide. There are other registrants of the pesticide, however.

Also in 2020, existing federal litigation continued to move through the courts, as the NGO petitioners continued to press the Ninth Circuit Court of Appeals to rule, in effect, to ban chlorpyrifos. Lawsuits have also been filed in California state courts against Corteva raising state law claims of negligence, failure to warn, and design defect. *Avila v. Corteva Inc.*, No. 20C-0311 (Cal. Super. Ct., Oct. 27, 2020); *Calderon de Cerda v. Corteva Inc.*, No. 20C-0250 (Cal. Super. Ct., Sept. 16, 2020).

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)). EPA intends to issue a Notice of Intent to Cancel under FIFRA to cancel registered food uses of chlorpyrifos associated with the revoked tolerances. The tolerances for chlorpyrifos will be revoked on **February 28, 2022**, six months after the final rule published on August 30, 2021, in the *Federal Register*. The rule was issued in response to the Ninth Circuit's order directing EPA to issue a final rule in response to the 2007 petition filed by PANNA and NRDC. After considering public comments, EPA will proceed with registration review for the remaining non-food uses of chlorpyrifos by issuing the interim decision by the **end of 2022**, which may consider additional measures to reduce human health and ecological risks.

New conclusions about the assessment of chlorpyrifos could 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. As a result, expect 2022 to include a high-profile discussion and heated debate on EPA's chlorpyrifos decision and process, with potential Congressional involvement and legal action, including implications of the chlorpyrifos decision for other organophosphates and FIFRA processes.

Arguments similar to the tolerance revocation petition regarding chlorpyrifos 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." In 2022, EPA will need to assess this Petition and comments filed in response to it.

8. Dicamba

As a result of the widespread use of glyphosate-resistant crops, certain weed species have evolved to withstand treatment with glyphosate, which has induced certain weed species to be resistant and have a significant impact on the 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 so 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.

First approved in 2016, EPA approved these low-volatility dicamba products for limited time periods to continue the evaluation of possible risks from off-target movement. In 2018, use of dicamba was approved for another two-year period, as reports of damage were evaluated and as EPA made additional changes to the label requirements and requirements for applicator training designed to further reduce the risk of drift, and evaluate whether reported incidents were reduced by the additional requirements.

These products were first used in the 2017 growing season, but sale of the genetically modified organism (GMO) seeds came before the approval of the new, lower volatility dicamba formulations. Many drift incidents were reported during the 2017 season. At the time, it was unclear whether the large number of incidents were caused by misuse (using the older, already-registered products), difficulty in following new application and stewardship requirements (*e.g.,* buffer zones, wind speeds), or unanticipated effects of the new formulations. In addition, the first approvals were time-limited and to continue use, needed to be renewed by the end of 2018.

In 2018, EPA announced that it was extending the registration of the new dicamba products for an additional two years. EPA added requirements intended to reduce the likelihood of drift problems, including additional training, timing, recordkeeping, and stewardship that EPA hoped would reduce or eliminate injury reports. Some of these requirements were more generally noteworthy, since they are not a type typically imposed as a condition of use, such as the requirements for increased training and stewardship by the registrants, requiring that all applicators must be certified applicators (not allowing use by applicators "under the supervision" of a certified applicator), and the time limit (two years) to the registration.

The time-limited registration provided EPA additional time to assess whether further changes to the registration might be necessary after reviewing injury reports. These include, for example, whether injury reports are mostly due to misuse (applicators who do not use the new formulations designed to reduce volatility, which is a label violation since the "old dicamba" product is considered more prone to cause drift injury) or are due to characteristics of the new formulations that are not yet fully understood and that lead to unexpected volatility and other drift problems. Some also have argued that problems are due to the difficulty (or reluctance) in following the more prescriptive requirements for the new formulations. The two-year renewal kept the new formulations on a "short leash" to let EPA closely monitor injury and misuse reports, as well as to allow continued academic and registrant research into the cause of reported problems before the next registration decision was made.

On October 27, 2020, EPA announced its approval of the low-volatility dicamba products for a five-year period. Based on its review of continued research, incident reports, and investigative reports from the states (states had varying reports of problems, including some with a relatively large number of reported incidents), EPA modified the label to allow continued use of the new formulations while continuing to reduce the likelihood of unintended drift and damage to nearby crops.

These additional restrictions included adding buffering agents to the tank mix to reduce expected volatility, large downwind buffers to protect adjacent crops and to protect endangered species, cutoff dates to avoid use in certain periods when the risk of drift may be greater (*i.e.,* conditions of high temperature or expected hot weather), and "simplified" instructions to help ensure the label instructions are able to be followed.

This 2020 approval was challenged by affected grower groups which argue that EPA overstepped its authority and that certain changes, particularly EPA's temporal dicamba application restrictions and spatial application buffers, are not needed to satisfy FIFRA's registration standard (*i.e.*, no unreasonable adverse effects to human health or the environment). *American Soybean Ass'n et al. v. EPA*, Case 1:20-cv-03190 (D.C. Dist. Court, Nov. 4, 2020) is somewhat novel, since while affected growers may be upset about decisions EPA has made about any number of pesticides, growers have not often filed lawsuits as the users of the pesticide.

As expected, the Biden Administration is reviewing the decision, although it was approved by EPA for a five-year period. On September 9, 2021, EPA sent letters to registrants of products containing dicamba for post-emergent

uses, with EPA emphasizing its requirements under FIFRA Section 6(a)(2): "If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator."

Currently, EPA is working with growers, state agencies, and other experts to evaluate the effectiveness of the current requirements. EPA convened a dicamba listening session on August 30, 2021, with the Weed Science Society of America, various academics, state agriculture extension agents, and the USDA. On September 2, 2021, the Agency held another listening session with the Association of American Pesticide Control Officials. In 2022, look for potentially significant activities for dicamba.

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.

In September 2020, EPA became aware of PFAS contamination of a mosquito control product used in Massachusetts. In December 2020, 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. In March 2021, EPA became 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.

In September 2021, 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 2022. If the issue is broader or more prevalent than currently understood, this could be an important area of focus for OPP and an issue to follow closely.

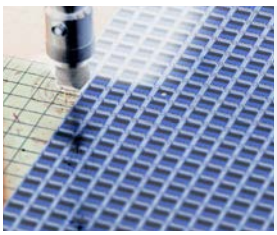
10. Pollinators

During the Trump Administration, there continued to be relatively slow movement on the subject of pollinators. EPA continued its work under initiatives announced in 2013 when it issued revised labeling requirements for neonicotinoid insecticides, eventually followed in 2015 by "EPA's Proposal to Mitigate Exposure to Bees from Acutely Toxic Pesticide Products."

The 2015 plan targeted pesticide use by those who use contracted pollinator services and included a list of pesticides (not only insecticides) to which the new labeling requirements would apply. EPA received comments from many grower groups and state pesticide officials critical of various elements of the proposal and did not issue a revised policy until January 12, 2017. *See* "EPA Releases Final Policy to Address Acute Risks to Bees from Pesticides and Three Pollinator-Only Risk Assessments for Neonicotinoid Insecticides." EPA described the 2017 "Policy to Mitigate the Acute Risks to Bees from Pesticide Products" as a revised approach that is "more flexible and practical" and that includes conditions when acutely toxic pesticides might be used while minimizing risks to pollinators.

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 for the "Pollinator Protection Home Page," 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. During the Trump Administration, OPP applied specific mitigation measures on individual registration decisions, unlike the Obama years, when EPA made more sweeping statements about the issue generally and imposed new conditions broadly.



EPA has stated that it intends to release the final risk management decisions for the major neonicotinoid insecticides in 2022.

In 2020, EPA released the proposed registration review decisions for the major neonicotinoid insecticides, including acetamiprid, clothianidin, dinotefuran, imidacloprid, and thiamethoxam. In these decisions, EPA proposed the following conditions for these products' registrations:

- Management measures to help keep pesticides on the intended target and reduce the amount used on crops associated with potential ecological risks;
- Requiring the use of additional PPE to address potential occupational risks;
- Restrictions on when pesticides can be applied to blooming crops to limit exposure to bees;
- Language on the label that advises homeowners not to use neonicotinoid products; and
- Canceling spray uses of imidacloprid on residential turf due to health concerns.

EPA also stated that it would be working with industry stakeholders on developing and implementing stewardship and best management practices for these insecticides.

EPA has stated that it intends to release the final risk management decisions for these products in 2022. These important decisions will likely spark renewed attention and debate on pollinator policies at OPP, during a time when PRIA 5 negotiations are coming to a close and Farm Bill negotiations are beginning in earnest — so 2022 might again have the title of "the year of the bee."

11. Pesticide Registration and Improvement Act

PRIA of 2018 (PRIA 4) was passed and signed into law on March 8, 2019, reauthorizing PRIA through FY **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 authorized use of the maintenance fees in the registration review process to offset costs for endangered species assessment. OPP must complete the current registration review cycle by **October 1, 2022**.

OPP continued its work on PRIA submissions in 2021, with various accommodations to manage a remote workforce during a pandemic that we expect will continue well into 2022. Like in 2020, there was an increase in the number of PRIA submissions in 2021, particularly those destined for the AD related to EPA's Emerging Viral Pathogen policy, virucidal claims, and other amendments or new registrations related to SARS-CoV-2 and EPA's List N.

In 2020 and 2021, OPP diverted resources to AD to address this increased demand, but these AD submissions are decreasing and staff is finding its pre-COVID-19 cadence. Through early November 2021, published data indicate EPA has been successful in its efforts to expedite reviews. All indications are that this trend will continue, particularly following EPA's October 2020 publication and subsequent implementation of its Interim Guidance for residual surface disinfectant and antimicrobial claims.

PRIA and its reauthorizations have directed set-asides for funding specific projects. Of note, PRIA 4 created a new set-aside to support inspections for compliance with GLP standards. COVID-19 diminished in-person activities in 2021, but these and other inspection activities continue to increase under the Biden Administration and as pandemic restrictions are lifted. In April 2021, CDC announced that the risk of being infected with COVID-19 by touching contaminated surfaces is considered low. Given this information, EPA is no longer prioritizing public health emergency requests for new products that address surface transmission of SARS-CoV-2. EPA is shifting resources to expedite applications for products with novel COVID-19 claims, such as killing of airborne SARS-CoV-2.

In FY 2021, OPP completed over 2,400 PRIA actions, and we expect this level of effort to continue in 2022. OPP registered 14 new active ingredients and approved 60

FIFRA Section 18 emergency exemption decisions, providing growers with tools to control economically threatening pests. Again, we expect similar numbers in 2022.

In 2021, EPA processed a higher volume and more complicated applications than ever before with less resources. For 2022, the House-passed version of the EPA appropriations bill would provide $130.259 million for pesticide registration activities, which is above the President's budget request of $128.799 million and above the $128.3 million minimum federal appropriations requirement specified in PRIA. If the House funding level is ultimately enacted, it will mark the first time in several years that the PRIA funding level will be met, which will help support program progress.

Although it would not need to be in effect until **October 2023**, expect PRIA 5 authorization to be a priority for both EPA and industry in 2022. This early reauthorization would avoid having this issue added to the list of many things in the next Farm Bill that will be a higher priority for Congressional attention. EPA will look for PRIA 5 to address resource challenges and timelines; incorporate ESA consultations into registration review and registration timeframes and fees; include maintenance fee set-asides; incorporate EJ concepts; incorporate possible new PRIA categories for some of the non-PRIA actions; and incorporate some new fee categories and tweaks to existing categories.

For PRIA 5 authorization, industry should look for priorities that include: ensuring that EPA has the resources it needs to meet deadlines for both PRIA and non-PRIA actions, while ensuring that there is more EPA accountability or measurable goals around deadlines; creating a mechanism to ensure that non-PRIA actions are processed in a timely manner and that current backlog is addressed; prioritizing process improvements, efficiencies, and consistency among reviewers and registering divisions; and ensuring that OPP user-fee based operations can continue during a government shutdown.

12. 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 about hiring and spending have hindered fully utilizing 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. This may be due in part to the earlier uncertainty surrounding reauthorization of PRIA; now that PRIA issues are resolved, and with the Biden Administration's commitment to replenish EPA staff, and with the FY 2022 EPA budget targeting more than 80 new staff members for OCSPP, OPP may be enabled to fully fill additional positions in 2022.

a. Budget

Worth noting, at the time of this writing, Congress supports $130.26 million for pesticide registration activities, which is above President Biden's budget request of $128.8 million and above the $128.3 million minimum federal appropriations requirement specified in PRIA. If enacted, it would mark the first time in several years that the PRIA funding level will be met and would set a positive outlook for program progress in 2022.

b. Rodenticides

Draft risk assessments for the rodenticides were completed in 2020, and comments are being considered in drafting the Proposed Interim Decisions, which EPA plans to issue in 2022. The interim decisions for the rodenticides are also scheduled for 2022. If OPP meets its commitments, 2022 could 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.

c. Pyrethroids

Throughout 2020 and 2021, EPA published numerous proposed interim decisions, as well as some interim decisions for the pyrethroids. EPA plans to publish the remaining pyrethroid interim decisions in 2022.

In 2021, EPA collected pet incident data, and this will be an issue area to be aware of in 2022. In August 2021, EPA announced its plan to collect pet incident data on MGK-264, piperonyl butoxide, pyrethrins, and amitraz used in agricultural and non-agricultural settings, including residential pet products. These data will allow EPA to conduct

a comparative assessment of pet incidents across registered pet products to better determine whether changes to pet product registrations and labels are necessary.

d. 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 coordinate with OPP staff on finalizing Agency review of submitted certification plans. To date, EPA has completed review of 29 of 63 state, territory, and tribal certification plans. OPP plans to complete the remaining reviews in **early 2022**. Prior to October 1, 2021, EPA was unable to take action on revising the certification rule because of a prohibition of such actions imposed by PRIA 4. EPA is in the process of developing a rule that would extend the date by which plans must be approved and ensure existing plans can remain in place during this time-limited extension; this is something we expect to see in 2022.

e. Process Improvements

In 2021, OPP launched a new set of process improvements that the pesticide community hopes 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 SOPs to gain efficiencies for individual pesticide workflows; and continued to deploy Information Technology (IT) Modernization and Digital Transformation work.

f. Scientific Integrity

Enhancing scientific integrity will be an important theme for OPP in 2022. In March 2021, Assistant Administrator Michal Freedhoff issued an OCSPP-wide internal memo that affirmed her commitment to scientific integrity as an essential and critical element to our 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, look for these new council and advisor positions to influence decision-making processes in OPP.

g. Staffing

In a larger sense, government-wide personnel policies, budget uncertainty, threats to pension and promotion practices, and increased bureaucratic politicization in the past few years have had a negative impact on morale. The recruitment of OPP staff to bulk up the toxics program in OCSPP as a result of the implementation of the 2016 TSCA Amendments continues with its own deadlines and budget issues and has also had an impact.

h. Registration Review Deadline

The clock continues to tick toward the 2022 registration review deadline for the bulk of the program registrations. EPA states the affected universe is 742 "active ingredient cases." Progress has been made, but review of many of the more controversial or widely used active ingredients remains to be completed. 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.

i. Workforce

In addition to the many challenges facing OCSPP, the aging working force of EPA specifically and the federal government generally presents a serious workforce issue. There have been estimates that as much as or more than 40 percent of the federal workforce is eligible to retire now or in the near future, leaving many critics to question whether government personnel policies for recruitment, hiring, and training will be adequate to meet the challenge this demographic wave represents.

j. Morale

Under the Biden Administration, EPA budget and staffing increases, 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.

k. At Last — Integrated Location for OPP and OPPT (Planned Since the 1970s)

In 2021, OPP completed its move from Crystal City, Virginia, to EPA's Washington, D.C., Headquarters location, and is now co-located with OPPT and OCSPP front office staff. Although staff is working from home, and boxes generally await staff in these new offices to return, finally, after almost 50 years, in 2022 both the pesticides and the toxics programs will be together in one location. This has the potential to, over time, improve the consistency of assessments between the programs and allow for closer coordination of other program activities. Both programs conduct their own risk assessments, process new product applications, and face common issues of dealing with uncertainty while protecting health and the environment under their respective authorizing legislation. Planning for this "merger," of a sort, has been in the works for decades, with "almost" efforts finally coming to fruition since what is now OCSPP was first created as a separate media program in 1976.

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

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D. NANOTECHNOLOGY

1. National Institute for Occupational Safety and Health

In July 2020, the National Institute for Occupational Safety and Health (NIOSH) published a draft technical report entitled *Approaches to Developing Occupational Exposure Limits or Bands for Engineered Nanomaterials: User Guide and Technical Report*. The draft report describes an evidence-based approach to evaluate the scientific information available to derive occupational exposure limits (OEL) or occupational exposure bands (OEB) for engineered nanomaterials. The approach can be used to group engineered nanomaterials into categories based on how much their effects may harm the health of exposed workers.

NIOSH requested that comments place special emphasis on certain issues, including whether the draft document adequately describes the process for gathering and evaluating the information available on OELs or OEBs for engineered nanomaterials; whether it adequately describes the development of a framework for categorizing engineered nanomaterials by potential occupational health hazard from inhalation exposure; and whether the clustering and classification modeling methodologies are reasonable for these data. Comments were due in September 2021. Only one comment is posted in the online docket, Docket ID CDC-2021-0067, from AIHA. AIHA states that the draft document "appears to be sufficient for evaluating and developing OELs/OEBs for inhalation exposures." It is uncertain whether NIOSH will publish the final document in 2022.

2. National Nanotechnology Initiative

On October 8, 2021, the National Nanotechnology Coordination Office (NNCO) announced the release of the 2021 *National Nanotechnology Initiative Strategic Plan*, which outlines the goals, objectives, and actions for the National Nanotechnology Initiative (NNI) over the next five years. After considering the recommendations from advisory bodies, stakeholders, and input from the public, NNI agencies determined that NNI's overarching goals to support nanotechnology R&D, commercialization, infrastructure, and responsible development should remain and that a new goal be added to focus efforts more clearly on education and the workforce. With the release of the plan, the White House Office of Science and Technology Policy (OSTP) and the NNI agencies launched NNI's next phase. For the next five years, NNI will focus on the following goals:

- ***Goal 1: Ensure that the United States remains a world leader in nanotechnology R&D.*** NNI agencies will continue to fund nanotechnology R&D, using more deliberate mechanisms to connect and build communities, both within NNI and with other initiatives and priorities.

- ***Goal 2: Promote commercialization of nanotechnology R&D.*** NNI will enhance efforts to accelerate the scale-up, translation, and commercial application of nanotechnology R&D into the marketplace to ensure that economic, environmental, and societal benefits are realized and to help the United States build back better with high-paying jobs. NNI will expand the Nanotechnology Entrepreneurship Network as a forum to connect innovators and share best practices.

- ***Goal 3: Provide the infrastructure to support sustainably nanotechnology research, development, and deployment.*** NNI will support the increasing role of the cyber infrastructure that is critical for nanotechnology innovation enhanced by artificial intelligence, machine learning, and advanced design tools. Facilities that support prototyping and early stages of the manufacturing process are also important for the development community and will be explored in collaboration with the private sector.

- ***Goal 4: Engage the public and expand the nanotechnology workforce.*** In recognition of the importance of education, workforce development, and public engagement to the entire nanotechnology enterprise, these areas are now a stand-alone goal of NNI.

- ***Goal 5: Ensure the responsible development of nanotechnology.*** A key tenet of responsible development remains the protection of human health and the environment through an under-

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standing of not only the applications of nanomaterials, but also the potential implications. Responsible development further includes consideration of ethical, legal, and societal implications, as well as a new emphasis on inclusion, diversity, equity, and access and the responsible conduct of research.

3. National Strategic Plan for Advanced Manufacturing

OSTP published a request for information (RFI) on October 5, 2021, requesting input on the development of a National Strategic Plan for Advanced Manufacturing. 86 Fed. Reg. 55022. Through the RFI, OSTP seeks input from the public on ways to improve government coordination and on long-term guidance for federal programs and activities in support of U.S. manufacturing competitiveness. According to the RFI, advanced manufacturing is a family of activities that: depend on the use and coordination of information, automation, computation, software, sensing, and networking; and/or make use of cutting-edge materials and emerging capabilities enabled by the physical and biological sciences, for example, nanotechnology, chemistry, and biology. Advanced manufacturing involves both new ways to manufacture existing products and the manufacture of new products emerging from new advanced technologies.

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Exploring the Environmental Footprint of the Digital Economy — A Conversation with David Rejeski

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Responses were due December 17, 2021. OSTP and the National Science and Technology Council will consider the responses as they work with federal agencies and other stakeholders to develop the strategic plan. More information is available in our October 5, 2021, blog item, "OSTP Requests Input on Development of a National Strategic Plan for Advanced Manufacturing."

4. American Conference of Governmental Industrial Hygienists

In 2022, 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. ACGIH® is expected to release the TLV®-CS Committee's 2022 under study list by **February 1, 2022**.

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E. BIOTECHNOLOGY

The U.S. Food and Drug Administration (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, growth, and differentiation of cells. With the exception of *Siluriformes* fish, seafood falls under FDA's jurisdiction, while meat, including *Siluriformes* fish, and poultry are under the jurisdiction of USDA's Food Safety and Inspection Service (FSIS). While FDA was expected to announce in 2021 how it will proceed regarding the labeling of foods comprised of or containing cultured seafood cells, FDA has not yet done so. FDA requested information on October 7, 2020, pertaining to the labeling of these foods. 85 Fed. Reg. 63277.

FDA invited comment on names or statements of identity for foods comprised of or containing cultured seafood cells; consumer understanding of terms that have been suggested for the names or statements of identity of foods comprised of or containing cultured seafood cells; and how to assess material differences between the foods that are the subject of the notice and conventionally produced foods. FDA has not publicly indicated what type(s) of action, if any, it will take to ensure that these foods are labeled properly.

On March 8, 2021, the Animal and Plant Health Inspection Service (APHIS) reopened the comment period on a December 28, 2020, Advance Notice of Proposed Rulemaking (ANPRM) soliciting public comment on a contemplated regulatory framework that would transition portions of FDA's pre-existing animal biotechnology regulatory oversight to USDA. 86 Fed. Reg. 13221. Under the regulatory framework being contemplated, USDA would promulgate regulations using the authorities granted to it through the Animal Health Protection Act, the Federal Meat Inspection Act (FMIA), and the Poultry Products Inspection Act (PPIA). Pursuant to these authorities, APHIS would conduct a safety assessment of animals subject to the FMIA or PPIA that have been modified or developed using genetic engineering that may increase the animals' susceptibility to pests or diseases of livestock, including zoonotic diseases, or ability to transmit the same. FSIS would conduct a pre-slaughter food safety assessment to ensure that the slaughter and processing of certain animals modified or developed using genetic engineering would not result in a product that is adulterated or misbranded. According to the online docket for Docket ID APHIS-2020-0079, more than 51,000 comments were submitted, although many are identical, or nearly so, opposing the transfer of authority from FDA to USDA. APHIS has not yet stated its timeline for next steps.

USDA's FSIS published an ANPRM on September 3, 2021, to request comments pertaining to the labeling of meat and poultry products comprised of or containing cultured cells derived from animals subject to FMIA or PPIA. 86 Fed. Reg. 49491. Issues raised in the comments submitted in response to the ANPRM will inform future rulemaking to establish labeling requirements for these products. The ANPRM also discusses how FSIS will generally evaluate labels for these products if they are submitted before FSIS completes the rulemaking.

APHIS could issue a final rule in 2022 to exempt plants with additional modifications that could otherwise be achieved through conventional breeding from the regulations that govern the introduction (importation, interstate movement, or release into the environment) of certain organisms modified or produced through genetic engineering. APHIS published a proposed rule on July 19, 2021. 86 Fed. Reg. 37988. According to APHIS, the exempt plants would have distinct modifications on the paternal and maternal alleles of a single gene resulting from repair of a targeted DNA break; deletions generated using an externally provided repair template; or deletions resulting from repair of two targeted double strand breaks on a chromosome.

Although APHIS was scheduled to complete implementation of its 2020 final Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient (SECURE) rule in 2021, it has not yet issued a final guide detailing the information requirements and process for submitting a Regulatory Status Review (RSR) request. APHIS accepted comments until October 25, 2021, on a draft guide. Developers of certain GMOs may use the RSR process to determine the regulatory status of the organisms.

APHIS is authorized by the Plant Protection Act to evaluate potential plant pest risks resulting from certain organisms developed using genetic engineering techniques. 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 introduction of the RSR process. The RSR process was implemented for select crops on April 5, 2021, and was fully implemented for all crops on October

1, 2021. More information on the draft guide is available in our August 31, 2021, blog item.

In 2022, EPA will continue to implement its mature regulatory systems for managing review of biotechnology innovations for pesticides and industrial chemicals. EPA promulgated several temporary or permanent tolerance exemptions for plant-incorporated protectants (PIP) in 2021, for example.

On October 9, 2020, EPA proposed an exemption under FIFRA and FFDCA for certain PIPs 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). EPA has not stated its timeline for issuing the proposed rule in final.

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 as a way 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. On May 5, 2021, EPA hosted a webinar to educate the public about this technology and EPA's approval of the EUP; the recorded webinar is available here. In August 2021, EPA sought public comment on a proposed amendment to the EUP to extend it another 24 months, from 2022 to **2024**, and expand testing from Florida to California.

EPA continues to review Microbial Commercial Activity Notices (MCAN) under TSCA. EPA received a total of 22 MCANs during FY 2021. Two were submitted in late September 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 reviewed two TSCA Environmental Release Applications (TERA) and completed (and granted) both in under 60 days. EPA's biotechnology reviews are a bright spot in EPA's new chemicals review program.

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ARTICLE

"The importance of regulatory diligence in funding," *Financier Worldwide,* April 2021.

Stakeholders in the biobased chemical industry should plan to monitor activities on Capitol Hill, including the Sustainable Chemistry Research and Development Act, passed in July 2020 as part of the National Defense Authorization Act for FY 2021.

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 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.

Global and national policy reforms continue to focus increasingly on a circular economy as a critical part of addressing climate change. In 2021, for example, the U.S. Department of Energy (DOE) continued to concentrate on incentivizing biotechnology and energy efficiency through renewable and sustainable sources. In 2022, industry stakeholders can expect similar DOE funding and activities that incentivize a circular economy. DOE has already announced several funding opportunities in 2022 for efforts focused on the development of novel biobased chemistry.

Internationally, in May 2021, the European Parliament (EP) created a Just Transition Fund (JTF) to assist EU countries to address climate neutrality through its 2021-2027 Multiannual Financial Framework (MFF) and NextGenerationEU, funding projects focused on the transition into a sustainable and circular European economy. JTF is part of the European Green Deal's Just Transition Mechanism (JTM) initiative, which provides targeted support to regions and sectors in the EU that are most affected by the transition into a circular economy. Similarly, in an effort to develop a circular economy, the European Agency for Safety and Health at Work (EU-OSHA) created the High-Level Roundtable on Implementation of the Chemicals Strategy for Sustainability expert group. The expert group's specific tasks include identifying and addressing social, economic, and cultural barriers to the transition toward safe and sustainable chemicals.

These efforts are mere examples of the global effort to develop a green economy by revitalizing the biobased and renewable chemicals industry through new initiatives and smart policy reforms. B&C expects that such efforts will only continue to grow in 2022.

Stakeholders in the biobased chemical industry should also plan to monitor activities on Capitol Hill, including the Sustainable Chemistry Research and Development Act, passed in July 2020 as part of the NDAA for FY 2021. Subtitle E established an IWG to coordinate federal programs and activities in the creation of a roadmap for sustainable chemistry in the United States. The Act states that the IWG will be co-chaired by the Director of OSTP and a representative

ARTICLE

"Why the US EPA can, and should, evaluate the risk-reducing role a new chemical may play if allowed on the market," *Chemical Watch,* February 22, 2021.

from EPA, the National Institute of Standards and Technology (NIST), the National Science Foundation (NSF), or DOE, as selected by the Director of OSTP. As of November 2021, there is no evidence that the IWG has been formed or, if formed, is meeting. This is why it will be important in 2022 to monitor developments under this initiative for opportunities to engage with policymakers and stakeholders. More information about the Act is available in B&C's January 19, 2021, memorandum, "Sustainable Chemistry Research and Development Act Passed as Part of National Defense Authorization Act."

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 2022.

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G. PROPOSITION 65

Companies in California had adapted relatively comfortably to the California Office of Environmental Health Hazard Assessment's (OEHHA) Proposition 65 (Prop 65) amended labeling requirements, effective as of August 31, 2018. That did not stop OEHHA from issuing proposed revisions to the requirements for the "short-form" warning option that is now often utilized by industry as a means to satisfy warning obligations under the amended regulations. OEHHA's January 8, 2021, proposal significantly limits the opportunities when the short-form warning could be used, much to industry's dismay. Specifically, under this initial proposal, a short-form warning would be used only when three conditions are met: (1) the total surface area of the product available for labeling is five square inches or less; (2) the package shape or size cannot accommodate the full-length warning content described in Section 25603(a); and (3) the entire warning is printed in a type size no smaller than the largest type size used for other consumer information on the product, but in no case smaller than 6-point type.

The first two conditions are new, proposed by OEHHA to address its concern that businesses "use the short-form warning for products that can easily accommodate a longer warning." The third condition has been modified to specify that the warning must be "printed"; OEHHA states it added this "for consistency with the requirement that the short-form warning be used only on product labels." If these conditions are met, there are additional extensive changes to the short-form warning language by requiring that the warning include the name of a Prop 65-listed substance. OEHHA also is proposing to restrict the circumstances when a short-form warning can be used by eliminating entirely the option for Internet and catalog warnings. *See* our January 21, 2021, memorandum "Proposition 65: OEHHA Proposes Significant Changes to "Short-Form" Warnings."

In written comments, and during a March 11, 2021, hearing, industry argued that OEHHA's proposal is unwarranted and its concerns with the current warning requirements unfounded. Industry also expressed frustration with the expected significant resources and costs that implementation of these changes would inspire. This frustration is particularly acute since many in industry are still smarting from the considerable resources and costs derivative of satisfying the warning requirements issued just three years ago.

On December 13, 2021, OEHHA responded in part to the comments submitted by issuing a notice proposing modifications to the revisions it first proposed on January 8, 2021 (Notice). Full details regarding the Notice are available in our December 14, 2021, memorandum. The five modifications include: (1) increasing the maximum surface area of the label from five to 12 square inches for the short-form warning to be applicable; (2) rescinding the initially proposed prohibition against using the short-form warning online and in catalogs, and instead reverting to the original regulatory language that allows use of the short-form warning on websites and in catalogs when the short-form warning is provided on a consumer product; (3) adding two options in addition to the signal word "WARNING" – "CA WARNING" or "CALIFORNIA WARNING"; (4) providing alternative warning language that "more directly addresses exposure to carcinogens or reproductive toxicants" (*e.g.,* "Exposes you to [NAME OF ONE OR MORE CHEMICALS KNOWN TO CAUSE CANCER], a carcinogen"); and (5) revising the regulations to change "product label" to "label" to avoid confusion.

OEHHA is requesting comments on its Notice and the modifications to the proposed regulatory text to be submitted no later than **January 14, 2022**. If issued in final, all of these proposed amendments would be operative one year after the effective date of the amendments, with a "sell-through" provision for consumer products manufactured prior to the effective date that are in compliance with the prior warning requirements. These label changes will create significant burdens to determine if the short-form warning can be used, and if so, necessary language changes. In 2022, affected companies should begin to assess whether these amendments, if issued in final, would affect their current compliance efforts with warning requirements.

The issue of the applicability of Prop 65 warning requirements for pesticide products containing glyphosate continued in 2021 and will extend to 2022. EPA and OEHHA have previously clashed over Prop 65 warnings on glyphosate-registered products, with OEHHA listing glyphosate as a chemical known to the state of California to cause cancer based on an International Agency for Research on Cancer (IARC) determination that glyphosate is "probably carcinogenic" in humans. EPA declined to permit Prop 65 warnings on registered glyphosate pesticide product labeling because it disagreed with the IARC classification. The issue is in litigation, with a notable decision issued on June 22, 2020, by the U.S. District Court for the Eastern District of California. The court granted summary judgment for the Plaintiffs in *National Association of Wheat Growers et al. v. Becerra* and entered a permanent injunction against en-

forcement of a Prop 65 warning label for pesticide products containing glyphosate. The court found that requiring the registrants of glyphosate products to include such a warning could not be justified as a valid restriction on commercial speech and, therefore, violates the First Amendment of the Constitution.

OEHHA appealed the District Court's decision in the Ninth Circuit. The appeal is currently being held in abeyance while OEHHA proposes a new rulemaking with warning language tailored to glyphosate that was not considered by the District Court. On July 23, 2021, OEHHA proposed the rule, stating that it addresses the concerns expressed by the District Court. OEHHA proposes a new Section 25607.49 to establish tailored safe harbor warning language for consumer product exposures to glyphosate:

> **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. Other authorities, including US EPA, have determined that glyphosate is unlikely to cause cancer, or that the evidence is inconclusive. A wide variety of factors affect your personal cancer 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.

Industry's response was predictably critical of the proposal, arguing that it continues to violate the First Amendment and is preempted by FIFRA. This litigation merits monitoring in 2022 to determine if the language is adopted and whether the legal challenge will continue. The case raises interesting questions regarding how courts will address legal challenges based on a chemical's carcinogenicity or reproductive toxicity. 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 in May 2021 granted an emergency stay pending appeal, allowing parties again to enforce Prop 65 warning requirements for acrylamide in food and beverages. The stay will remain in effect during the pendency of the case at the Ninth Circuit. Oral arguments are set for **January 12, 2022**.

In September 2021, OEHHA proposed tailored safe harbor warning language in a new subsection to Section 25607.2 for food exposures to glyphosate. 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." This case, and potentially others relying upon similar arguments, will continue to be monitored in 2022.

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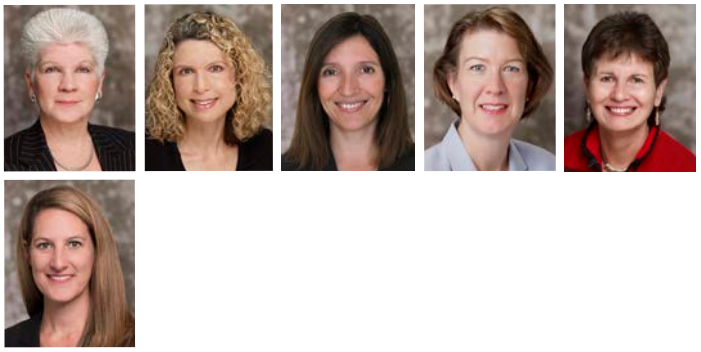

H. FDA FOOD AND COSMETICS REGULATIONS

2021 continued to be a challenging year for FDA due to the pandemic, and FDA made little progress on proposed rules issued in 2019 - 2020. FDA was delayed in issuing the NPRM for Food Standards Modernization, the comment period on which was re-opened in 2020, and the NPRM for Food Contact Substance Notification That Is No Longer Effective. The Fall 2021 Regulatory Agenda included proposed rules to clarify changes to the Registration of Food Facilities rule, including proposed edits to definitions expected by **May 2022**, and amendments to requirements in hazard analysis and risk-based preventive controls for human and animal food, expected in **March 2022** and **January 2022**, respectively.

Emergency Use Authorizations (EUA) derivative of COVID-19 required significant FDA resources to address. As of July 2021, 396 tests for detecting COVID-19 were authorized under EUAs and 630 drug development programs were in planning stages. FDA approved one treatment in August, the first vaccine, and, most recently, FDA authorized a single booster dose of the three vaccines, currently authorized or approved, for eligible populations. FDA also reviewed more than 1,486 reports of fraudulent products.

Well into 2022, we expect many of the products medical professionals and consumers are using now will be manufactured for sale and distribution under the auspices of a specific EUA. In June 2021, FDA revoked the EUA for non-NIOSH-approved disposable respirators and the EUA for decontamination and bioburden reduction systems for health care personnel in health care facilities. In October 2021, FDA withdrew the applicable EUA that allowed for the temporary preparation of certain alcohol-based hand sanitizers. The notice of withdrawal indicates that firms

> ... must cease production of these products by December 31, 2021. Firms must 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. After **March 31, 2022**, FDA intends to cease its temporary policy of not taking action with regard to distribution of hand sanitizers, or alcohol for use in alcohol-based hand sanitizers, prepared consistent with the circumstances described in the guidance documents.

We expect that FDA will continue to withdraw EUAs in 2022 and that if products are not approved through formal processes, they will no longer be allowed to be used.

1. Food and Food Additive Safety

FDA announced in April 2019 "The New Era of Smarter Food Safety" initiative. The FDA process eliciting feedback began in 2019 and was open during the majority of that year. The initiative is said to be Food Safety Modernization Act (FSMA)-based, with the inclusion of modern technology, and builds on the foundational rules issued in 2011 with the enactment of FSMA. In 2020, FDA outlined goals and convened a webinar in late 2020 to review the "First 100 Days" of the initiative. FDA hosted in 2021 several collaborative public events with the goal of addressing core elements, including issuance of the proposed Food Traceability Rule, development of smarter tools for prevention and outbreak response, retail modernization, and internal training for FDA inspection staff. We expect similar activities in 2022 as FDA continues to develop the core elements of the initiative.

In September 2021, the U.S. District Court for the Southern District of New York granted a motion for summary judgment upholding FDA's current regulatory framework for substances that are considered Generally Recognized as Safe (GRAS). The NGO litigants that brought the lawsuit claimed that FDA violated the APA by "indefinitely operating under a proposed rule in lieu of ... a final rule." The NGO litigants had until the end of November 2021 to appeal the decision. FDA, in the coming year, is expecting additional legal challenges to the GRAS process and other regulatory processes viewed as lacking transparency and that are not sufficiently protective of public health and safety.

2. 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 signed into law. The CARES Act seeks to modernize the over-the-counter (OTC) drug review

ARTICLE
"Is FDA Food Safety Revision in Our Future?," *Chemical Processing*, August 24, 2021.

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

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 also 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 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 with the exception of 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. Expect that in 2022 significant progress on the transition will take place as FDA moves to address OTC reform.

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II. KEY GLOBAL CHEMICAL MANAGEMENT PREDICTIONS

A. GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELING OF CHEMICALS

1. Overview

2020 ended 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 2021, many countries began to issue rules updating their standards to a newer revision of GHS, or began to implement GHS. In 2022, we expect that final rules will be issued to revise the U.S. and Canadian regulations implementing GHS and more countries will consider the UN model and available editions to it. Companies will continue to 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.

PODCAST:
Changes to Safety Data Sheets in the EU and what it might mean for US Businesses

2. United Nations

The 39th session of the UN Sub-Committee of Experts on the Globally Harmonized System of Classification and Labeling of Chemicals, scheduled for July 10, 2020, was postponed due to COVID-19. The 39th session was a hybrid meeting held December 9 - 11, 2020, in Geneva, Switzerland. The 40th session was held July 5 - 7, 2021, again as a hybrid session. The agenda included continued discussions on non-animal testing methods, the development of a list of chemicals classified in accordance with GHS, and continued development of guidance on the application of GHS criteria. The 41st session was held as a hybrid session December 8 - 10, 2021. The proposed agenda included the items discussed in the 40th session.

The ninth revised edition (Rev 9) of GHS was published in September 2021. The major changes from Rev 8 to Rev 9 include extensive revisions to Chapter 2.1 on Explosives and adjustments to the format and content of many decision trees within the entire edition. Many countries proposing updates in 2020 - 2021 were proposing to update to Rev 7. Proposed updates to legislation to align with Rev 7 of GHS will find many countries continuing to play catch up with the UN as the most recent version is Rev 9 in 2021.

3. U.S. OSHA HCS 2012

On May 25, 2012, OSHA revised and updated the Hazard Communication Standard (HCS). Currently, all substances and mixtures are required to comply with HCS 2012, as the transition period ended in 2015. On February 5, 2021, OSHA issued an NPRM to amend the 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 extended to May 19, 2021.

In September, OSHA held an informal public hearing to allow interested parties to participate in further dialogue on the NPRM. Comments on the NPRM are being reviewed. The final rule is expected **late 2022** or **early 2023**. Transition periods were included in the proposed rule, but based on the number of comments received; it is difficult to predict if those implementation dates will remain as proposed.

PODCAST:
What's happening with GHS and OSHA? — A Conversation with Karin Baron

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 country's 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. 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 publication and 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 of 2017. In July of 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.

In 2022 companies are urged to review the impact of these amendments and prepare updates to hazard communication elements, including additional elements that are now incorporated due to the changes from Rev 3 to Rev 7. The deadline for compliance is **December 31, 2022**. 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. It is expected that in 2022 the draft will be complete and companies will be able to use the revised standard as soon as it is issued. 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 Decree 57, approving the Regulation on the Classification, Labelling, and Notification of Chemical Substances and Mixtures on February 9, 2021. The regulation aligns with Rev 7 of GHS and provides transition periods for substances and mixtures for industrial and non-industrial uses. The implementation dates for industrial substances is **February 9, 2022**, and for industrial mixtures is **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.

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

The 14th Adaptation to Technical Progress amendments and additional classification requirements for many substances, including the obligations to classify respirable titanium dioxide particles as a category 2 carcinogen, came into force September 9, 2021.

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, Chemical Abstracts Service (CAS) Registry Number (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, or 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

The 12th Adaptation to Technical Progress (ATP) to CLP, published on March 27, 2019, implements Rev 6 and Rev 7 of UN GHS and entered into force on October 17, 2020. The changes include the introduction of new hazard classes and categories for various physical hazards, clarification of definitions and details for various physical and health hazard classes, and the introduction of new hazard and precautionary statements.

The 14th ATP amendments and additional classification requirements for many substances, including the obligations to classify respirable titanium dioxide particles as a category 2 carcinogen, were enacted on October 4, 2019, and came into force September 9, 2021. These amendments to substances included in Annex VI of CLP are from vari-

ARTICLE
"Expert Briefing: What could the European Commission's plan to strengthen CLP mean for industry?," *Chemical Watch,* August 2, 2021.

ous Risk Assessment Committee (RAC) 2017 opinions on harmonized classifications.

On August 11, 2020, the 15th 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 begins **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 is the first ATP that will not be automatically adopted by the United Kingdom (UK).

The 17th ATP was published in the EU *Official Journal* on May 28, 2021. This update includes RAC adopted opinions on roughly 50 substances dating back from March 2019 - December 2019. The enforcement of the 17th ATP will begin on **December 17, 2022**, to allow suppliers to update SDSs and labels and to sell through existing labeled inventory.

A draft of the 18th ATP was released in August 2021. It is expected that the 18th ATP will progress in 2022 with implementation expected in **2023 or later**.

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

Expect 2022 to be an active year of transition with amendments to CLP and Annex II that will require consideration. Enforcement activities in member states (MS) 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 does not include provisions for Poison Center Notifications.

We expect that in 2022, variations between the EU and the UK will emerge as the UK considers ATPs that are not within the scope of the current GB CLP Regulation. There are two options: the UK could adopt changes in line with the EU approach or, during its evaluation, opt to adopt an alternative approach to classification and labeling for individual substances. These changes will require considerable diligence for those navigating trade within the region.

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 Agency (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 2022, companies will need to consider how these significant changes impact the SDSs, 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, SDSs, 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 importer into South Korea provide a copy of the Material Safety Data Sheet (MSDS) to the Ministry of Employment and Labor (MoEL) and include, as a separate submission, substantiation for any content that companies wish to maintain as CBI for MoEL to review and approve (with limited exceptions). The CBI review and approval process is daunting, and MoEL's expectations on the types of proof that demonstrate disclosing hazardous ingredients would result in commercial harm are substantial. Foreign manufacturers wishing to protect CBI on the MSDS are able, through the appointment of an 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 South 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. The deadlines are **January 16, 2022**, for existing products manufactured or imported at 1,000 tons or more per year and **January 16, 2023**, for 100 - 1,000 tons per year.

13. Peru

Peru has no chemical management framework in place, but a draft bill was circulated in 2020. The draft bill 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 2022.

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 regulations take effect on **September 29, 2022**. The update does not indicate which revision of GHS is being considered 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, or 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.

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B. LATIN AMERICA

1. Overview

Due to the impact of the COVID-19 pandemic, the development of chemical substance legislation in many countries in Central and South America has been delayed. While Argentina, Brazil, and Peru made some progress, Chile and Colombia passed chemicals regulation legislation in 2021. This legislation creates a national inventory of industrial chemicals, establishes a method for risk evaluation of priority substances, and implements the UN GHS. The most notable progress in 2021, however, was the strong initiatives to promote regulatory cooperation between the countries in the region. These initiatives came from three main stakeholders: the UN, the Latin American Regulatory Cooperation Forum (LARCF), and MERCOSUR.

Most Latin American countries are at similar stages of developing chemicals regulation legislation and recognize the economic and logistical benefits of collaborating and sharing resources, as well as the favorable timing for creating a uniform regulatory landscape for Latin America. It remains to be seen to what extent the intentions and goals of these cooperative initiatives will bear fruit, given that national legislative proposals for chemicals regulation are moving at a faster pace than the cooperative initiatives. The existence of these initiatives does not guarantee that the legislation developed by individual countries will reflect the goals of these cooperation efforts.

2. Regional Cooperative Initiatives

a. UN's Forum of Ministers of Environment

The Intergovernmental Network on Chemicals and Waste for Latin America and the Caribbean (Intergovernmental Network) was established by the UN Forum of Ministers of Environment in 2016, with the goal of "strengthening the environmentally sound management of chemicals and waste through regional cooperation and the exchange of information and experiences among countries." To accomplish this goal, the Intergovernmental Network developed and plans to implement an Action Plan on chemicals and waste in the region of Latin America and the Caribbean.

The Action Plan for regional cooperation on chemicals and waste management 2021-**2024** (Action Plan) was published in February 2021, and it defines the priorities during that period, together with the Work Program, which lists specific activities to be implemented during 2021-2022.

Among the Action Plan's priorities are improving the availability of data, strengthening capacities for environmental risk assessments for chemicals and chemical products, disseminating methodologies for the definition of a list of priority chemicals for control and monitoring, and promoting collaboration and knowledge exchange among laboratories of the region. The Action Plan also focuses on implementing the UN's Basel, Rotterdam, and Stockholm Conventions on chemicals and waste through developing inventories of new persistent organic pollutants (POP).

b. Latin American Regulatory Cooperation Forum

LARCF is a joint industry-government group that facilitates the technical exchange and cooperation among industry and governments regarding the development of draft regulations and laws in the region. In April 2021, LARCF published a roadmap to serve as a guide for the countries in the region to develop "consistent, economically efficient and scientifically-based regulatory systems." The roadmap was developed by a virtual working group consisting of nearly 50 industry and government participants from 11 countries.

This initiative is particularly important, as several Latin American countries are in the process of developing chemical regulatory frameworks. It ensures that the governments of participating countries are aware of the planned provisions of other countries' chemicals regulations, avoiding conflicting requirements in the region. Additionally, the cooperation of industry and government ensures that during the development of chemicals regulation, the small- and medium-sized enterprises (SME) are not left out of the loop in a region where most of the industrial sector is comprised of SMEs.

The roadmap recommends a step-by-step process for building a regulatory framework, including the development of a national plan for chemicals management, the implementation of GHS, the establishment of an inventory of existing chemicals in the country, as well as risk evaluation and prioritization.

In September 2021, the Chemical Industry Associations of Latin America, comprised of national trade associations of six Latin American countries (Argentina, Brazil, Chile, Colombia, Mexico, and Uruguay), part of LARCF, published a "Letter of Regulatory Cooperation Principles," emphasizing

the need for greater regulatory cooperation in the region, to use "resources more efficiently, making it possible to raise transparency and public trust in regulatory decisions."

The letter sets out a common vision of sound chemicals management, an overview of best practices, opportunities for regulatory cooperation in the region, and a step-by-step process to building a regulatory framework.

c. MERCOSUR

MERCOSUR, the South American trade bloc comprised of Argentina, Brazil, Paraguay, and Uruguay, published in June 2021 the "Mercosur Action Plan on Management of Chemical Substances and Products 2021–**2024**" (MERCOSUR Action Plan), focused on common issues shared by the countries in the trade bloc. Aside from increased financial support for implementing the same version of the GHS, the MERCOSUR Action Plan sets out 23 activities to be completed before **2024** within the following categories: increasing capacity for chemicals management, regulatory cooperation and convergence, international chemicals and waste conventions and initiatives, and environmental information on chemicals and chemical products.

Another important objective of the MERCOSUR Action Plan is strengthening border control for substances and products with an environmental impact for the trade bloc. It is not clear yet which products and chemicals will be targeted, but it could include products that contain substances banned or restricted under the UN's Rotterdam and Stockholm Conventions, such as perfluorooctanoic acid (PFOA). Finally, the MERCOSUR Action Plan proposes implementing pollutant release and transfer registers (PRTR) in each country.

3. Argentina

In mid-2019, Argentina published draft chemicals legislation, the Reglamento del Marco Técnico Aplicable a las Sustancias Químicas Para Uso Industrial o Contenidas en Otros Productos, que se Producen o Importan en Argentina (Technical Framework Regulation Applicable to Chemical Substances for Industrial Use or Contained in Other Products, which Are Produced in or Imported into Argentina). Initially, the expectation was that Congress would approve the Regulation in 2020, but following the governmental elections in Argentina in fall 2019, and the subsequent COVID-19 pandemic in 2020, no further legislative action was taken.

At the outset of 2021, Argentina's new government announced plans to redraft parts of the Technical Framework Regulation. Specifically, chapters under revision include content related to the establishment of an inventory or registry for chemical substances, risk assessment and evaluation, and implementing the GHS. The government planned to publish the revised draft later in 2021, but not before Argentina held its legislative elections in October 2021. It is plausible that an amended draft will be published in 2022.

Also expected in 2022 are the development of a national hazardous substance monitoring program and an action plan for managing plastics throughout their lifecycle.

4. Brazil

a. Chemical Control

Brazil's draft Industrial Chemicals Regulation failed to make meaningful legislative progress in 2021. Industry representatives and former members of Brazil's National Chemical Safety Committee (CONASQ) made an effort in late 2020 to put a draft chemical regulation on Congress's agenda. On December 6, 2021, a Committee head in the Chamber of Deputies voted for the approval of the bill that will bring the EU REACH-inspired legislation closer to an earlier version developed by CONASQ. The bill must pass a plenary vote in the Chamber of Deputies and then pass the Senate before enactment. The Committee's vote suggests that Brazil's adoption of a comprehensive chemicals regulation framework is not off the legislative agenda.

Government and industry representatives are involved in all three major cooperative efforts concerning chemicals regulation in Latin America. Expectations for 2022 are that as the COVID-19 pandemic situation becomes less acute, legislative focus will shift to passing some version of the long-awaited draft chemical legislation, similar to other countries in the region.

b. Personal Care and Pesticides

As of November 5, 2021, personal hygiene products, cosmetics, and perfumes placed on the market in Brazil must be labeled in Portuguese with each product's chemical ingredients. Options for compliance include listing the ingredients on the original product label or on a complementary label. When there is no recognized Portuguese translation of a chemical substance name, companies must provide the

On October 8, 2021, Brazil published a decree with important amendments regarding pesticide products. The new decree is a broad reform intended to reduce bureaucratic obstacles, while at the same time bolstering enforcement provisions.

translation according to the International Nomenclature of Cosmetic Ingredients (INCI).

On August 11, 2021, Brazil's National Health Surveillance Agency (Anvisa) updated the list of substances prohibited in personal care products, cosmetics, and perfumes. The Ministry of Health (MoH) published a resolution on August 4, 2021, prohibiting specific substances, as well as prohibiting the following substances with dangerous properties:

- Substances classified as Group 1 carcinogens by IARC; or
- Substances classified by the European Commission (EC) as carcinogenic, mutagenic, or toxic to reproduction (CMR) in categories 1A, 1B, or 2.

This resolution brought Brazil into line with MERCOSUR standards and repealed the existing list from 2016. In September 2021, Anvisa published a series of three standards that incorporate updated MERCOSUR standards on regulated substances in personal care products, cosmetics, and perfumes. The new standards include a list of preservatives permitted and excluded in these products and a list of substances that personal care products should not contain except under specific conditions, and the fragrance and aroma components that must be indicated on the product label. In October 2021, Anvisa published its new list of approved active ingredients for pesticides, sanitizing disinfectants, and wood preservatives.

On October 8, 2021, Brazil published a decree with important amendments regarding pesticide products. The new decree is a broad reform intended to reduce bureaucratic obstacles, while at the same time bolstering enforcement provisions. Industry is optimistic the new timelines will speed up approvals of pesticide products. Among the newly introduced provisions is the mandatory use of GHS for pesticide products and labeling, expanding GHS beyond the workplace. New provisions also address chemicals for organic agriculture.

5. Chile

On February 9, 2021, the 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). Decree No. 57 establishes a national inventory of industrial chemicals, establishes a method for risk evaluation of priority substances, and implements GHS. The Decree applies to manufacturers and importers of chemical substances and mixtures that are not already regulated by other regulations, exempting pharmaceutical products, food products for human or animal consumption, cosmetic products, pesticide residues in food, and hazardous waste. The chemical notification aspect of the Decree applies to manufacturers and importers of hazardous substances and mixtures, in quantities of one metric ton or more per year, for industrial and non-industrial uses.

The Decree will be implemented in stages. Notification will be done through an online portal that was launched in beta version in late summer 2021. The government plans to publish the first national inventory by **December 31, 2024**. Notification is required every two years, by August 30. The first notifications for industrial substances are due **August 30, 2024**, and notifications for mixtures are due **August 30, 2027**. The first notifications for substances for non-industrial uses are due **August 30, 2025**, and the first notifications for mixtures are due **August 30, 2029**.

Chile, as the front-runner in developing, publishing, and implementing a chemicals regulation framework in Latin America, will serve as an example for the other countries in the region. Several other countries (*e.g.*, Argentina, Brazil, Colombia, and Mexico) are expected to publish similar legislation, some of them very likely in 2022.

6. Colombia

In 2019, Colombia published a draft National Industrial Chemical Management decree addressing industrial chemical substances that, among other aspects, mandates indus-

trial users to register with the national authority. According to the proposal, manufacturers and importers would report basic information regarding all substances imported or produced in Colombia at more than 100 kilograms (kg)/year. On December 29, 2020, Colombia's government revised the draft decree, scaling back certain provisions in response to industry comments on a July 2020 draft. In the December 2020 draft, certain provisions for establishing a registry of industrial chemicals were amended. Colombia's National Association of Industries (Asociación Nacional de Empresarios de Colombia; ANDI) expressed concern that under the previous draft, it was a possibility that all industrial chemicals would be subject to registration. The latest draft was revised to state that only chemicals identified as a priority for health and the environment will be subject to registration. The provisions requiring suppliers of certain hazardous substances, such as CMRs, would have to have risk reduction and management programs and report regularly to the government.

On November 30, 2021, the Colombian Ministry of the Environment and Sustainable Development published Decree 1630 of 2021, thereby adopting the country's first comprehensive chemicals regulation framework. The REACH-inspired Decree applies to industrial chemicals identified as hazardous by GHS that are manufactured or imported in quantities over 100 kg per year. Articles and polymers are exempt from regulation. The government must establish an online registration portal within six months from entry into force of the Decree. Manufacturers and importers have three years from the date the country's online portal becomes operational to register their substances under the National Inventory of Industrial Chemicals and to report the required information. The information submitted must be updated annually.

The Ministry will determine priority chemicals. Chemicals must be labeled according to GHS requirements. The new registry will track covered chemicals in a PRTR for environment impacts and a toxicology management system for health risks. Implementing legislation is expected as early as 2022, to begin the regulatory process, but the basis of a comprehensive chemicals regulation framework now exists in Colombia. Once the online portal becomes operational, companies can begin registering their chemicals.

a. Mercury

In April 2021, Colombia enacted a decree bringing the country into compliance with its Minamata Convention obligations. The decree bans manufacture, import, and export of mercury-added products listed by tariff code. The list includes products such as cosmetics, personal care products, switches and relays, pesticides and herbicides, batteries, medical and measuring devices, and lamps. Exemptions are provided for cases when it can be proven that no replacement exists and for certain maximum content limits. Restrictions on certain chemicals in products can be noticed more and more throughout Latin America. More bans can be expected in 2022 and upcoming years, on more of the POPs regulated by the Stockholm Convention.

7. Mexico

As in 2020, Mexico's plan to publish a comprehensive chemical law made no significant progress in 2021, 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. 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 December 2020, Mexico's chemical industry association (Asociación Nacional de la Industria Química; ANIQ) issued a written proposal to the Mexican health authority to establish a national inventory of chemicals as a basis for future chemicals regulation and management. ANIQ's proposal differs from Mexico's General Health Council's (Consejo de Salubridad General; CSG) proposal to establish a registry of chemicals, which would require more information on the substances listed. The CSG's response to ANIQ's proposal is not known to date.

In developing a comprehensive law for managing chemical substances, Mexico has a unique situation among the Latin American countries; Mexico is part of the 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 EU REACH. This is at odds with the USMCA, that backs a risk-based approach for regulating chemicals, similar to TSCA.

Given the unique situation Mexico is in, it is likely that 2022 will see much progress toward adopting comprehensive chemicals legislation. Mexico must first find a way to reconcile the goals of cooperating with other countries in the region to establish uniform chemicals regulation, and conforming to its treaty obligations with the United States and Canada.

a. Cosmetics

On September 2, 2021, Mexico passed a bill banning animal testing in cosmetics. Mexico is the first country in North America to pass such a law, and the third country in Latin America after Guatemala and Colombia.

The law prohibits the manufacture, import, and marketing of cosmetic products, or those that contain any ingredients or combinations of them, that have been tested on animals. The law provides a two-year transition period for manufacturers to replace animal testing with alternative methods to assess the safety and efficacy of cosmetic products. Manufacturers and importers must indicate on the packaging that no animal testing has taken place. Additionally, sanctions for not complying with the law range from fines to prison sentences of two to seven years.

8. Peru

Peru made no progress in 2021 in developing a chemical management framework. On July 24, 2021, Peru enacted its long-awaited PRTR (Registro de Emisiones y Transferencias de Contaminantes; RETC), where companies must report their emissions of listed pollutants. The trackable and reportable contaminants are broken into categories, including chemical substances, physical/chemical parameters, and hazardous waste streams. This reporting obligation will become mandatory after the initial voluntary three-year period expires in **2024**.

The regulation of hazardous substances is clearly not off of Peru's agenda. It is possible that in 2022 Peru will publish its first official draft chemicals management framework. Peru ispart of LARCF and cooperates with other countries in the region that are developing chemicals legislation. Additionally, Peru is a partner in OECD. Developing a comprehensive chemicals management framework is part of the obligations to join OECD.

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C. UNITED KINGDOM/GREAT BRITAIN

1. Overview

The UK completed its first year of complete separation from the EU in 2021. 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) in 2022. While the major regulations pertaining to chemicals were carried over into UK law mostly unchanged after the Brexit transition period, the UK now makes its own decisions, and divergence between the UK and EU regulations will continue in 2022 and beyond.

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. GB's HSE received almost 9,000 grandfathering notifications, for approximately 4,000 unique substances. These figures do not reflect the downstream user import notifications (DUIN) for which the initial submission deadline was October 27, 2021.

Eligible companies that missed the April 30, 2021, deadline might have opportunities to grandfather their EU REACH registrations in 2022 and perhaps beyond. The HSE intends to reactivate the grandfathering option in the Comply with UK REACH IT system for limited time periods, depending on input from stakeholders. The HSE reactivated the grandfathering process from the morning of June 30 until midnight on July 1, 2021, allowing delayed registration regardless of the reason for missing the April 30, 2021, deadline. Companies outside of GB holding EU REACH registrations that are not eligible for grandfathering must register under UK REACH to remain in commerce in GB.

WEBINAR

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As of January 1, 2021, 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. Over 5,000 importing customers or their suppliers submitted up to one million DUINs by the October 28, 2021, deadline. The HSE has been silent on how many individual substances were notified.

HSE left the DUIN process open past the deadline and asked companies to submit DUINs as soon as possible. Qualifying GB importers that have not already done so should submit a DUIN as soon as possible. Despite the flexibility demonstrated by HSE regarding the DUIN deadline, companies should not rely on HSE being as flexible with the registration deadlines. The DUIN substances require registration within the applicable timeframe, which is currently 300 days plus two, four, or six years from the end of the transition period, depending on the tonnage and hazard profile of the imported substances.

The combined total of grandfathered substances and substances covered by DUINs may still fall short of the 22,500 substances registered under EU REACH. The HSE requires time to sift through the enormous amounts of information submitted by downstream users. Some of the DUINs might have been precautionary, and the company may not follow through with a full registration. The upcoming years will tell how many substances will be registered and remain on the GB market.

On November 9, 2021, the UK adopted the Environment Act 2021 (EA 2021), a landmark environmental bill that gives the secretary of state the power to amend UK REACH and UK REACH enforcement regulations via secondary legislation. The government responded to concerns about regression from EU environmental standards by enacting legislation to keep UK REACH up to date and respond more effectively to the emerging needs for management of chemicals. The "no data, no market" provision remains, reducing the government's power to concede to pressures to reduce its requirements for chemical safety data. Adoption of EA 2021 is a pragmatic step that enables

Regardless of one's role, whether manufacturer, importer, non-Great Britain (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.

the UK to forge its own path for regulating chemicals and diverging from EU REACH.

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. Although two important deadlines have passed, HSE has been flexible, providing further opportunities for companies to take advantage of simplified procedures. The first registration deadline of **October 27, 2023**, for 1,000 tonnes or more per year is approaching rapidly, and its extension is under consideration. The Secretary of State for Environment, Food and Rural Affairs (DEFRA) stated in its December 6, 2021, letter to the Chemical Industries Association (CIA) DEFRA's intentions to engage with stakeholders to explore a new UK REACH transitional model and consult on extending the current registration deadlines. Companies should act quickly to understand their rights and obligations under UK REACH to maintain continuity of their supply chains and market access.

3. Cosmetics

As of January 1, 2021, Regulation (EC) No 1223/2009 of the EP and of the Council on cosmetic products (Cosmetics Regulation) no longer applies in the UK. The UK legislation adopts and adapts many of the provisions in the Cosmetics Regulation, including the designation of a "responsible person" in GB to assume responsibility for GB Product Information Files (PIF) and other aspects of GB regulatory compliance, and the establishment of a GB Cosmetic Product Notification Portal (CPNP).

The provisions of the Ireland/Northern Ireland Protocol (IE/NI Protocol) stipulate that a cosmetic product placed on the market in 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.

On October 4, 2021, the HSE published guidance for companies seeking to make available cosmetic products in GB. The guidance does not cover cosmetic products made available in NI, for which the company must be established in NI or the EU. There is separate technical guidance available for both NI and GB. The guidance covers all practical aspects of the UK Cosmetics Regulation, from the role of a "responsible person" to the role of the UK's Office for Product Safety and Standards (OPSS), CMRs, and notification of nanomaterials in cosmetics. According to the guidance, good manufacturing practices can be demonstrated through compliance with the ISO 22716 standard.

There are no significant differences between the EU and the UK Cosmetic Regulations following Brexit, and imminent divergence between the two is not expected. 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 product approval (UK BPR). While the UK BPR reflects the current EU framework, EU authorizations and mutual recognition are no longer applicable in GB. The HSE replaced ECHA for active substance evaluations and approvals as well as biocidal product authorizations in GB. Companies wishing to place a biocidal product on the market in both the European Economic Area (EEA) and GB must comply with two regulatory frameworks and submit separate applications to ECHA and the HSE. Divergence between the EU and UK regulations is likely, increasing the regulatory burden 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 must 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. Pending product applications that were not completed on or before December 31, 2020, had to be resubmitted to the HSE by applicants seeking authorization in GB.

GB established its own version of the list of approved active substance suppliers, known as the GB Article 95 list. Companies that were on the EU's list on December 31, 2020, will also be on GB's list. To remain on GB's list, a company must be established in the UK and must submit to HSE within two years the same information required to be submitted to ECHA under BPR.

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; HSE GB supports HSE NI in this role. In practice, therefore, businesses should submit their applications to HSE GB, which will evaluate applications on behalf of HSE NI. An authorization granted in NI is not mutually recognized in other parts of the EU, while an authorization granted by other EU MSs can be mutually recognized in NI. Companies that wish to market a product only in NI must apply to the NI competent authority, which is in effect HSE GB. Companies established in NI can also apply for an authorization in GB. Conversely, however, a company that is only established in GB cannot hold an authorization in NI, as in any other EU MS.

On November 5, 2021, HSE published an open invitation for companies to take over the role of participant for over 90 active substances/product-type combinations that have not been resubmitted under the GB Biocidal Active Substance Review Programme (Programme). The Programme evaluates active substances; the deadlines for resubmitting applications in GB were March 31, 2021, and June 29, 2021.

Companies or consortia interested in taking the role of participant for any of the active substances must notify the HSE by **November 12, 2022**, to ensure that their biocidal products can remain on the GB market. Substances lacking a participant will not be approved under GB BPR, and the biocidal products containing these substances will have to be removed from the GB market.

5. PPP

As of January 1, 2021, GB has its own independent regulatory regime for plant protection products (PPP). Existing MRLs, approvals of active substances, and PPP authorizations were brought into UK legislation and remain valid until their amendment by HSE (MRLs) or expiry date (active substances and products); existing parallel trade permits will remain valid until their expiry date, or **December 31, 2022**, whichever is sooner.

As of 2021, HSE is the competent authority for new active substance approvals. Approved active substances will be included in a statutory active substance 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. While the application format and data requirements for submissions to GB and the EU remain the same, a company also wishing to gain access to the EU market must submit separate applications under the GB and EU regimes. MRLs could diverge between the UK and the EU, and it will be essential for those companies producing food products to understand the impact of such changes on their intended markets.

One year after Brexit, pesticide regulation in GB remains mostly unchanged from the EU regulation it copied into its law. 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 legal developments in 2022. After a slow start, GB might make amendments that diverge from pesticide regulation in the EU.

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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 EU Chemicals Strategy for Sustainability (Strategy), as implemented through amendments to EU chemicals regulations, is foreseen in 2022 and beyond to achieve the goals of the Green Deal.

2. EU REACH

Amending EU REACH, which entered into force in 2007, is a plausible step forward to achieving the Strategy's objectives of sustainability and circularity by **2024**. Amendment of REACH in 2022 is unlikely, as the Commission's work program, adopted on October 19, 2021, did not propose specific revisions to REACH. The Commission's proposal on REACH revision is expected to be released during the **last quarter of 2022**.

Deadlines for expert group proposals addressing two of the most pressing issues under the Strategy, legislation on registration of polymers and increased data requirements for the identification of endocrine disruptors, appear to have been extended by one to two years. The polymer group's mandate was extended until the **end of 2022**, and the endocrine disrupting chemicals group's until **2023**.

The Strategy proposes to address the risks of exposure to mixtures of substances (*i.e.*, combination effects) by introducing mixture assessment factors (MAF) into REACH, as additional risks that may arise from unintentional exposure to mixtures of chemicals are not generally part of risk assessment under REACH. Introducing MAFs into REACH raises the possibility that thousands of registrations would have to be updated and would likely cause nominal risk values to increase.

Another controversial and ambitious plan is to amend or even do away with the authorization process under REACH.

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Compliance Checks and REACH — A Conversation with Karin Baron

MSs, such as Germany, Sweden, and Belgium, oppose eliminating the authorization process and instead advocate amendments to improve the efficiency of the authorization process. Stakeholders concur that removing the authorization process is not a viable option, with industry favoring merging authorizations and restrictions, while NGOs appear to prefer adding clarifications and simplifications to the current authorization process.

Achieving the ambitious goals of the Strategy timely is expected to place heightened emphasis on REACH compliance and enforcement in 2022 and beyond. In addition to the existing enforcement authority under REACH, which is granted principally to MSs, ECHA will continue to seek changes that grant it enforcement authority to address noncompliance by registrants with respect to decisions on compliance checks, conditions of restrictions, and authorizations.

European regulators are struggling to improve compliance with REACH for online sales of chemicals and products. One option under discussion is mandating ORs for online sellers that have no legal entity established in the EU to facilitate enforcement via the OR against online sales that violate REACH.

As of December 12, 2020, companies were required to comply with specific deadlines for updating their REACH registration dossiers to reflect changes in company information, tonnage band, or data. Companies were then required to update their dossiers within three months for administrative updates, such as a change in the registrant's identity, and within six, nine, or 12 months for more complex updates. In July 2021, ECHA began a new campaign to screen dossiers of REACH Annex XIV substances, to verify compliance with dossier update obligations. ECHA will focus on screening substances for which the sunset date has passed and no applications were made for authorization. This is expected to involve 26 substances and 148 registration dossiers.

As of January 1, 2021, companies are required to comply with updated requirements for SDSs, following the amendment of Annex II of REACH, bringing the regulation in line with the sixth and seventh editions of GHS (*see* the GHS section for details). In a December 2020 amendment, Category 1A and 1B CMR substances were added to the restricted substances list under Annex XVII, to align with rules under the CLP regulation.

Revisions of REACH Annexes VII to XI will apply as of **January 8, 2022**, changing several information require-

ments for registering chemicals. Companies are advised to prepare for these amended requirements, because they could trigger the need to update their dossiers.

In August 2021, ECHA released an updated Guidance on Registration, which describes when to register and update the registration dossier of a substance under REACH. Companies are advised to consult the guidance document to help comply with their obligations under the REACH Regulation.

MSs are scheduled to evaluate 58 substances between 2021 and **2023**, under the current draft Community Rolling Action Plan (CoRAP). The substances are distributed for evaluation among 16 MSs for the years 2021, 2022, and **2023**. In 2021, eight substances were evaluated by six MSs. In 2022 and **2023**, it is planned to evaluate 40 and 10 substances, respectively. Changes may be introduced for the substances listed for years 2022 and **2023** in the next CoRAP update in **March 2022**. ECHA advises registrants of a listed substance to coordinate their actions, and contact the evaluating Member State Competent Authority (MSCA). Downstream users of a listed substance are advised to review "the information they have available and share it with the registrants." Entities subject to REACH substance evaluation processes can benefit from reviewing ECHA's guidance document entitled "Registrant's guide — How to act in substance evaluation."

Nearly two years after the deadline to register nanomaterials, only 150 substances in nanoform have been registered under REACH so far. According to ECHA, this is half the number of nanomaterials ECHA estimates to be currently on the market. ECHA voiced concerns that many nanomaterials are on the market and are non-compliant, leading to a lack of data on their safety.

Finally, with completion of the Brexit transition period, ECHA revoked 2,964 GB-held EU REACH registrations that were not transferred to EU legal entities. More than 8,000 dossiers were transferred to EU legal entities by December 31, 2020.

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 imminent to accommodate the EC's vision of sustainability by promoting uniform risk management across various chemical sectors, centralizing chemical reviews, and addressing environmental concerns. In October 2021, the EC published an inception impact assessment (IIA), which marks the beginning of the revision process and outlines potential amendments to the law. The EC plans to launch an open public consultation in **early 2022** to complement the IIA. The finished assessment will be presented together with the proposal for the revised legislation in the **fourth quarter of 2022**. The proposal will then go through the normal legislative process. The final revised Cosmetics Regulation is expected to come into force by **2023** or **2024** at the latest.

Under the EC's current proposal, the scope of the Cosmetics Regulation would be expanded to address environmental endpoints for the first time, to ensure that cosmetics do not contain chemicals that are persistent and bioaccumulative. 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.

The proposal to extend the generic approach to risk assessment (GRA) from CMR chemicals to include other hazard classes has caused some controversy. Industry expressed concern that such changes risk creating trade barriers if the EU is the only jurisdiction to regulate cosmetics in this manner. Industry argues that the same level of protection can be achieved by adapting existing mechanisms, such as the mandatory cosmetic product safety assessment, to manage the risks from high-priority substances under the Strategy.

On November 3, 2021, the EC amended Annexes II, III, and V of the Cosmetics Regulation to prohibit 23 CMR chemicals from use in cosmetics as of **March 1, 2022**, unless there is an exemption. One example is zinc pyrithione, classified as a Category 1B carcinogen, which will be removed from the Annex III list of restricted cosmetic ingredients, where its use in leave-on hair products in concentrations up to 0.1 percent was permitted, and from the Annex V list of permitted preservatives in cosmetics, where it had previously been allowed in concentrations up to 1 percent in rinse-off hair products and 0.5 percent in other products.

Given the significant changes underway regarding the Cosmetics Regulation, companies are advised in 2022 to follow developments in the legislative process closely. Companies can participate in the process, engage with the European authorities, and voice their concerns before the amendments are final.

The biocides Review Program continues to progress, though at a slower pace than anticipated, and with skepticism about meeting the December 31, 2024, deadline for completion.

4. Biocides/Endocrine Disruptors

In March 2021, Commission Delegated Regulation (EU) 2021/525 **was published,** amending BPR Annexes II and III to require more data on reproductive toxicity, developmental neurotoxicity, and developmental immunotoxicity. The delegated Regulation establishes a testing strategy and methods for determining endocrine-disrupting properties of substances. The data requirements apply as of **April 15, 2022**, but applicants for active substance approvals or biocidal product applications may apply the changes introduced by the delegated Regulation voluntarily before that date.

The biocides Review Program continues to progress, though at a slower pace than anticipated, and with skepticism about meeting the **December 31, 2024**, deadline for completion. The purpose of the program is to examine existing biocidal active substances contained in biocidal products. In a July 2021 report on the implementation of the BPR, the EC identified the slow progress in the evaluation of active substances as the main problem. The EC plans to provide MSCAs technical support to complete their evaluations. A full evaluation of the BPR is planned for **2025** to analyze whether the current regulatory framework regulates biocides appropriately.

ECHA's Biocidal Products Committee (BPC) discussed the future workload to accomplish the Review Program deadline. BPC expects to adopt an unprecedented 80 opinions in 2022, and to process between ten and 15 applications for the Union authorization of biocidal products per meeting in 2022.

Also in an attempt to speed up the Review Program, ECHA started a campaign aiming to identify by the end of 2022 all active substances that may require redefinition. MSCAs should confirm by **March 31, 2022**, that the identity listed in Annex II of the BPR is correct for those active substances under their responsibility or inform ECHA of a need for redefinition.

While progress under BPR is comparatively slow, and no major amendments should be expected until **2025**, ECHA had clear intentions to devote more energy and resources to working with MSs and support the efficient implementation of BPR. Biocidal products and endocrine disruptors are a high priority in European chemicals regulation, especially in the context of the Strategy.

5. PPP

In light of the EU's ambitious goals for a toxic-free environment, Regulation (EC) No 1107/2009 concerning PPPs (PPP Regulation) is one of the chemicals regulations that is being reviewed for efficiency and effectiveness in promoting the Strategy's goal. Regarding pesticides, it is a high priority in the coming years to tackle "pesticide dependency" and to "significantly reduce the use and risk of chemical pesticides." For now, however, it seems that a revision of the PPP Regulation is not the means chosen by the EU to achieve these goals.

In a May 2020 report, the EC evaluated the PPP Regulation and concluded that the current legislative framework is effective, but that its implementation could be improved significantly. The immediate focus will be, therefore, improving the implementation in 16 areas identified for short- and medium-term action. A swift phase-out of active substances that do not fulfil the approval criteria, combined with enhanced implementation, will, according to the EC, reduce dependency on chemical pesticides and contribute to more sustainable food production systems. With the focus on improving implementation, a revision of the PPP Regulation does not appear to be on the EU's radar at the moment.

The EU food policy, the Farm to Fork Strategy (F2F), which will be embedded within the framework of the Green Deal, will target the reduction of risk and use of pesticides through legislative actions. The goal of the F2F is to increase the sustainability of the entire food chain from production to consumption and to neutralize its impact on the environment.

Within the EU Strategy, the combined and cumulative impacts of pesticides on human and environmental health will be assessed. Such impacts happen through the use of

multiple pesticides that can persist as residues on food, and through industrial processes and consumer products. As the EU turns increasing attention toward endocrine disruptors, this will affect pesticides, because many pesticides are known to have such properties.

On March 24, 2021, Regulation (EU) No. 2021/383 entered into force, amending Annex III of the PPP Regulation. Annex III lists the co-formulants that cannot be accepted in the composition of a PPP, an adjuvant, or a combination product. MSs that granted marketing authorizations for PPPs, including adjuvants and combination products, containing co-formulants listed in Annex III must withdraw them as soon as possible, and at the latest within two years after the entry into force of Regulation (EU) No. 2021/383. Companies holding an authorization, or that applied for an authorization before March 24, 2021, are advised to review their obligations and the timelines.

While the revision of the PPP Regulation might be in the more distant future, the overhaul of Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides (Sustainable Use of Pesticides Directive) seems to be a more immediate priority for the EC in the agricultural sector. The Directive aims to reduce the risks and the impacts of pesticide use on human health and the environment but has received criticism for its poor implementation in the MSs. As outlined in the F2F, the EC aims to bring the Directive in line with the objectives of the European Green Deal. The amendment is expected sometime in 2022.

PODCAST:
Update on European Union Chemical Management Issues — A Conversation with EPPA's Meglena Mihova

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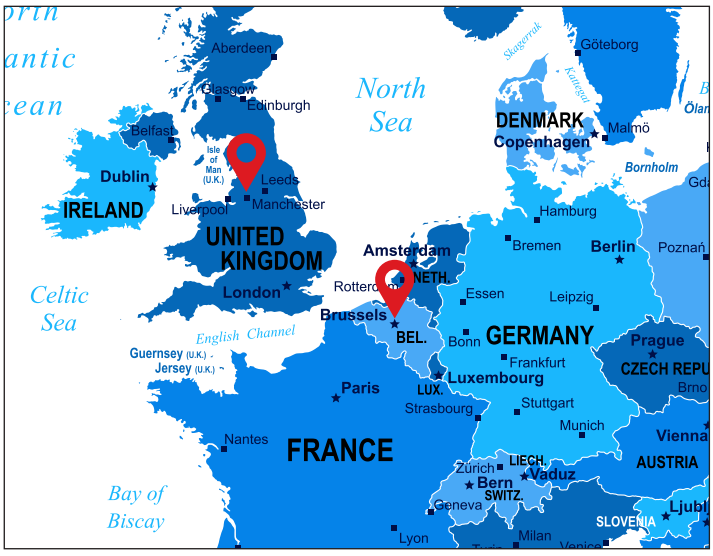

E. EURASIA/RUSSIA

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 Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), includes elements from the EU REACH, as well as U.S. TSCA. For example, like EU REACH, both new and existing substances must be registered, and, similar to TSCA, the framework regulation begins with the formation of an initial inventory of existing chemical substances.

Two draft implementing sub-regulations, one proposing the procedure for creating and maintaining a register of substances and mixtures, and the second proposing the procedure 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 draft implementing sub-regulations were available for public comment until April 1, 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.

Other notable deadlines include:

- **July 1, 2022**, for EAEU MSs to complete their inventories of substances (including those contained in mixtures) in circulation and planned for circulation in the EAEU customs territory;
- **September 1, 2022**, to form the national parts of the Register of substances and submit relevant information to the EEC; and
- **October 1, 2022**, to analyze the information obtained from the inventory and inform the competent authority about analysis results.

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 spring 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 would 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, most likely because of the delays to TR EAEU 041/2017. An additional reason for the delay concerns the requirement that registrants prepare chemical safety passports (CSP). The CSP would contain information about a chemical's hazardous properties, information about the manufacturer or importer, and safety requirements.

Unless exempt, a CSP would be required for all chemical products placed on the EAEU market, and registrants would be required to disclose the full composition of their products during the registration process. Industry concerns about the CSPs include how this requirement would be implemented in practice and whether CBI will be protected, especially if registrants are required to disclose the composition of their mixtures to the authorities.

The implementing sub-regulations could become effective in the **beginning of 2022**, considering that the negotiations concluded in 2021, and the current deadlines in the drafts are as early as **July 2022**. With the controversy surrounding the CSP, and the entry in force of the standards being linked to TR EAEU 041/2017, it is also possible that the implementing sub-regulations will be delayed until after the standards are agreed upon.

1. Russian Federation

The Russian Federation continues to develop its own regulatory framework. In 2016, the Russian Federation issued, in final, the Technical Regulation on the Safety of Chemical

Products (TRSCP; Decree No. 1019). TRSCP aims to establish a chemicals framework with implementation dates similar to the EAEU framework regulation. Russia started compiling an inventory of chemical substances in May 2019 and published a transitional inventory in June 2020.

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 2022, Russia will most likely continue to progress in advance of the EAEU in developing its regulatory framework for chemicals. By establishing its final inventory of existing substances, Russia has met the EAEU **July 2022** deadline in the draft implementing sub-regulations.

2. Ukraine

In February 2021, Ukraine's Ministry of Economic Development, Trade and Agriculture published the Draft Technical Regulation on the Safety of Chemical Products, aiming to transpose into Ukrainian law EU REACH. Ukraine would not transpose the Annex II SDS requirements for unique formula identifiers (UFI), nanomaterials, and poison center notification (PCN). Currently, Ukraine has no legislation in place regulating the safety of chemicals produced or imported into the country. Ukraine may adopt the legislation in 2022 as a sign of its commitment to the EU and the EU-Ukraine Association Agreement, as Ukraine continues negotiations for joining the EU following the 23rd EU-Ukraine Summit in October 2021.

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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 2021 to align its legislative framework with the main European chemicals regulations. By far, the most activity in 2021 was implementing the KKDIK regulation (Kimyasalların Kaydı, Değerlendirilmesi, İzni ve Kısıtlanması). In January, Turkey began the first phase of registration under the KKDIK regulation. Turkey also amended its cosmetics and biocidal products regulations to harmonize with the equivalent European regulations.

2. KKDIK

Implementation of the KKDIK regulation continued in 2021 with Substance Information Exchange Forum (SIEF) formation and designation of lead registrants (LR) following the conclusion of the initial pre-registration phase on December 31, 2021. The first draft KKDIK regulation was published in 2013 and was amended several times. On June 23, 2017, the Turkish Ministry of Environment and Urbanization (MoEU) published the current version of the KKDIK, and the regulation entered into force on December 23, 2017.

KKDIK is a hazard-based chemical regulatory framework that requires registration of chemicals manufactured or imported in quantities of one metric ton or more per year in Turkey. KKDIK data requirements are aligned with the same annual tonnage bands as the EU REACH (*i.e.*, 1 - 10 metric tons, 10 - 100 metric tons, 100 - 1,000 metric tons, greater than 1,000 metric tons). Unlike EU REACH, the registration timeline is not staggered according to tonnage band. Registrations for all tonnage bands may be submitted by **December 31, 2023**.

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

Companies that pre-registered began forming SIEFs, are negotiating the nomination of LRs, and are developing strategies for the distribution of data and sharing of costs. These negotiations continued throughout most of the year, though initially they were expected to conclude sometime in the summer. Officially, the MoEU had scheduled the LR declarations to begin February 15, 2021, but then deferred it to March 1, 2021, to integrate the electronic voting system for LRs into its chemical registration system IT platform. Voting is not mandatory, and the MoEU reserves its right to request the casting of votes or ask to see the ballot results in the future, if it deems necessary.

Under EU law, ECHA does not intervene in disagreements among SIEF members. Under KKDIK, in cases where SIEF members cannot agree on an LR, MoEU may intervene to resolve the dispute. The ministry then directs the SIEF members to the online voting platform to solve the deadlock and determine an LR.

Turkey planned to integrate Chesar, an application developed by ECHA, to assist companies with the development of chemical safety assessments (CSA), by the end of 2021.

As dossier development continues into 2022, a few points to note include that the entire dossier must be translated into Turkish with minor exceptions for analytical data (*e.g.*, tables on the endpoint of study reports), the details on the identity of importers is expected, and the entire submission is completed using the KKS platform.

The next two years will continue to see the implementation of the KKDIK registration phase, and it is expected that the government will likely issue guidance documents, similar to the EU, to assist companies.

3. Cosmetics

In June 2021, Turkey published a draft Implementing Regulation on Cosmetic Products (Implementing Regulation) to ensure continued harmonization with the EU's Cosmetics Regulation 1223/2009/EC (Cosmetics Regulation), as required by the EU-Turkey Customs Union Agreement. Together with the Implementing Regulation, Turkey published a separate communiqué on cosmetic ingredients. The communiqué has been prepared based on Turkey's Regulation on Cosmetic Products published in the *Official Gazette* No. 25823 of May 23, 2005.

The draft Implementing Regulation would rearrange the annexes to conform to the EU's Cosmetics Regulation. The communiqué applies to cosmetic products within the scope of Turkey' Cosmetics Regulation and will enter into force first, followed by the amended Implementing Regulation.

The objective of the communiqué is to determine the categories of products placed on the market and the properties of the ingredients they contain. The communiqué aligns with Annexes II to VI of the EU Cosmetics Regulation and will be updated according to the developments in the EU legislation.

4. Biocidal Products

In August 2021, Turkey's Ministry of Health proposed to amend its 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 EU BPR. Specifically, the amendments intend to facilitate implementation of the regulation, to reduce confusion regarding the provisions on applicant/application, sampling, and authorized laboratories. The amendments entered into force on January 1, 2022.

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G. MIDDLE EAST AND AFRICA

1. Uganda

Uganda is working to ban eight phthalates from textiles. The National Bureau of Standards (UNBS) published a draft standard that, while exempting PPE, would ban the use of these phthalates in plastics and coatings in textiles. The draft standard also includes implementing international chemical textile standards ISO 14362, ISO 16373, and ISO 14389. The draft standard is expected to become mandatory by the end of the 2021. Given Uganda's work throughout 2021 to update textile standards, the phthalate ban will likely affect importers and producers in **2022**. Producers should also be watching for new developments in textile standards as the year progresses.

2. Egypt

Effective January 15, 2021, companies that produce or import chemicals into Egypt are required to use SDSs for their products. The SDS requirement adheres to the international SDS standard (ISO 11014/2009). This standard does not follow the UN's GHS, and Egypt does not currently participate as a member at the UN level. The mandatory standard allowed for a six-month transition period, but companies wishing to import chemicals into Egypt in 2022 should familiarize themselves with the new standards.

3. Ghana

Ghana had planned to publish a draft industrial chemicals management bill for public consultation in early 2021. The industrial chemicals management bill proposes a registration scheme similar to EU REACH for chemicals placed on the Ghanaian market in quantities exceeding one tonne per year, subject to Ghana Environmental Protection Agency (Ghana EPA) approval. Ghana EPA has asked for international experts to consult on the draft bill to identify points of better alignment with either the UN GHS for classification and labeling of chemicals or EU REACH for registration and risk assessments. The draft, written in January 2020, has yet to be published, and Ghana EPA needs to develop a fee registration system as well as establish transition periods for registered substances. Once published, the draft bill will also need to go through public consultation. It will likely be some time before Ghana has a comprehensive industrial chemicals bill in effect, as it is unclear whether the draft bill will be published in 2022.

4. Guinea

The environment and health ministries of Guinea have published a draft decree aimed at limiting lead in paint and heavy metal concentrations in toys and cosmetics. If the decree comes into effect, it will place a ban on the import, manufacture, and sale of toys, cosmetics, and electronic and electrical waste (e-waste) containing 12 heavy metals. The ban will also apply to those handling the recycling or waste of products containing these heavy metals. The draft decree additionally contains restrictions on mercury, moving Guinea further in compliance with the Minamata Convention. Under the draft decree, mercury would be banned in cosmetics and medical equipment, limits would be set on light bulbs, and the import of mercury for the use of small-scale gold mining would be prohibited. The decree is expected to be signed into effect by the Prime Minister in 2022.

5. Iraq

Iraq has become the 134th country to ratify the Minamata Convention. Although Iraq had signed onto the convention in 2013, it was not until September 2021 that the country ratified the pledge. The Minamata Convention works to better human health and the environment by phasing out mercury from products as well as reducing other heavy metals used in products. The effects of Iraq's ratification began on December 15, 2021. Importers and producers should be aware of new mercury and heavy metal limits beginning to take effect in 2022.

6. Israel

Israel's Ministry of Environmental Protection is reviewing public comments made to the draft Industrial Chemicals Registration Law, first published 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 draft law aims to create an inventory of existing chemical substances through a mandatory registration process. Once the registration periods ends, all substances will then 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 tonnes, 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 expects the law to be approved in late 2021 and to take effect on **March 1, 2023**. The Ministry of Environmental Protection has announced that during the transition period of **2022-2024**, the use, trade, and manufacture of chemical substances will remain unaffected and will not be subject to new rules.

The Standards Institution of Israel has proposed to amend permitted migration limits in toys. If adopted, Israel will adhere to the EU's EN 71-3:2019, Safety of Toys-Part 3: Migration of certain elements. The EU standard includes requirements and test methods for measuring the migration of 19 heavy metals and chemical elements. Israel has been conducting a variety of studies to push through standards on chemicals exposure to sensitive populations and will likely use these data in support of adopting the EU toy migration limits in 2022.

7. Kenya

Kenya is continuing to work on developing legislation for a national chemical database and safety program. The process has been ongoing since 2009, but in early 2021, the Kenyan environment ministry published a new draft of the policy. The policy aims to implement GHS classification and labeling, promote chemical safety, and review known chemical safety data. Kenya is working to achieve the goal of a unified national policy for chemicals among industry and governmental bodies. An interministerial committee has been formed to work on policy, Responsible Care programs, and establishing a chemical database. It is unclear when any of these initiatives will come into effect or be prepared in final. These initiatives may be additionally hindered by Kenya's reliance on funding from the UN Environment Programme's Special Programme, which ended in August 2021.

8. Pakistan

In furtherance of fulfilling the national commitment on the Sustainable Development Agenda, **2030**, Pakistan issued the final Pakistan Persistent Organic Pollutants Management Rules in September 2020. The final rules work to align Pakistan with the UN's Stockholm Convention for manufacturing, handling, and transporting POP chemicals.

Pakistan's Ministry of Climate Change (MoCC) approved a draft national chemicals management policy on December 31, 2020. The draft awaits approval by the Pakistani prime minister and Federal Cabinet, which had been anticipated in mid-2021, but will now likely be approved in 2022. If the draft passes, MoCC intends to proceed with publishing a chemical substances act, which aims to regulate the import and export of chemicals in Pakistan. The draft policy is a big step in achieving Pakistan's goal of implementing an overarching chemicals act **by 2023**.

9. Saudi Arabia

The Saudi Standards, Metrology and Quality Organisation (SASO) published a technical regulation requiring companies to meet electronic and electrical 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 Directive on the restriction of hazardous substances (RoHS), but the regulation omits four phthalates — DEHP, BBP, DBP, and DIBP. Before entering the Saudi market, all products will be required to undergo conformity assessment and prove conformity requirements are met. Products that will be subject to the technical 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 is set to take effect on **January 5, 2022**. Manufacturers will have until **July 9, 2022**, to sell products that are already on the market that do not meet the EEE restrictions.

CONTRIBUTORS

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H. ASIA/PACIFIC RIM

1. Australia

The Australian Industrial Chemicals Introduction Scheme (AICIS), which replaced the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) in July 2020, has published its chemical evaluation roadmap and rolling action plan. The roadmap and action plan serve to provide guidance and strategic planning for how AICIS will prioritize industrial chemicals for evaluation and risk assessment. AICIS has set a goal of evaluating approximately 20 percent of the 39,422 chemicals currently 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**.

On June 24, 2021, Australia published the Industrial Chemical Environmental Management Standard (IChEMS). IChEMS will be managed by the Department of Agriculture, Water and the Environment (DAWE) and seeks to reduce industrial chemical impacts on the environment. Based on AICIS chemical evaluation assessments, industrial chemicals will be categorized into seven schedules. Scheduling on the IChEMS register is expected to occur in **early 2022** and will initially focus on industrial chemicals of high concern (such as perfluorooctanesulfonic acid (PFOS), mercury, and POPs). Adherence to IChEMS will be mandatory for the use, storage, handling, and disposal of industrial chemicals.

2. China

a. Chemical Substances

Many of the regulatory developments that China initiated last year will continue to evolve in the upcoming year. China is still working on developing a new overarching chemical law that includes a regulatory focus on hazardous and toxic substances. The Ministry of Ecology and Environment (MEE) published a second draft of the law in 2019, but has yet to issue it in final. The draft law, projected to be entitled the Environmental Management of Toxic and Hazardous Substances, would manage both new and existing chemicals and encompass the recently passed MEE Order 12.

China's MEE has announced a draft action plan that aims to phase out priority chemicals by **2025**. MEE has identified 28 substances or substance groups that it considers "new pollutants." Priority chemicals subject to a ban on the production, use, and import include decaBDE, pentachlorophenol (PCP), perfluorohexanesulfonic acid (PFHxS), short-chain chlorinated paraffins (SCCP), HCBD, dechlorane plus (DCC-CO), and nonylphenol in pesticide formulation. Production and use of PFOA and PFOS are scheduled to be subject to severe restrictions by **2025**. Under the action plan, MEE intends to issue new guidelines, regulations, restrictions, and bans on new pollutants and has established a timeline of **2035** to achieve a new pollutant control system.

MEE published final technical guidelines to assist industry with MEE Order 12 compliance: Technical Guidelines for Environmental and Health Hazard Assessment of Chemical Substances (Trial); Technical Guidelines for Environmental and Health Exposure Assessment of Chemical Substances (Trial); and Technical Guidelines for Environmental and Health Risk Characterization of Chemical Substances (Trial). It is projected that while additional guidelines and regulations will be developed under the new pollutants action plan, these technical guidelines will remain in effect to assist industry in risk evaluations and testing.

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. Under CSAR, special-use cosmetics are those products that present a higher level of risk, such as hair dyes and hair perming products, anti-freckle and whitening products, sunscreen, hair loss prevention, and products claiming new efficacies. General-use cosmetics include products for hair growth, breast beauty, depilating, slimming, and deodorizing. Toothpaste is now also classified as a general-use cosmetic, while soaps still remain exempt from the scope of CSAR unless containing a special-use efficacy claim. To be registered and enter commerce, special-use cosmetics must adhere to CSAR. General-use cosmetics must be notified through the National Medical Products Administration (NMPA) website. CSAR requires new cosmetics to be registered or notified, but processes vary depending on whether the product is exclusively made for the Chinese market, is imported, or contains a blend of imported and domestic ingredients. CSAR contains additional regulatory requirements, such as labeling, cosmetic product classification, and new cosmetics ingredients registration. With certain exceptions, such as products used on children or products containing ingredients not listed

China's Cosmetics Supervision and Administration Regulation creates a shift by China's National Medical Products Administration to place the burden of safety and efficacy requirements onto industry.

on the Inventory of Existing Cosmetic Ingredients in China (IECIC), CSAR allows for exemptions on animal testing toxicology for general-use cosmetics.

CSAR creates a shift by China's NMPA to place the burden of safety and efficacy requirements onto 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. In October 2021, China's NMPA announced a nationwide, year-long inspection plan to ensure that all cosmetics products sold in China and through online sales adhere to the new CSAR regulations. NMPA has issued guidance on inspections to assist cosmetics companies in preparation for inspections as well as disposal guidance for cosmetics not meeting CSAR standards.

China's NMPA has published a draft measure aimed at reporting and tracking adverse reactions to cosmetics. If finalized, the Measures for Cosmetic Adverse Reaction Monitoring would apply to any registered or notified product and would require companies to set up reporting systems for information tracking. Companies would be required to maintain adverse reaction records for at least three years.

NMPA has additionally published finalized regulations on the Supervision and Administration of Children's Cosmetics. The new regulations are set to take 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 must 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 negative feedback from the international community wishing to participate in the Chinese market.

c. Food Contact Substances

China has continued its work on assessing and regulating food contact materials (FCMs) during 2021. The National Health Commission (NHC) added ten substances, including additives and resins, to the food positive list (GB 9685-2016) this year. The NHC additionally expanded the approved uses of another nine substances in FCMs. Throughout 2021, NHC has opened consultation on the addition of 21 other FCM substances. If approved and added to the positive list, substances must adhere to GB 4806.1 before being used in FCMs. China expects to continue assessing FCMs in the coming year and updating its food positive list.

The NHC has 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 takes effect **on March 7, 2022**, and will repeal the existing standard, GB 31604.8-2016.

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. In light of feedback received from select industry stakeholders, India instead began working on a sixth revised draft version of the Rules. Industry concerns and pushback stemmed from registration timelines for priority chemicals, penalty schemes, and lack of administrative systems for registering substances and processing registrations. If the new Rules come into effect, manufacturers and importers will have a 180-day Initial

Notification Period (INP) beginning one year from the Rules' effective date to register substances as existing chemicals.

New chemicals entering the market will have a 60-day notification process before entering commerce. 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. While the full text of the sixth draft version of the Rules has not been publicly circulated, India's Department of Chemicals and Fertilizers announced intentions to circulate the sixth draft version by the end of 2021 and for it to be the finalized version of India REACH. Companies operating in India should watch for the sixth draft in 2022 to be issued in final and be aware of its expected regulatory impacts.

India's Cosmetics Rules 2020 came into effect in January 2021. The new Rules operate under the prior Drugs and Cosmetics Rules 1945, and they mandate the regulation of cosmetics separately from pharmaceuticals. In light of these amendments, India's Ministry of Health and Family Welfare (MHFW) has formulated a committee to begin working on constructing a New Drugs, Cosmetics and Medical Devices Act to clarify industry and consumer confusion over the amendments. The draft of the new Act was expected to be complete by the end of 2021. It is unclear when the Act will come into effect and what impact it will have on the Cosmetics Rules 2020.

4. Indonesia

In an effort to meet Stockholm Convention requirements, Indonesia's environment ministry has passed regulations to manage and phase out the use of polychlorinated biphenyls (PCBs). 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 allow 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) has announced that as of **September 2022**, PFOA related substances will be banned from manufacture, import, and use. The substances will be classified under Japan's Chemical Substances Control Law (CSCL) as Class I substances. As a party of the Stockholm Convention, METI is also reviewing and considering adding four other POPs to the list of Class I substances.

Japan's METI has been working throughout 2021 to update and add substances to its PRTR. In October 2021, METI added 87 substances to the PRTR. All substances included on the PRTR require SDSs when the substances, or products containing those substances, are transferred between business operators. Those substances listed as Class I will additionally require annual reports to be submitted to Japan's Ministry of Environment (MoE). Requirements for these newly added substances will go into effect **April 1, 2023**. METI has also announced that it intends to transition into a chemical management numbering system by **2024**. Under the numbering system, companies would be required to include the substance's number on all SDSs to signify whether and how the substance is subject to the PRTR.

6. Myanmar

As part of its obligations as a party to the Stockholm Convention, Myanmar has published its national implementation plan (NIP). The plan has been approved by the National Environmental Conservation and Climate Change Central Committee and submitted to the Conference of the Parties (COP). Myanmar's NIP seeks to address POPs through responsible management, elimination, and waste disposal. To provide funding for the NIP, the plan proposes an extended producer responsibility framework. As outlined, producers would be responsible for paying the cost of waste disposal for products such as PCBs, e-waste, plastics, end-of-life vehicles, and synthetic carpets. The NIP additionally proposes to implement a national chemicals management legal framework within the **next ten years**.

7. New Zealand and the Philippines

The New Zealand government is working to ratify the already signed Minamata Convention. The Ministry for the Environment (MfE) had initially projected ratification in 2021, but is now projecting a timeline of **early 2022**. 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 is continuing to work on passing the 2019 amendments to the HSNO Act. After drafting the amendments and soliciting public comments, the bill was

published on August 3, 2021. If approved, the amendments to the HSNO Act aim to update the New Zealand EPA 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's parliamentary Environment Committee scheduled hearings throughout the remainder of 2021 with the expectation of passing the HSNO Act amendments in 2022.

New Zealand's Ministry of Health has updated its Smoke-Free Environments Regulations to include herbal and vaping products. Regulations require manufacturers and importers of the products to adhere to labeling requirements. Annual reports addressing the previous year's activities must be submitted to the Ministry of Health by January 31 of each subsequent year. Manufacturers and importers are required to submit the first report on **January 31, 2023**.

The Philippines has not yet passed legislation to create the anticipated Environmental Protection and Enforcement Bureau (EPEB) within the Department of Environment and Natural Resources (DENR). While awaiting the creation of the EPEB, Environment Secretary Roy. A. Cimatu signed an administrative order in June 2021 creating an interim Environmental Law Enforcement and Protection Service (ELEPS) to work alongside of other Filipino agencies in environmental protection and enforcement activities. The DENR is still working to push Congress in passing bills to create the EPEB. While there is great support for creating the much-needed EPEB, it is not clear whether it will muster the support of President Rodrigo Duterte and be signed into law in 2022.

In the effort of implementing the Minamata Convention on Mercury, the Philippines has been working on banning mercury in certain medical devices and electronic products. Comments have been solicited for draft proposals, but final regulations have yet to be passed. The DENR has been working to reduce mercury limits in products since the Philippines ratified the Minamata Convention in 2020, and will likely pass final regulations in 2022.

8. South Korea

a. New Legislative Developments

South Korea has promulgated two new Acts in 2021, each working to supplement and focus on specific arenas of already existing legislation. Both Acts will take effect in **January 2022** and will place additional responsibilities on industry participating in the South Korean market.

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 finalized piece of chemical safety legislation. Taking effect on **January 27, 2022**, South Korea's Serious Accidents Punishment Act (SAPA) will require large companies to inspect and report on the substances and products within their facilities at least twice per year. With the intended purpose of reducing worker exposure, illness, and accidents from hazardous substances, SAPA mandates include trainings, disaster response procedures, and company health and safety departments. Those companies that rely on outsourced or subcontracted workers must also have health and safety policies in place for these workers and ensure that contractors follow the companies' health and safety procedures.

The Act on Risk Assessment of Products for the Human Body, administered by the Ministry of Food and Drug Safety (MFDS), aims to establish a comprehensive risk assessment system for all products and substances which come in contact with the human body. The Act will operate 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 aims to assess the risks associated with the chemical, biological, and physical factors presented by bodily contact with one or more substances. MFDS will set safety standards and implement a risk assessment master plan based on, but not limited to, products banned overseas; products using new materials, technology, or ingredients that do not have existing safety standards; and those products for which consumer groups request risk assessments. The Act comes into effect **January 28, 2022**, and will allow 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 has revised portions of its Cosmetics Act. Under the revisions, the sale of cosmetics prod-

South Korea's Ministry of Environment (MoE) has set up a government-funded support program to assist with data and testing costs and has identified 120 substances that are eligible for the support program.

ucts or cosmetics ingredients that use animal testing will be banned, with limited exceptions. The revisions also broaden the scope of parties now subject to the Cosmetics Act. Companies that combine, modify, and repackage existing cosmetics, often referred to as customized cosmetics, will now be subject to the Act. The new changes will take effect on **February 18, 2022**.

b. K-REACH

The first round of substance registration deadlines under South Korea's Act on the Registration and Evaluation of Chemicals (K-REACH) came to a close in 2021. 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 made adjustments to 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.

While the pre-registration deadline tolled in 2019, MoE continued to add substances to the pre-registration list throughout 2021, with the goal of assisting new manufacturers and importers in joint registration. In March 2021, MoE announced that it would conditionally extend the pre-registration deadline **by two years**. Pre-registration allows companies to continue to manufacture or import substances while proceeding through full registration. The late pre-registration extension deadline will apply to those companies that are importing or manufacturing substances over one tonne 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.

MoE has announced that over the course of the next five years, it will begin adding substances identified under the Stockholm Convention as POPs to K-REACH's list of priority control substances. Substances include PFOS, PFAS, and other flame retardants. The initiative is part of South Korea's Persistent Organic Pollutants Act, which took effect in 2020, and will incorporate limits on allowable concentrations of PCBs used in transformers and dielectric oils.

MoE has additionally set up a government-funded support program to assist with data and testing costs and has identified 120 substances that are eligible for the support program. The program ranges from 30 percent to 80 percent in cost reimbursements, depending on qualifying factors. As part of the program, MoE announced that for those qualifying substances requiring registration by **2024**, MoE will seek out and purchase certain data sets from domestic and international sources.

South Korea has passed an amendment to K-REACH extending responsibility to downstream users of products containing substances not registered under K-REACH. The new amendment came into effect in October 2021. Under the amendments, MoE now has the authority to recall products and ban manufacturers, importers, and exporters from using or selling products that contain unregistered substances. The amendment allows MoE to request additional information from other authorities, such as the Customs Office, as it pertains to unregistered 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. South Korea's MoE and National Institute of Environmental Research (NIER) have continued to develop K-BPR approval policy throughout 2021, and this is expected to continue as registration deadlines come near and grace periods end.

In 2020, MoE announced a simplified approval process under K-BPR. Substances already registered under EU BPR or U.S. FIFRA may be able to submit a reduced data set for K-BPR registration. In response, MoE has been updating which substances qualify for the simplified approval process. During 2021, 27 substances were rejected, while 15 have been approved, leaving the amount of substances that qualify at approximately 130. MoE has also announced that for those substances considered high risk or toxic, if the substances will not be permitted approval or renewal under EU BPR or U.S. FIFRA, MoE will likely not approve the substances under K-BPR.

The pre-registration deadline for existing active biocides and substance approval registration submission deadlines under K-BPR came to a close in 2021. So long as companies have not missed these deadlines, they will now be subject to grace periods that vary with the type and use of the existing substances. Manufacture and import may continue during these grace periods.

NIER has been working to publish guidance documents in 2021 for substance approval application dossiers, including approval procedures and processes for completing the application dossier. NIER has also issued a guide that aims to help industry navigate the rules of K-BPR for biocidal substances and products. The guide currently contains 15 types of products and NIER plans to update the guide periodically to reflect changes under K-BPR.

NIER has also published the updated list of low-risk substances which are exempt from K-BPR registration. With the addition of glycerol, sodium hydrogen carbonate, calcium carbonate, and sodium chloride, the exempt list now stands at 23 biocidal substances. NIER has the authority to remove and add substances to the K-BPR exempt list, and it intends to review those substances deemed exempt every three years.

9. Taiwan

Taiwan is considering postponing, for a third time, the issuance of a firm standard registration deadline for priority existing chemicals (PEC). Taiwan Environmental Protection Administration's (Taiwan EPA) second extension date had been proposed as **December 31, 2023**, for the manufacture or import of more than one tonne per year for all listed PECs. In 2019, 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. Under Taiwan's Toxic and Chemical Substances of Concern Control Act (TCSCCA), companies are required to submit to Taiwan EPA nine data items for registration assessment. Due to the delay, expense, and length of time to prepare, Taiwan EPA is allowing companies to delay submitting two of these data items, hazard assessments and exposure assessments. Taiwan EPA has not provided a deadline as to when companies must submit these two data items.

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 will have until **August 1, 2022**, to attain approval from Taiwan EPA for the manufacturing, 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 begin on **February 1, 2022**. Taiwan EPA reports that non-compliance with CCS regulations will be met with heavy penalties, including fines and potential imprisonment.

10. Thailand

Thailand's attempts to update and further regulate chemical substances went through a few iterations this year, leaving industry without a clear conclusion. In January 2021, Thailand's FDA published its fourth draft of the Chemical Substance Act (CSA). If approved, the CSA would replace Thailand's existing Hazardous Substance Act (HSA). Beginning in March 2021, the Ministry of Industry (MoI) began work on amending the HSA to include: new regulatory reporting requirements for chemicals on the hazardous substances list; prohibiting the manufacturing, importing, exporting, or use of certain PFOAs except in limited circumstances; and approving a draft fifth revision of the HSA. On June 30, 2021, MoI announced that it would delay final approval of the fifth revision of the HSA indefinitely. Meanwhile, Thailand has yet to approve the fourth revision of the CSA. The fourth draft removes the proposal to establish a new National Chemical Agency and instead broadens the scope of FDA's authority over chemical regulation. There has been no indication of a timeframe for when the CSA may be approved.

The MoI did publish a notice adding 153 hazardous substances to the list of chemicals that must be reported to the Department of Industrial Works (DIW) every six months if a company is handling more than 100-kg volumes of the substance. The six-month reporting requirement applies to all producers, importers, exporters, and handlers of the substances. Companies that handle less than 100 kg are exempt from reporting.

The DIW issued a proposed draft amendment to include ten new substances to the hazardous substances list, including PFOA and its compounds. The update to the list signals an effort by DIW to adhere to the Stockholm Convention, of which Thailand is a signatory. There has been no date set for when this amendment would take effect, but it is expected to enter into force immediately after final approval and publication.

11. 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 has issued five mandatory national technical regulations (NTR). Three that took effect on January 1, 2022, require limitations on and technical specifications for poly aluminum chloride (PAC), sodium hydroxide, and ammonia. As of **July 1, 2022**, all paints and varnishes may not contain more than 500 parts per million (ppm) of lead. On **July 1, 2027**, this limit will be reduced to 90 ppm. On **July 1, 2022**, new limits on the quantities of mercury permissible in fluorescent lamps are set to take effect. The NTRs apply to all manufacturers, importers, and distributors in Vietnam.

Vietnam's Ministry of Industry and Technology (MOIT) published a draft decree amending portions of Vietnam's Chemical Law (Decree 113/2017/ND-CP). In an effort to align the country with the Stockholm Convention, the draft decree will add substances to both the list of restricted chemicals and the list of prohibited chemicals. The draft decree was scheduled to take effect at the end of 2021.

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) is now working 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 not yet released the inventory of existing chemicals with the inclusion of the newly nominated substances.

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III. APPENDIX A: B&C SPEECHES AND WRITINGS

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Lynn L. Bergeson, "EPA Orders Testing for Nine Chemicals," *Chemical Processing*, February 22, 2021.

Lynn L. Bergeson, "Environmental Justice: Operationalizing TSCA to Fulfill Its Destiny," *American College of Environmental Lawyers (ACOEL) Blog*, February 4, 2021.

Lynn L. Bergeson, "OECD Will Hold Webinar on Assessing the Dispersion Stability and Dissolution of Nanomaterials in the Environment," *Nanotechnology Now*, February 2, 2021.

Lynn L. Bergeson, "EPA Proposes Revisions to TSCA Fees Rule," *Chemical Processing*, January 19, 2021.

Lynn L. Bergeson and Lara A. Hall, "M&A Activity in the Analytical Services Sector: Points to Consider," *Financier Worldwide*, January 2021.

PRESENTATIONS

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

"Product Sustainability Webinar Series: Part 2," Lynn L. Bergeson, Chemical Watch (November 17, 2021).

"Plastics Panel," Lynn L. Bergeson, American College of Environmental Lawyer's Education Committee (November 10, 2021).

"Moving Towards "Cradle-to-Cradle": Regulatory Drivers and Barriers in Reducing Waste and Achieving Sustainable Lifecycle Management and a Circular Economy," Lynn L. Bergeson, Section of Environment, Energy, and Resources (SEER) 29th Fall Conference (October 14, 2021).

"Chemical policy evolution in the US," Lynn L. Bergeson and Richard E. Engler, Ph.D., Chemical Watch Global Electronics Summit (September 21, 2021).

"TSCA Regulatory Activity, Industry Strategy and Actions 2021 and Beyond," Lynn L. Bergeson, IAEG Fall Virtual Meeting (September 20, 2021).

"PFAS Reporting Rules — What Every Company Needs to Know," Lynn L. Bergeson and Richard E. Engler, Ph.D., Bergeson & Campbell, P.C. (September 9, 2021).

"Pre-Conference Regulatory TSCA Workshop," Richard E. Engler, Ph.D., NACD ChemEdge (August 11, 2021).

"U.S. Chemical Regulation: What's New, What's Hot," Lynn L. Bergeson and Richard E. Engler, Ph.D., Mondaq (July 28, 2021).

"Law & Policy of Products Regulation," Lynn L. Bergeson, ELI Summer School (July 20, 2021).

"California Chemical Regulatory Policy Update," Lynn L. Bergeson and Lisa R. Burchi, NACD (July 15, 2021).

"TSCA and Environmental Justice," Lynn L. Bergeson, TSCA Reform — Five Years Later (June 30, 2021).

"TSCA Litigation Update," Lynn L. Bergeson, TSCA Reform — Five Years Later (June 30, 2021).

"TSCA and PFAS," Dennis R. Deziel, TSCA Reform — Five Years Later (June 30, 2021).

"New Chemical Review," Richard E. Engler, Ph.D., TSCA Reform — Five Years Later (June 30, 2021).

"TSCA Fundamentals," Richard E. Engler, Ph.D., Chemical Watch (June 3, 10, 17, and 24, 2021).

"Chemical Identity and the EPA Process for Approving New PFAS Chemicals," Richard E. Engler, Ph.D., Chemical Watch PFAS Updates 2021 (June 23, 2021).

"The TSCA Evolution: Future Impacts You Need to Prepare For," Lynn L. Bergeson, Supply Chain Insight 2021 (June 17, 2021).

"Green and Sustainable Chemistry in Manufacturing for More Sustainable Household and Personal Care Products," Richard E. Engler, Ph.D., 25th Annual Green Chemistry & Engineering Conference (June 14, 2021).

"TSCA: It Is Not What You May Think," Lynn L. Bergeson, RILA (June 10, 2021).

"TSCA Jurisdiction: It's Not Just over Chemicals," Lynn L. Bergeson, Chemical Watch TSCA Developments 2021 (June 9, 2021).

"Plastics and UNEA," Richard E. Engler, Ph.D., GlobalChem 2021 (March 31, 2021).

"Product Stewardship and the Pandemic: Surviving and Thriving in Disruptive Times," Lynn L. Bergeson, Product Stewardship Society (March 31, 2021).

"What To Expect From the Biden EPA?," Lynn L. Bergeson, Business & Learning Resources (March 30, 2021).

"CBI Challenges and Opportunities," Richard E. Engler, Ph.D., GlobalChem TSCA Workshop (March 29, 2021).

"TSCA Enforcement under the Biden Administration," Lynn L. Bergeson, Key Regulatory Updates: Europe, Asia and the Americas 2021 (March 25, 2021).

"FIFRA Hot Topics," Lisa R. Burchi, Key Regulatory Updates: Europe, Asia and the Americas 2021 (March 25, 2021).

"Chemicals Regulation: Latest Developments," Lynn L. Bergeson, Environmental Law 2021 (February 25, 2021).

"What To Expect When You're Electing (a New President)," Lynn L. Bergeson and Richard E. Engler, Ph.D., Bergeson & Campbell, P.C. (January 28, 2021).

IV. APPENDIX B: WEBINARS AND PODCASTS

2022 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)
Forecast — What to Expect in Chemicals in 2022	January 26, 2022 12:00 p.m. - 1:00 p.m. (EST) Register now
FIFRA Hot Topics	March 16, 2022 12:00 p.m. - 1:00 p.m. (EDT) Register now
UK REACH, What's Happened and What's Next?	April 20, 2022 11:00 a.m. - 12:00 p.m. (EDT) Register now
Domestic Chemical Regulation and Achieving Circularity (TSCA and FIFRA)	May 18, 2022 12:00 p.m. - 1:00 p.m. (EDT) Register now
TSCA New Approach Methodologies	August 3, 2022 12:00 p.m. - 1:00 p.m. (EDT)
PFAS in Europe with EPPA	September 14, 2022 11:00 a.m. - 12:00 p.m. (EDT)
Food Safety Issues in the United States	October 26, 2022 12:00 p.m. - 1:00 p.m. (EDT)
Two Years Later, How Has the Chemicals Strategy for Sustainability Changed REACH?	November 16, 2022 11:00 a.m. - 12:00 p.m. (EST)
Articles under TSCA	December 7, 2022 12:00 p.m. - 1:00 p.m. (EST)

WEBINARS FROM 2021 AVAILABLE ON DEMAND

PFAS Reporting Rules — What Every Company Needs to Know

Lynn L. Bergeson, Managing Partner, B&C, and President, Acta and BCCM, and Richard E. Engler, Ph.D., Director of Chemistry, B&C and Acta, explain EPA's proposed PFAS rules and what the regulated community must know and do to comply. This webinar covered three actions announced on June 10, 2021, intended to protect communities from PFAS:

- Proposing a rule designed to obtain comprehensive data on more than 1,000 PFAS manufactured in the United States;
- Withdrawing guidance that EPA believes weakened its July 2020 SNUR restricting certain long-chain PFAS; and
- Publishing a final rule that incorporates three additional PFAS into the TRI maintained under EPCRA.

A recording is available now.

U.S. Chemical Regulation: What's New, What's Hot

Lynn L. Bergeson and Richard E. Engler, Ph.D. presented "U.S. Chemical Regulation: What's New, What's Hot," focusing on new topics in U.S. industrial chemical regulation, their implications for chemical stakeholders, and suggested actions for chemical producers, importers, processors, and manufacturers of finished goods containing chemicals. A recording of the webinar is available now.

TSCA Reform - Five Years Later

The Environmental Law Institute (ELI), the George Washington University Milken Institute School of Public Health, and B&C hosted the fifth 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 EPA is implementing Section 6 risk evaluation provisions, changes in new chemical review, existing chemical risk management provisions, and TSCA's role in achieving environmental justice, 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.

Product Stewardship and the Pandemic: Surviving and Thriving in Disruptive Times

The COVID-19 global pandemic has had far-reaching impacts on business operations. Lynn L. Bergeson moderated the Product Stewardship Society's (PSS) webinar looking at how businesses can strengthen organizational resilience going forward, by examining lessons learned and positioning product stewardship as a key player in business continuity and crisis management. This future-focused webinar identified the broad range of complex, unresolved, and evolving issues product stewards have faced and continue to face because of the pandemic. A recording of this webinar is available now.

What To Expect When You're Electing (a New President)

On January 28, 2021, Lynn L. Bergeson, Richard E. Engler, Ph.D., and James V. Aidala, Senior Government Affairs Consultant, B&C and Vice President, Policy and Government Affairs, Acta, presented "What To Expect When You're Electing (a New President)," focusing on the then-incoming Biden Administration, including what policies and initiatives could be expected in the next four years and how any likely regulatory directions might affect the chemical industry. A recording of this webinar is available now.

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

PODCASTS 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.

What do "reasonably foreseen" and "unreasonable risk" really mean? — A Conversation with Richard Engler, Ph.D. and Todd Stedeford, Ph.D.

Lynn L. Bergeson, Richard E. Engler, Ph.D., and Todd J. Stedeford, Ph.D., Of Counsel, B&C and Senior Scientist and Regulatory Advisor, Acta, discuss a range of issues regarding EPA's all-important implementation of the Lautenberg amendments to TSCA. This conversation includes EPA new chemical reviews, when is something "reasonably foreseen," and what is an "unreasonable risk," among other topics.

A Conversation with Michal Freedhoff, Ph.D., Assistant Administrator, OCSPP

Lynn L. Bergeson and Michal I. Freedhoff, Ph.D., Assistant Administrator, OCSPP, EPA, discuss OCSPP's priorities, plans for the new year, and a few key issues, including new chemical review, industrial chemical testing, EPA's PFAS Action Plan for per- and polyfluoroalkyl substances, and how OCSPP is dealing with a workload that is not matched by existing resources.

Higher Education, Management, and Climate Change — A Conversation with Kurt Landgraf — *transcript available*

Lynn L. Bergeson speaks with Kurt M. Landgraf, former Chairman and CEO of DuPont Pharmaceuticals Company and most recently, former President of Washington College, located in Chestertown, Maryland. This conversation explores Kurt's extraordinarily diverse background with an interesting mix of pharmaceutical management issues, higher education, and Kurt's observations on preparing students for careers in environmental disciplines.

Exploring the Environmental Footprint of the Digital Economy — A Conversation with David Rejeski — *transcript available*

Lynn L. Bergeson and David Rejeski, Visiting Scholar with ELI, discuss David's engagement in the Project on the Energy and Environmental Implications of the Digital Economy. With support from the Alfred P. Sloan Foundation, ELI, the Yale School of the Environment, and the Center for Law, Energy and the Environment at UC Berkeley, the Project is shedding much-needed light on the true environmental and energy implications of the digital economy, focusing on blockchain technologies, sharing platforms, artificial intelligence, and other technologies.

TSCA Reform Reform? — A Conversation with Dennis Deziel — *transcript available*

Lynn L. Bergeson and Dennis R. Deziel, Senior Government Affairs Advisor, B&C and Acta, discuss TSCA reform. Dennis served as Director of Federal Government Affairs for the Dow Chemical Company when the TSCA amendments were considered and eventually enacted by Congress in 2016. After leaving Dow, Dennis served as EPA Region 1 Administrator (New England). Dennis brings a unique perspective to TSCA Reform, as it was happening when he was a senior executive for one of the world's largest chemical companies, and then as a Senate-confirmed political appointee, after TSCA reform was enacted and he was part of the team implementing the new law.

EPA and PBTs: A New Normal? — A Conversation with Richard E. Engler, Ph.D. — *transcript available*

Lynn L. Bergeson and Richard E. Engler, Ph.D., discuss EPA's continuing struggle to regulate certain PBT chemicals, especially those found in finished products, what EPA refers to as "articles." TSCA has always applied to the products, or articles, that contain chemical substances of interest to EPA under TSCA. While EPA previously used that authority somewhat sparingly, the 2016 Amendments to TSCA have jumpstarted a new wave of regulations that expressly apply to articles. EPA is required under TSCA to regulate certain PBTs, and EPA issued a final rule earlier this year that inspired chaos in the business community, especially in the electronics sector and its complicated supply chain. Rich and Lynn discuss these PBT rules and help explain what may well be the new normal with regard to the regulation of finished products under TSCA.

A Conversation with the NRDC's Daniel Rosenberg — *transcript available*

Lynn L. Bergeson and Daniel Rosenberg, Director, Federal Toxics Policy, Healthy People & Thriving Communities Program, at the NRDC, discuss new TSCA, EPA's implementation of the 2016 amendments to TSCA under Lautenberg, several recent regulatory initiatives involving PBT chemicals and PFAS, and much more. An engaging and formidable advocate, Daniel's views are always forcefully spoken and clearly articulated.

Compliance Checks and REACH — A Conversation with Karin Baron — *transcript available*

Lynn L. Bergeson and Karin F. Baron, MSPH, Senior Regulatory Consultant, B&C and Acta, discuss REACH Article 41 "compliance checks," an innocuous-sounding component of REACH that has the potential to cause considerable business anxiety, delay, and expense if a company's REACH dossier is found to be deficient as a result of a compliance check. Karin walks us through what these checks are for, what could happen if you are caught up in one, and how best to respond if your dossier becomes ensnared in a compliance check.

Occupational Exposure Limits for Nanomaterials — A Conversation with Carla Hutton — *transcript available*

Lynn L. Bergeson and Carla N. Hutton, Regulatory Analyst, B&C, and co-editor of B&C's Nano Blog, discuss a report the National Institute for Occupational Safety and Health (NIOSH) recently issued on developing occupational exposure limits or "bands" for engineered nanomaterials. There are thousands of chemicals in use in the workplace, but far fewer government-issued, authoritative, peer-reviewed occupational exposure limits for workplace chemicals. The recent NIOSH report discusses an approach to evaluate sci-

entific information to derive occupational exposure limits or bands for engineered nanomaterials.

An explosive conversation about GHS and combustible dust — with Karin Baron — *transcript available*

Lynn L. Bergeson and Karin F. Baron, MSPH, tackle the daunting topic of combustible dust, a common workplace hazard that is more pervasive perhaps than people think. Combustible dust poses an explosion hazard in a wide variety of industries, including food, plastic, wood, and textiles, among many others. Karin explains what combustible dust includes and then explains the somewhat complicated governance frameworks that have emerged among OSHA, private standard-setting organizations, and the GHS. The space is crowded and remarkably unclear, especially given the severity of the incidents that have occurred over the years.

New PFAS: Is anything NOT reportable? — A Conversation with Richard E. Engler, Ph.D. – *transcript available*

Lynn L. Bergeson and Richard E. Engler, Ph.D., discuss EPA's "all of agency" approach to address the risks posed by PFAS that can accumulate in humans and remain in the body for long periods. PFAS have been widely used in many consumer articles for years, and the action plan represents the totality of EPA's actions to identify areas of risk and steps to address risks to human health and the environment.

Changes to TSCA for Small Businesses? — A Conversation with Bruce Jarnot, Ph.D. — *transcript available*

Lynn L. Bergeson and Bruce Jarnot, Ph.D., DABT®, Senior Manager, Product Compliance, at Assent Compliance discuss EPA's implementation of TSCA and certain new rules that apply to manufacturers of finished goods, called "articles" under TSCA. Several rules issued in final this year or proposed apply to importers of finished goods and other downstream entities. A proposed reporting rule issued in June would apply to small businesses, a cohort historically exempt from TSCA reporting requirements. They discuss these rules and their significant commercial impacts, and they speculate on whether these broad reporting requirements are the new normal under new TSCA.

Update on European Union Chemical Management Issues — A Conversation with EPPA's Meglena Mihova

Lynn L. Bergeson and Meglena Mihova, Managing Partner, EPPA, the Brussels-based premier consultancy on matters involving key business sectors, including chemicals and chemical regulation, discuss all matters involving ECHA and the complex relationships between and among ECHA, EU MSs, the EC, and other stakeholders. Meglena chairs the Environment Committee of the American Chamber of Commerce to the EU, which is the leading U.S. business representation body in the EU. The conversation covers a lot of territory including amendments to REACH regulations, the EU Green Deal, the chemicals strategy for sustainability under the EU Green Deal, and the regulation of PFAS and microplastics.

TSCA Section 4 and Consortia Formation — A Conversation with Heather Blankinship and Richard Engler, Ph.D.

Lynn L. Bergeson, Heather J. Blankinship, Senior Regulatory Consultant, B&C and Acta, Senior Manager, BCCM, and Richard E. Engler, Ph.D., discuss chemical testing under TSCA. Since Congress amended TSCA in 2016, EPA has been slowly ratcheting up required chemical testing under TSCA Section 4. Congress gave EPA expanded testing authority under the 2016 Amendments, and EPA is exercising its new authority to compel chemical data production. These test orders authorize EPA to demand the production of new test data by the manufacturers and sometimes processors of the chemical substances at issue. Transactionally, this means that competitors in the marketplace band together to generate the data EPA seeks. They discuss the reality of quickly forming these consortia and the business and scientific challenges consortia managers face in complying with these federally enforceable test orders. It is not as easy as you may think!

Pesticide Use on Cannabis in Colorado — A Conversation with Brenna Finn

Lynn L. Bergeson and Brenna Finn, Assistant Attorney General, Colorado Department of Law, discuss Colorado's regulation of pesticides used on cannabis and the key enforcement issues on which Brenna's unit focuses. Brenna's substantive skills in FIFRA and TSCA regulation have served her well in private practice and prepared her for her current position with the State of Colorado Attorney General's office, where Brenna heads up the Agricultural Unit in the Business & Licensing Section of the Colorado Department of Law. They also review other enforcement priorities in the state, as Colorado grows many crops in addition to cannabis.

Let's Talk About Europe's Plastics Implementing Measure — A Conversation with Scott Burya, Ph.D.

Lynn L. Bergeson and Scott J. Burya, Ph.D., Regulatory Chemist, B&C and Acta, discuss how U.S. regulatory professionals working in the all-important food contact space can leverage an EU measure applicable to plastic FCMs and articles. The Plastics Implementing Measure, or PIM, includes, among other features, a list of more than 1,000 chemical substances and specific migration levels. Scott describes the EU measure and its strengths and perceived deficits and discusses how U.S. regulatory professionals in this space can leverage the PIM and the specific migration limits in other regulatory contexts here in the United States and elsewhere.

What will the Biden Trade Plan look like? — A Conversation with Daniella Taveau

Lynn L. Bergeson and Daniella Taveau discussed the then-incoming Biden Administration's approach to trade, what the Biden Trade Plan might include, what chemical and pesticide companies might expect in the months ahead, and some of the key differences between the new Administration's approach to trade and the former Administration's trade strategy. As a former International Trade Negotiator for EPA, Daniella represented the United States in all U.S. Free Trade Agreements and before the World Trade Organization, the U.N. Food and Agriculture Organization, and the Asia-Pacific Economic Cooperation. Daniella also served as an International Policy Analyst with the U.S. FDA.

Changes to Safety Data Sheets in the EU and what it might mean for US Businesses — A Conversation with Karin Baron

Lynn L. Bergeson and Karin F. Baron, MSPH, discuss the EU's Commission Regulation issued in June 2020 relating to the completion of SDSs. SDSs are critically important commercial documents that describe the hazards identified with a particular chemical product or mixture as it makes its way in commerce. While this is an EU rule, Karin explains why the new regulation has important consequences for U.S. businesses.

Is Everything Carcinogenic? — A Conversation with Jane S. Vergnes, Ph.D. and Richard E. Engler, Ph.D.

Lynn L. Bergeson, Jane S. Vergnes, Ph.D., DABT®, Director of Toxicology, B&C and Vice President, Scientific Affairs and Director of Toxicology, Acta, and Richard E. Engler, Ph.D., discuss the provocative question "Is everything carcinogenic?" In asking this question, Jane and Rich discuss the marketing and labeling implications of a cancer classification for a chemical substance found as an ingredient in a consumer or industrial product. In today's "informed consumer" market, product manufacturers are challenged as never before to contextualize the significance of a cancer classification or other hazard characteristic. If Proposition 65 has taught us anything, it is that "over" warning dilutes the significance of important product information and dulls consumer awareness of information that could be communicated more meaningfully.

What's happening with GHS and OSHA? — A Conversation with Karin Baron

Lynn L. Bergeson and Karin F. Baron, MSPH, discuss GHS, the non-mandatory framework intended to aid in identifying, classifying, and communicating information on the hazards of chemicals or substances for occupational, consumer, and environmental exposures. Despite the "harmonization" part of GHS, there continue to be significant areas of non-harmonization on a global scale that confound stakeholders at all levels. For professionals working in this space, GHS can be rewarding, immensely confusing, and a bit frustrating. Karin reviews foreseeable changes in OSHA's implementation of HCS and the recently proposed rule that will amend the HCS, brings us up to date on the current status of GHS Revision 9, and addresses the status of GHS more globally, especially in Canada, as what is going on with our northern neighbors is always significant for U.S. businesses.

How will the New Administration affect the EPA? — A Conversation with James Aidala and Richard E. Engler, Ph.D.

Lynn L. Bergeson, James V. Aidala, and Richard E. Engler, Ph.D. review how a new Administration fills key positions and otherwise prepares to take the reins and discuss a few topics on everyone's mind — what can be expected from a Biden EPA on critical topics like climate change, environmental justice, TSCA implementation, pesticide policy, and more. EPA policies are always front and center in a new Administration, but with climate issues bearing down, the stakes are even more consequential in this transition.

How will the Biden Administration Interpret Amended TSCA? — A Conversation with Richard E. Engler, Ph.D.

Lynn L. Bergeson and Richard E. Engler, Ph.D. discuss some of the many uncertainties facing businesses as the new Administration begins. Key new terms like "conditions of use" and "reasonably foreseen" have been defined over the past years, and regulated entities have much riding on their known definitions. Rich explains how a new Administration might see things differently and what businesses might expect in the months ahead. Rich also shares his view on how the Trump EPA did in meeting its statutory obligations under TSCA, how the courts are viewing EPA's implementation efforts, and what to watch out for in the Biden EPA.

One Last Conversation with EPA Assistant Administrator Alexandra Dunn

Lynn L. Bergeson and Former EPA Assistant Administrator Alexandra Dunn sit down to look back at Alex's many achievements since taking office, including implementation of the amendments to TSCA, which Congress enacted in 2016. Alex also addressed some of the most controversial pesticides — glyphosate, dicamba, and chlorpyrifos, among others — all the while implementing one of the most consequential pieces of environmental legislation ever passed by Congress.

APPENDIX C: GLOSSARY

2,4,6-TTBP — 2,4,6-Tris(tert-butyl)phenol
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 Association
AICIS — Australian Industrial Chemicals Introduction Scheme
AIHA — American Industrial Hygiene Association
ANDI — Asociación Nacional de Empresarios de Colombia (Colombia)
ANIQ — Asociación Nacional de la Industria Química (Mexico)
ANPRM — Advance Notice of Proposed Rulemaking
Anvisa — National Health Surveillance Agency (Brazil)
APA — Administrative Procedure Act
APHIS — Animal and Plant Health Inspection Service
ASTM — American Society for Testing and Materials
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 — Bioengineered
BPC — Biocidal Products Committee
BPR — Biocidal Products Regulation
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
CCS — Concerned Chemical Substances
CDC — Centers for Disease Control and Prevention
CDR — Chemical Data Reporting
CEQ — Council on Environmental Quality
ChemSTEER — Chemical Screening Tool for Exposures and Environmental Releases
CIS — Chemical Information System
CIS Center — Commonwealth of Independent States Coordinating Information Center
CLP — Classification, Labeling and Packaging
cm² — Square Centimeters
CMR — Carcinogenic, Mutagenic, and Toxic to Reproduction
CONASQ — National Chemical Safety Committee (Brazil)
COP — Conference of the Parties (Myanmar)
CoRAP — Community Rolling Action Plan
CPNP — Cosmetic Product Notification Portal
CPSC — Consumer Product Safety Commission
CSA — Chemical Safety Assessment; Chemical Substance Act (Thailand)
CSAR — Cosmetics Supervision and Administration Regulation
CSCL — Chemical Substances Control Law
CSG — General Health Council (Mexico)
CSP — Chemical Safety Passport
D4 — Octamethylcyclotetra-siloxane
DAWE — Department of Agriculture, Water and the Environment
DBP — Dibutyl Phthalate
DCC-CO — Dechlorane Plus
decaBDE — Decabromodiphenyl Ether
DEFRA — Department of Environment, Food and Rural Affairs (UK)
DEHP — Di-ethylhexyl Phthalate
DENR — Department of Environment and Natural Resources
DIBP — Di-isobutyl Phthalate
DIDP — Di-isodecyl Phthalate
DINP — Di-isononyl Phthalate
DIW — Department of Industrial Works (Thailand)
DOE — U.S. Department of Energy
DUIN — Downstream User Import Notification
E-FAST — Exposure and Fate Assessment Screening Tool
EA 2021 — Environment Act 2021 (UK)
EAEU — Eurasian Economic Union
EC — European Commission
ECA — Enforceable Consent Agreement
ECHA — European Chemicals Agency
EDF — Environmental Defense Fund
EEA — European Economic Area
EEC — Eurasian Economic Commission
EEE — Electrical and Electronic Equipment
EJ — Environmental Justice
ELEPS — Environmental Law Enforcement and Protection Service
EO — Executive Order
EP — European Parliament
EPA — U.S. Environmental Protection Agency
ESA — Endangered Species Act
EU — European Union
EUA — Emergency Use Authorization
EUP — Experimental Use Permit
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
FMIA — Federal Meat Inspection Act
FQPA — Food Quality Protection Act
FSIS — Food Safety and Inspection Service
FSMA — Food Safety Modernization Act
FY — Fiscal Year
GB — Great Britain
GE — Genetically Engineered
Ghana EPA — Ghana Environmental Protection Agency
GHS — Globally Harmonized System of Classification and Labeling of Chemicals
GISP — Governmental Industry Information Exchange Platform
GLP — Good Laboratory Practice
GMO — Genetically Modified Organism
GRA — Generic Approach to Risk Assessment
GRAS — Generally Recognized as Safe
HBCD — Hexabromocyclododecane, Cyclic Aliphatic Bromide Cluster
HCBD — Hexachlorobutadiene
HCS — Hazard Communication Standard
HDPE — High-density Polyethylene
HHCB — 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran
HPR — Hazardous Products Regulation
HSA — Hazardous Substance Act (Thailand)
HSE — Health and Safety Executive
HSIA — Halogenated Solvents Industry Alliance
HSNO — Hazardous Substances and New Organisms
HVACR — Heating, Ventilation, Air-Conditioning, and Refrigeration
IARC — International Agency for Research on Cancer
IATA — Integrated Approach to Testing and Assessment
IChEMS — Industrial Chemical Environmental Management Standard
IE/NI Protocol — Ireland/Northern Ireland Protocol
IECIC — Inventory of Existing Cosmetic Ingredients in China
IH — Industrial Hygiene
IHLAP — Industrial Hygiene Laboratory Accreditation Program
IIA — Inception Impact Assessment
INCI — International Nomenclature of Cosmetic Ingredients
INP — Initial Notification Period
IQA — Information Quality Act
IT — Information Technology
ITC — Interagency Testing Committee
IWG — Interagency Working Group
JTF — Just Transition Fund
JTM — Just Transition Mechanism
K-BPR — Consumer Chemical Products and Biocides Safety Act
K-OSHA — Occupational Safety and Health Act (South Korea)
K-REACH – Act on the Registration and Evaluation of Chemicals (South Korea)
kg — Kilogram
KKDIK — Kimyasalların Kaydı, Değerlendirilmesi, İzni ve Kısıtlanması
LARCF — Latin American Regulatory Cooperation Forum
Lautenberg — Frank R. Lautenberg Chemical Safety for the 21st Century Act
LC_{50} — Lethal Concentration in 50 Percent of Animals
LCPFAC — Long-chain Perfluoroalkyl Carboxylates
LR — Lead Registrant
LVE — Low Volume Exemption
MAF — Mixture Assessment Factor (EU)
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)
MFF — Multiannual Financial Framework
mg — Milligram
mg/m^3 — Milligrams per Cubic Meter
MHFW — Ministry of Health and Family Welfare
MoCC — Ministry of Climate Change (Pakistan)
MoE — Ministry of Environment (Chile, Japan, South Korea)
MoEL — Ministry of Employment and Labor (South Korea)
MoEU — Ministry of Environment and Urbanization (Turkey)
MOH — Ministry of Health (Brazil, Chile)
MoI — Ministry of Industry (Thailand)
MoIT — Ministry of Industry and Trade (Vietnam)
MPPD — Multiple-Path Particle Dosimetry
MRL — Maximum Residue Limit
MRRE — Manufacturer-Requested Risk Evaluation
MS — Member State
MSCA — Member State Competent Authority
MSDS — Material Safety Data Sheet
NAA — No Action Assurance
NAM — New Approach Methodology
NASEM — National Academies of Sciences, Engineering, and Medicine

NCEL — New Chemical Exposure Limit
NDAA — National Defense Authorization Act
New Zealand EPA — New Zealand Environmental Protection Authority
NGO — Non-governmental Organization
NHC — National Health Commission
NI — Northern Ireland
NICNAS — National Industrial Chemicals Notification and Assessment Scheme
NIER — National Institute of Environmental Research
NIOSH — National Institute for Occupational Safety and Health
NIP — National Implementation Plan
NIST — National Institute of Standards and Technology
NMP — N-methylpyrrolidone
NMPA — National Medical Products Administration
NNCO — National Nanotechnology Coordination Office
NNI — National Nanotechnology Initiative
NOA — Notice of Arrival
NOC — Notice of Commencement
NORA — Notice of Refusal of Admission
NPRM — Notice of Proposed Rulemaking
NRDC — Natural Resources Defense Council
NSF — National Science Foundation
NTP — National Toxicology Program
NTR — National Technical Regulation
OCSPP — Office of Chemical Safety and Pollution Prevention
OEB — Occupational Exposure Band
OECD — Organization for Economic Cooperation and Development
OEHHA — Office of Environmental Health Hazard Assessment
OEL — Occupational Exposure Limit
OFR — Organohalogen Flame Retardant
OIG — Office of Inspector General
OMB — Office of Management and Budget
OPP — Office of Pesticide Programs
OPPT — Office of Pollution Prevention and Toxics
OPSS — Office for Product Safety and Standards (UK)
OR — Only Representative
ORD —Office of Research and Development
OSH Act — Occupational Safety and Health Act
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
OTNE — Octahydro-tetramethyl-naphthalenyl-ethanone
PAC — Poly Aluminum Chloride
PANNA — Pesticide Action Network North America
PBB — Polybrominated Biphenyl
PBDE — Polybrominated Diphenyl Ether
PBT — Persistent, Bioaccumulative, and Toxic
PCB — Polychlorinated Biphenyl
PCN — Poison Center Notification
PCP — Pentachlorophenol
PCTP — Pentachlorothiophenol
PEC — Priority Existing Chemical
PFAS — Per- and Polyfluoroalkyl Substances
PFHxS — Perfluorohexanesulfonic Acid
PFOA — Perfluorooctanoic Acid
PFOS — Perfluorooctanesulfonic Acid
PIF — Product Information File
PIP — Plant-incorporated Protectant
PIP (3:1) — Phenol, Isopropylated Phosphate (3:1)
PMN — Premanufacture Notice
POP — Persistent Organic Pollutant
PPE — Personal Protective Equipment
PPI — Producer Price Index
PPIA — Poultry Products Inspection Act
ppm — Parts Per Million
PPP — Plant Protection Product
PRIA — Pesticide Registration Improvement Act
PRIA 4 — Pesticide Registration Improvement Extension Act of 2018
PRN — Pesticide Registration Notice
Prop 65 — Proposition 65
PRTR — Pollutant Released and Transfer Register
PSLT — Poorly Soluble, Low Toxicity
PTL — Priority Testing List
PV29 — C.I. Pigment Violet 29
QSAR — Quantitative Structure-Activity Relationship
R&D — Research and Development
RAC — Risk Assessment Committee
RCRA — Resource Conservation and Recovery Act
REACH — Registration, Evaluation, Authorization and Restriction of Chemicals
RETC — Registro de Emisiones y Transferencias de Contaminantes (Peru)
Rev — Revised Edition
RFC — Request for Correction
RFCU — Reasonably Foreseeable Condition of Use
RFI — Request for Information
RFR — Request for Reconsideration
RIN — Renewable Identification Number
RoHS — Restriction of Hazardous Substances Directive
RSR — Regulatory Status Review
SACC — Science Advisory Committee on Chemicals

SAPA — Serious Accidents Punishment Act (South Korea)
SASO — Saudi Standards, Metrology and Quality Organisation
SCCP — Short-chain Chlorinated Paraffin
SDS — Safety Data Sheet
SECURE — Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient
Services — U.S. Fish and Wildlife Service and National Marine Fisheries Service
SIA — Semiconductor Industry Association
SIEF — Substance Information Exchange Forum
SME — Small- and Medium-Sized Enterprise
SNUR — Significant New Use Rule
SOP — Standard Operating Procedure
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)
TDR — Tiered Data Reporting
TERA — TSCA Environmental Release Application
Thailand FDA — Thailand Food and Drug Administration
TLV®-CS — Threshold Limit Values for Chemical Substances
ToxValDB — Toxicity Value Database
TPP — Phosphoric Acid, Triphenyl Ester
TR — Technical Regulation
TRSCP — Technical Regulation on the Safety of Chemical Products (Decree No. 1019)
TSCA — Toxic Substances Control Act
UFI — Unique Formula Identifier
UK — United Kingdom
UN — United Nations
UNBS — Uganda National Bureau of Standards
U.S. — United States
USDA — U.S. Department of Agriculture
USMCA — United States-Mexico-Canada Agreement
VCERC — Vietnamese Centre for Emergency Response to Chemicals
WHMIS — Workplace Hazardous Materials Information System
WHS — Work Health and Safety Laws (Australia)
WOE — Weight of Evidence
WPS — Worker Protection Standard
WWTP — Wastewater Treatment Plant

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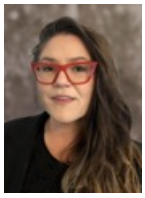

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