BERGESON & CAMPBELL, P.C.

Forecast for U.S. Federal and International Chemical Regulatory Policy 2021

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FORECAST 2021

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 2021. In this document, rich with detail and helpful content, the legal, scientific, and regulatory professionals of B&C, Acta, and BCCM distill key trends in U.S. and global chemical law and policy, and provide our best informed judgment as to the shape of key developments we are likely to see in 2021. With a new Administration and dynamic new faces at the U.S. Environmental Protection Agency, Council on Environmental Quality, and other key federal offices, 2021 will almost certainly be fascinating and consequential.

Our unique business platform and growing global team of highly skilled professionals are exceptionally well suited to offer this detailed 2021 Forecast. Our core business, about which each of us feels passionately, is 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 scientists (six Ph.D.s), including toxicologists, chemists, exposure experts, and geneticists; regulatory and policy experts; and lawyers is deeply versed in chemical law, science, and policy. Our unique business platform seamlessly leverages and ensures the integration of law and science to achieve success 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 MacDougall Davidson and Heidi Brown Lewis for their editing and lay-out skills and devotion to detail.

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A. Introduction

As 2021 brings a new Administration to Washington, D.C., punditry abounds with sage prognostications from many fronts and provocative questions arise about the future of the Republic generally and environmental issues particularly. Will the Biden Administration be torn apart from internal battles within the Democratic Party (progressives vs. centrists)? Will majority control of the Senate (if the Democrats fail in Georgia) make governing easier or harder for the new Administration? Will the Senate remain a Dead Sea of deadlock or provide hope for bipartisan cooperation?

The task of this section of the Forecast fortunately is more limited to describing the outlook about the range of issues surrounding chemical and pesticide regulation in 2021. The larger dynamic of underlying partisan jockeying and prospects for bipartisan cooperation will nonetheless affect greatly what may happen in the more limited context of chemical regulation. The ongoing COVID-19 pandemic will inevitably play a role in everything from the degree of public focus to the amount of political capital available to spend on chemical regulatory issues. Competing issues of significance include COVID-19, health care, cyber security, foreign policy, and a long list of other priorities needing attention by the new Administration.

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1. Unfinished Business

As part of a transition to a new Administration, the outgoing Administration typically uses the time before the inauguration to complete as much "unfinished business" as possible. Many initiatives are not close enough to completion to be able to complete in this limited time period, but those that are close, or determined to be of sufficient importance, might be completed (or at least issued) before **January 20, 2021**, when the new President arrives. This selection of important priorities and projects to complete will occur across all of the federal agencies, with the Office of Management and Budget (OMB) acting as the *de facto* "traffic cop," channeling Administration priorities and adjudicating last-minute inter-agency disagreements.

For the U.S. Environmental Protection Agency (EPA), perhaps the most controversial is the proposed "science rule," which would require EPA to base regulations on scientific information only if the underlying information from foundational scientific studies is publicly available. This initiative appears aimed at some regulations issued by EPA's Air Program, and it has received over 600,000 adverse comments as part of the public comment period. The requirements as proposed, however, would apply to all EPA rules, including some of those developed to implement the chemical and pesticide programs.

Completing such last-minute homework by the outgoing decision-makers is often entirely symbolic since the new arrivals can reverse policies and guidance, and even fundamentally change a completed regulation. Even if the new agenda is to reverse completed rules, making changes will take significant time and resources since the relatively cumbersome requirements for rulemaking will continue to apply to the agenda of the new Administration (and sometimes this is exactly why the "old guard" completes the process).

2. Biden Administration Priorities

The Biden Administration will focus on four initial environmental priorities:

a. Climate Change -- Domestic Policies

Addressing climate change was a high-profile subject during the 2020 election. Democrats stressed the need to address the problem, respect the science, and establish new federal approaches to reduce carbon emissions. The goal of carbon neutral by **2050** was explicitly in the Biden platform, along with major infrastructure spending to achieve climate goals. Re-establishing the Obama-era Clean Power Plan, and renewed interest in reducing reliance on coal as an energy source, will be part of the "un-Trump" agenda. At the same time, there will be pressure by advocates of the "Green New Deal" to go further than what is likely to be offered -- on this and many related issues.

b. Climate Change -- Global Leadership

The incoming Administration has already announced an intention to rejoin the Paris Accord "on Day One." Climate issues will be part of the U.S. foreign policy agenda, with more spending on international programs and research to find climate solutions, along with explicit mention of addressing climate change as part of American policy concerns. Part of this effort can include re-engagement with the global community to reach more aggressive carbon reduction goals, coordinate research, and develop joint approaches to the climate crisis. This could also affect trade policy goals with foreign governments.

c. Reversing "Damage" Done by the Trump Administration

Reversing climate policies will be only a small part of being the "un-Trump" process. Such emphasis will be a guiding factor for many federal programs and actions across EPA and other government agencies. For pesticides and chemicals, this will include 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) (Lautenberg Amendments) and decisions on various specific pesticides (most notably, or most notoriously, chlorpyrifos). More specific policies and products that may be "reversed" or otherwise revisited during the Biden Administration will be discussed later in this Forecast.

d. Environmental Justice

We are mindful of the emergence of environmental justice as a core component of the Biden Administration's environmental agenda and, in particular, the role chemical exposures play in disproportionately affecting vulnerable

General EPA priorities will likely include greater enforcement resources along with exhortations to "follow the science" -- and not just regarding climate change.

subpopulations and marginalized communities. The nominations of Michael Regan as EPA Administrator and Brenda Mallory to head the White House Council on Environmental Quality (CEQ) demonstrate the seriousness of the Biden Administration's commitment to environmental justice as each has a clear record of accomplishment as a champion of the topic. The challenging part will be to operationalize a goal that historically has been more aspirational than real in chemical law and policy. The opportunities are enormous and this commitment could fundamentally alter the legal and regulatory landscape. For an excellent overview of the subject, *see* The Debate: Advancing Racial Justice Means Advancing Environmental Justice, *ELI. The Environmental Forum*, November/December 2020, pg. 50.

3. Priorities for EPA's Office of Chemical Safety and Pollution Prevention

EPA priorities likely to affect the Office of Chemical Safety and Pollution Prevention (OCSPP) may be less prominent than the emphasis on climate change, but will likely include increases in EPA budget and emphasis on "more protective" policies regarding pesticide and industrial chemical regulation. Budget increases alone would allow both programs to do more to address statutory deadlines and policy development. The toxics program faces significant statutory deadlines regarding chemical assessments coming due as the 2016 Lautenberg Amendments approach the five-year mark. The pesticide program is under continued pressure to meet decision deadlines for new products under the Pesticide Registration Improvement Act (PRIA) (the industry fee provisions to contribute resources) and the statutory deadline of **October 2022** for completing the 15-year cycle for registration review of all existing pesticides.

General EPA priorities will likely include greater enforcement resources (past Democratic Administrations have emphasized that "the cop is back on the beat"), along with exhortations (and uncertain implications) to "follow the science" -- and not just regarding climate change. Under Democratic leadership, one can expect renewed emphasis on environmental protection and a strong economy as mutually supportive goals. Throughout EPA agenda-making, various constituencies can be expected to inflame, or at least monitor, the tension between a President Biden "centrist" approach or something more aggressively aligned with the "progressive" suggestions advocated by various environmental groups.

For OCSPP, key issues likely to result from the review of Trump Administration policies include:

- For the pesticide program -- emphasis on more conservative (protective) risk assessment assumptions (example: risks from pesticide drift); additional estimates of risk on "vulnerable" subpopulations (example: infants and children, women of child-bearing age); and review, and possibly revisions, of Trump Administration decisions on various individual pesticides (examples: chlorpyrifos, atrazine, dicamba, glyphosate, neonicotinoids); and

- For the industrial chemicals program -- OCSPP will remain focused on TSCA implementation and the grueling risk evaluation timetable. Important risk evaluation policies and interpretation of what makes a chemical assessment compliant with the 2016 TSCA amendments will be a primary focus. Examples include definition of reasonably antici-

WEBINAR

What To Expect When You're Electing (a New President), January 28, 2021, 1:00 p.m. EST

B&C is pleased to present "What To Expect When You're Electing (a New President)," a webinar focusing on the incoming Biden Administration, including what policies and initiatives can be expected in the next four years and how any likely regulatory directions may affect our clients. Registration is now open.

pated uses and how to produce sufficiently thorough assessments and meet the statutory deadlines. Also receiving significant attention will be the new chemical review process to make safety determinations, deadlines for first batches of risk assessment determinations, and efforts to require chemical testing as outlined under the 2016 Lautenberg Amendments.

4. Prospects for Change

As we noted four years ago when the then-new Trump Administration arrived with an "ambitious" agenda, like all new Administrations, there are a variety of factors that necessarily hinder the ability of a new President to effect even modest change. Substantive or significant change is slow, hard, and largely done through time and resource intensive procedures required by rulemaking. This is one reason Presidents rely on Executive Orders where they can, but there are often limitations to what can be implemented without legislative or regulatory change.

a. New Sheriff in Town

President-elect Biden and the Democratic Party platform outline a number of environmental goals, especially focused on addressing climate issues. Few or no OCSPP issues rose to any level of notice as part of the election campaign beyond the climate change and the fundamental "not Trump" approach to environmental policies and decisions. It remains unclear how much time, how many resources, and what degree of management attention will be directed to OCSPP issues beyond what has already been mentioned. The degree of change may be impacted by unpredictable outside factors such as party control of the Senate, and the implications of having to continue dealing with the COVID-19 pandemic, that will continue to consume much attention and budget during the early days of the new Administration.

b. Party Control of the Senate

Party control of the Senate is among the most impactful unknowns at this point. If the Democrats control the Senate, the expectations of various Democratic constituencies will expand to include more "progressive" policies on environmental issues across the board (big budgets, new legislation and regulations, and more aggressive initiatives). If environmental groups see little opportunity for legislative changes in the Senate, that may increase demands (or at least expectations) for more aggressive litigation strategies and perhaps more advocacy pressure through intensive oversight activity in relevant House Committees.

The Senate also controls agency political leadership appointments and even with changed filibuster rules, split party control might lead to a more moderate slate of appointees. Once again, the unknown question here is how "centrist" the Biden Administration will be and what priority will be given to the political capital needed to drive change or reform in various environmental programs.

Regardless of Senate party control, it also takes significant time for a new Administration to put in place a slate of political appointees at the Cabinet and sub-Cabinet levels. For example, OCSPP did not have a Senate-confirmed Assistant Administrator sworn in until early 2019. The vetting process has become increasingly longer over the past decades, and what is clear is that either party will have a slim party majority. This could lead to delays due to substantive disagreements or simply partisan theatrics designed to disrupt the new Administration's agenda, signs of which already abound. Unsurprisingly, Republican leaders have already alluded to concerns with several of President-Elect Biden's nominees.

Party control of the Senate will also be critical in the number of federal legislative challenges that may face the pesticide and industrial chemical industries. During the Trump years, both houses of Congress introduced legislation to direct specific regulatory controls (mostly prohibitions) on specific pesticides (chlorpyrifos, for example) and chemicals (per- and polyfluoroalkyl substances (PFAS), for example, *see* below). The level of activity of such directives has not been seen in Congress for decades, since the late 1980s with legislation about pesticides such as Alar. Frustration and distrust of the Trump Administration led to serious legislative proposals

regarding chlorpyrifos and organophosphates as a class, and controls on neonicotinoid insecticides. With the Senate under Republican Party control, such measures were seen as certain to fail, while the House entertained more Committee action on some proposals. If the House, Senate, and White House are all under Democratic Party control, such measures would have a much better chance of enactment, which could lead to more legislation directing regulatory outcomes for both specific pesticides and chemicals.

In parallel, also indicating opposition to EPA actions (or inaction) under the Trump Administration, states and some localities also sought to impose legislatively restraints and prohibitions on certain pesticides and chemicals. State and local actions seem dependent on the party control of the jurisdiction, with proposals coming mostly from Democratic areas. Under a Biden Administration, and with Biden appointees leading EPA, it is not clear whether such state or local initiatives will continue or abate somewhat. If "all politics are local," then federal EPA decisions under Democratic appointees will be questioned.

c. Raised Expectations

Countering any centrist tendencies or policies of the new Administration will be raised expectations about President Biden. Much campaign energy and rhetoric focused on the need fundamentally to change Washington, D.C. and government agencies with President Trump as Chief Executive. As a result, the Biden Administration will face the pressure of greatly increased expectations about making an immediate impact and fundamental changes at EPA and most other government agencies. Also impactful will be the raised expectations of career EPA staff who have been widely reported as being at odds with the Trump political leadership since their arrival. Whether and how different options development, Agency morale, and government employee recruitment will be is unknown and could affect Agency behavior over time.

Managing raised expectations will also affect the agenda and methods of various stakeholders. Might there be less litigation by environmental groups if the Supreme Court members are considered more conservative? Will state and local governments, and their political leadership, be more willing to defer to EPA decisions and policies? Will Congressional Committees, even in the House with Democratic control, give more deference (or less static) to Agency decisions appointed by a Democratic President? Answers to these questions will be a factor in the day-to-day lives of the new political appointees at EPA and across the government.

B. TSCA

1. Predictions and Outlook for the OCSPP's Office of Pollution Prevention and Toxics

The Office of Pollution Prevention and Toxics (OPPT) will keep its focus on TSCA implementation consistent with the statutory time limits, including completion of required risk evaluations and risk management actions on certain existing chemicals, and review of and determinations on new chemical premanufacture notifications (PMN). In 2020, OPPT centered on completing risk evaluations for the "first 10" chemicals designated by EPA for risk evaluation and initiating the development of risk management actions where it found unreasonable risk in completed risk evaluations. In 2021, EPA will need to complete a few outstanding risk evaluations of the "first 10" chemicals and begin developing proposals for the Section 6 risk management rules required by the risk evaluation conclusions. 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 expect risk management to present difficult, if not daunting challenges to EPA in 2021 as it works to sort through and satisfy the many legal and policy issues at play. EPA directed significant energy to developing risk evaluations for the "next 20" chemicals designated as high-priority for risk evaluations through the TSCA prioritization process; absent major policy changes by the Biden Administration or litigation outcomes that affect substantially the approaches taken by EPA in developing risk evaluations, this work is expected to continue through 2021 until

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the **end of 2022**, and perhaps until the **first half of 2023**. EPA also now has three and could have shortly four manufacturer-requested risk evaluations, as discussed herein, that will parallel the "next 20" chemicals for review.

For the risk evaluations for the "first 10" substances that are or will be completed in 2021, the Biden Administration is expected to take a hard look at their nature and scope, including how they address potentially exposed or susceptible subpopulations as required under TSCA. Exposures to workers and populations bordering chemical facilities are likely to receive increased attention consistent with the Biden Administration's planned elevated consideration of environmental justice. Additionally, exposures addressed under other EPA-administered authorities, exposures generally not evaluated under the Trump Administration in the completed and ongoing risk evaluations, may be reviewed by the Biden Administration under the TSCA standards. These changes could result in EPA's issuance of supplemental/revised risk evaluations for those completed under the Trump Administration, and 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 will have to consider carefully if it will proceed with risk management on unreasonable risks already identified and supplement as risk evaluations are reconsidered or if EPA will reassess the risk evaluations in their entireties.

We also expect increased use of TSCA Section 4 test orders and Section 8 information gathering rules to strengthen the data sets that are available to EPA on the 20 high-priority chemicals that are undergoing risk evaluation. For new chemicals, we expect that the new Administration will reconsider the use of non-order Significant New Use Rules (SNUR) in lieu of consent orders and SNURs. EPA may also seek more test data on new chemicals, although EPA will need to justify additional testing if such testing includes vertebrates. It is also critically important that EPA develop a more transparent and predictable path to market.

2. Section 6 -- Existing Chemicals

a. Prioritization

EPA continued the process of reviewing existing chemicals under amended TSCA. TSCA Section 6(b)(2)(B) required EPA to have at least 20 high-priority chemicals undergoing risk evaluation and 20 low-priority chemicals designated by December 22, 2019 (three and one half years after enactment of the Lautenberg Amendments to TSCA). On December 20, 2019, EPA published the final list of high-priority chemicals and on February 20, 2020, it published the final list of low-priority chemicals.

The 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

The low-priority chemicals are:

1. 1-Butanol, 3-methoxy-, 1-acetate
2. D-gluco-Heptonic acid, sodium salt (1:1), (2.xi.)-
3. D-Gluconic acid
4. D-Gluconic acid, calcium salt (2:1)
5. D-Gluconic acid, .delta.-lactone
6. D-Gluconic acid, potassium salt (1:1)
7. D-Gluconic acid, sodium salt (1:1)
8. Decanedioic acid, 1,10-dibutyl ester
9. 1-Docosanol
10. 1-Eicosanol
11. 1,2-Hexanediol
12. 1-Octadecanol
13. Propanol, [2-(2-butoxymethylethoxy)methylethoxy]-
14. Propanedioic acid, 1,3-diethyl ester
15. Propanedioic acid, 1,3-dimethyl ester
16. Propanol, 1(or 2)-(2-methoxymethylethoxy)-, acetate
17. Propanol, [(1-methyl-1,2-ethanediyl)bis(oxy)]bis
18. 2-Propanol, 1,1'-oxybis
19. Propanol, oxybis-
20. Tetracosane, 2,6,10,15,19,23-hexamethyl-

Final designation of a chemical as a high-priority substance initiates the three to three and a half year risk evaluation process, which concludes with a finding of whether the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use. More information is available in our December 20, 2019, memorandum, "Final List of High-Priority Chemicals Will Be Next to Undergo Risk Evaluation under TSCA," and our February 25, 2020, memorandum, "EPA Announces Final List of Low-Priority Chemicals under TSCA."

Although EPA must designate additional high-priority chemicals upon completion of a risk evaluation, additional designations are not expected until EPA completes the risk evaluations for the 20 high-priority chemicals that are currently undergoing risk evaluation; these risk evaluations should be completed in **late 2022 to early 2023**.

b. Risk Evaluations

Chemicals that will be undergoing risk evaluation in 2021 are either stragglers among the "first 10" chemicals initial risk evaluations required under TSCA Section 6(b)(2)(A), among the "next 20" chemicals designated as high-priority, or the subject of a manufacturer request for a risk evaluation under TSCA Section 6(b)(4)(C)(ii) that EPA has granted.

i. "First 10" Chemical Risk Evaluations

On December 19, 2016, EPA selected the "first 10" chemicals for risk evaluation from the 2014 Update to the TSCA Work Plan as follows.

1. 1,4-Dioxane
2. 1-Bromopropane (final)
3. Asbestos
4. Carbon Tetrachloride (final)
5. Cyclic Aliphatic Bromide Cluster (known as HBCD) (final)
6. Methylene Chloride (final)
7. N-methylpyrrolidone (NMP) (final)
8. Pigment Violet 29 (PV29)
9. Tetrachloroethylene, also known as perchloroethylene (final)
10. Trichloroethylene (final)

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. To date, EPA has completed risk evaluations on methylene chloride (announced June 19, 2020), 1-bromopropane (announced August 12, 2020), the Cyclic Aliphatic Bromide Cluster (HBCD) (announced September 25, 2020), carbon tetrachloride (announced November 3, 2020), trichloroethylene (TCE) (announced November 23, 2020), and perchloroethylene (announced December 14, 2020). EPA released the final risk evaluation for N-methylpyrrolidone (NMP) on December 23, 2020. EPA has stated that the remaining risk evaluations on the "first 10" chemicals are expected by the end of 2020, but given developments in late 2020, it now appears that certain may be issued in 2021.

EPA published final risk evaluations for seven of the "first 10" chemicals in 2020. EPA found that numerous conditions of use for these chemicals presented unreasonable risks to health or the environment. One of the key aspects of these risk evaluations that the incoming Administration may revisit is EPA's exclusion of general population exposures, *e.g.*, from ambient air or drinking water, if the substance is subject to regulation under another statutory authority implemented by EPA, such as the Clean Air Act (CAA), Clean Water Act (CWA), Safe Drinking

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Water Act (SDWA), or Resource Conservation and Recovery Act (RCRA). Whether excluding these exposures from the conditions of use in risk evaluations meets the statutory requirements is unsettled. The key findings are noted below.

The final risk evaluation for methylene chloride finds that there are unreasonable risks to workers, occupational non-users, consumers, and bystanders under 47 out of 53 conditions of use. EPA did not find unreasonable risk to the environment. More information on EPA's final risk evaluation for methylene chloride is available in our June 25, 2020, memorandum, "Final Risk Evaluation for Methylene Chloride Is First Completed under Lautenberg Act Amendments."

For 1-bromopropane, the final risk evaluation identifies unreasonable risks to workers, occupational non-users, consumers, and bystanders under 16 out of 25 conditions of use. EPA did not find unreasonable risks to the environment or the general population from the evaluated uses. More information is available in our August 12, 2019, memorandum, "EPA Draft Risk Evaluation for 1-BP Finds Unreasonable Risks to Workers, Occupational Non-Users, Consumers, and Bystanders under Certain Specific Uses."

The final risk evaluation for HBCD determines that there are unreasonable risks to the environment for six out of 12 conditions of use. EPA found unreasonable risks to workers and occupational non-users from the use and disposal of HBCD in building and construction materials. EPA did not find unreasonable risks to the general population or consumers. More information on EPA's final risk evaluation for HBCD is available in our September 28, 2020, memorandum, "EPA Publishes Final Risk Evaluation for HBCD."

The final risk evaluation for carbon tetrachloride determines that there are unreasonable risks to workers and occupational non-users for 13 out of 15 conditions of use. EPA found no unreasonable risks to the environment. EPA states that there are no consumer uses of this chemical. More information on EPA's final risk evaluation for carbon tetrachloride is available in our November 4, 2020, memorandum, "Final Risk Evaluation for Carbon Tetrachloride Finds Unreasonable Risks to Workers and Occupational Non-Users."

The final risk evaluation for TCE shows that there are unreasonable risks to workers, occupational non-users, consumers, and bystanders for 52 out of 54 conditions of use. Two conditions of use (distribution in commerce and consumer use in pepper spray) do not present an unreasonable risk. EPA also found no unreasonable risks to the environment. More information on EPA's final risk evaluation for TCE is available in our November 24, 2020, memorandum, "EPA Evaluates 54 Conditions of Use for TCE, Finding That 52 Present an Unreasonable Risk."

In the final risk evaluation for perchloroethylene (PCE), after evaluating 61 conditions of use of PCE, EPA determines that PCE presents an unreasonable risk under 59 conditions of use. This includes unreasonable risks to workers and occupational non-users when domestically manufacturing or importing the chemical; processing the chemical for a variety of uses; and when used in a variety of industrial and commercial applications. This also includes unreasonable risks to consumers from all consumer uses, and when exposed to dry cleaned articles, and to bystanders for most consumer uses. EPA determines that PCE does not present an unreasonable risk to the environment for all conditions of use. More information on EPA's final risk evaluation for PCE is available in our December 17, 2020, memorandum, "Final Risk Evaluation for Perchloroethylene Finds 59 Conditions of Use Pose Unreasonable Risks to Workers, ONUs, Consumers, and Bystanders."

The final risk evaluation for NMP shows that there are unreasonable risks to workers and consumers from 26 conditions of use. EPA found no unreasonable risks to the environment, general population, bystanders, or occupational non-users. More information on EPA's final risk evaluation for NMP is available in our December 29, 2020, memorandum, "EPA Releases Final Risk Evaluation for NMP."

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 explains this decision 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 explains 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 furthers 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).

It is unclear how the incoming Administration might view this strategy. If a new Administrator wished to broaden the scope of the future TSCA risk evaluations to include exposure pathways and associated risks addressed under other EPA-administered statutes and regulatory programs, the path would be seemingly clear. There are, however, practical difficulties associated with EPA taking steps to broaden the "first 10" risk evaluations to cover these aspects, given resource, technical expertise, and statutory timing constraints.

As an alternative, EPA could gain experience in evaluating those exposure pathways in future risk evaluations, and then apply that experience to re-do or supplement the work done on the "first 10" risk evaluations. For risk evaluations that have been completed with findings of no unreasonable risk being issued by order under Section 6(i), the path would be less clear. One possible approach, where EPA has determined by order that a chemical substance does not present an unreasonable risk and that action is the subject of litigation challenging EPA's approach that excludes exposure pathways, would be for EPA to settle the case, agreeing to supplement or expand the risk evaluation to include the pathways of exposure previously not considered. Any intervenors in the case may have a right to object to the settlement, however, and that approach could be forestalled.

Alternatively, as noted above, EPA could announce its intention to develop a supplemental risk evaluation that takes into account the previously excluded pathways. The approach would be similar to one being taken by EPA in the development of the risk evaluation for asbestos, where EPA, in accord with the decision in *Safer Chems. v. U.S. EPA*, 943 F.3d 397 (9th Cir. 2019) that EPA must consider potential risks from future activities associated with past, discontinued uses (legacy uses) and associated disposals, in which EPA is developing supplemental material to address risks from those legacy uses and associated disposal. Regardless, any risk management action based in whole or part on consideration of risks from exposure pathways under the jurisdiction of other EPA-implemented authorities would have to stand up to challenge.

Risk evaluations remain to be completed for three chemicals and the status of each is discussed below.

On October 30, 2020, EPA announced the availability for comment of a revised draft risk evaluation for PV29 that includes significant revisions to the draft risk evaluation. EPA provided a 30-day comment period (later extended by 20 days to December 19, 2020) for the revised draft risk evaluation and concurrent with the public comment, initiated a letter peer review of the revised draft. Significant changes to the draft risk evaluation include the addition of data from 24 full study reports and associated systematic review that were originally considered as confidential business information (CBI); two sets of particle size distribution (PSD) data for PV29; two sets of data for breathing zone monitoring of dust in the Sun Chemical Corporation workplace; and solubility testing. Some of the added data used in the revised draft risk evaluation were received by EPA under two Section 4(a)(2) TSCA test orders

with requirements including solubility testing of PV29 in water and octanol and a dust monitoring study of Particulates Not Otherwise Regulated at Sun Chemical Corporation's (the domestic manufacturer) workplace. The additional data on PSD and dust monitoring were used to update the original methodology to assess the human health risks from inhalation of the substance. Critical changes in the revised draft include the choice of a different surrogate chemical for assessing inhalation hazards based on the new PSD data and the revision of breathing zone dust exposures for occupational users and occupational non-users in the Sun Chemical Corporation workplace. The revised draft risk evaluation now shows unreasonable risk to workers for 11 out of 14 conditions of use; the initial draft risk evaluation showed unreasonable risk for no conditions of use. More information on EPA's revised draft risk evaluation for PV29 is available in our November 24, 2020, blog item, "EPA Extends Comment Period for Draft Risk Evaluation for PV29."

On November 20, 2020, EPA announced the availability of a supplemental analysis to the draft risk evaluation for 1,4-dioxane and provided a 20-day public comment period. The supplemental analysis includes eight consumer uses where 1,4-dioxane is present as an impurity. The supplemental analysis also assesses exposure to the general population from 1,4-dioxane in surface water. In the supplemental analysis to the draft risk evaluation, EPA preliminarily found no unreasonable risk to consumers from the eight conditions of use assessed. EPA also preliminarily found no unreasonable risks under any of the conditions of use to the general population from exposure to 1,4-dioxane. More information on EPA's supplemental analysis to the revised draft risk evaluation for 1,4-dioxane is available in our November 25, 2020, blog item, "EPA Seeks Comment on Supplemental Analysis to Draft Risk Evaluation of 1,4-Dioxane."

EPA released the draft risk evaluation for asbestos in March 2020 and in the draft, EPA did not find unreasonable risks to the environment under any of the conditions of use, but found unreasonable risk to workers, occupational non-users, consumers, and bystanders under certain conditions of use. More information on EPA's draft risk evaluation for asbestos is available in our memorandum, "EPA Publishes Draft Risk Evaluation of Asbestos, Will Hold Virtual Peer Review Meeting."

As one of its last administrative actions in 2020, EPA released on December 30, 2020, the final risk evaluation for asbestos, part 1: chrysotile asbestos. Of the six use categories evaluated (chlor-alkali diaphragms, sheet gaskets, other gaskets, oilfield brake blocks, aftermarket automotive brakes/linings, and other vehicle friction products), EPA states that it found that there is unreasonable risk to workers, occupational non-users, consumers, and/or bystanders within each of the six chrysotile asbestos use categories. EPA found no unreasonable risk to the environment.

EPA's next step in the process required by TSCA is to develop a plan to reduce or eliminate the unreasonable risks found in the final risk evaluation. EPA states 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." The potential actions that EPA could take to address these risks include regulating how chrysotile asbestos is used or limiting or prohibiting the manufacture, processing, distribution in the marketplace, use, or disposal of chrysotile asbestos, as applicable.

Although EPA has to date met the vast majority of deadlines under the Lautenberg Amendments to TSCA, only one risk evaluation was completed by the June 22, 2020, extended deadline for the "first 10" chemical substances, with others completed since then and the rest targeted for completion by the end of 2020. Most, if not all of the unfinished cases will be completed in the **first quarter of 2021**.

ii. "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." As required under TSCA Section 6(b)(4)(D), the scope document for each chemical substance includes the conditions of use, hazards, exposures, and the potentially exposed or susceptible subpopulations that EPA plans to consider in conducting the risk evaluation for the chemical substance. Comments on the draft scopes issued in April 2020 addressed the general approach to the risk evaluation process (*e.g.*, collection, consideration, and systematic review of

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"Feeling the Pinch: Who Pays TSCA Risk Evaluation Fees?," *Financier Worldwide*, September 2020.

EPA makes clear that as a result of the decision in Safer Chemicals v. EPA, "EPA will no longer exclude legacy uses or associated disposal from the definition of 'conditions of use.'"

relevant information), the specific elements of the scope documents (*e.g.*, hazard, exposure, and potentially exposed or susceptible subpopulations), information specific to the chemical substances (*e.g.*, relevant studies, assessments, and conditions of use), and topics beyond the draft scope document phase of the process (*e.g.*, risk management). EPA published a response to comments document that contains a summary of and response to public comments received on the 20 draft scope documents. Not unexpectedly, EPA makes clear that as a result of the decision in *Safer Chemicals v. EPA*, "EPA will no longer exclude legacy uses or associated disposal from the definition of 'conditions of use.' Rather, when these activities are intended, known, or reasonably foreseen, these activities will be considered uses and disposal, respectively, within the definition of 'conditions of use.'"

iii. Manufacturer-Requested Risk Evaluations

Manufacturer-requested risk evaluations 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 manufacturer-requested risk evaluations, with an extension available for up to six months.

On October 6, 2020, EPA granted a manufacturer request for a risk evaluation of octamethylcyclotetra-siloxane (D4), a chemical used to make other silicone chemicals and as an ingredient in some personal care products. D4 is included in the 2014 Update to the TSCA Work Plan. The requesting manufacturers asked that EPA evaluate conditions of use, including manufacture of D4, processing of D4 as a reactant or by incorporation into a formulation, mixture, or reaction product, and commercial/consumer uses of products that include D4 in their manufacture (*e.g.*, adhesives and sealants, automotive care products, cleaning and furnishing care products, paints and coatings, plastic and rubber products, polishes and sanitation goods, and soaps and detergents), and disposal. EPA determined that the circumstances identified in the request constitute conditions of use and identified additional possible conditions of use for D4 that it may consider in conducting the risk evaluation.

On November 27, 2020, EPA announced the availability of the draft risk evaluation scopes for diisodecyl phthalate (DIDP) and diisononyl phthalate (DINP) and provided a 45-day public comment period for them. 85 Fed. Reg. 76077; 85 Fed. Reg. 76072. DIDP and DINP were the subjects of the first manufacturer request for risk evaluations granted by EPA.

As announced by EPA on December 8, 2020, EPA received a request from International Flavors and Fragrances, Inc. (IFF), Privi Organics USA Corporation (Privi), and DRT America, Inc. (DRT), through the OTNE Consortium, to conduct a risk evaluation for four chemical substances as a category, the octahydro-tetramethyl-naphthalenyl-ethanone (OTNE) chemical category. Within 60 days of the receipt of this request, EPA is required to open a public comment period of no less than 45 days. OTNE is used as a fragrance ingredient. The four chemical substances in this chemical category (Chemical Abstracts Service Registry Numbers (CAS RN) 54464-59-4, 54464-57-2, 68155-67-9, and 68155-66-8) were identified in the 2014 Update to the TSCA Work Plan. We note that two of the OTNE chemicals (the chemicals identified by CAS RNs 54464-59-4 and 54464-57-2) were identified as chemicals that are persistent, bioaccumulative, and toxic (PBT) under the criteria in TSCA Section 6(h) and thus potentially subject to expedited risk management action under TSCA Section 6(h)(1). EPA received an initial manufacturer request for risk evaluation for these substances in September 2016 under TSCA Section 6(b)(4)(C)(ii), however, and pursuant to TSCA Section 6(h)(5), this resulted in the chemicals being excluded from the TSCA Section 6(h)(1) PBT risk management rulemaking, described below.

c. Risk Management

i. "First 10" Chemicals

In 2021, assuming the Biden Administration does not put a hold on the process to take another look at the underlying risk evaluations, EPA will continue the development of Section 6(a) risk management rules on those of the "first 10" risk evaluation chemicals for which EPA has found or finds unreasonable risk, as described above. 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. A two-year extension, less the six-month extension EPA exercised to complete the final risk evaluations (recognizing EPA needed more than the added six months to the risk evaluations for nine of the ten chemicals), is available for these chemicals in total for issuance of both the proposed and final rules, with justification. EPA should be issuing proposed TSCA Section 6(a) risk management rules for each of the "first 10" chemicals where EPA found 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.

ii. PBTs

EPA met the June 2019 deadline in TSCA Section 6(h) for proposing regulatory action and released on December 22, 2020, 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 the final actions are as follows.

- Hexachlorobutadiene (HCBD), used as a solvent and functional fluid:
  - EPA is prohibiting 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.
- Phenol, isopropylated phosphate (3:1) (PIP (3:1)), used as a flame retardant, functional fluid, and in other uses:
  - EPA is prohibiting processing and distribution in commerce of PIP (3:1), and products containing the chemical substance, for all uses, except for certain limited uses.
    - EPA is requiring that persons manufacturing, processing, and distributing in commerce PIP (3:1) and products containing PIP (3:1) notify their customers of these restrictions.
    - EPA is also prohibiting releases to water from the remaining manufacturing, processing, and distribution in commerce activities, and requiring 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-Tris(tert-butyl)phenol, (2,4,6-TTBP), antioxidant used as fuel/lubricant additive:
  - EPA is prohibiting the distribution in commerce of 2,4,6-TTBP and products containing 2,4,6-TTBP at concentrations above 0.3% by weight in any container with a volume of less than 35 gallons in order to effectively prevent the use of 2,4,6-TTBP as a fuel additive or fuel injector cleaner by consumers and small commercial operations.
  - EPA is also prohibiting 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% by weight regardless of container size.
- Pentachlorothiophenol (PCTP), used as cross-linking agent in rubber:
  - EPA is prohibiting 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% by weight.

- Decabromodiphenyl ether (decaBDE), used as a flame retardant:

  - EPA is prohibiting the manufacture (including import), processing, and distribution in commerce of decaBDE, and products containing decaBDE, for all uses, except for certain limited uses.

iii. Other Section 6 Risk Management

On January 19, 2017, EPA proposed a Section 6(a) ban on methylene chloride in consumer and commercial paint and coating removal uses. 82 Fed. Reg. 7464. On March 27, 2019, EPA issued a final Section 6(a) rule banning the use of methylene chloride in consumer paint and coating removal products. 84 Fed. Reg. 11420. Although EPA has not issued in final the restrictions in the proposed rule concerning commercial paint and coating removal, on March 27, 2019, EPA issued an advance notice of proposed rulemaking (ANPRM) addressing such uses. 84 Fed. Reg. 11466. That notice requested input on approaches, including training, certification, and limited access programs, that could be an alternative to the ban action in the proposed rule. The Trump Administration opted not to take further action on the January 2017 proposed ban of commercial paint and coating removal uses or the March 2019 ANPRM on alternatives to the proposed ban in light of the now complete TSCA Section 6(b) risk evaluation of methylene chloride noted above. In 2021, a Biden EPA could take up anew these targeted actions on commercial paint and coating removal uses, especially as the completed risk evaluation confirms unreasonable risk from these uses.

d. Risk Evaluation Litigation

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. On July 16, 2020, a coalition of environmental and labor organizations filed suit in the U.S. Court of Appeals for the Ninth Circuit for review of EPA's "final risk evaluation and order" determining that methylene chloride does 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 members of petitioners are exposed and face risks of exposure to methylene chloride. *Neighbors for Env'l Justice v. EPA*, No. 20-72091. The Halogenated Solvents Industry Association (HSIA), the American Chemistry Council, and the N-Methylpyrrolidone Producers Group, Inc. moved to intervene on the side of EPA, and the court has granted their motions.

On August 18, 2020, a group of state and municipal petitioners filed suit in the U.S. Court of Appeals for the Second Circuit for review of EPA's "final agency action whereby EPA issued an order determining that methylene chloride 'does not present an unreasonable risk of injury to health or the environment.'" *New York et al. v. Wheeler*, No. 20-2729. On November 4, 2020, the court granted EPA's motion to transfer the case to the U.S. Court of Appeals for the Ninth Circuit, and on November 19, 2020, the court granted EPA's unopposed motion to consolidate the cases. Briefing will begin in 2021.

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. Briefing will begin in 2021. On December 8, 2020, California Professional Firefighters, California Communities Against Toxics, Learning Disabilities Association of America, and Sierra Club filed a second suit seeking review of EPA's final risk evaluation for HBCD in the U.S. Court of Appeals for the Ninth Circuit. *Cal. Prof'l Firefighters v. EPA*, No. 20-73578. More information on EPA's final risk evaluation for HBCD is discussed above.

e. Risk Management Litigation

As discussed above, in March 2019, EPA issued a final TSCA Section 6(a) rule banning use of methylene chloride in consumer paint and coating removal products. Multiple challenges to EPA's final methylene chloride rule were filed in the U.S. Court of Appeals for the Second Circuit, and the court has consolidated the cases. *Labor Council for Latin Am. Advancement v. EPA*, No. 19-1042. Several public interest groups and two mothers are challenging the final rule for allowing commercial use of methylene chloride to continue. According to their October 16, 2019, opening brief, EPA's final rule fails to regulate methylene chloride's paint

stripping uses "to the extent necessary so that [they] no longer present[]" unreasonable risk, as required by TSCA Section 6(a). The petitioners cite EPA's risk assessment for methylene chloride, noting that it shows that workers face the greatest risks from methylene chloride and that delayed protections may result in additional deaths. Petitioners ask that the methylene chloride rule be remanded to EPA with instructions to issue final requirements for commercial uses consistent with its risk assessment. HSIA also challenged EPA's final rule for making it "effectively impossible" for small businesses to obtain methylene chloride paint strippers in practical quantities. HSIA asks the court to "overturn the parts of the rule that have so disrupted the supply chain." Briefing continued in 2020 and oral argument has not yet been scheduled. More information on EPA's final rule is available in our March 20, 2019, memorandum, "EPA Bans Consumer Sales of Methylene Chloride Paint Removers, Seeks Comment on Program for Commercial Uses."

3. Section 5 -- New Chemicals

In 2020, EPA has made significant progress in resolving older cases (defined as those more than six months past the submission date). Some cases continue to languish, however.

EPA continues to use "non-order SNURs" in lieu of Section 5(e) orders for cases in which EPA does not find unreasonable risk under the intended conditions of use. The approach, still controversial to some stakeholders, offers administrative streamlining because it reduces the number of Section 5(e) orders that EPA must produce, while implementing SNUR requirements that would presumably have been required under Section 5(f)(4) after an order is signed. EPA also continued its efforts to address backlogged SNURs. EPA proposed 136 non-order SNURs in fiscal year (FY) 2020. It is unclear how the Biden Administration will view this construct, but we would not be surprised if EPA revises its approach and relies on consent orders with conforming SNURs.

Table 1 presents statistics on the number of PMNs submitted annually since 2016 and the outcomes obtained following completion of EPA's review. Table 2 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.

Table 1: Number of PMNs submitted in FYs 2016-2020

			Percent of Completed PMNs[1]							
FY	Submitted PMNs	Complete PMNs	Consent Order	Invalid	Not Likely	Not Likely Based on SNUR	Not Likely, Follow-Up SNUR	Withdrawal	PMNs Still under Review	
2016	363	345	40%	7%	11%	6%	4%	32%	18	5%
2017	437	419	60%	4%	10%	5%	6%	15%	18	4%
2018	411	327	20%	4%	16%	15%	31%	13%	84	20%
2019	187	155	40%	7%	17%	9%	23%	3%	32	17%
2020	171	101	19%	7%	23%	3%	18%	31%	70	41%
	1,569	**1,347**	**40%**	**5%**	**13%**	**8%**	**15%**	**19%**	**222**	**14%**

Statistics based on PMN status posted on EPA's website as of December 20, 2020.

1 Only the "Not Likely" and "Invalid" categories are non-regulated outcomes, although some withdrawals may be for business reasons rather than withdrawal in the face of regulations. "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 reasonably foreseeable conditions of use, but EPA still has concerns for the substance and intends to propose a SNUR.

Table 2: Average number of days from receipt ("Day 1") to final decision on PMN cases

FY	All PMNs (days)	Completed PMNs (days)	Consent Order (days)	Invalid (days)	Not Likely (days)	Not Likely Based on SNUR (days)	Not Likely, Follow Up SNUR (days)	Withdrawal (days)	Under review (days)
2016	526	469	436	45	295	974	1,095	489	1,616
2017	347	306	229	51	181	890	828	377	1,305
2018	519	421	495	19	312	535	423	418	897
2019	208	142	165	32	104	212	129	217	523
2020	173	121	135	76	123	232	114	100	253

a. Discussion of Table 1

i. Total PMNs Submitted

There has been a marked decrease in the number of PMNs submitted since Lautenberg was enacted in 2016. We suspect that many submitters, including our clients, are frustrated by the long review times and unpredictable outcomes from PMNs and may have elected to avoid submitting PMNs and the associated cost of the increased PMN fee.

ii. PMN Outcomes

Assuming that only a "not likely" is an unregulated outcome, the percent of cases that are not regulated has risen slightly in 2019 and 2020 (10%-11% of completed cases in 2016 and 2017, 16%-17% in 2018-2019, and 23% in 2020). The 2020 "not likely" count may drop as more of the 2020 cases are completed. "Not likely" outcomes (along with the "follow-on SNUR" outcomes) tend to resolve more quickly than cases that are regulated through consent orders and "based-on SNURs" simply because EPA must complete the regulatory action prior to the final determination. While the higher incidence of "not likely" cases may appear to reflect a "lighter touch" by OPPT, it may also be that companies are avoiding substances included in categories that are likely to be regulated in ways that would present significant commercial disadvantage in the market. Some of our clients have elected to abandon the U.S. TSCA market to focus on U.S. Food and Drug Administration (FDA)-regulated uses and registrations around the world, including the European Union (EU), Canada, and China. Those products will not be available in the U.S. marketplace for TSCA uses and thus result in an unknown but potentially significant adverse effect on chemical innovation in the U.S. relative to that which is occurring in countries that compete commercially with America.

There is a popular, but entirely false, narrative that the Trump EPA is letting many dangerous chemicals onto the market with no controls. The 17% of "not likely" cases in 2019 represents just 27 cases, hardly a flood of new products. Furthermore, 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 2019, 152 of 1,398, or 11%, of the PMNs are yet to be completed, including 17% of the cases from 2019. 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. The discussion of Table 2 explores this issue from another perspective.

b. Discussion of Table 2

i. Length of Review Period

Table 2 shows the mean number of days between "Day 1" and the final disposition of cases in each FY. For cases still under review, the value represents the number of days through December 21, 2020. Although EPA's record

of accomplishment is improving, there are still issues to resolve. These issues include thinly supported PMNs (e.g., those without robust release and exposure information or without test data on the substance or analogs), errors in EPA's assessment that require rework, and negotiations over the regulatory outcome of cases. There are clear signs of progress, however, and the averages for FY 20 are promising. Time to a signed consent order and time to "not likely" are approaching 90 days.

These statistics do not reflect the delays in EPA promulgating proposed SNURs. Although some batches of SNURs have proceeded smoothly through notice and comment, other cases have been languishing, some for more than a year. This is especially problematic for SNURs that are derivative of consent orders. Consent orders include boilerplate language that prohibits the submitter's customer from further distributing the substance. This effectively means that the direct customer must also be the end user -- an unrealistic scenario for many TSCA chemicals. This restriction on distribution automatically sunsets 75 days after EPA promulgates the SNUR derivative of the order, but delays in EPA publishing SNURs in final mean delays in the sunset of such distribution restrictions. B&C doubts that the new Administration will continue to employ the "based-on SNUR" construction. This means that additional cases that receive consent orders instead of a non-order SNUR will suffer from the commercial delays associated with the limitations on distribution that are part of the consent order boilerplate.

In general, the New Chemicals Program has made progress, but still has a way to go. EPA needs to settle on more predictable and consistent criteria for what is likely or not likely and what is reasonably foreseeable (as opposed to what is imaginable). EPA seems to be equating "not likely to present unreasonable risk under the reasonably foreseeable condition of use" as "reasonable certainty of no harm." The new Administration will almost certainly grapple with these terms from a position of trust and, we hope, give stakeholders confidence that EPA decisions are properly supported by both the science and the law.

On March 18, 2020, a coalition of non-governmental organizations (NGO), including the Environmental Defense Fund (EDF) and Natural Resources Defense Council (NRDC), filed a lawsuit regarding "EPA's repeated and ongoing failures to comply with TSCA's nondiscretionary mandates to disclose to the public information about new chemical substances reviewed by EPA" in the U.S. District Court for the District of Columbia, claiming that EPA fails to disclose required information about new chemical substances under TSCA. *EDF v. Wheeler* (No. 1:20-cv-762). According to the plaintiffs' complaint, EPA fails to publish full and complete notices of its receipt of new chemical applications in a timely fashion and does not disclose all non-confidential information, including health and safety studies, supporting such applications. Plaintiffs argue that TSCA requires EPA to conduct its review of new chemicals transparently, providing the public access to information about the new chemical, including potential uses, effects, and exposures, and an opportunity to participate in EPA's decision-making process. Since July 2020, the plaintiffs and EPA have conferred on a number of occasions. According to the joint case management statements, the parties agree that the case is amenable to resolution by motions for summary judgment and that there is no need for a trial, but they disagree about whether administrative records exist and 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. We presume that the new Administration will settle the lawsuit and dedicate more resources to the publication of notices and making publicly available the non-confidential information supporting the applications. It is unclear where OPPT will find the resources to do so, but a court settlement will certainly elevate the priority of EPA's taking action in this regard.

We note that, as reflected in the Fall 2020 Unified Agenda of Regulatory and Deregulatory Actions (Regulatory Agenda), EPA now plans on issuing, in **October 2021**, a final rule it proposed in July 2016 to amend aspects of the SNURs 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 would align, where possible, EPA's regulations with the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (HCS) regulations at 29 C.F.R. Section

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"Effectively Managing Supply Chain Communications under TSCA," *Bloomberg Law*, April 28, 2020.

Having gained experience with the development and implementation of the initial TSCA Section 4 test orders on PV29, EPA should be better positioned to require testing relatively quickly to inform its future prioritization actions and risk evaluations.

1910.1200. Given this action has been delayed repeatedly since 2016, whether the rule is now a priority for EPA, or will be under the new Administration, remains to be seen.

Additionally, in **May 2021**, EPA reportedly plans to propose regulations that would revise the new chemical regulations at 40 C.F.R. Part 720 to "improve the efficiency of the 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 risks assessment and, ultimately, the length of time that new chemicals are under review." While it is unclear what, specifically, EPA will 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 will likely be regarded as a significant success by industry. On the other hand, if the regulations 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 upfront what information it needs to override its default assumptions about releases and exposures.

At the end of September, EPA reorganized OPPT. The key functions that support new chemicals review, including chemistry, risk assessment, and risk management, now all reside in a single division. The hope is that this will help diminish the backlog of cases now that the scientific risk assessment teams and regulatory risk management teams, both dedicated to new chemicals, report to a single division director in the OPPT New Chemicals Division.

4. Section 4 -- Testing

a. Test Orders

EPA issued its first, and so far only, TSCA testing action since the passage of the Lautenberg Amendments to TSCA with the issuance on February 28, 2020, of TSCA Section 4(a)(2) test orders on PV29. The testing required under the orders is to inform the development of the TSCA Section 6(b) risk evaluation of the chemical, which is among the "first 10" chemicals identified by EPA for risk evaluation under TSCA Section 6(b). The tests ordered by EPA address uncertainties in the draft risk evaluation of PV29 highlighted by the Science Advisory Committee on Chemicals (SACC) and public comments, and are of the type that could be conducted in a relatively short time period. Specifically, the test orders required testing to confirm the solubility of PV29 and worker respirable dust monitoring of the chemical in the manufacturing facility. The data EPA considered in revising PV29's risk evaluation are discussed above.

Having gained experience with the development and implementation of the initial TSCA Section 4 test orders on PV29, EPA should be better positioned to require testing relatively quickly to inform its future prioritization actions and risk evaluations. EPA has sharpened one tool in its toolbox for addressing data needs. It is our view that, in 2021 and beyond, EPA will use its TSCA Section 4 testing authority increasingly and its Section 8 information collection authorities to address less-studied chemicals in implementing TSCA Section 6 prioritization, risk evaluation, and risk management processes.

b. Alternative Test Methods

TSCA Section 4(h)(1) requires EPA to reduce and replace, to the extent practicable, the use of vertebrate animals in the testing of chemical substances or mixtures. EPA is also required to promote the development and incorporation of alternative test methods or strategies that do not re-

quire new vertebrate animal testing. In 2018, EPA, as required by TSCA Section 4(h)(2), published the Strategic Plan to Promote the Development and Implementation of Alternative Test Methods within the TSCA Program. This section also requires EPA to provide a periodic progress report on the implementation of the Strategic Plan to Congress -- and EPA must issue its first progress report in **June 2021**.

In June 2020, EPA released a New Approach Methodologies (NAM) Work Plan that will "serve[] as a roadmap for meeting its animal testing reduction goals set forth in Administrator Andrew Wheeler's 2019 Directive." The NAM Work Plan describes how EPA plans to develop, test, and apply chemical safety testing approaches that reduce or replace the use of animals. The objectives of the NAM Work Plan include:

- Evaluating regulatory flexibility for the use of NAMs, with a report to be issued in 2021;
- Establishing baselines and metrics for assessing progress, with a report to be issued annually as part of EPA's NAM annual conference;
- Developing NAMs that fill critical information gaps;
- Establishing scientific confidence in NAMs;
- Demonstrating NAMs application to regulatory decisions; and
- Engaging with stakeholders to incorporate their knowledge and address their concerns regarding EPA's phase-out of mammalian testing.

More information on the 2019 directive to prioritize efforts to reduce animal testing is available in our September 11, 2019, blog item, "EPA Administrator Signs Directive Intended to Reduce Animal Testing, Awards $4.25 Million for Research on Alternative Methods to Animal Testing."

Given the clear statutory mandate to reduce vertebrate testing, B&C does not expect the change in Administration to change significantly EPA's approach to meeting the requirements under Section 4(h).

5. SNURs on Existing Chemicals

On July 27, 2020, EPA published a final SNUR for long-chain perfluoroalkyl carboxylate (LCPFAC) and perfluoroalkyl sulfonate chemical substances. 85 Fed. Reg. 45109. EPA first proposed a SNUR for LCPFAC and perfluoroalkyl sulfonate chemical substances on January 21, 2015. 80 Fed. Reg. 2885. On March 3, 2020, EPA issued a proposed supplemental SNUR for LCPFAC chemical substances that would make inapplicable the exemption for persons who import a subset of LCPFAC chemical substances as part of surface coatings on articles. 85 Fed. Reg. 12479. The March 2020 proposed supplemental SNUR was responsive to the article consideration provision at TSCA Section 5(a)(5), which was added by the Lautenberg Amendments to TSCA. TSCA Section 5(a)(5) states that articles can be subject to notification requirements as a significant new use provided that EPA makes an affirmative finding in a rule that the reasonable potential for exposure to a chemical from an article or category of articles justifies notification.

The final SNUR requires persons to notify EPA at least 90 days before commencing the manufacturing (including importing) or processing of a subset of LCPFAC chemical substances for any use that was not ongoing after December 31, 2015; the manufacturing (including importing) or processing of all other LCPFAC chemical substances for which there were no ongoing uses as of January 21, 2015 (the date of the original proposed SNUR); the import of a subset of LCPFAC chemicals as part of a surface coating on articles; and the import of perfluoroalkyl sulfonate chemical substances as part of carpets. The final SNUR prohibits the commencement of such manufacturing and processing for a significant new use until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are

EPA plans to issue a final TSCA Section 8(d) health and safety data reporting rule in March 2021 for the 20 high-priority chemicals now undergoing risk evaluation, and for 30 organohalogen flame retardant chemicals being evaluated by the CPSC.

required in association with that determination. We note that under Section 7352 of the National Defense Authorization Act for Fiscal Year 2020, EPA was required to "take final action" on the January 21, 2015, proposed rule by June 22, 2020, and that the final rule was signed and EPA posted a prepublication version of it on the June 22, 2020, deadline. More information on the final SNUR on LCPFAC and perfluoroalkyl sulfonate chemicals is available in our July 27, 2020, memorandum, "EPA Issues Final SNUR for LCPFAC and Perfluoroalkyl Sulfonate Chemical Substances."

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 risk evaluations for the 20 chemicals designated as "high-priority" for risk evaluation and the risk management actions on the "first 10" chemicals, we believe it is unlikely that EPA will act further on these and other long-dormant SNURs in 2021.

6. Sections 8 and 14 -- Reporting and Confidential Information

a. New Sections 8(a) and 8(d) Reporting Rules Planned

EPA plans to propose a TSCA Section 8(a) information collection rule in **April 2021** 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 for Fiscal Year 2020 that amended TSCA Section 8(a) that requires EPA to, not later than January 1, 2023, promulgate a rule requiring each person who has manufactured a perfluoroalkyl or polyfluoroalkyl 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).

Additionally, in **November 2021**, EPA intends to issue a TSCA Section 8(a) rule to gather information on certain chemicals on the 2014 Update to the TSCA Work Plan, including occupational, environmental, and consumer exposure information to inform TSCA prioritization and risk evaluation. TSCA Section 8(a) authorizes EPA to collect a wide range of information from manufacturers (including importers) and processors of chemical substances; it is unclear, however, specifically who would be required to report, what chemicals would be the subject of reporting, or what information would be required. While the target date for this action in the Fall 2020 Regulatory Agenda is one year later than originally planned by the Trump Administration as reflected in the Spring 2020 Regulatory Agenda (and listed among other "long-term" actions), we expect that the Biden Administration will move forward with this action as planned.

The Fall 2020 Regulatory Agenda also reflects EPA's plan to issue a final TSCA Section 8(d) health and safety data reporting rule in **March 2021** for the 20 high-priority chemicals now undergoing risk evaluation under TSCA Section 6(b), as described above, and for 30 organohalogen flame retardant chemicals being evaluated by the Consumer Product Safety Commission (CPSC). This action would require chemical manufacturers and importers of these substances to report lists and copies of studies on health effects, environmental effects, environmental fate, and occupational, general population, and consumer exposure for these chemicals. Given the timeline for EPA's issuance of the final risk evaluations for the 20 "high-priority" chemicals as described above, EPA will need to review and assimilate quickly, as appropriate, the information reported under the rule to inform the development of the risk evaluations for the chemicals.

We highlight that EPA is working with the TSCA Section 4 Interagency Testing Committee (ITC), established under TSCA Section 4(e), to facilitate the efficient collection of the needed 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 organohalogen flame retardants 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.) The types of unpublished health and safety studies EPA and CPSC are seeking include studies on health effects, environmental effects, environmental fate, and occupational, general, and consumer exposure for these chemicals.

b. Chemical Data Reporting Rule

On April 9, 2020, EPA published a final TSCA Section 8(a) rule amending the Chemical Data Reporting (CDR) rule. 85 Fed. Reg. 20122. Key revisions include allowing manufacturers to use certain processing and use data codes already in use by many chemical manufacturers as part of international codes developed through the Organization for Economic Cooperation and Development (OECD); updating requirements for asserting confidentiality claims to align with the requirements in amended TSCA; and adding reporting exemptions for specific types of byproducts manufactured in certain equipment. According to EPA, the amendments are intended to reduce the burden for certain CDR reporters, improve the quality of CDR data collected, and align reporting requirements with certain Lautenberg Amendments. Additionally, the rule extended the reporting period for CDR data submitters from September 30, 2020, to November 30, 2020, to provide additional time for the regulated community to familiarize themselves with the amendments and to allow time for reporters to familiarize themselves with an updated public version of the reporting tool.

On November 25, 2020, EPA again extended the deadline -- from November 30, 2020, to **January 29, 2021**. 85 Fed. Reg. 75235. EPA extended the deadline this second time in response to comments from stakeholders who raised concerns about the ability to report by the deadline due to technical problems with electronic reporting using EPA's Central Data Exchange (CDX) system and issues arising from the COVID-19 pandemic.

Key for small businesses is the related final rule that resets the small manufacturer definition for purposes of certain TSCA Section 8(a) report and recordkeeping rules, including CDR. 85 Fed. Reg. 31986. EPA raised the parent company annual sales thresholds from $4 million without regard to domestic production and import volume and $40 million for chemicals manufactured or imported at less than 100,000 pounds per year, per site, to $12 million and $120 million, respectively.

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**.

c. 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.

We note that the lawsuit on the Inventory notification rule (*EDF v. EPA*, No. 17-1201, discussed below) implicates the CBI review rulemaking process. The final rule includes two additional questions on reverse engineering that

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New forward-looking activity notice filers claiming specific chemical identity as confidential were required by the rule to address all substantiation questions after the effective date of the final CBI rule.

manufacturers and processors are required to answer to substantiate their specific chemical identity CBI claims. These two questions were added as part of EPA's response to the court-ordered remand of part of the TSCA Inventory Notification (Active-Inactive) Requirements Rule.

Persons who filed a retrospective activity notice (Notice of Activity Form A) under the Active-Inactive rule and claimed the specific chemical identity as confidential had until November 1, 2020, to amend voluntary substantiations or file new ones consistent with the requirements of the final CBI rule. Persons who have already filed a forward-looking activity notice (Notice of Activity Form B) under the Active-Inactive rule and claimed the specific chemical identity as confidential had until June 4, 2020, to update their substantiations to address the two new substantiation questions. New forward-looking activity notice filers claiming specific chemical identity as confidential were required by the rule to address all substantiation questions after the effective date of the final CBI rule. More information on the final rule on Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory is available in our February 28, 2020, memorandum, "EPA Releases Final Rule for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory."

d. Inventory Notification Rule Litigation

On April 26, 2019, the U.S. Court of Appeals for the District of Columbia Circuit issued its decision in the EDF's challenge to the final TSCA Inventory Notification (Active-Inactive) Requirements Rule. The court granted in part, denied in part, and remanded the case without vacatur of the challenged rule for EPA to address its arbitrary elimination of substantiation questions regarding reverse engineering, for the reasons in the accompanying opinion. *EDF v. EPA*, No. 17-1201.

EDF challenged five distinct features of the final rule: (1) EPA's exclusion of substantiation questions regarding reverse engineering; (2) the final rule's criteria for "maintaining" a confidentiality claim; (3) EPA's choice not to incorporate certain regulatory requirements into the final rule; (4) EPA's failure to implement TSCA's "unique identifier" (UID) requirements; and (5) the final rule's exemption of exported chemicals from its notification requirements. The court stated that only the first claim succeeds past the standard of review required under both the Administrative Procedure Act (APA) and TSCA, however; specifically, EPA acted arbitrarily and capriciously in its "omission of any inquiry into a chemical identity's susceptibility to reverse engineering [which] effectively excised a statutorily required criterion from the substantiation process." Even though EPA included several substantiation questions to address reverse engineering in the proposed rule, EPA did not include any "substantiation questions related to the requirement that a substance's chemical identity not be susceptible to reverse engineering" and declined altogether to "'secure answers' substantiating a company's 'assertion' that its chemical product cannot be reverse engineered" in the final rule. The court stated that this error was "fatal" and remanded this issue back to EPA for EPA to "address its arbitrary elimination of substantiation questions regarding reverse engineering." EPA addressed this error identified by the court as discussed in the preceding discussion of the "CBI Inventory Review Rule."

e. UID Implementation

In 2019, EPA published a copy of the TSCA Inventory that included UIDs as required by TSCA Section 14(g)(4). At that time, EPA had assigned 441 UIDs to substances on the confidential portion of the Inventory. The most recent copy of the TSCA Inventory (June 2020) has the exact same number of UIDs despite the fact that 94 substances have been added. There may be an explanation for why

UIDs were not assigned to the additional chemicals, but it may also be the case that EPA has not been keeping up with assigning UIDs. EPA is, presumably, assigning UIDs to substances as it reviews CBI claims on Form A Commercial Activity Notices.

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 that 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). 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 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. 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. Mercury Reporting Rule Litigation

On June 5, 2020, the U.S. Court of Appeals for the Second Circuit issued its decision in a case challenging three exemptions from EPA's final mercury inventory rule. *NRDC v. EPA*, No. 18-2121). NRDC and Vermont challenged the final rule, arguing that EPA unlawfully exempted too many manufacturers and importers to protect human health and the environment effectively. The court found that the exemption for importers of products containing mercury-added components is an unlawful interpretation of TSCA because it lacks a reasoned explanation. The court found that the exemption for manufacturers of products with mercury-added components and the exemption for high-volume manufacturers are lawful in light of Congress's directive to "not require reporting which is unnecessary or duplicative."

7. Section 26 -- Administration of TSCA; Fees Rule

Under TSCA Section 26(b) as amended, EPA has authority to collect fees from chemical manufacturers and importers to defray a portion of the EPA costs associated with implementation efforts. The TSCA Fees Rule (40 C.F.R. Part 700 subpart C) requires payment of fees for eight categories of fee-triggering events under TSCA, including EPA-initiated risk evaluations under TSCA Section 6. Under the Fees Rule, EPA is required to prepare a preliminary list of manufacturers subject to fee obligations for EPA-initiated Section 6 risk evaluations. EPA published a *Federal Register* notice on January 27, 2020, identifying the preliminary lists of manufacturers (including importers) of the 20 high-priority chemical substances for risk evaluation for which fees will be charged under the TSCA Fees Rule. 85 Fed. Reg. 4661. During the comment period (as extended twice by EPA to June 15, 2020), manufacturers (including importers) were required to self-identify as manufacturers of a high-priority substance irrespective of whether they were included on the preliminary lists identified by EPA.

On March 25, 2020, EPA announced that it would consider the development of a proposed rule that would look at potential exemptions to the TSCA Fees Rule in response to stakeholder concerns about implementation challenges. EPA stated that by considering a proposal to narrow the broad scope of the current requirements, it "could significantly reduce burden on potentially thousands of businesses across the country while maintaining the ability to successfully implement the Lautenberg Act amendments" to TSCA to protect human health and the environment. According to EPA, it planned to initiate a new rulemaking process to consider proposing exemptions to the current rule's self-identification requirements associated with EPA-initiated risk evaluations for manufacturers that

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import the chemical substance in an article; produce the chemical substance as a byproduct; or produce or import the chemical substance as an impurity. EPA stated that it may also consider proposing other changes to the rule during this process consistent with TSCA's requirement to reevaluate the Fees Rule every three years. EPA noted that it believes that considering exempting certain entities from self-identification requirements will not impede the ability to collect fully the necessary fees and will still allow it to achieve the ultimate objective of the TSCA Fees Rule and the statute -- "to defray a portion of EPA's TSCA implementation costs."

EPA released a prepublication version of the proposed Fees Rule on December 21, 2020. 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;

- Ensuring fees are fairly and appropriately shared across companies by proposing a production-volume based fee allocation and including 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 and manufacturer-requested risk evaluations; and

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

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

In the March 25, 2020, announcement, EPA stated additionally that "in light of the extremely unusual circumstances of this situation and the undue hardship imposed on certain businesses who would be required to collect and report information" under the TSCA Fees Rule, that it issued a "no action assurance" for the three categories of manufacturers (*i.e.*, for manufacturers that import the chemical substance in an article; produce the chemical substance as a byproduct; or produce or import the chemical substance as an impurity). More specifically, EPA stated that it "will exercise its enforcement discretion regarding the self-identification requirement for the three categories of manufacturers" for which EPA intends to propose an exemption. EPA suggested that businesses that are erroneously on the preliminary lists of fee payers or fall into one of the three categories discussed above should see its frequently asked questions (FAQ) for more information about how to certify as such to EPA and to avoid fee obligations.

On September 4, 2020, EPA published a *Federal Register* notice announcing the "final" lists of manufacturers of the 20 high-priority chemical substances for risk evaluation for which fees will be charged under the Fees Rule. 85 Fed. Reg. 55283. In that notice, EPA stated that the "TSCA Fees Rule provides EPA flexibility to refine the final list of manufacturers in a manner that is reasonable and prudent, in light of statutory and regulatory obligations related to TSCA risk evaluations and associated fee payment obligations. As such, the Agency decided to not charge a fee to those importers who were only importing small quantities of the 20 [high-priority substances] for research and development purposes only." On November 25, 2020, EPA released updates to the lists, stating that the updated list includes additional manufacturers not identified on the final list of companies and removes manufacturers that self-identified

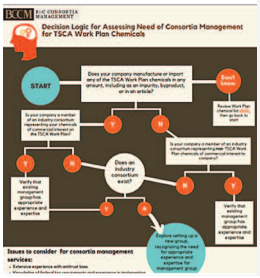
in error or imported the chemical solely for the purpose of R&D. EPA stated further that it is committed to ensuring the list is accurate and plans to use the updated list to begin invoicing for fees. EPA added that due to the public health emergency, EPA is exploring options for payment flexibilities; payment options had been advocated for by certain prospective fee payers. Under 40 C.F.R. Section 700.45(g)(3)(iv) of the Fees Rule, fee payments are due January 2, 2021, 120 days from publication of the final scopes of the risk evaluations for the 20 high-priority chemical substances now undergoing risk evaluation. We are aware, however, that at least certain EPA invoices received by manufacturers required to pay a fee require payment of only one third of the fee by January 2, 2021, with the remaining amounts due at a later date. To the extent this approach is being applied uniformly, which we expect (but had heard no formal EPA announcement on the topic as this document was being prepared), the deferral of two-thirds of the payment to a later date will be viewed by prospective fee payers as a welcomed development, we believe.

8. Section 21 -- Litigation and Petitions

Lawsuits challenging EPA's denial of TSCA Section 21 petitions have continued. Two suits in the U.S. District Court for the Northern District of California concerning EPA's dismissal of TSCA Section 21 petitions regarding asbestos have been combined. The Asbestos Disease Awareness Organization (ADAO) and five other NGOs petitioned EPA in 2018, requesting that EPA initiate rulemaking under TSCA Section 8(a) to amend the CDR rule to increase reporting of asbestos to CDR. EPA denied the petition on the grounds that the petitioners did not demonstrate that it is necessary to amend the CDR rule. On February 18, 2019, ADAO filed suit regarding EPA's denial of its petition. *ADAO v. EPA,* 3:19-cv-871. In the second case, following EPA's dismissal of a January 2019 petition, a coalition of 11 state attorneys general filed suit against EPA for its failure to initiate an asbestos reporting rule under TSCA Section 8(a). *California v. EPA*, No. 3:19-cv-3807. On November 12, 2020, the court heard motions for summary judgment. Plaintiffs argued that EPA's refusal to use its TSCA rulemaking authority to obtain the minimum information necessary about the impacts of asbestos on human health was arbitrary and capricious and contrary to law and should be set aside under the APA. EPA maintained that plaintiffs failed to show that EPA overlooked potential uses or exposures when it denied the petitions. According to EPA, plaintiffs also failed to meet their burden to show that the denial of their petitions was arbitrary or capricious. The court asked all parties how much information is reasonable for EPA to obtain as it determines whether asbestos poses so much risk that its uses must be regulated.

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*, Case 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. After hearing closing arguments, the judge noted that the evidence presented by both parties was not confined to the administrative record and that he allowed both parties to use evidence that was available after plaintiffs filed their petition in 2016. 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 August 10, 2020, the court ordered the case held in abeyance and directed the plaintiffs to file a new petition with EPA. According to the court, doing so will enable the plaintiffs to address "serious standing issues" and will also afford EPA an opportunity to consider the significant



Forming an industry consortium to address TSCA issues -- present and future -- is a critical commercial move. Organizing an industry group means reduced cost, greater flexibility, increased time for strategic planning, and less aggravation in the long run. B&C® Consortia Management (BCCM) has been forming and managing chemical consortia for many years. Learn more about why and how to form an industry consortium with this overview of the process.

scientific developments that have occurred since the original petition was filed in 2016. On November 4, 2020, plaintiffs filed a supplement to their petition that includes the evidence identified by the court, including data released November 4, 2020. 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. The court held a status conference on November 5, 2020, noting that the record will include the final National Toxicology Program (NTP) fluoride review and pooled benchmark dose study when completed, and that EPA may include a Spanish study that is being considered for publication. The court will hear EPA's motion for relief from the order holding the proceedings in abeyance in 2021.

On June 3, 2020, the American Coatings Association (ACA), National Association of Manufacturers, Toy Association, National Association of Home Builders, and U.S. Chamber of Commerce filed a petition under TSCA Section 21 requesting that EPA develop a risk management procedural rule under TSCA Section 6. According to the petition, such a rule is necessary to implement the Lautenberg Amendments. The petitioners noted that the prioritization and risk evaluation framework rules "serve an essential role to guide affected stakeholders through these new processes." The petitioners requested a TSCA Section 6 rulemaking to establish a similar degree of procedural consistency, guidance, and transparency for EPA's risk management process. Under TSCA Section 21, EPA has 90 days from filing to grant or deny the petition. If EPA grants a petition for action under TSCA Section 6, EPA must promptly commence an appropriate proceeding in accordance with TSCA Section 6. If EPA denies a petition, it must publish its reasons for the denial in the *Federal Register* and petitioners can challenge that decision in accordance with TSCA Section 21(b)(4).

In a letter dated July 28, 2020, EPA acknowledged receipt of the petition and stated that the request was not a valid petition under TSCA Section 21. EPA went on to state "[u]nder TSCA section 21, as it relates to TSCA section 6, any person may petition EPA to initiate a proceeding for the issuance, amendment, or repeal of a rule under TSCA section 6 imposing chemical-specific regulatory controls for setting forth facts showing such action is 'necessary'" and that "Section 21 does not provide a means for petitioning EPA to initiate a procedural rule." The acknowledgement letter further stated that "EPA will, however, consider your request as a petition under the Administrative Procedure Act (APA) for the issuance of a procedural rule" and that the "petition is under review by the Office of Pollution Prevention and Toxics (OPPT), which is responsible for programs under TSCA." We observe that in the Fall 2020 Regulatory Agenda, EPA lists a proposed rule on "Procedures for Rulemaking Under Section 6 of the Toxic Substances Control Act" that appears to be consistent generally with the action requested in the Section 21 petition. That proposed rule is planned for publication in **October 2021**. Whether the Biden Administration adopts the plan and schedule for proposing the regulation remains to be seen. More information on the petition is available in our July 10, 2020, memorandum, "Industry Associations Petition EPA to Develop Risk Management Procedural Rule under TSCA Section 6."

On October 14, 2020, a coalition of North Carolina NGOs petitioned EPA for a TSCA Section 4 test rule for 54 PFAS manufactured by The Chemours Company (Chemours) at its chemical production facility in Fayetteville, North Carolina. The petition, filed under TSCA Section 21, seeks issuance of a rule or order under TSCA Section 4 compelling Chemours to fund and carry out testing under the direction of a panel of independent scientists. EPA states in its letter acknowledging receipt of the petition that under TSCA Section 21, it has 90 days after the date the petition is filed to grant or deny the petition (**January 11, 2021**, in this case). If the Administrator grants the petition, the Administrator must promptly commence an appropriate proceeding. If the Administrator denies the petition, the Administrator must publish the reasons for such a denial in the *Federal Register*. The petition was filed by Center for Environmental Health, Cape Fear River Watch, Clean Cape Fear, Democracy Green, the NC Black Alliance, and Toxic Free NC. More information is available in our October 29, 2020, memorandum, "TSCA Section 21 Petition Seeks Section 4 Test Rule for 54 PFAS."

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C. FIFRA

1. Predictions and Outlook for the OCSPP's Office of Pesticide Programs

For EPA's Office of Pesticide Programs (OPP), 2020 was largely devoted to addressing ongoing issues: continuing the march towards meeting the **2022** deadline for registration review of pesticides registered before 2006, the ongoing attempt to comply with the requirements of the Endangered Species Act (ESA), meeting PRIA deadlines for registration applications, and responding to the latest chapters in the long saga behind responding to an environmentalist petition to stop effectively use of the organophosphate chlorpyrifos (initially filed in 2007). One cannot ignore the large impact that the COVID-19 pandemic had, especially on the pesticide program since products to disinfect against COVID-19 and other coronaviruses are reviewed and approved by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The surge in applications for such disinfectant products caused EPA leadership to reallocate resources and personnel to meet the critical need for timely review of products designed to help control pandemic risks.

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How EPA's Office of Pesticide Programs Is Handling COVID-19 -- A Conversation with Lisa Campbell

The election results in November also pushed certain "unfinished business" towards the front of the program queue with which to close a busy year for OPP. What it leaves behind for 2021 is less clear; as mentioned earlier, the new Administration will arrive in January with an uncertain schedule for securing political personnel appointments and what may be an even more urgent initial need for OCSPP to respond to deadlines and controversial policies surrounding the 2016 Lautenberg Amendments. The pesticide program has its own deadlines and controversies, of course, and the major issues facing the program in 2021 are likely to include the following topics.

2. Pesticide Registration and Improvement Act

After considerable legislative activity, the Pesticide Registration Improvement Extension Act 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 has continued its work on PRIA submissions in 2020, with various accommodations to manage a remote workforce during a pandemic that we expect will continue well into 2021. There has been a significant increase in the number of PRIA submissions in 2020, particularly those destined for the Antimicrobials Division (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. To the extent possible, OPP has diverted resources to AD to address this increased demand. AD has stated that it will try to complete PRIA actions for products intended to address the pandemic in one to two months faster than the assigned PRIA review schedule. Through early November 2020, published data indicate EPA has been successful in its efforts to expedite. All indications are that this trend will continue, particularly following EPA's October 2020 publication of its Interim Guidance for residual surface disinfectant and antimicrobial claims. For more information on the Interim Guidance, please see our October 28, 2020, blog, "EPA Seeks Comment on Its Interim Guidance on Residual Efficacy 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 the Good Laboratory Practice (GLP) standards. COVID-19 diminished in-person activities in 2020, but these and other inspection activities will increase under a Biden Administration and as pandemic restrictions are lifted.

The PRIA 4 reauthorization was delayed due to Senate concerns about possible changes to the Worker Protection Standards (WPS) provisions that were published in November 2015 and the Certification and Training rule published in January 2017. PRIA 4 precludes changes to these rules except for revisions, after public comment, to the Application Exclusion Zone (AEZ) provisions of the rule.

The arrival of a new Biden Administration in 2021 is likely to inspire review of the status of chlorpyrifos. Many expect EPA will halt remaining uses of the insecticide.

The AEZ was designed to ensure that if anyone was within a certain distance of a pesticide application, the application would stop even if the person was in the AEZ. These requirements were thought redundant with application rules already designed to assure persons nearby would be protected. During the earlier rulemaking, comments about the AEZ included concerns about the complexity and enforceability of the requirements. EPA proposed revisions to the AEZ to clarify what and how the exclusion provisions would be interpreted and enforced, and a final rule with these revisions was published on October 30, 2020. 85 Fed. Reg. 68760.

Finally, OPP increased PRIA 4 fees on October 1, 2019, by 5%, consistent with past increases. The revised fees will remain in effect until **September 30, 2021**.

3. 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."

The Trump Administration arrived long after the beginning of this controversy and only a few months before the court-ordered March 3, 2017, deadline for final EPA action on chlorpyrifos. As many expected, in meeting the deadline for a decision on the petition, the Trump EPA denied the petition and stated that it would continue to review the safety of chlorpyrifos. The Trump EPA also stated then that it viewed the deadline for a renewed determination of whether the pesticide met the safety standard was the deadline for the registration review of chlorpyrifos, due in **2022**.

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 Republican 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 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 continue 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).

EPA stated in its 2019 response to the related petition denial that sometime in summer 2020 it would make available for public comment any updates to the human health and drinking water assessments. Those assessments came in September 2020, when EPA issued the following assessments: *Chlorpyrifos: Draft Ecological Risk Assessment for Registration Review, Chlorpyrifos: Third Revised Human Health Risk Assessment for Registration Review*, and Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review. On December 7, 2020, EPA issued for comment the Proposed Interim Decision (PID) for chlorpyrifos. 85 Fed. Reg. 78849. EPA announced it is proposing new risk mitigation measures to address potential human and environmental risks identified in EPA's September 2020 draft risk assessments. The PID proposes the following measures:

- Label amendments limiting application to address potential drinking water risks of concern.
- Additional personal protection equipment (PPE) and application restrictions to address potential occupational handler risks of concern.
- Spray drift mitigation, in combination with the use limitations and application restrictions identified to address drinking water and occupational risks, to reduce exposure to non-target organisms.

Comments on both the September 2020 draft risk assessments and the PID are due on or before **February 5, 2021**. *See* B&C's December 10, 2020, blog, "EPA Issues Proposed Interim Registration Review Decision to Require New Risk Mitigation Measures for Chlorpyrifos."

The arrival of a new Biden Administration in 2021, however, is likely to inspire review of the status of chlorpyrifos. Many expect EPA will halt remaining uses of the insecticide. The larger issue will be the legal basis for any such action.

New conclusions about the assessment of chlorpyrifos could have 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.

4. 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 the 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 ten 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

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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, as well as policies between EPA and the Services, but delays and litigation continue unabated. In 2017, with the arrival of the Republican Administration and with Republican majorities in both the House and Senate, there was initially hope that some more practical, or at least predictable, process for ESA compliance could be put into place. Two events initiated during the Trump Administration continued to drive the issue in 2020.

a. Interagency Working Group

On January 31, 2018, the Administration announced a Memorandum of Agreement (MOA) between the Department of the Interior, the Department of Commerce, and EPA to evaluate the current ESA review process and coordinate in fashioning revisions, in the words of Administrator Pruitt: "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 CEQ acting as chair.

Like other Administrations before, the Trump Administration embarked on a journey to address the problem of how to integrate ESA assessment and consultation requirements with the FIFRA registration process. The 2018 MOA 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 very limited success in getting the bureaucracies to understand better the work and mission of the individual agencies. Now, as the Trump Administration ends, it seems little progress was made despite more cooperative interactions and conclusions of the Services and EPA.

The second significant effort during the Trump Administration was 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 con-

ference process essentially codifies the February 2018 MOA announcement by requiring the agencies to better coordinate and utilize 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 inter-agency 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 (BE's) for pesticides." *See* our May 16, 2019, blog, "EPA Issues Draft Revised Method for ESA Pesticide Assessments." Generally speaking, registrants and pesticide users have 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.

Many of the court decisions issued to date have found EPA to be in violation of ESA requirements, with some notable exceptions. An important ESA case ruling that supported EPA's approach was issued in July 2020, regarding the low-volatility formulation of 2,4,-D registered by Corteva, known as Enlist. In its ruling, the Ninth Circuit Court of Appeals supported EPA's authority to make a "no effect" determination and register the herbicide. This is important because for EPA to have any chance of meeting court deadlines involving ESA assessments or to meet FIFRA registration review deadlines, the ESA review process needs to avoid having all pesticide assessments require further review from the Services. The Services do not have the organizational capacity to review hundreds of pesticide active ingredients, especially in a timeframe that would allow the pertinent deadlines to be met. In the Enlist case, the court found that EPA had conducted a sufficiently thorough review to make a no effect determination (imposing label requirements to ensure no effect on listed species), although it did send one petition back to EPA for further consideration of the impact on monarch butterflies from the use of Enlist on milkweed in application areas. The path taken on Enlist with regard to resolving ESA issues may not be the path for all pesticide reviews, but it may provide a template for what it will take for more timely completion of ESA reviews in the future.

ARTICLE:

"Pesticides, Chemical Regulation, and Right-to-Know 2019 Annual Report," in *The Year in Review 2019: Environment, Energy, and Resources Law*, ABA (2020).

This was an unusual win for EPA on ESA matters, and may outline an assessment method pathway for compliance with ESA review as part of the FIFRA registration approval process. If this success can be repeated and routinized, it would greatly help integrate the requirements of both statutes and allow for a more predictable process for pesticide registration approvals.

Notwithstanding this recent legal success, 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**.

5. 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 EPA 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 which 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 Homepage," 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, less like the Obama years when EPA made more sweeping statements about the issue generally and imposed new conditions broadly.

The most important development in 2020 was the release of the proposed registration review decisions for the major neonicotinoid insecticides. In January 2020, EPA released proposed interim decisions for 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 in order to limit exposure to bees;
- Language on the label that advises homeowners not to use neonicotinoid products; and
- Cancelling spray uses of imidacloprid on residential turf due to health concerns.

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

Since these PIDs were proposed, EPA has stated that it intends to release the final PID for these products sometime before the end of 2020. This has not happened, however.

6. Dicamba

As a result of the widespread use of glyphosate-resistant crops, certain weed species have evolved to become able to withstand treatment with glyphosate, thus certain weeds themselves are now considered to be resistant and can have a significant impact on the production yields (up to 100%). 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 dicamba formulations were believed to present a risk of drift to nearby crops, and so pesticide registrants developed formulations designed with low volatility to reduce the risk of off-target drift. This was intended to allow use of the new dicamba formulations around other crops (beside the dicamba-resistant ones) without causing damage to those 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 drift. In 2018, use of dicamba was approved for another two-year period, as reports of damage were evaluated and as EPA made addi-

On October 27, 2020, EPA announced its approval of the low-volatility dicamba products for a five-year period. This decision may come under review by the Biden Administration before the expiration date.

tional changes to the label requirements and requirements for applicator training designed to further reduce the risk of drift, and evaluate whether reported drift 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 further requirements intended to reduce the likelihood of drift problems. These requirements included 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 as a result of reviewing significant data points. 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 (which 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 who 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. Environmental groups also are expected to challenge the approval but for different reasons, that EPA's proposed changes are insufficient.

Although approved by EPA for a five-year period, this decision may also come under review by the Biden Administration before the expiration date granted by the Trump Administration.

7. Atrazine

Another widely used pesticide for which EPA completed its registration review interim decision is the herbicide atrazine. Atrazine has been controversial for many years and subject to continued EPA review through many different Administrations. In September 2020, EPA released its final interim decision document. EPA's interim decision allows continued use with additional restrictions to protect applicators, reduced application rates, the elimination of some use sites, intended to reduce risks to children, and measures to protect endangered and threatened species. Environmental groups strongly disagree with EPA's conclusions, and on October 30, 2020, filed a challenge to the registration review decision. Given the controversy over this registration review decision, any Biden Administration response will be closely watched.

8. Glyphosate

Glyphosate is one of the most widely used herbicides worldwide. Its use greatly expanded since the advent of biotech crops in the mid-1990s that engineered herbicide tolerance to glyphosate into a variety of crops. Partly as a result, stakeholders who raise safety concerns about the development and use of genetically modified crops have taken a strong interest in potential health and safety issues that could arise from glyphosate exposure.

In 2015, the International Agency for Research on Cancer (IARC) issued a report that concluded, based on its assessment nomenclature and evaluation methods, that exposure to glyphosate is "probably carcinogenic to humans." Later, the outcome of various tort cases in California led to even more media and public concern and further fueled the debate over the safety of glyphosate. EPA assessments for many years had not reached a similar conclusion about the safety of glyphosate exposure, and on May 6, 2019, EPA released its Proposed Interim Registration Review Decision on glyphosate. *See* our May 6, 2019, blog, "EPA Releases Proposed Interim Registration Review Decision for Glyphosate; ATSDR Announces Availability of Draft Toxicological Profile for Glyphosate."

In that decision, EPA states it did not identify any human health risks from exposure to any use of glyphosate, thus rebutting the IARC conclusion. EPA later, on August 7, 2019, took the further step of issuing guidance to pesticide registrants that products that included the California Proposition 65 (Prop 65) cancer warning statement -- required by California based on the IARC classification -- would no longer be registered. *See* B&C's August 15, 2019, blog, "EPA Issues Guidance Regarding Prop 65 Labeling Requirements for Glyphosate Products and OEHHA Responds." Further, EPA stated, "pesticide products bearing the Proposition 65 warning statement due to the presence of glyphosate are misbranded" under FIFRA. EPA released its final registration review interim decision in January 2020. The January 2020 decision reiterates EPA's determination that glyphosate is not a carcinogen.

These EPA pronouncements are considered a full-frontal assault on a long-simmering issue of possible conflict and preemption issues between federal EPA requirements and conclusions and the authority of California state regulators. Resolving this jurisdictional conflict may require additional legal action.

9. 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 towards 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 EU. The simple summary of 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 towards 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. This has potential major implications not only for those who sell glyphosate for use in Mexico but also 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. This decision is not final and may yet undergo revision or retraction as U.S. officials continue discussions with the Mexican government. Nevertheless, the specter of wider adoption of the precautionary principle among U.S. trading partners threatens a growing proportion of U.S. agricultural exports.

A new Biden Administration will face similar questions of what should be the appropriate policy on these and related issues relating to agricultural exports, and how aggressively (or whether) to continue U.S. opposition to such policies that may be adopted by other countries.

Lastly, the issue of establishing Maximum Residue Limits (MRL) is another long-standing issue of concern for U.S. growers. 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.

10. COVID-19 Pandemic

The COVID-19 pandemic that affected the daily lives of Americans throughout 2020 was especially impactful on EPA's pesticide program. Certain disinfectants that claim to kill viruses such as COVID-19 must be registered with EPA as pesticide products. 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.

Starting in March, 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 Centers for Disease Control and Prevention (CDC) and other health agencies. As of October 2020, EPA claimed its List N contains over 500 disinfectant products and the List N website had been viewed over 20 million times.

Putting aside other work, pulling resources from other divisions (disinfectants are reviewed in OPP's 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

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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.

11. Clock Ticking on Registration Reviews, OPP Staffing and Budget, and Moving Downtown

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 large 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 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, OPP may be enabled to fill available positions.

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

Meanwhile, the clock continues to tick towards 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.

On top of the 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 high as over 40% 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.

With the arrival of the Biden Administration, expectations are for an increased EPA budget, along with generally a more supportive attitude towards federal workers and workplace conditions. Whether these new atmospherics materially influence morale or ability to recruit new staff remains uncertain.

OPP staff is scheduled to move offices to be located with the other staff of OCSPP at EPA's Washington, D.C. location. Finally, after almost 50 years, 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.

CONTRIBUTORS

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D. U.S. NANOTECHNOLOGY

1. American Conference of Governmental Industrial Hygienists

In 2020, 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 2018 and 2019 lists of chemicals substances and other issues under study.

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A NanoBCA Retrospective -- A Conversation with Vincent Caprio

2. National Institute for Occupational Safety and Health

The National Institute for Occupational Safety and Health (NIOSH) could publish its long-awaited *Current Intelligence Bulletin: Health Effects of Occupational Exposure to Silver Nanomaterials* (CIB) in 2021. As reported in our 2019 and 2020 Forecast memoranda, in September 2018, NIOSH issued a revised draft CIB that includes a recommended exposure limit (REL) for silver nanoparticles (<100 nanometers (nm) primary particle size) of 0.9 micrograms per cubic meter (µg/m³) as an airborne respirable eight-hour time-weighted average (TWA) concentration. The REL would apply to processes that produce or use silver nanomaterials. In 2019, NIOSH reviewed peer reviewed and stakeholder comments as it prepared the final CIB. More information on the revised draft CIB is available in our September 19, 2018, blog item, "NIOSH Publishes Revised Draft CIB on Health Effects of Occupational Exposure to Silver Nanomaterials, Will Hold Online Meeting."

NIOSH is preparing a draft Technical Report on approaches to developing occupational exposure limits (OEL) or bands for engineered nanomaterials for external peer review. NIOSH published a *Federal Register* notice on December 17, 2019, seeking information on toxicological and physicochemical data of engineered nanomaterials to evaluate in developing categorical OELs. 84 Fed. Reg. 68935. NIOSH requested information, including published and unpublished reports and research findings, to evaluate the possible adverse health risks of occupational exposure to engineered nanomaterials. NIOSH will make the draft Technical Report available for public comment in a subsequent Federal Register notice.

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3. National Nanotechnology Initiative

The National Nanotechnology Coordination Office (NNCO), on behalf of the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the National Science and Technology Council (NSTC), is developing the 2021 National Nanotechnology Initiative (NNI) Strategic Plan. According to NSTC's October 13, 2020, request for information, a restructuring of the NNI is under consideration. 85 Fed. Reg. 64535. NSTC asked for information to identify effective mechanisms, strategies for communication, and priority topics to inform the future directions of the NNI. NNI will hold a 2021 NNI Strategic Planning Stakeholder Workshop on **January 11-13, 2021**. The workshop will provide stakeholders another opportunity to provide comments to NSTC.

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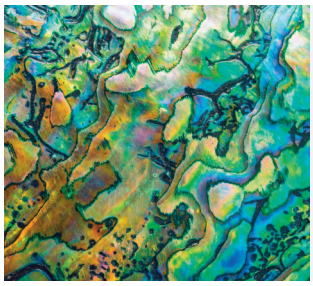

In 2021, USDA will continue working to stimulate innovation so that U.S. agriculture can achieve USDA's goal of increasing agricultural production by 40% while cutting the environmental footprint of U.S. agriculture in half by 2050.

E. BIOTECHNOLOGY

In 2021, FDA will review comments pertaining to the labeling of foods comprised of or containing cultured seafood cells. According to FDA, such foods are being developed and may soon enter the marketplace. FDA requested information on October 7, 2020, pertaining to the labeling of these foods. 85 Fed. Reg. 63277. After the comment period closes in **March 2021**, FDA will use the submitted information and data to determine what type(s) of action, if any, it should take to ensure that these foods are labeled properly. 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.

USDA's Animal and Plant Health Inspection Service (APHIS) will be working in 2021 to complete implementing its 2020 final Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient (SECURE) rule. 85 Fed. Reg. 29790. The May 2020 rule updates and modernizes USDA's biotechnology regulations under the Plant Protection Act, amending the regulations regarding the movement (importation, interstate movement, and environmental release) of certain genetically engineered (GE) organisms in response to advances in genetic engineering and APHIS's understanding of the plant pest risk posed by GE organisms, thereby reducing the regulatory burden for developers of organisms that are unlikely to pose plant pest risks. While several provisions took effect in 2020, the following will take effect in 2021:

- **April 5, 2021** (key changes are implemented):
  - Permitting -- The notification process is discontinued. Applicants begin following the new permitting process described in Section 340.5.
  - Petitions/Regulatory Status Reviews (RSR) -- The RSR process described in Section 340.4 is implemented for certain crops, including corn, soybean, cotton, potato, tomato, and alfalfa. APHIS will continue accepting petitions for all other crops until **September 30, 2021**.
- **October 1, 2021** (the rule is fully implemented):
  - Petitions/RSR -- The RSR process takes effect for all crops. APHIS will no longer accept any petitions.

More information is available in B&C's May 18, 2020, memorandum, "Final SECURE Rule Will Update and Modernize USDA's Biotechnology Regulations."

USDA announced its ambitious Agriculture Innovation Agenda (AIA) in February 2020, and in 2021, USDA will continue working to stimulate innovation so that U.S. agriculture can achieve USDA's goal of increasing agricultural production by 40% while cutting the environmental footprint of U.S. agriculture in half by **2050**. As part of the AIA, on April 1, 2020, USDA published a request for information (RFI) on agricultural innovations. 85 Fed. Reg. 18185. USDA asked respondents to identify transformational innovation opportunities for the next era of agriculture productivity and environmental conservation and propose approaches to these opportunities with an eye to the public- and private-sector research needed to support them. Based on stakeholder input from the RFI, USDA intended to release a comprehensive U.S. agriculture innovation strategy by the end of 2020, which did not happen. More information on the AIA is available in our August 24, 2020, memorandum, "USDA Hosts Stakeholder Forum for Discussion and Feedback on AIA."

During 2021, USDA will continue supporting regulated entities in complying with the National Bioengineered (BE) Food Disclosure Standard. The Standard, issued on December 21, 2018, requires food manufacturers, importers, and retailers that package and label food for retail sale or sell bulk food items to disclose information about BE food and

BE food ingredient content. 83 Fed. Reg. 65814. The Standard defines BE foods as those that contain detectable genetic material that has been modified through lab techniques and cannot be created through conventional breeding or found in nature. The implementation date of the Standard was January 1, 2020, except for small food manufacturers, whose implementation date was January 1, 2021. The mandatory compliance date is **January 1, 2022**. Regulated entities may voluntarily comply with the Standard until **December 31, 2021**.

In 2021, EPA will continue to implement its maturing regulatory systems for managing review of biotech innovations for pesticides and industrial chemicals. On October 9, 2020, EPA proposed an exemption under FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA) for certain plant-incorporated protectants (PIP) that are created in plants using biotechnology. 85 Fed. Reg. 64308. EPA proposed exempt status for select PIPs created through biotechnology if those PIPs could otherwise have been created through conventional breeding and pose no greater risk than PIPs that EPA already has concluded meet the applicable safety standard. EPA preliminarily determined that PIPs meeting the exemption criteria have no risks of concern to humans or the environment. EPA's proposed exemption for PIPs created through biotechnology seeks to facilitate through a more efficient regulatory process the development of new tools for American farmers to protect their crops and control agricultural pests. According to EPA, by reducing "antiquated" regulations restricting access to the market for biotechnology products, science-based innovations to agriculture will become far more accessible to American farmers, potentially increasing the U.S. food supply.

According to EPA's PIP Registrations website, one PIP was registered in 2020 for the protection of soybeans from plant-parasitic nematodes.

On March 10, 2020, EPA issued a final rule adding two strains of microorganisms to the list of microorganisms eligible for an exemption from certain reporting requirements under TSCA. 85 Fed. Reg. 13760. Manufacturers of new intergeneric *Trichoderma reesei* (strain QM6a) and *Bacillus amyloliquefaciens* (subspecies *amyloliquefaciens*) may now be eligible to undergo a streamlined review process under TSCA's New Chemicals Program with reduced TSCA fees.

According to EPA's New Chemicals Notice Status website, EPA reviewed 18 Microbial Commercial Activity Notices (MCAN) in FY 2020. Of those 18, EPA found that nine are not likely to present an unreasonable risk under the conditions of use (including reasonably foreseeable conditions of use). EPA has not posted the results of the other cases. As with years past, organisms reviewed included yeast modified to produce biofuels and microbes used to produce an unspecified chemical substance. This pace of submissions was down again from previous years, although whether that is due to EPA's process or a reflection of an industry trend, is not clear. In any case, EPA continues to review and approve MCANs.

An interesting trend is that a number of submissions have "Day 1" start dates that are nominally in FY 21. Below is the table of cases that would have been submitted to EPA in FY 20 (as is evidenced by the "J-20" leader on the case number, but "Day 1" dates in FY 21.

Case	"Day 1"
J-20-0005	10/16/2020
J-20-0013 – J-20-0018	10/27/2020
J-20-0025	11/03/2020

B&C suspects that this is due to EPA restarting the "Day 1" clock if a submission is found to be deficient and the submitter amends the case with additional information rather than withdrawing. This practice will certainly help EPA keep its review times within or closer to the 90-day review period by putting the onus on the submitter to provide a sufficient data set before the review clock begins. It strikes us as a fair balance for EPA not to invalidate the case if it does not contain sufficient detail -- MCANs are extraordinarily complex -- but also not to put EPA on the clock until such detail is forthcoming from the submitter.

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F. BIOBASED AND RENEWABLE CHEMISTRY

The biobased chemicals and renewable products industry continues to play an important role in building a resilient, dependable, and sustainable system that fosters innovation around the world. Progress in this industrial sector is key to achieving energy efficiency and the conservation of non-resources. To achieve the larger sustainability promise, biobased chemicals must progress quickly from R&D platforms to commercially available products.

In 2020, the U.S. Department of Energy (DOE) continued to lead efforts focused on renewable energy technology and biobased chemicals. Funding incentivizing biotechnology and energy efficiency through renewable and sustainable sources will continue to be one of DOE's priorities. DOE is expected to continue to play an important regulatory role in 2021 in partnership with other U.S. federal agencies such as EPA, FDA, and USDA.

Stakeholders in the biobased chemical industry should also plan to monitor activities on Capitol Hill, including the Streamlining Advanced Biofuels Registration Act, introduced by U.S. Representatives Cheri Bustos (D-IL) and Jim Hagedorn (R-MN). The bill would eliminate existing barriers for biofuel plants to increase production of cellulosic biomass into renewable fuels. It would also ensure that EPA acts on outstanding applications under the Renewable Fuel Standard.

Internationally, efforts to shift into a more sustainable and energy-efficient chemical industry also continue and will persevere in 2021. The government of Manitoba, Canada, is working to amend three regulations under its Biofuels Act to update its clean fuel standards by increasing the ethanol and renewable fuel content in gasoline. Similarly, the European Commission (EC) has approved the prolongation of tax exemptions for biofuels in Sweden in 2021.

These types of government coordination will prove vital for increasingly moving the biobased chemicals and renewable products markets forward in 2021 and in the decade to come.

PODCAST

Product Stewardship and Circular Economy -- A Conversation with Kate Sellers

1. Biobased and Renewable Products Advocacy Group

Having created an impressive legacy of regulatory and policy success for biobased and renewable chemicals and chemical products, The Biobased and Renewable Products Advocacy Group (BRAG®) sunset at the end of 2020. BRAG was formed in 2013 to give biobased chemical stakeholders expertise and a collective voice necessary to educate legislative and administrative decision-makers during the negotiations occurring at that time regarding TSCA reform, and to help its members understand and comply with the application of TSCA to their products and operations. As the only trade group solely focused on addressing the unique challenges that biobased chemicals face under TSCA, BRAG developed strong and compelling advocacy platforms to ensure the robust commercialization and growth of biobased and renewable chemical feedstocks, efforts that will continue to deliver results now that the original goals of BRAG have been realized.

Reviewing the accomplishments and highlights of BRAG's efforts, these are a few of the standouts:

- ***TSCA CDR***: In response to a petition filed by BRAG in 2014, EPA issued a final rule in 2016 amending the list of chemical substances that are partially exempt from additional reporting requirements under the CDR rule, including six biodiesel chemicals that are very similar to petroleum-based biodiesel chemicals that are already on the exempt list. This rulemaking was expected to save more than 65 hours, or almost 1.5 weeks of staff time *per report*, equalizing what had been an uneven regulatory reporting field for biodiesel products.

- ***Chemical Nomenclature***: BRAG led industry efforts to resolve nomenclature rules that caused some complex biobased chemical products designed as greener equivalents to existing chemical products to be considered new chemicals, and thus subject to obtaining a new chemical name and undergoing new chemical notification under TSCA. BRAG and the Biotechnology Innovation Organization issued a joint white paper, "Proposal for a Toxic Substances Control Act (TSCA) Inventory Representation and Equivalency Determinations for Renewable and Sustainable Bio-based Chemicals," which was presented to EPA in June 2018 and continues to inform

Companies have generally adapted to California's Prop 65 labeling requirements though a few issues derivative of the revisions to the Prop 65 Article 6 "clear and reasonable warnings" regulations continue to challenge stakeholders.

EPA as it reviews biobased chemicals. BRAG also led a pilot project to prepare and submit requests for TSCA equivalency determinations of biobased Class 2 chemical substances that are functionally equivalent to another Class 2 chemical.

- ***Legislative and Agency Engagement:*** BRAG regularly engaged with federal and state legislators and EPA personnel to educate these stakeholders about biobased interests by: participating in expositions giving biobased producers opportunities to showcase their technology to Hill staffers; submitting comments on proposed rulemakings; and promoting BRAG interests to programs such as the USDA's BioPreferred Program and EPA's Green Chemistry Awards.

- ***Input into Industry Standards***: Through BRAG, member companies participated in a variety of pertinent standard-setting processes, including reviewing and voting on the American Society for Testing and Materials' (ASTM) proposed international standard, *Standard Terminology for Industrial Biotechnology*, and ASTM's proposed *Standard Classification for Industrial Microorganisms*.

BCCM is proud of BRAG's contributions that will have long-term and significant positive impact on the biobased and renewable products arena. While the group itself sunset on December 18, 2020, BRAG's popular and award-winning news and commentary vehicles, the BRAG Biobased Products Blog and Biobased News and Policy Report newsletter will continue publication via B&C as the B&C Biobased and Sustainable Chemicals Blog and the Biobased Products News and Policy Report. These publications will carry on sharing regulatory, legal, policy, and business developments in renewable chemicals, biofuels, and other biobased products.

BRAG and its member companies regularly accessed B&C's deep bench of experts in the law, regulation, science, and policy of TSCA. B&C's exceptional knowledge regarding the commercialization of biobased chemicals remains available through B&C's biobased chemicals and biofuels practice group. For more information about how B&C can assist with bringing greener, more innovative biobased products to market, call or e-mail B&C Managing Partner Lynn L. Bergeson at (202) 557-3801 or lbergeson@lawbc.com.

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G. PROPOSITION 65

Companies have generally adapted to the California Office of Environmental Health Hazard Assessment's (OEHHA) Prop 65 labeling requirements that became effective on August 31, 2018. A few issues derivative of the revisions to the Prop 65 Article 6 "clear and reasonable warnings" regulations continue to challenge stakeholders.

Some changes, such as those announced on January 14, 2020, and effective as of April 1, 2020, are intended to address issues with OEHHA's regulations set forth at Section 25600.2 regarding who -- manufacturers or "retail sellers" -- is responsible for providing warnings. OEHHA stated that it intended these revisions to: (1) clarify that compliance may be achieved if the business to which the authorized agent for a retail seller provides the written notice is subject to Section 25249.6 of Prop 65; (2) provide that written notices to retail sellers must be renewed annually during the period in which the product is sold in California by a retail seller; (3) clarify that entering into a written agreement is

not limited to retail sellers, but that other intermediate parties -- businesses to which they are selling or transferring product -- may also enter into a written agreement; and (4) modify the definition of "actual knowledge" to remove knowledge of "sufficient specificity" and instead define "actual knowledge" to mean the time when the retail seller "receives information from any reliable source that allows it to identify the specific product or products that cause the consumer product exposure."

OEHHA proposed other amendments that were subsequently withdrawn following comments that such amendments, intended to modify the regulations set forth at Section 25602 regarding the method of transmission of consumer product exposure warning requirements, were in fact a vast change to the regulations that would eliminate online warnings as a safe harbor warning method. In September 2020, OEHHA withdrew significant modifications previously proposed to the Prop 65 regulations. It retained what it described as "minor, non-substantive" modifications to Section 25607.3 regarding the method of transmission for alcoholic beverage exposure warnings.

In 2020, OEHHA issued three Safe Use Determinations (SUD) for exposures to Bisphenol A, crystalline silica, and styrene for specific products. SUDs are written statements issued by OEHHA, following its review of facts and data submitted by a particular company or industry group, that a particular exposure or discharge of a listed chemical from use of a specific product is below a safe harbor level and thus not subject to the warning requirement or discharge prohibition. According to OEHHA's website, only 12 SUDs have been issued since Prop 65 regulations were implemented; this signifies the increased interest of companies to obtain OEHHA determinations that certain products do not require Prop 65 warnings.

A significant issue that received considerable attention in 2020 is the applicability of Prop 65 warning requirements for pesticide products registered under FIFRA. These issues are discussed in the FIFRA Section of our Forecast, as EPA and OEHHA clashed over Prop 65 warnings on glyphosate-registered products. OEHHA listed glyphosate in July 2017 as a chemical known to the state of California to cause cancer thereby triggering Prop 65 warning requirements. Based on an IARC determination that glyphosate is "probably carcinogenic" in humans, EPA responded that it would not allow a Prop 65 warning to be added to the labeling for any registered glyphosate product because it disagreed with the IARC classification and thus any such Prop 65 warning would be misleading and would cause the product to be "misbranded" under FIFRA.

On June 22, 2020, the U.S. District Court for the Eastern District of California granted summary judgment for the plaintiffs in *National Association of Wheat Growers et. al. v. Becerra*, and entered a permanent injunction against enforcement 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 is contrary to the First Amendment of the Constitution. *See* our June 30, 2020, blog, "District Court Rules That Prop 65 Warning for Glyphosate Is Barred by the First Amendment and Grants Permanent Injunction against Enforcement."

In 2021, OEHHA will likely modify its warning regulations along the lines last September. It also may amend its warning regulations to address issues that have been raised since they were first adopted, including online warning requirements. Stakeholders can be expected to submit SUD applications in 2021 given the successes of 2020. In addition, following the precedent now set in the glyphosate case, it would not be surprising to see additional industry challenges in 2021 of Prop 65 listings based on commercial speech rights in cases where the science underlying the OEHHA listing decision is under dispute.

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Many products addressing COVID-19 are being manufactured under a specific Emergency Use Authorization (EUA). Sponsors of an EUA product are encouraged to follow up with a premarket approval submission so the product can remain on the market if FDA withdraws the EUA.

H. FDA FOOD AND COSMETICS REGULATIONS

Many of the FDA Regulatory Agenda items that appeared in our 2020 Forecast from the fall 2019 agency rules list are still noted, as of late 2020, as proposed rules. This includes the extension of comment periods for Food Standards Modernization, issuing a Notice of Proposed Rulemakings (NPRM) for Food Contact Substance Notification That Is No Longer Effective, and Streamlining Provisions for Foreign Supplier Verifications. Most indicate action in 2020 or 2021. The clear reason behind the delays in the forward movement of FDA's Regulatory Agenda is COVID-19. 2020 has been a challenging and incredibly busy time within the various Centers at FDA. Most notably, FDA issued as of December 2020 305 tests for detecting COVID-19, more than 590 drugs development programs were in various stages of planning, FDA reviewed more than 390 drug trials for various therapies for treating COVID-19 and the serious conditions caused by COVID-19, and facilitated approval of two vaccines. The majority of these actions are through various Emergency Use Authorizations (EUA). FDA EUAs and continued updates to its guidance have resulted in an unprecedented amount of progress towards prevention and treatment of COVID-19.

FDA also notes that as of November 2020, it identified more than 1,200 fraudulent and unproven medical products and issued 132 warning letters to sellers. FDA continues to provide daily updates on progress and posts FAQs and podcasts that offer insight on PPE and hand hygiene. See FDA's website.

While all of us are impacted by these actions, many of the products medical professionals and consumers are using now are being manufactured for sale and distribution under the auspices of a specific EUA. If in 2021 FDA decides to withdraw the applicable EUA, any manufacturing occurring in accordance with the various conditions of the EUA will cease to comply, become unapproved, and require manufacturers to ensure compliance with all elements of the applicable legislation. This includes manufacture of medical devices (*e.g.*, surgical facemasks and respirators) and drugs (*e.g.*, alcohol-based hand sanitizers) that are currently being manufactured for sale and distribution under an EUA. FDA notes that it "…may revise or revoke EUAs during a declared emergency for certain reasons, including if revising or revoking the EUA is appropriate to protect the public health or safety. . . . Sponsors of an EUA product are encouraged to follow up with a premarket approval submission so that its product can remain on the market once the EUA is no longer in effect."

1. Over-the-Counter Reform

In March, 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 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. User fees include OTC Monograph Order Request fees and annual facility fees. 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.

The reforms include provisions addressing the Sunscreen Innovation Act (SIA). The SIA will sunset on **September 30, 2022**, and any sunscreen order, under the SIA, will be deemed a final order under FFDCA Section 505G. Any sponsor of an OTC sunscreen active ingredient that is subject to a proposed order under the SIA has the option to transition the review, within 180 calendar days of enactment of OTC Monograph Reform, to the new process. If no election is made, the

drug review process continues under the SIA. In 2021, expect considerable movement on proposed orders under this reform. FDA is required to issue a proposed order no later than 18 months after enactment of OTC Monograph Reform.

2. Food and Food Additive Safety

FDA announced in April of 2019 "The New Era of Smarter Food Safety" initiative. The FDA process of 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 foundation rules that were established in 2011 with the enactment of FSMA. FDA intended to progress the initiative in early 2020 but was delayed due to the COVID-19 pandemic. In July, FDA announced the "Blueprint" for this initiative. The Blueprint "was developed with valuable input provided by a variety of internal and external experts" with the intent of "bend[ing] the curve of foodborne illness in this country by reducing the number of illnesses."

The Blueprint consists of the following four core elements:

- Tech-enabled Traceability;
- Smarter Tools and Approaches for Prevention and Outbreak Response;
- New Business Models and Retails Food Modernization; and
- Food Safety Culture.

FDA held a webinar in late 2020 reviewing the "First 100 Days" of the initiative. Of note for 2021 and **2022** is the progress of the FSMA Food Traceability Rule (85 Fed. Reg. 59984), progress with recall technology, including communication tools for retail and consumers, and a potential food safety summit with international stakeholders.

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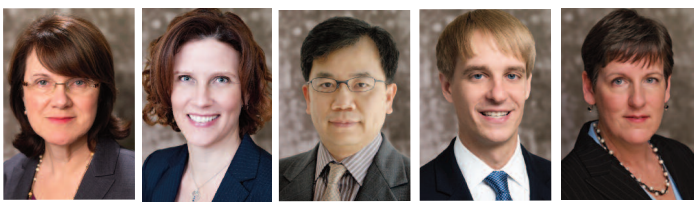

II. KEY GLOBAL CHEMICAL MANAGEMENT PREDICTIONS

A. INTERNATIONAL PROGRAMS AND FRAMEWORKS

1. Organization for Economic Cooperation and Development

OECD has long been an effective stakeholder in addressing chemical management issues. 2020 was an especially busy year. Among the key accomplishments in 2020 by the OECD chemicals program are the following:

- OECD updated the eChemPortal with the February 2020 release of version 3.0 of the OECD Global Portal to Information on Chemical Substances. The new version includes a modernization of the user interface architecture, a refreshed design, and more efficient searching, including direct searching from the homepage. The portal attracts more than 100,000 queries per month.
- Thailand joined the OECD system of Mutual Acceptance of Data (MAD) in September 2020. This step ensures that Thailand's non-clinical safety data related to the protection of human health and the environment will be accepted by all 44 countries adhering to MAD. The MAD system -- a multilateral agreement -- allows participating countries to share mutually the results of various non-clinical safety tests done on chemicals and chemical products, such as industrial chemicals and pesticides. This collaboration saves governments and chemical producers around EUR 309 million annually. At present, all 37 OECD countries, as well as Argentina, Brazil, India, Malaysia, Singapore, South Africa, and Thailand, adhere to the system.
- OECD released a Working Document on Considerations for the Environmental Risk Assessment of the Application of Sprayed or Externally Applied dsRNA-Based Pesticides in September 2020. This document provides a broad set of recommendations relating to risk assessment considerations for exogenously-applied double-stranded RNA (dsRNA)-based products, with a focus on issues relating to data requirements for determining the environmental fate of spray-applied RNA molecules and for examining the potential risks to non-target organisms. This document is intended to provide an overview of available scientific information

related to RNA interference (RNAi), and considerations on regulating this technology for pest control.

- OECD released a Guidance Document on Determining BAT, BAT-Associated Environmental Performance Levels and BAT-Based Permit Conditions during 2020. Assisting the growing number of governments seeking to adopt Best Available Techniques (BAT) approaches as part of the regulatory framework to prevent and control industrial emissions, the guidance aims to provide governments with relevant steps, tools, and best practices on how to identify and establish BAT, BAT-associated emission levels (BAT-AEL) and other BAT environmental performance levels (BAT-AEPL), as well as BAT-based permit conditions, including emission limit values.

The New Year promises to be as busy. Priority efforts and deliverables for 2021 include:

- Development of a guideline based on "Defined Approaches for Skin Sensitization (DASS)." A defined approach to testing and assessment consists of a fixed data interpretation procedure (DIP) used to interpret data generated with a defined set of information sources, that can either be used alone or together with other information sources, to satisfy a specific regulatory need. The guideline would be covered by the MAD agreement and will include selected DASS based on a number of validated alternative methods. OECD believes that the guideline, when completed, has the potential to replace the corresponding animal test in numerous instances. It is expected that the guideline will be published in **Q2 2021**.

- The OECD project on "Criteria for Sustainable Design of Plastics from a Chemicals Point of View" aims to identify the key criteria that should be considered at each step in the product life cycle as well as the potential trade-off between criteria. It is based on the preparation of two sets of case studies focusing on different plastics sectors and then on specific applications within these sectors: construction and packaging. Issuance in final of the case studies is expected for **early 2021**. A workshop is planned for **Q1 2021** to reflect on the case studies and possibly develop the criteria.

- OECD is engaged in an effort to strengthen intellectual property rights related to chemical safety data. In 2018, member countries supported an initiative to develop an updated version of the 1983 OECD Council Recommendation concerning the "Protection of Proprietary Rights to Data submitted in Notifications of New Chemicals" and to develop a separate Best Practice Guide (BPG) that could accompany an updated council action. An *ad hoc* group has been set up to reach a consensus on the draft text for the council action and to develop the BPG. The adoption of the revised council action and publication of the BPG is scheduled for 2021.

2. Strategic Approach to International Chemicals Management

The Strategic Approach to International Chemicals Management (SAICM) is a voluntary policy framework agreed to internationally in 2006 intended to promote chemical safety around the world by the year 2020. Efforts have been underway over the past several years to develop an approach to SAICM for the years beyond 2020. In light of restrictions due to the COVID-19 pandemic, agreement was reached during

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2020 to establish a number of Virtual Working Groups (VWG) to support the work of the intersessional process to advance its deliberations and to develop proposals for tangible outcomes, including identifying gaps and developing new or alternate text, as appropriate. The VWGs will work on a few specific, concrete and rather technical issues in the following areas: targets, indicators, and milestones; governance and mechanisms to support implementation; issues of concern; and financial considerations. The outcomes of the VWGs and other work will be discussed and the text negotiated at the Fifth International Conference on Chemicals Management (ICCM5) that is planned to be held in **July 2021** in Germany.

B. GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELING OF CHEMICALS

1. Overview

Readers will recall that at the end of 2019, there were several countries that were expected to implement or revise regulations based on the United Nations (UN) Globally Harmonized System of Classification and Labeling of Chemicals (GHS) model. The pandemic resulted in a significant shift for the field of occupational health and safety from updates to hazard communication to management of COVID-19 in the workplace and beyond. As we enter 2021, most expect these countries will begin to issue rules either updating the standards to a newer revision of GHS or beginning to implement GHS. As more countries consider the UN model and the various editions available, companies will need to monitor which revision a country adopts, and 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 impact communication tools (*i.e.*, safety data sheets (SDS) and labels).

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. An informal online platform was provided to all participants for comments on all working documents. The 39th session was a hybrid meeting held on December 9 - 11, 2020, in Geneva, Switzerland.

The agenda includes review for a new Chapter 2.1 Explosives. The aim of the revisions to Chapter 2.1 is to be able to classify explosives for sectors other than transport. New decision logics and associated communication elements to assist with assignment of classification and allocation of precautionary phrases are part of the revisions. The agenda also includes continued work on the development of non-animal testing methods for classification of health hazards.

The ninth revised edition (Rev 9) is expected to be published in 2021. Many countries proposing updates in 2020 were delayed and most 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 it moves toward Rev 9 in 2021.

3. U.S. OSHA HCS 2012

On May 25, 2012, OSHA revised and updated the HCS. Currently, all substances and mixtures are required to comply with HCS 2012, as the transition period ended on June 1, 2015, for manufacturers and December 1, 2015, for distributors. OSHA extended the deadline under very specific circumstances on May 29, 2015. Those circumstances are considered to be limited and must be documented to demonstrate compliance. OSHA continues to issue guidance to employers on how to address specific aspects of HCS 2012, but no new substantial changes or updates to the regulation have occurred. The Regulatory Agenda has stated for some time that OSHA intends to publish a proposed rule to update HCS 2012 to the latest edition of GHS. The current HCS is based on Rev 3. OSHA has stated that the timing for the NPRM is unknown, but is in the final stages of department review and the update will include up to Rev 7, but consideration for Rev 8 is also under discussion.

2021 could bring the much-anticipated NPRM. OSHA has not provided much detail on the specific content of the NPRM. OSHA has stated that the addition of hazard classes currently excluded (e.g., acute toxicity category 5 or environmental hazards) is not expected, but consideration for hazard classes that were part of subsequent revisions of GHS (*i.e.*, the expansion of aerosols chapter) should be expected. If the NPRM is issued in 2021, implementing any changes could take years.

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

Health Canada notes that it intends to update the Health Products Regulation to align with Rev 7 through a proposed amendment that will be published in Canada Gazette I sometime in early 2021.

System (WHMIS). WHMIS 2015 significantly altered the previous system (WHMIS 1988) and is a modified criteria-based approach following Rev 5 of the UN GHS model. Health Canada worked with the United States to align, as much as possible, each countries' GHS implementation.

Health Canada notes that it intends to update the HPR to align with Rev 7 through a proposed amendment that will be published in *Canada Gazette* I sometime in **early 2021**. The publication will be subject to a 70-day public consultation period. Health Canada indicates that it will attempt to issue the publication at or near the same time as the release of the U.S. NPRM to update the HCS to ensure that efforts for coordination and synchronization continue and to reduce the burden of the anticipated impacts of the proposed amendments on industry.

Both Health Canada and OSHA continue to provide guidance to industry that address the few variances that do currently exist between the two systems. Comparison documents on labeling and regulatory processes are available. It is expected that synchronized updates to HCS 2012 and WHMIS 2015 in 2021 to Rev 7 will continue and further these joint efforts toward alignment.

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 will be inserted into the model WHS Regulations from January 1, 2021, with a two-year transition period. The amendments do not automatically apply to all jurisdictions. During the transition period, either Rev 3 or Rev 7 is allowed.

2021 will start the review and application consideration in local jurisdictions. Companies should 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. 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 and is expected to be published in 2021. The standard will remain the same, but will combine all four parts into one document with 17 annexes. The intention of the update is to align with Rev 7 of UN GHS, including concentration limits for classification of mixtures. Companies will have a two-year transition period after the standard is published.

7. Chile

Chile has not officially adopted UN GHS. The draft version of the UN GHS implementation regulation, *Reglamento de Clasificación, Etiquetado y Notificación de Sustancias Químicas y Mezclas* (Regulations on the classification, labeling and notification of chemical substances and mixtures), was finished and

published by the Health Ministry in 2017. The Health Ministry was expected to announce a public comment period followed by the regulation being prepared in final. The implementation was expected in 2020, but the Chilean government and industry continue to work on the implementation, and the expected date is unknown.

Chile accepts UN GHS classifications in accordance with Chilean Standard NCh2245:2015. The Standard indicates GHS classification, including the appropriate pictograms, signal words, hazard statements, and precautionary statements that are allowed in Section 2 of the SDS and on labels, but the additional standards, NCh382:2017: Hazardous substances classification and NCh2190:2003: Transport of hazardous substances -- Risk identification, and Signaling [Labeling also for GHS], should be consulted to determine if additional information specific to Chile is required.

8. Colombia

The Colombian *Ministerio de Trabajo* (Ministry of Labor) implemented Rev 6 of UN GHS through Decree 1496 on August 6, 2018. The decree stated that various sectors were to establish deadlines for implementation. The SDS and label must be prepared by the manufacturer and/or importer, according to UN GHS. In 2020, The Ministry of Labour and the Ministry of Health and Social Protection notified that the resolution was open for a comment period with provisions for a two-year implementation deadline. 2021 could see the publication and eventual implementation period begin for chemical products in the workplace.

9. EU Annex II to REACH and CLP

The 12th Adaptation to Technical Progress (ATP) to the Classification, Labeling and Packaging (CLP) regulation 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 on definitions and details for various physical and health hazard classes, and the introduction of new hazard and precautionary statements.

2021 will bring 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. These amendments to substances included in Annex VI of CLP are from various Risk Assessment Committee (RAC) 2017 opinions on harmonized classifications. The 14th ATP amended CLP on October 4, 2019, and the changes apply **from September 9, 2021**.

The requirements for the SDS will change as Commission Regulation (EU) 2020/878 of June 18, 2020, amends Annex II to the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and shall apply from January 1, 2021. Article 2 specifically notes that SDS not complying may continue to be provided **until December 31, 2022.**

The major changes include the following;

- Addition of the unique formula identifier in Section 1;
- Inclusion of endocrine disruptors in Sections 2, 11, and 12;
- New considerations for the disclosure of ingredients in Section 3;
- Clarifications on content and order of details presented in Section 9;
- New sub-headers in Sections 11 and 12;
- Clarifications on maritime transport in Section 14 for bulk cargoes; and
- Specific provisions for authorizations and restrictions in Section 15.

2021 will be a year of transition with amendments to CLP and Annex II that will require consideration. Companies using software to generate SDS will need to ensure the new requirements, especially the addition of new sub-headers, are addressed as these types of changes are easy to identify by enforcement officials.

PODCAST

EU Classification, Labeling, and Packaging Legislation — A Conversation with Karin Baron

After years of relative inaction with respect to chemical substance legislation, many of the countries of Central and South America have either begun or accelerated the development of such legislation.

10. GCC

See Middle East and Africa Section.

11. New Zealand

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

On October 29, 2019, the 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 comes 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. Companies should consider obligation within New Zealand in **early 2021** to ensure compliance within specified periods.

12. Peru

Peru does not have a 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 2021.

C. LATIN AMERICA

1. Overview

After years of relative inaction with respect to chemical substance legislation, many of the countries of Central and South America have either begun or accelerated the development of such legislation. One of the drivers of these chemicals management initiatives is likely the efforts of Latin American countries to join OECD. The benefits expected from OECD membership are to strengthen the region's reputation in the global market, attract more foreign investments, and increase opportunities of exchange with other OECD countries.

2020 was expected to see several big steps toward the development of chemical substance legislation in several countries, such as Mexico, Brazil, Argentina, and Peru. The COVID-19

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pandemic, and in some cases political reasons, however, have further slowed or even halted these chemical policy developments.

Even though progress was slower than expected, progress was nonetheless made. Colombia published in draft its Draft National Industrial Chemical Management Decree on sound chemicals management, and there are active attempts in Brazil to put the *Regulação de Substâncias Químicas Industriais* (Industrial Chemicals Regulation) back on Congress's agenda. These proposed regulations largely incorporate ideas prevalent in other global systems, such as registration of substances (via notification and/or as part of an inventory system) and evaluation of the substances via a host of risk management measures, which may impact their ability to be manufactured or imported.

2. Argentina

In mid-2019, Argentina published its own 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 Regulation). One of the key aspects of the regulation is to create a national chemical substance inventory, the *Inventario Nacional de Sustancias Quimicas* (National Inventory of Chemical Substances; INSQ). It would be developed from an analysis of substances known to be in commerce and/or to have other commercial uses.

Initially, the expectation was that Congress would approve the Regulation in 2020. Following the elections in Argentina in the fall of 2019 and the subsequent COVID-19 pandemic in 2020, however, there was no further legislative action taken. In Argentina, if a bill does not pass after two years, it must be reintroduced. It is possible that in 2021 the proposal may be considered by Congress, thus avoiding having to start the legislative process again.

Argentina continues to focus on chemicals management through initiatives to comply with commitments to international conventions. In early 2020, for example, a resolution to ban substances newly listed under the UN's Stockholm Convention on persistent organic pollutants (POPs) was passed. It includes perfluorooctanoic acid (PFOA) and its compounds, the newest substance added to the Convention in May 2019. A draft of the regulation is expected in 2021. Argentina is also in the early stages of developing a regulation that will restrict hazardous substances in electrical and electronic equipment (EEE), similar to the EU's Restriction of Hazardous Substances Directive (RoHS).

Other initiatives that have secured international funding are expected to also influence Argentinian chemicals regulation in 2021 and beyond. The sound management of plastics will likely become a focus in the near future, similar to Brazil, influenced by the example set in Europe. Argentina is currently working on developing a legislative initiative entitled "Environmentally sound management of plastics throughout their lifecycle." Similarly, Argentina is rolling out a "Specific international program for enhancing the implementation of the Minamata Convention" during 2021.

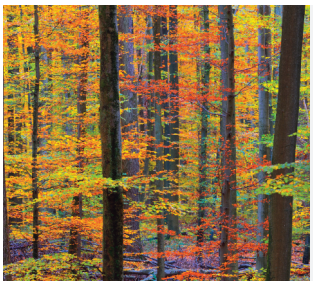
3. Brazil

a. Chemical Control

Brazil's draft Industrial Chemicals Regulation, published on June 30, 2016, has languished through a series of fits and starts on the path to final passage. When Brazilian President Jair Bolsonaro took office in January 2019, he disbanded Brazil's National Chemical Safety Committee (CONASQ) and shelved the chemicals regulation CONASQ proposed.

On October 19, 2020, federal Deputy Rodrigo Agostinho held a virtual meeting with members of the former CONASQ and Brazil's Chemical Industry Association (ABIQUIM) to discuss launching a chemical regulation proposal onto Congress's agenda in late 2020. Representatives from industry, environmental NGOs, and labor authorities (comprised of former CONASQ members) all expressed support for the draft regulation.

Taking into account the dire situation occasioned by the COVID-19 pandemic in Brazil, and the resulting shift in legislative focus, it is unclear if this latest effort to revive the Industrial Chemicals Regulation will bear fruit. There is strong support within government and industry for the bill and the year 2021 could see more progress towards the goal of establishing a regulatory framework for chemicals in Brazil.



As of November 2021, personal hygiene products, cosmetics, and perfumes placed on the market in Brazil must be labeled with a listing of each product's chemical composition in Portuguese.

b. Personal Care and Food Contact

As of **November 2021**, personal hygiene products, cosmetics, and perfumes placed on the market in Brazil must be labeled with a listing of each product's chemical composition in Portuguese. Options for compliance include listing the chemical composition on the original product label or on a complementary label. When there is no recognized Portuguese translation of a chemical substance, companies must provide the translation according to the International Nomenclature of Cosmetic Ingredients (INCI).

As part of Brazil's initiative to develop overarching legislation for plastics used as food contact materials (FCM), in September 2020, Brazil's National Health Surveillance Agency (Anvisa) proposed to reduce the permitted migration limit of Bisphenol A in FCMs and align Brazil's limits with those of the EU. If adopted, the legislation reduces the limit of BPA in FCMs from 0.6 milligrams/kilogram (mg/kg) to 0.05 mg/kg. This latest effort by Brazil supports the broader goal of MERCOSUR, the South American trade bloc comprised of Argentina, Brazil, Paraguay, and Uruguay, to align its regulations with the EU's restrictions on plastics and FCMs. Brazil was expected to implement MERCOSUR's latest positive additives permitted in plastic FCMs in June 2020 but that date is delayed by the COVID-19 pandemic to 2021.

4. Chile

As an OECD member, Chile is expected to continue harmonizing its chemicals legislation with the requirements of the OECD. It is expected to make further progress in 2021 as part of Chile's National Policy on Chemical Safety Action Plan 2017-2022.

Chile is currently developing an inventory of hydrofluorocarbons (HFC) on the Chilean market, with the goal of identifying the users and uses of these substances and available alternatives for HFCs. As a ratifying country of the Kigali Amendment to the Montreal Protocol, Chile is committed to phasing out ozone depleting substances (ODS) and is expected to freeze its consumption of HFCs at the baseline for the year **2024** and reduce this level by 10% by **2029**.

5. Colombia

Unlike similar initiatives in other Latin American countries, the process of issuing a draft chemical substance legislation is moving forward in Colombia. Colombia published in 2019 a draft National Industrial Chemical Management Decree addressing industrial chemical substances that, among other aspects, mandates industrial users to register with the authority.

A key driver for Colombia moving forward as planned is its confirmation as a member of the OECD in April 2020. Colombia must align, as part of its OECD membership, its chemicals regulations with OECD guidelines. According to the proposal, manufacturers and importers would report basic information regarding all substances imported or produced in Colombia at more than 100 kg/year. After reporting, the government would have two years, from the decree's publication in final, to develop a "Registry of Chemical Substances for Industrial Use."

The proposal provides one year for the implementation of the inventory. The timeline may be extended at the request of industry. Colombia's national association of industries (Asociación Nacional de Empresarios de Colombia; ANDI) welcomes the initiative, but is critical about the hazard-based approach in the proposed decree.

This chemical regulation is expected to move through the legislative process quickly. It may enter into force sooner than similar bills that have been introduced in recent years in Brazil and Argentina.

The Colombian law banning asbestos, passed in 2019, entered into force on January 1, 2021, starting the five-year

transition period for companies that use asbestos. The ban prohibits the mining, sale, distribution, and export of all types of asbestos. This is the first law banning asbestos in an asbestos mining country. Similar legislation in countries with an asbestos industry, such as Brazil, have been rejected in recent years.

a. Cosmetic Ingredients and Products

In August 2020, Colombia's President signed a law prohibiting the use of animal testing in the development of cosmetics and their ingredients. The law will become effective as of August 2024. Companies producing cosmetics should be aware of the upcoming ban and should plan accordingly, given that the law provides for only two narrow exceptions for allowing animal testing in cosmetics beginning in **2024**.

6. Costa Rica

Costa Rica proposed in June 2020 an amendment of its pesticide registration regulations to create a registry of technical grade active ingredients by accepting the analyses in technical studies approved by the regulatory authorities of OECD member countries.

This proposal comes after OECD countries unanimously decided, in April 2020 to invite Costa Rica to become an OECD member. Similar proposals for amendments of its chemicals legislation may follow in 2021, as Costa Rica begins to align its legislation with OECD standards, with the goal of acceding to the Convention. That would bring Costa Rica in line with other Latin American countries that are all at different stages in harmonizing their chemical regulations with the OECD.

7. Mexico

Mexico's plan to publish a comprehensive chemical law did not progress in 2020, 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. Similar to REACH, industry would have the burden of proving the safety of the substances that it imports or uses in the country.

Although the General Health Council (CSG) planned to pass the law in 2021 and make the inventory effective in **2022**, priorities shifted due to the COVID-19 pandemic and delayed this ambitious timeline. Another reason for the delay might be the hazard-based approach proposed in the national chemical law, a standard that would be at odds with the United States-Mexico-Canada Agreement (USMCA) entered into force in July 2020. This trade deal backs a risk-based approach for regulating chemicals in the region, as opposed to the hazard-based approach taken under the EU REACH. As a result, there was little progress in 2020 regarding the issuance of the chemicals law.

Perhaps the year 2021 will see more progress, as the Mexican government and the country's chemical industry association (Asociación Nacional de la Industria Química; ANIQ) continue to discuss and negotiate its provisions. ANIQ is reportedly developing an alternative proposal that better represents the industry's interests.

a. Cosmetic Ingredients and Products

In March 2020, a bill to ban animal testing in cosmetics was passed by the Mexican Senate. If passed by the Chamber of Deputies, it would become law and animal testing would be prohibited in Mexico for the manufacture and marketing of cosmetic products. The law would also ban the import of cosmetics tested on animals. As of December 2020, there has been no further development regarding this bill.

8. Peru

In June 2020, a draft regulation on hazardous substances for industrial and domestic use (Reglamento de Regulacion y Control de Sustancias Peligrosas y Similares de Uso Domestico, Industrial y/o en Salud Publica; Regulation) was published, with a 90-day comment period. The draft did not contain a proposed date for adoption.

The draft Regulation applies to the manufacture and import of chemical products. It contains provisions for the handling of chemical substances, a list of prohibited substances, and requirements for labeling and packaging. Additionally, the draft Regulation sets out the requirements for registration of disinfectants, cleaners, and pesticides used in industrial or domestic settings, but not for agricultural pesticides. Certain

categories, including hydrocarbons, food additives, and pharmaceuticals, are exempted.

Reportedly, there are plans in Peru to establish a framework for the management of chemicals in the country similar to other Latin American initiatives in countries such as Brazil, Argentina, and Colombia. As in those countries, this plan is likely inspired by Peru's desire to join the OECD.

The planned framework adopts a risk-based approach and establishes a national register of chemicals covering both substances and mixtures. Although neither a timeline nor an official draft is available publicly, a draft based on declarations from the Peruvian government may be published in 2021. Peru would become one more Latin American country taking concrete steps towards developing a comprehensive regulatory framework for chemicals.

9. Uruguay and Paraguay

Uruguay and Paraguay published in July 2020 a proposal for a positive list of additives that manufacturers could use in FCMs. If adopted, the list would contain restrictions and specifications for substances permitted in FCMs and would set migration limits for heavy metals. Uruguay and Paraguay have not set a date for adoption and implementation. The goal, however, is to align the regulations with those of other countries in the MERCOSUR trade bloc, such as Brazil's adoption of this same list that will enter into force in 2021.

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D. UNITED KINGDOM/GREAT BRITAIN

1. Overview

The United Kingdom (UK) completed its withdrawal from the EU on December 31, 2020, and, as of January 1, 2021, is a "third country" from the EU perspective. Companies worldwide must be aware of the significant implications for chemical regulatory compliance under several regimes, including the EU's REACH regulation and Biocidal Products Regulation (BPR) in 2021.

2. UK REACH

The EU REACH regulation will be adopted into UK law according to the Withdrawal Agreement, with the necessary changes to adjust from the EU to the Great Britain (GB) context. UK REACH will retain the main principles of EU REACH, such as the precautionary principle, the "no data, no market" principle, and the "last resort" principle for animal testing, but the two REACH regulations will operate independently of each other. Companies must comply with both regulations when sourcing or supplying chemical substances and mixtures across GB-EU jurisdictional lines. According to the Ireland/Northern Ireland Protocol (IE/NI Protocol), NI will remain under EU REACH. Companies are advised to review the applicable regulations for transactions between NI and GB (England, Scotland, and Wales).

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 Only Representatives (OR), can "grandfather" their registration under UK REACH. The company must open an account on the new UK REACH IT system called "Comply with UK REACH," and provide basic information to the Health and Safety Executive (HSE) within 120 days from the end of the transition period (by **April 30, 2021**). 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.

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 the 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 to ensure continued access to the GB

market, GB importers must complete a notification to the HSE in the UK REACH IT system.

The substance must subsequently be registered within the applicable timeframe, which is 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. In light of these requirements, GB-based importers are encouraged to consult with their suppliers regarding the notification and subsequent registration of substances under UK REACH. Either the importing customer or its supplier should ensure that a notification is completed by **October 28, 2021**, which is within 300 days of the end of the transition period.

EU REACH Article 9 exemptions for substances imported or manufactured in GB for purposes of product(s) and process-oriented research and development will be grandfathered into UK REACH if basic information is provided to the HSE within 120 days (by **April 30, 2021**), and will be subject to the same conditions imposed by the European Chemicals Agency (ECHA).

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 act quickly to understand their rights and obligations under both EU and 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 European Parliament and of the Council on cosmetic products (Cosmetics Regulation), as well as other EU provisions in the cosmetics field, stopped applying in the UK. The UK legislation taking its place adopts and adapts many of the provisions in the EU 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).

From offices in Manchester, UK, and Brussels, Belgium, Acta provides local expertise and boots-on-the-ground representation to assist clients in gaining and maintaining compliance in both jurisdictions. Acta's Manchester office can be reached at +44 (0) 330 223 0610.

As of January 1, 2021, cosmetic products manufactured in the UK and placed on the market in the EU are regarded as cosmetic products imported from a third country and the UK must be indicated on the label of the cosmetic product as country of origin. Safety assessments carried out by safety assessors in GB will no longer be valid in the EU, as the safety assessor must hold the required qualifications from an EU (MS).

According to the Withdrawal Agreement, existing and individually identifiable cosmetic products lawfully placed on the market in the EU or the UK before December 31, 2020, may continue to be made available and may circulate between the two markets until they reach end users. Any company relying on this provision must be able to document that the cosmetic product was placed on the market before January 1, 2021. The provisions of the 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.

4. Biocides

As of January 1, 2021, GB has its own independent regulatory framework for biocidal product approval (UK BPR). While the UK BPR will reflect the current EU framework, EU authorizations and mutual recognition will no longer be applicable in GB. The HSE will replace ECHA for active substance evaluations and approvals as well as biocidal product authorizations in GB.

A biocidal product authorization valid in GB at the end of the transition period will remain 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. Companies doing business in GB might need to resubmit data to HSE to keep their biocidal product on the market

Biocidal product applications that were being processed on December 31, 2020, as part of the EU-wide authorization process, need to be resubmitted with HSE within 90 or 180 days after the end of the transition period, if the applicant is seeking authorization in GB.

GB will establish its own version of the list of approved active substance suppliers, known as the 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 submit to HSE within two years the same information required to be submitted to ECHA under BPR.

While divergence between the two regulations over time is expected, the nature, manner, and extent of the inevitable drift apart is unknowable at present, but is likely to be affected by regulatory initiatives such as the EU's Strategy.

5. PPP

As of January 1, 2021, GB has its own independent regulatory regime for plant protection products (PPP). Existing Maximum Residue Levels (MRL), approvals of active substances, and PPP authorizations will be 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, GB will have its own process, performed by HSE, 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 are expected to remain the same (at least near term), 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.

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E. EUROPEAN UNION

1. Overview

The EU aims to be climate neutral by **2050**, according to its Green Deal published in December 2019. Amending the EU's chemicals regulatory framework for better alignment with the Green Deal's targets of climate neutrality and circularity 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 legislations, is foreseen in 2021 and beyond to achieve the goals of the Green Deal Strategy.

2. EU REACH

Amending REACH, which entered into force in 2007, would be a plausible step forward to achieve the Strategy's objectives of sustainability and circularity by **2024**. Achieving the ambitious goals of the Strategy timely is expected to place heightened emphasis on REACH compliance and enforcement in 2021 and beyond. In addition to the existing enforcement authority under REACH, which is granted principally to MS, ECHA will seek changes that grant it enforcement authority to address noncompliance by registrants with decisions on compliance checks, conditions of restrictions, and authorizations that the current legislation lacks.

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 are now 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. The chemical safety report (CSR) will now be included in the registration dossier completeness check.

As of January 1, 2021, companies were required to comply with updated requirements for SDS, 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).

MS are scheduled to evaluate 32 substances in 2021 under the current draft Community Rolling Action Plan (CoRAP), which is expected to be updated in **March 2021**. ECHA advises registrants of a listed substance to coordinate their

With completion of the Brexit transition period, as of January 1, 2021, companies in GB that have not transferred their substance registrations to an entity within the European Economic Area (EEA) will no longer hold valid registrations under EU REACH.

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."

Finally, with completion of the Brexit transition period, as of January 1, 2021, companies in GB that have not transferred their substance registrations to an entity within the European Economic Area (EEA) will no longer hold valid registrations under EU REACH; under the IE/NI Protocol, NI will remain under EU REACH.

3. Cosmetics

Amendment of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (Cosmetics Regulation) is expected in the near future, to accommodate the EC's vision of sustainability by promoting uniform risk management across various chemical sectors, centralizing chemical reviews, and addressing environmental concerns.

Most notably, and of concern to industry, the current risk-based assessment of cosmetics and cosmetic ingredients could be abandoned for a hazard-based approach for products containing substances of concern, including endocrine disruptors. The EC might, in light of the Strategy, amend the Cosmetics Regulation automatically to ban the use of substances classified as carcinogens, mutagens, and reproductive toxicants (CMR) in cosmetics.

NGOs and industry are also concerned that increased information requirements could lead to a rise in animal testing of cosmetic ingredients, especially in light of the EU General Court's 2020 landmark decision, which found that REACH registrants are not automatically exempted from animal testing of cosmetic ingredients simply because the substance is used solely as an ingredient in cosmetics. Appeal proceedings could take up to two years.

4. Biocides/Endocrine Disruptors

In October 2020, the EC published in final its Fitness Check Roadmap on Endocrine Disruptors (Fitness Check), as part of the Chemicals Strategy for Sustainability. Amendments to the BPR can be expected in the upcoming years to address the conclusions of the Fitness Check, and to achieve the objectives of the Strategy and the EU's Green Deal.

A delegated regulation was published in May 2020, amending BPR Annexes II and III to require more data on reproductive toxicity, developmental neurotoxicity, and developmental immunotoxicity. Industry and NGOs voiced concerns about the complexity and costs of the proposed tests, as well as their reliance on vertebrate animals. The EC pointed out that the use of *in vitro* and *in silico* methods is also allowed, where possible. The final delegated Regulation is expected to enter into force in 2021.

The biocides review program continues to progress, though at a slower pace than anticipated, and with skepticism about meeting the **2024** deadline for completion. The purpose of the program is to examine existing biocidal active substances contained in biocidal products.

The pressure for more efficient and comprehensive regulation of endocrine disruptors is also coming from the EU MS. In June 2020, prior to publication of the Fitness Check results, five MS (Denmark, Belgium, France, the Netherlands,

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and Sweden) published a comprehensive list of endocrine disruptors to spur action on endocrine disruptors by the EC and industry.

Effective enforcement of the BPR will receive additional attention in the coming years, after a report from the EC found that it is difficult for MS to enforce the BPR due to both the wide range of biocidal products, and the regulation of biocidal products under multiple pieces of legislation, for which several authorities have jurisdiction. The EU is expected to prioritize issuing guidance to support effective enforcement and to promote the exchange of information, cooperation, and harmonization among MS enforcement authorities.

As the COVID-19 pandemic continues into 2021, emergency permits can be extended for a maximum period of 550 days, if there is a need. In that case, MS requesting an extension must identify the companies and products in question. The BPR does not preclude the option of granting a new 180-day emergency permit, but the MS should confirm that the demand cannot be met with authorized disinfectants from recognized suppliers.

5. PPP

In light of the EU's ambitious goals for a toxic-free environment, Regulation (EC) No 1107/2009 concerning PPP also falls under the category of chemicals regulations that will most likely be amended in the near future. This trend was foreshadowed before the EU published its Strategy, when in January 2020 the European Parliament voted on a resolution that contained a reference to tackling "pesticide dependency" and to "significantly reduce the use and risk of chemical pesticides."

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 (synergistic) and cumulative impacts of pesticides on human and environmental health will be assessed. Such impacts happen through the use of multiple different pesticides that can persist as residues on food, and through industrial processes and consumer products. Even though the EU recognizes that it is not possible or feasible to evaluate every combination of all the chemicals used in industry, there is an increasing need to take the impacts of "chemical cocktails" into account and integrate them into chemical risk assessments. As the EU is turning more and more of its attention towards endocrine disruptors, this will also affect pesticides, because many pesticides are known to have such properties.

In October 2020, the European Court of Justice issued a ruling holding that MS may issue a ban on pesticides even if those pesticides are permitted at the EU level, provided that they officially inform the EC about the ban. This ruling confirmed that MS can be more protective of their citizens and the environment than the EU. One of the consequences may be that single states will issue stricter bans of pesticides than on the EU level.

F. EURASIA

In 2017, the Eurasian Economic Union (EAEU) member countries issued in final a regional chemical framework, Technical Regulation (TR) EAEU 041/2017 on safety of chemical products. Member countries of the EAEU include the Republic of Armenia, the Republic of Belarus, the Republic of Kazakhstan, the Republic of Kyrgyzstan, and the Russian Federation. This regional chemical framework, also referred to as EAEU REACH, includes elements from EU REACH, as well as U.S. TSCA. For example, like EU REACH, both new and existing substances must be registered, and,

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After the two implementing sub-regulations did not enter into force by the 2018 target deadline, the Eurasian Economic Commission (EEC) postponed the June 2, 2021, deadline for the entry in force of the Technical Regulation to what will most likely be November 30, 2022.

similar to TSCA, the framework regulation begins with the formation of an initial inventory of existing chemical substances.

The EAEU's framework regulation would contain requirements that differ from the EU REACH and TSCA. Unlike EU REACH, there would be no minimum volume threshold requirement, like one tonne per year. TSCA has no volume threshold. All substances as such, and substances present in mixtures above 0.1%, regardless of the volume placed on the market, must be included in the inventory. A minimum volume requirement may, however, be introduced sometime in the future, because some EAEU MS have already suggested it.

Unlike TSCA, there is no broad exemption from registration for naturally occurring substances. Under the EAEU framework regulation, minerals in deposits, however, are exempted, as well as ore, ore concentrates, cement clinker, natural gas, liquefied gas, gas condensate, coal, and coke. This requirement is more similar to the Annex V substances that are exempt from registration under EU REACH.

After the two implementing sub-regulations did not enter into force by the 2018 target deadline, the Eurasian Economic Commission (EEC) postponed the **June 2, 2021**, deadline for the entry in force of the TR to what will most likely be **November 30, 2022**. Currently, the two implementing sub-regulations are expected to enter into force sometime in 2021. Implicitly, the nomination process for the regional inventory was also postponed until sometime after the sub-regulations are agreed upon. According to the draft, all substances will have to be on the chemical inventory regardless of their hazard properties or classification.

The Russian Federation continues to lead in developing its own regulatory framework. The Russian Federation issued, in final, the Technical Regulation on the Safety of Chemical Products (TRSCP; Decree No. 1019) in October 2016.

TRSCP aims to establish a chemicals framework with implementation dates similar to the EAEU framework regulation. According to the Decree, Russia started compiling an inventory of chemical substances in May 2019, and published a transitional inventory in June 2020. A final inventory is expected to follow, when all the notifications submitted before the August 1, 2020, deadline are verified. Chemicals not listed on the final inventory will be considered new chemicals and will have to go through the complete registration process before they may be placed on the Russian market. The Russian Decree is expected to be rescinded when/if the EAEU sub-regulations are implemented.

The latest estimate for when the final inventory is expected to be published is **early 2021**. Substances that are not yet registered can remain on the Russian market until the TRSCP enters into force. After the entry into force of the regulations, the substances will have to go through the registration process.

For substances that have been in circulation on the Russian market, but which are not listed on the official inventory, companies can submit data before **June 2, 2023**, including proof of circulation. More details about this procedure are still expected to be published by the Russian authorities.

Unlike at the Eurasian level, where the implementing sub-regulations are expected to include guidelines regarding protection of CBI, in the Russian Federation, the current inventory listings include CAS RNs and International Union of Pure and Applied Chemistry (IUPAC) substance names.

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Originally, data on use and volume were supposed to be published, but after receiving feedback from industry, the Russian authorities decided against it. Therefore, it is possible that in the future, the Russian law will address the industry's CBI concerns and offer an option for protecting the identity of substances placed on the inventory or registered as CBI.

Once the Russia Federation's inventory is developed, the requirement for Safety Passports will be gradually implemented. Russian Safety Passports are similar to SDSs, which are now required to be translated into Russian for the use in the Russian Federation.

The Russian Federation adopted Rev 4 of the UN GHS for industrial chemicals on a voluntary basis on August 1, 2014 (Russian standards, GOST 32419 (Chemical Hazard Classification) and 32424 (Environmental Hazard Classification of Chemicals)). In practice, these standards are followed only by Russian companies exporting to the EU. Labeling must be in the Russian language. Currently, all key GOSTs on SDSs, Chemical Hazard Classification, and Chemical Labeling Requirements are under revision, with the goal of harmonizing them with Rev 7 of the GHS. The updates to these standards are not expected until 2022 and will become effective over the next couple of years.

G. TURKEY

1. Overview

In anticipation of membership in the EU, and the EU-Turkey Customs Union, in existence since 1995, Turkey has been aligning its legislative framework with the main European chemicals regulations, with the broader goal of harmonization with the EU's body of law. As a result, much is underway.

2. KKDIK

Implementation efforts are ongoing to harmonize chemical regulations through the gradual entry into force of Turkey's equivalent to the EU's REACH regulation, the KKDIK (Kimyasalların Kaydı, Değerlendirilmesi, İzni ve Kısıtlanması). 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 reflects the same annual tonnage bands as EU REACH (i.e., 1 to 10 metric tons, 10 to 100 metric tons, 100 to 1,000 metric tons, greater than 1,000 metric tons), and requires the same data as EU REACH for each tonnage band.

The pre-registration deadline under KKDIK was December 31, 2020, and the registration deadline is set for **December 31, 2023**, without consideration to the tonnage band. Companies that miss the pre-registration deadline for substances already on the Turkish market were required to stop manufacturing or importing those substances beginning January 1, 2021. A late pre-registration will be allowed until **December 31, 2023**, however, for substances manufactured in Turkey, or imported into the country for the first time by a company, at one metric ton or more. Beginning **January 1, 2024**, a full registration is required for substances that have not been pre-registered.

The year 2020 has been a busy one for entities focused on Turkish compliance. As of fall 2020, there were more than 90,000 pre-registrations and the numbers continued to increase rapidly until the December 31, 2020, deadline. It is not certain how many of these substances will be fully registered by **December 21, 2023**. 2021 expectations include the organization and formation of Substance Information Exchange Forum (SIEF) groups and the nomination process of a lead registrant for pre-registered substances. Turkey is a country with more importers than manufacturers and there is a possibility that companies registering smaller volumes would need to be motivated to take on the role of lead registrant.

Many companies placing similar products on EU and Turkish markets will likely seek to secure, between now and **2023**, legitimate rights to EU REACH data for KKDIK reliance and sub-licensing. For many entities, this may

represent a significant challenge due to the nature of EU REACH contracts, regulatory, and commercial issues.

Data sharing for KKDIK registration will be a hot topic in 2021 and beyond due to the significant consequences for KKDIK compliance, and the time and efforts required to yield necessary outcomes.

With the registration period beginning on January 1, 2021, the MoEU adopted the final fee schedule on January 4, 2021, unchanged from the fee schedule proposed by the MoEU in September 2020. The registration fees for KKDIK are a fraction of the registration fees under EU REACH. For example, the fee for a one to ten tons substance registration under KKDIK is the equivalent in Lira (TL) of 109.94€ for an individual submission and 82.46€ for a joint submission (calculated on the day of publication of the final KKDIK fee schedule, at an exchange rate of 1€ = 9,10TL). The equivalent registration fees under REACH are 1,739€ for an individual submission and 1,304€ for a joint submission. Fluctuating exchange rates may shift the ratio between the KKDIK fees and the fees paid under EU REACH. Fees are expected to be updated annually by the MoEU.

At the end of November 2020, the MoE launched its upgraded KKS IT platform, just in time for the high traffic in chemical substance registrations expected as of **January 2021**. The new platform is compatible with ECHA's IUCLID and more user-friendly, but it can be accessed mainly from domestic servers.

2021 should see activities increase under KKDIK, and many aspects of the regulation are expected to be clarified. The fact that the text of the KKDIK is very similar to EU REACH might be helpful for companies that are already familiar with the REACH provisions and procedures in the EU. The similarity of the text does not guarantee by itself that Turkey will implement the KKDIK in the same manner as the EU REACH has been implemented. For example, it is unclear how enforcement under KKDIK will be carried out, and what tools and authority Turkey has to ensure companies remain in line as the SIEFs are formed. It is also possible, at least in theory, that a substance is approved under EU REACH without restrictions, but not under KKDIK, given that the two regulations are implemented by different regulatory authorities of different jurisdictions. Turkey will, however, likely consider prior evaluations by the EU of substances in its own substance evaluations since Turkey is seeking to align its laws with the EU.

3. Classification, Labeling, and Packaging

One of Turkey's achievements in harmonizing its chemicals regulations with the European requirements was the implementation of the By-Law on the Classification, Labelling and Packaging of Substances and Mixtures (CLP, abbreviated as SEA in Turkish), published in the Official Gazette, number 28848, and in effect since December 11, 2013. One requirement unique to SEA is the appointment of a legal representative on behalf of importers in Turkey. The reason for introducing this requirement is to avoid problems with exporters and CBI concerns.

In 2018, the MoEU published a draft update of the SEA, to bring the regulation in line with the EU's CLP. With some delay, this update was adopted and published in the December 10, 2020, Official Gazette. The most significant changes include aligning with the CLP up to the 13th adaptation to technical and scientific progress (ATP). Previously, SEA was aligned with the fourth ATP. In August 2020, however, the EU amended the CLP as part of the 15th ATP.

Following the update, notifications will apply to all substances subject to registration under KKDIK, not only to hazardous substances. No notification will be required for substances already registered under KKDIK. Substances placed on the market before January 1, 2023, will not have to be reclassified and relabeled, allowing for a two-year transition period. Lastly, the poison center notification obligation, mirroring the CLP's requirement in Annex VIII, is included in SEA with a January 1, 2025, deadline for all notifications. Turkey's Ministry of Health is listed as the responsible authority.

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Pakistan intends to develop a national chemicals control act and the expected timeframe for the act is in 2021. This is an ambitious goal and will be relevant to those currently importing products into the country.

H. MIDDLE EAST AND AFRICA

1. Overview

The two main legislative initiatives expected in 2020 were delayed by the COVID-19 pandemic and there is no clear timeline for when the planned regulations will be issued. Saudi Arabia's draft national chemical safety program has not been published and there is no established chemical inventory at this time. The Gulf Standards Organization (GSO) did not, as expected, publish in final a harmonized standard to align hazard communication in the region with Rev. 5 of the UN's GHS of classification and labeling of chemicals. GSO sent a final draft to member countries for approval on March 16, 2020, but that draft has not yet been adopted as a technical regulation. These initiatives could advance in 2021 and as new proposed legislation in Israel and Pakistan may emerge.

2. Egypt

As of November 2020, toy manufacturers and importers in Egypt must comply with national standard ES 3123-3 that sets out new migration limits for 19 heavy metals in toys. It aligns with the European standard on migration limits in toys (EN 71-3:2013+A3:2018).

3. Ghana

Ghana plans to publish a draft industrial chemicals management bill for public consultation in early 2021. The draft, written in January 2020, but not published yet, proposes a registration scheme similar to REACH, for chemicals placed on the Ghanaian market in quantities exceeding one tonne per year. Manufacturers or importers would submit a registration dossier for each substance to Ghana's EPA and the EPA would decide whether or not to grant registration.

Before publication, Ghana's EPA is consulting international experts on its draft bill. It is not clear yet what the planned transition period for the registration of substances will be, what the registration fees will be, or what revision of the GHS the bill will adopt.

4. Israel

Israel's Ministry of Environmental Protection published a draft Industrial Chemicals Registration Law that is expected to become effective on **March 1, 2023**. The law, based on a review of approaches from various chemical control frameworks, would establish a national inventory of chemicals. It contains provisions for risk assessment and management, and approaches for safer alternatives. If enacted in its current form, manufacturers and importers in Israel would have until **September 1, 2024**, to notify substances. The initial notification process would not require extensive details or data requirements but is primarily centered on chemical properties, quantities, and uses. Israel intends to establish a prioritization list and manufacturers would be required to provide additional data for any substance noted as priority.

5. Pakistan

The government in Pakistan reportedly is reviewing a draft national chemicals management policy that was expected to be published by the end of 2020. After publication, Pakistan intends to develop a national chemicals control act and the expected timeframe for the act is in 2021. This is an ambitious goal and will be relevant to those currently importing products into the country.

In late 2020, a national inventory of chemicals used in key industries (such as dyes and pigments, textiles, or fertilizers) was expected to be published. The inventory, which will now most likely be published in 2021, will list what chemicals and raw materials are used and their corresponding quantities.

Pakistan is also in the process of ratifying the UN's Minamata Convention on Mercury. Pakistan has been a signatory since 2013, and this year the ratification was approved by the country's Prime Minister.

6. Saudi Arabia

Saudi Arabia was expected to publish a draft national chemical safety program by mid-2020. The draft was not intended to be a comprehensive chemicals framework like EU REACH or U.S. TSCA. The draft program would have included the development of a chemical inventory as a first step towards developing a comprehensive framework. This first step was delayed in large part by the COVID-19 pandemic. To date, it is unclear when a draft program will emerge.

7. South Africa

The South African government issued a bill seeking to ban the manufacture and sale of cosmetics tested on animals. If the bill is enacted into law, South Africa would be the first African country to ban animal testing and would join the nearly 40 countries worldwide that ban this testing method. There is no firm timeline for when this ban could become effective.

8. GHS

The Gulf Cooperation Council (GCC) intends to implement GHS in the region, even though the draft Technical Regulation publication was not published in 2020. GCC is comprised of the governments of the State of the United Arab Emirates (UAE), The Kingdom of Bahrain, The Kingdom of Saudi Arabia, The Sultanate of Oman, The State of Qatar, and The State of Kuwait. Currently, none of GCC's members follows the GHS and chemicals labeling and classification in the region is not consistent. In 2019, the GCC Standardization Organization published a first draft of a Technical Regulation to adopt GHS in the GCC member countries. The draft Technical Regulation aligns with Rev. 5 of GHS, and proposes to adopt the list of harmonized substance classifications in Annex VI of the EU CLP regulation.

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In March 2020, the final draft regulation was sent by GSO to member countries for approval. The draft may be adopted as a technical regulation in late 2020, after which the six GCC member countries would need to transpose it into their domestic laws. This could take two or three years.

I. ASIA/PACIFIC RIM

1. Australia

The Australian Industrial Chemical Introduction Scheme (AICIS) replaced the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) on July 1, 2020, established by a new regulatory scheme (the Industrial Chemicals Act 2019 (IC Act 2019)). Further information regarding the AICIS can be found here.

On the same date, a ban on the use of new animal test data for ingredients solely used in cosmetics came into force.

The new AICIS seeks to streamline the regulatory process, and, so far, the transition from NICNAS to AICIS seems to have gone smoothly. The Australian government issues and updates detailed guidance frequently on its regulatory initiatives and many find such guidance useful.

Unless exempted, all manufacturers and importers of industrial chemicals must submit an annual declaration under AICIS. This submission replaces annual reports. There were no annual declarations in 2020 due to the change in regulatory scheme. The first annual declaration is due by November 30, 2021, and covers the 14-month period from July 1, 2020, to **August 31, 2021.** Further information regarding annual declarations can be found online.

2. China

The regulatory regimes on chemicals, cosmetics, and food contact substances in China continue evolving. Several major regulatory developments will take place in China in 2021, including new chemical regulations and new cosmetic regulations that came into effect on January 1, 2021.

a. Chemical Substances

The Ministry of Ecology and Environment (MEE) Order No. 12, "*Measures on the Environmental Management*

Several major regulatory developments will take place in China in 2021, including new chemical regulations and new cosmetic regulations that came into effect on January 1, 2021.

Registration of New Chemical Substances," replaced the Ministry of Environmental Protection (MEP) Order No. 7, "Measures of Environmental Management of New Chemical Substances," on January 1, 2021. A guidance document "*Guidance for Environmental Management Registration of New Chemical Substances*" has been issued in final and also became effective on January 1, 2021. In addition, the draft Law on Safety of Hazardous Chemicals is expected to be issued in final to replace State Council Decree No. 591, "*Regulations on Safe Management of Hazardous Chemicals*," in 2021. These developments will significantly change the regulatory regime for new and existing chemical substances in China. Manufacturers, processors, users, and importers of chemical substances will be affected.

The MEE Order No. 12 focuses on the management of new chemical substances with persistent (P), bioaccumulative (B), and toxic (T) potential and introduces a new use rule, a five-year limit on CBI claims, more stringent requirements for registration and uses of PBT substances, and socioeconomic benefit assessment for high-hazard substances. The data requirements for new chemical substance registration remain hazard-oriented and test-based, however, and alternatives to test data such as quantitative structure-activity relationship (QSAR) and read-across are accepted only as supplemental information, unless the test is technically infeasible. The registration of new chemical substances having both annual volumes over 10 metric tons and PB potential will require significantly more tests from a lengthy checklist.

In addition, China added 18 groups of chemicals into its Priority Chemicals List on November 2, 2020, which include benzene, o-toluidine, PFOA, dioxins, benzo[α]pyrene, and thallium. The priority chemicals are subject to management to control the potential unreasonable risks to public health and the environment during their production and use.

b. Cosmetics and Cosmetic Ingredients

The State Council Decree No. 727, "*Regulations on Supervision and Administration of Cosmetics*," replaced the "*Regulations on Hygiene Supervision of Cosmetics*" on January 1, 2021, which will significantly change the regulatory management of both cosmetic ingredients and finished cosmetic products in China, affecting both manufacturers and importers. A series of draft implemental guidance documents, including "*Administrative Measures for Cosmetic Registration*," "*Cosmetic Good Manufacturing Practices*," "*Administrative Measures for Cosmetics Labeling*," "*Technical Guidelines for Cosmetic Safety Assessment*," "*Cosmetic Classification Rules and Catalog*," "*Instructions for Registration and Notification Dossiers of New Cosmetic Ingredients and Finished Cosmetic Products*," and "*Guidelines for Efficacy Claims and Evaluation Criteria of Cosmetics*," are expected to be issued in final soon.

State Council Decree No. 727 focuses on quality control and safety supervision, and includes toothpaste within the scope of the cosmetics regulations for the first time. Furthermore, the premarket approval requirement for new general use cosmetic ingredients and general use cosmetic products will be replaced with record filing notification. Premarket registration will still be needed for new special use cosmetics and new special use cosmetic ingredients, such as preservatives, sunscreens, colorants, hair dyes, freckle whitening, and others. Annual reporting for three consecutive years will be required for newly registered or notified new cosmetic ingredients. The new cosmetic ingredients will be added to the Inventory of Existing Cosmetic Ingredients in China (IECIC) if no safety issues occur during the three annual reporting years.

Based on the newly released draft "*Instructions for Registration and Notification Dossier of Finished Cosmetic Products*" that are expected to be implemented in 2021 as guidance documents for State Council Decree No. 727, registration or record filing notification of finished cosmetic products will be required to include quality and safety information for each ingredient, such as production processes, quality control information, evaluations by international organizations, and any known limits and/or restrictions, that the applicant must obtain from cosmetic

ingredient manufacturers. Cosmetic ingredient manufacturers could, alternatively, submit quality and safety information for their cosmetic ingredients directly to the National Medical Products Administration (NMPA). The submission of the quality and safety information for cosmetic ingredients may become a prerequisite to placing cosmetic ingredients on the Chinese market. The quality and safety information beyond that which appears on a Certificate of Analysis could involve disclosure of proprietary information, such as production processes, that is virtually certain to be of concern to both cosmetic ingredient and finished cosmetic manufacturers, if the draft guidance documents are released unchanged in final.

c. Food Contact Substances

China continues to develop its regulations on FCMs and products and released in 2020 several draft national food safety standards (NFSS) to supplement its regulatory regime. The draft NFSS include revised GB 14930.1 *Detergents*, revised GB 4806.8 *Food Contact Paper and Paperboard*, revised GB 4806.9 *Food Contact Metal Materials and Products*, draft *Food Contact Composite Materials and Products* to replace GB 9683-1988, draft *Food Contact Printing Inks*, and draft *Food Contact Bamboo and Wood Materials and Products*. These draft NFSS include definitions, basic requirements, and sensory requirements, impose limits on impurities (*e.g.*, heavy metal residues) and migration, provide new or revised positive and negative lists of raw materials, and are expected to be released in final in 2021. Based on the draft NFSS, plumbum, cadmium, arsenic, mercury, antimony, beryllium, and lithium will not be allowed for use as alloying elements in FCM materials. According to the regulatory regime on food safety, compliance obligations for these NFSS rests mainly with the manufacturers of FCMs and products, who should only supply compliant products and pass along compliance information to the downstream producers.

3. India

India issued the 5th draft version of its Chemicals (Management and Safety) Rules (Rules), also referred to as India REACH, on August 24, 2020. The Rules are expected to come into effect in 2021. Whether the 5th draft is the final version that will come into force is unclear as official assurances about past versions being the final ones have proven to be inaccurate.

Certain provisions of the Rules continue to generate confusion among manufacturers, importers, and downstream users. None of the five draft versions of the Rules has been made publicly available to date, but were instead circulated among select industry groups. This led companies affected by the provisions of the Rules to demand greater transparency.

If the 5th version of the Rules comes into force, companies in India will have to comply with notification, registration, and evaluation measures similar to other REACH-type chemicals regulations. SDS will be required as part of the notification procedure, animal testing will be allowed only as a last resort, and given the references throughout the Rules, India intends to adopt Rev 8 of UN GHS into its hazard communication practices. In addition, the latest draft states that a substance registered under another law in India will not be required to comply with the Registration, Chemical Safety Assessment and Evaluation and Restriction provisions of the Rules.

According to the latest draft of the Rules, India will accept data from foreign sources for substances registered in other jurisdictions, "to the extent possible." This might ease the burden on some companies, although the phrasing of accepted "to the extent possible" is vague and its application could be challenging.

2020 has seen two new draft versions of India's Chemicals (Management and Safety) Rules. Each version contains substantive changes and authorities assured that each draft would be the final one. If the current draft version is issued final, then as soon as the **first quarter of 2021**, companies in India will have to comply with India's version of a REACH-type regulation. Further, there are indications that India might become the first country to adopt Rev 8 of UN GHS.

In 2021, the Korean Chemical Management Association is expected to launch the one-stop chemical safety joint support project that will provide a guide for regulations and relevant services.

4. New Zealand and the Philippines

The New Zealand Ministry for the Environment (MfE) released in November 2020 a Cabinet paper on recommended amendments to New Zealand's HSNO Act. The amendments are intended to provide the New Zealand Environmental Protection Authority (New Zealand EPA) with simplified processes for chemical assessment and reassessment, enabling better use of information from trusted overseas regulations and recent New Zealand EPA assessments. The recommended amendments would provide a simplified process for updating the hazard classifications of substances and corresponding controls based on information from trusted regulators, and New Zealand EPA would be able to restrict temporarily certain uses of a hazardous substance.

Other recommended amendments include enabling more targeted consultations during modified reassessments; requiring New Zealand EPA to develop a publicly available work plan for reassessments; enabling New Zealand EPA to align the timeframes of the assessments and reassessments of related hazardous substances in specific situations; and providing a simplified process for updating controls on existing hazardous substances when New Zealand EPA has undertaken a recent assessment of a related hazardous substance. MfE notes that the recommended amendments relate only to hazardous substances and that there are no changes to the new organisms provisions of the HSNO Act. MfE will draft the amendments to the HSNO Act, to be considered by the next Parliament.

The changes to the HSNO Act are part of a broader government work program intended to improve the hazardous substances system, including New Zealand EPA's chemical modernization program. In 2021, New Zealand EPA intends to implement fully its multi-year program to modernize New Zealand's chemical regime. This includes replacing New Zealand's hazardous substances database, the sole repository for hazardous substances approved under the HSNO Act. The new database will enable stakeholders to record, store, maintain, and exchange data on chemicals in ways that are more aligned with other OECD member countries.

In the Philippines, the Environmental Protection and Enforcement Bureau (EPEB) could be created within the Department of Environment and Natural Resources (DENR) in 2021. Bills were introduced in 2020 in the House of Representatives and the Senate to create the EPEB. President Rodrigo Duterte was asked in November 2020 to certify the legislation as urgent, which would allow Congress to pass it on the third and final reading. A DENR spokesperson stated that a permanent enforcement bureau would make DENR more effective in stopping environmental crimes, such as illegal logging and smuggling of wildlife species.

5. South Korea

a. K-REACH

The South Korean Ministry of Environment (MoE) amended the Act on the Registration and Evaluation of Chemicals (K-REACH), which entered into force on January 1, 2019, and marked the beginning of the short initial pre-registration period that ended on June 30, 2019. In-country manufacturers and importers of chemicals are responsible for ensuring compliance with K-REACH. Registration of pre-registered substances in phases by volumes will occur over the next ten years, with the highest tonnage volumes expected in 2021.

The Korean Chemical Management Association (KCMA) is a mediator between industry and government. KCMA assists in familiarizing industry with the chemical registration process and provides resources in English on its website, thus helping foreign companies overcome the language barrier. In 2021, KCMA is expected to launch the one-stop chemical safety joint support project that will provide a guide for regulations and relevant services, including through phone counseling.

According to a list published by the MoE, a total of 16,905 chemical substances were pre-registered under K-REACH by the June 30, 2019, deadline. In addition to the highest volume substances, companies should note that a registration must be submitted by **December 31, 2021**, for CMR toxicants, regardless of tonnage. South Korea published a list of 364 CMR toxicants, which is similar but not identical to the list under EU REACH.

Since late 2019, the Joint Registration Substance Information Exchange Forum System has been open. The MoE urged importers and manufacturers to form consortia, select lead registrants, and prepare the joint registration dossiers to meet the **December 31, 2021**, deadline.

As of mid-2020, there were numerous substances for which no lead registrant was elected, or for which consortia were not fully established. 2021 is expected to be a busy time for companies subject to the requirement to register before the **December 31, 2021**, deadline. The first registrations for the highest volume substances and CMR toxicants will provide more information on the registration process. South Korea is likely to issue additional guidance and K-REACH could be revised during or after the conclusion of this first registration period. Data negotiations and data agreements will continue to be a challenge for industry as the first registration window draws closer. Companies that are expected to register in later registration windows will need to observe how this first set of registrations proceeds to determine if changes in registration strategy are needed to achieve successfully future co- and lead registrations.

i. MoEL Safety Data Sheet Provisions

Effective **January 16, 2021**, manufacturers or importers claiming CBI are authorized to use, with the non-disclosure approval of the Ministry of Employment and Labor (MoEL), alternative information (an alternative name and content range) to protect their data. The exact concentration of chemicals protected as CBI is not required on the SDS, and concentration ranges can instead be disclosed, depending on the concentration of the substance.

Certain documents can be omitted from submission for CBI non-disclosure approval for chemicals used for R&D purposes (such as scientific experiments or chemical product development). Grace periods for the preparation, submission, provision, and non-disclosure of SDS apply according to tonnage band. For example, for the manufacture or import of more than 1,000 metric tons per year, the grace period ends on **January 16, 2022**, whereas for the manufacture or import of less than 1 metric ton per year, the grace period ends on **January 16, 2026**. The submission of SDS or the application for a non-disclosure approval for CBI may be carried out by an OR on behalf of the foreign manufacturer.

b. K-BPR

The other main South Korean law regulating chemicals is the Consumer Chemical Products and Biocides Safety Act (K-BPR), in force since 2019. K-BPR regulates consumer chemical products, biocidal products, and biocide-treated articles. As of early October 2020, there were 743 biocidal active substances that have been notified under K-BPR; 115 of these substances, that include disinfectants, repellents, and insecticides, need approval under K-BPR by **December 31, 2022.**

Many of the biocidal substances under K-BPR are already approved under the EU's BPR, or the U.S. FIFRA. On September 16, 2020, the government published a simplified approval procedure under K-BPR. Under this process, a reduced data set is required for submission for substances already approved under BPR or FIFRA. The data for this simplified procedure, however, do not replace the submission of an approval dossier, for which the grace period ends on **December 31, 2022**.

In 2021, certain companies that have pre-reported existing substances under K-BPR will have to submit a plan for completion of their approval application, as the grace periods are nearing their end. For substances designated as "existing" before August 24, 2020, the plan for completion of their application for approval must be submitted by **August 23, 2021**. For substances designated as existing before December 31, 2019, the deadline expired on December 30, 2020. If the companies fail to comply with the deadlines, the manufacture or import of the substance in question will be banned.

If a chemical substance has an industrial and a biocidal use, it must be registered under K-REACH for its industrial use (not including the biocidal use) and also approved under K-BPR for its biocidal use. If downstream users or importers use a K-REACH-registered substance as a biocide, the substance must be approved under K-BPR as well.

Although Taiwan EPA notified companies in 2020 that it might extend the deadline to register priority existing chemicals to 2023 or later as a result of the COVID-19 pandemic, it has not yet amended the registration deadlines.

6. Taiwan

Some developments, but not many, are worth watching for in the new year. Readers will recall that in 2018, Taiwan enacted a bill amending the Toxic Chemical Substance Control Act (TCSCA) and renaming it the Toxic and Chemical Substances of Concern Control Act (TCSCCA). The legislation called for the Taiwan Environmental Protection Administration (Taiwan EPA) to draft a bill within one year to regulate existing chemicals manufactured, imported, and/or used in Taiwan. In 2019, Taiwan EPA amended the Regulation of New and Existing Chemical Substance Registration, designating the first batch of priority existing chemicals (PEC) for which a standard registration must be completed.

Registration of the 106 PECs was initially scheduled to begin July 1, 2019, but was postponed to January 1, 2020. For PECs manufactured or imported in volumes of 100 tonnes or more, registrations must be completed by **December 31, 2021**. For PECs manufactured or imported in volumes over one tonne but less than 100 tonnes, registrations are due **December 31, 2022**. Although Taiwan EPA notified companies in 2020 that it might extend the registration deadline to **2023** or later as a result of the COVID-19 pandemic, it has not yet amended the registration deadlines.

Taiwan EPA had initially intended to publish the second batch of PECs in 2021, one year after the original start date for registration of the first batch of PECs. If Taiwan EPA delays the registration deadline for the first batch of PECs manufactured or imported in volumes over 100 tonnes to 2023, it may not release the second batch of PECs until **2024**.

Taiwan EPA had planned to publish a "substances of concern" list by the end of 2019, but the pandemic delayed this initiative. Rather than publishing a list, Taiwan EPA announced in July 2020 that nitrous oxide will be listed as the first substance of concern. Taiwan EPA will work with the Ministry of Economic Affairs, the Ministry of Health and Welfare, and the National Police Agency to implement joint control. Activities that involve the manufacture, import, and sale of nitrous oxide require prior permission, and all transactions must be reported. In addition, online transactions of nitrous oxide are banned. Companies have until **May 1, 2021**, to comply with SDS and labeling rules.

7. Thailand

Following two public meetings in 2019 to introduce and discuss a proposed new chemicals law, Thailand's National Committee on Chemical Management Policy was set to consider, in July 2020, a next draft of the proposed new chemicals law. There is no indication, however, that this committee met to consider the draft. The next draft includes provisions such as the creation of a national chemical agency and a discussion of which government ministry will oversee the agency. Delays arising from the COVID-19 pandemic have forced the reallocation of resources and funding and slowed further progress on the new chemicals law in 2020.

Thailand continues to advance several initiatives that lay the foundation for a new chemicals framework that will introduce a new system for registering and classifying chemicals. After several years of delay, Thailand's Department of Industrial Works (DIW) published in final, in July 2020, the inventory of existing chemicals in Thailand. The long-awaited final inventory, that includes more than 11,000 substances, replaces the preliminary inventory published online in 2016.

Thailand joined in 2020 the OECD system for the MAD in the Assessment of Chemicals. This multilateral agreement allows participating countries to share the results of non-clinical safety tests done on chemicals and chemical products, including industrial chemicals and pesticides. In the first step toward participation in the MAD system, Thailand will work with OECD countries to make their compliance monitoring program on GLP acceptable to all members.

If the latest draft of the new chemicals law is approved by the National Committee, it will move to the Cabinet, where

additional revisions and public hearings are possible, before going to Parliament for consideration. Thailand's progress in 2020, in spite of the challenges presented by COVID-19, suggests it is determined to make progress in 2021 as the draft law continues through the rulemaking process.

8. Vietnam

From 2016 to 2018, Vietnam developed a series of national chemical lists through three nomination periods. As part of its continuing efforts to create a national chemical inventory, Vietnam opened a fourth nomination period in April 2020 that included, for the first time, a requirement to verify that nominated substances existed on the market, prior to placing them on the draft national chemical inventory. The fourth nomination period, said to be the final opportunity to nominate substances to the draft inventory, closed in May 2020. The indications earlier in 2020 were that a new decree on the national chemical inventory would be issued in late 2020.

The new decree, however, is now expected to be issued in **late 2021**, following an October 2020 announcement from the Vietnam Chemicals Agency that a fifth nomination period for substances to the draft chemical inventory will be open **until April 15, 2021**. In response to industry requests, this nomination period is longer to allow sufficient time for industry to collect, verify, and prepare the required documents. When the national inventory is published after the verification process is complete **sometime in 2021** or **2022**, any substance not verified and listed on the inventory will be considered a new chemical and subject to risk assessment.

Article 44 of Vietnam's chemicals law published in 2007 states that the Ministry of Industry and Trade (MoIT) will lay out the procedure for rules on new chemicals. There have been, however, no regulations made available for public consultation by MoIT, and there is uncertainty about how new chemicals will be regulated. The delay in the publication of the final national chemical inventory provides additional time for MoIT to prepare in 2021 the regulations and provide an essential piece of the overall framework for new chemicals management in Vietnam.

CONTRIBUTORS

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APPENDIX A: B&C SPEECHES AND WRITINGS

ABA Year in Review
Lynn L. Bergeson, Charles Auer, Richard Engler, Ph.D., and Kathleen Roberts, co-authors, "Pesticides, Chemical Regulation, and Right-to-Know 2019 Annual Report," in *The Year in Review 2019: Environment, Energy, and Resources Law*, American Bar Association (ABA) (2020).

ARTICLES
Recent articles on critical issues:

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

Lynn L. Bergeson, "EPA Fee Controversy Continues," *Chemical Processing*, December 16, 2020.

Lynn L. Bergeson and Eve C. Gartner, "The Essentials of TSCA Practice," *ABA Section of Environment, Energy, and Resources Trends*, November/December 2020.

Lynn L. Bergeson, "EPA Announces Carbon Tetrachloride Risks," *Chemical Processing*, November 20, 2020.

Lynn L. Bergeson, "Pandemic Spurs Enforcement Revisions," *Chemical Processing*, October 26, 2020.

Lynn L. Bergeson, "Off to the Races -- CDR Reporting Begins!," *Washington Watch*, Fall 2020.

Lynn L. Bergeson, "EPA Tells Businesses to Pay Up," *Chemical Processing*, September 16, 2020.

Lynn L. Bergeson, "Feeling the Pinch: Who Pays TSCA Risk Evaluation Fees?," *Financier Worldwide*, September 2020.

Lynn L. Bergeson, "EPA Eyes Carpet Chemicals," *Chemical Processing,* August 21, 2020.

Lynn L. Bergeson, "EPA Axes Temporary Enforcement Lull," *Chemical Processing*, July 22, 2020.

Lynn L. Bergeson, "EPA-Initiated TSCA Risk Evaluations: Who Is on the Hook for Fees Has Changed," *Washington Watch*, Summer 2020.

Lynn L. Bergeson, Charles M. Auer, and Richard E. Engler, Ph.D., "What Lies Ahead for the Next Four Years of TSCA?," *Chemical Watch*, July 14, 2020.

Lynn L. Bergeson, "Understand Chemical Data Reporting Changes," *Chemical Processing*, June 17, 2020.

Lynn L. Bergeson, "Compliance: Talk to Your Supply Chain," *Chemical Processing*, May 13, 2020.

Lynn L. Bergeson, "Effectively Managing Supply Chain Communications under TSCA," *Bloomberg Law*, April 28, 2020.

Lynn L. Bergeson, "Chemical Importers Are on the Hook for TSCA Risk Evaluation Fees," *Elements, the Magazine of Chemicals Northwest*, Spring 2020.

Lynn L. Bergeson and Christopher R. Blunck, "Expert Focus: What Are the Implications of the US EPA's Expected Final Rule on Persistent, Bioaccumulative and Toxic Chemicals?," *Chemical Watch*, March 26, 2020.

Lynn L. Bergeson, "TSCA Fee Controversy Continues," *Chemical Processing*, March 20, 2020.

Lynn L. Bergeson, "The Growing Spectre of Chemical Product Cancellations, and What To Do about It," *Financier Worldwide*, February 2020.

Lynn L. Bergeson, "Toxic Substances: Are You on the List?," *Chemical Processing*, February 24, 2020.

Lynn L. Bergeson, "EPA Revises "Working Approach" Document," *Chemical Processing*, January 14, 2020.

Lynn L. Bergeson, "Risk Evaluations under TSCA: The State of Play," *Specialty Chemicals Magazine*, December 2019/January 2020.

Lynn L. Bergeson and Richard E. Engler, Ph.D., "Chemical Innovation and New TSCA: The Good, the Bad, and the Evolving," *International Chemical Regulatory and Law Review*, Volume 2, Issue 4, Winter 2019.

Lynn L. Bergeson, "TSCA Citizen Petitions and Risk Evaluations: Are These Critical TSCA Tools Aligned?," *Environmental Quality Management*, Volume 29, Issue 2, Winter 2019.

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

"Potential Impacts of California's Rodenticide Restrictions on Urban Pest Management," Lisa M. Campbell, Moderator, New Developments in Pesticide Law and Policy Conference presented by the American Bar Association (ABA) Section of Environment, Energy, and Resources (SEER) and CropLife America (November 18, 2020).

"Nanotechnology: Evolving Regulatory and Policy Implications," Lynn L. Bergeson, Risk Governance/Global Challenges Chair, Sustainable Nanotechnology Organization 9th Annual Nano Conference (November 13, 2020).

"Regulatory Relief -- EPA and COVID-Related Disinfectants and FDA on Hand Sanitizers," Heather F. Collins, M.S., Lisa R. Burchi, Household & Commercial Products Association (HCPA) Cleaning Products: A Regulatory Review, Webinar Series (November 11, 2020).

"TSCA at Four Years: A Look Ahead to the Law's Future," Lynn L. Bergeson, Chemical Watch, Key Regulatory Updates: Europe, Asia, and the Americas (October 16, 2020).

"Pesticides, Farmworkers, Industry, and Environmental Justice," James V. Aidala, Moderator, Environmental Law Institute (ELI) Webinar (October 1, 2020).

"TSCA Fees," Lynn L. Bergeson, Chemical Watch, TSCA Developments 2020 Conference (July 16, 2020).

"A Look to the Future," Richard E. Engler, Ph.D., Panelist, Chemical Watch, TSCA Developments 2020 Conference (July 16, 2020).

"Law and Policy of Products Regulation," Lynn L. Bergson, Environmental Law Institute (ELI) Summer School 2020 (July 14, 2020).

"Understanding Pesticide Regulation and the 9th Circuit Dicamba Decision," James V. Aidala, American Agricultural Law Association Webinar (June 26, 2020).

"TSCA Implementation: Where Are We Now?," Lynn L. Bergeson, Richard E. Engler, Ph.D., panelists, TSCA Reform - - Four Years Later, presented by B&C, Environmental Law Institute (ELI), and the George Washington University Milken Institute School of Public Health (June 24, 2020).

"Regulatory and Policy Issues," Richard E. Engler, Ph.D., panelist, TSCA Reform - - Four Years Later, presented by B&C, Environmental Law Institute (ELI), and the George Washington University Milken Institute School of Public Health (June 24, 2020).

"Road-map for Innovators -- Commercialization in a Circular Economy," Richard E. Engler, Ph.D., 24th Annual Green Chemistry and Engineering Conference (June 15, 2020).

"Significant New Use Rules (SNUR)," Richard E. Engler, Ph.D., GlobalChem TSCA New Chemicals Webinar (May 13, 2020).

"Workshop on TSCA Chemical Data Reporting Rule (CDR)," Lynn L. Bergeson, Kathleen M. Roberts, ChemCon the Americas 2020 (March 2, 2020).

"The Amended TSCA and Its 2020 Priorities, Implementation, and Direction for New and Existing Chemicals," Lynn L. Bergeson, presenter, ChemCon the Americas 2020 (March 2, 2020).

"Toxic Substances and Emerging Contaminants: Legal Issues and Latest Developments," Lynn L. Bergeson, American Law Institute Continuing Legal Education (ALI CLE) and Environmental Law Institute (ELI) Environmental Law 2020 (February 6, 2020).

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

APPENDIX B: B&C WEBINARS AND PODCASTS AVAILABLE ON DEMAND

WEBINARS

Eurasia REACH: Achieving Timely Compliance with new Chemicals Requirements

Lynn L. Bergeson, President, The Acta Group, Heather J. Blankinship, Senior Regulatory Consultant, The Acta Group, and colleagues from EPPA present key similarities and differences between the Eurasian Economic Union (EAEU) regional chemical framework, Technical Regulation (TR) on the Safety of Chemical Products EAEU, commonly known as Eurasia REACH; EU Registration, Evaluation, Authorization and Restriction of Chemicals (REACH); and U.S. Toxic Substances Control Act (TSCA). Topics include implementation in the Russian Federation, insight into the regional political dynamics and impacts to implementation, and requirements to submit substances and mixtures to the Russian chemical inventory.

Navigating the Jurisdictional Tightrope between Biopesticides, Biostimulants, and Related Emerging Technologies

Lynn L. Bergeson, Managing Partner, B&C; Lisa R. Burchi, Of Counsel, B&C; and Sheryl Lindros Dolan, Senior Regulatory Consultant, B&C, deconstruct the jurisdictional boundaries distinguishing pesticides, biopesticides, plant regulators, biostimulants, and related technologies. The webinar focuses on draft EPA guidance intended to clarify the lines between and among those products that are subject to FIFRA registration as plant regulators and those biostimulant products not subject to FIFRA registration. The webinar also focuses on new and evolving chemistry and technology issues that may blur some jurisdictional lines or potentially move products from one category to another.

PODCASTS

All Things Chemical™ engages listeners in intelligent, insightful conversation about everything related to industrial, pesticidal, and specialty chemicals and the law and business issues surrounding chemicals. B&C's talented team of lawyers, scientists, and consultants keeps listeners abreast of the changing world of both domestic and international chemical regulation and provides analysis of the many intriguing and complicated issues surrounding this space. The issues that B&C pursues in its day-to-day business are unfailingly interesting, and we wish to share our knowledge, our insights, and our enthusiasm for these issues with you through our All Things Chemical podcast.

All Things Chemical is available now on iTunes, Spotify, Stitcher, and Google Play Music 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 Happened with the Presidential Election Last Year? — A Conversation with Howard Gutman

Lynn L. Bergeson speaks with Howard Gutman, who served as Ambassador to Belgium in the Obama Administration and is now a consultant for global businesses. Ambassador Gutman addresses a broad range of timely and important topics, including the 2020 elections and what happened exactly, and what CEOs should be thinking about because of the change in Administration, both for U.S.-based and foreign-based businesses. Given Ambassador Gutman's unique view of global business, the conversations also touches upon the European Union's precautionary principle and regulatory decision-making, European and American views on big tech, and some of the biggest challenges to global growth.

Product Stewardship and Circular Economy -- A Conversation with Kate Sellers

Lynn L. Bergeson and Kate Sellers, Technical Director at ERM and immediate past President of the Product Stewardship Society (PSS), discuss why now more than ever, businesses need to be sustainable, to shift from a linear to a circular economy, and to understand how to integrate product stewardship principles and practices into their business dealings. They also discuss the impact of the European Union's chemical strategy for sustainability on U.S. companies, COVID-19's influence on supply chain systems, and the role of Artificial Intelligence in governance.

TSCA and Environmental Justice -- A Conversation with Former OPPT Director Jeffery T. Morris, Ph.D.

Lynn L. Bergeson and Jeffery T. Morris, Ph.D., immediate past Director of EPA's Office of Pollution Prevention and Toxics (OPPT), look back on Jeff's leadership of OPPT and its accomplishments in implementing Lautenberg, which policies the current Administration has implemented that should continue, and how the new Administration should and can do more using TSCA to address social inequities and achieve the

goals of environmental justice. Jeff discusses his recent articles on this important topic, as well as the important role international collaboration plays in understanding both the commercial promise and chemical profile of nanomaterials.

Let's Talk about Europe -- A Conversation with Bjorn Hansen, Executive Director of ECHA

Lynn L. Bergeson, Jane S. Vergnes, Ph.D., and Bjorn Hansen discuss the end of the transition period between the EU and Great Britain under Brexit and the very recent issuance of the EU Chemicals Strategy for Sustainability Towards a Toxic-Free Environment. This new strategy includes some 50 initiatives intended to complement the European Green Deal under which the EU has committed to no net greenhouse gas emissions by 2050.

How EPA's Office of Pesticide Programs Is Handling COVID-19 -- A Conversation with Lisa Campbell

Lynn L. Bergeson and Lisa M. Campbell check in with the U.S. Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP), which has been extraordinarily busy since March keeping up with new products to combat the coronavirus and forging new ways of leveraging its resources while maximizing the public health benefits of these new products. The B&C partners also update listeners on a few other OPP developments unrelated to the pandemic, as OPP's jurisdiction extends far beyond approving new products to address COVID-19.

A NanoBCA Retrospective -- A Conversation with Vincent Caprio

Lynn L. Bergeson and Vincent Caprio, Founder and Executive Director of the NanoBusiness Commercialization Association (NanoBCA), discuss the early days of nanotechnology, how NanoBCA helped frame critical EHS issues in a way that moved the technology forward, Vincent's relationship with and deep engagement in the activities of the National Nanotechnology Initiative, his engagement with key Senators and Representatives on nano matters, and what's next for nanotechnology after the 2020 elections.

Pesticide Registration in a Pandemic -- A Conversation with Sheryl Dolan

Lynn L. Bergeson and Sheryl Lindros Dolan cover a broad range of topics, beginning with a check-in with how the U.S. Environmental Protection Agency's (EPA) Office of Pesticide Programs is faring under the now not-so-new pandemic-focused times. They discuss how EPA is addressing the greatly increased number of pesticide registration applications in response to the COVID-19 virus, the submission of emergency exemption applications under FIFRA Section 18, and how to manage client expectations, especially those harbored by innovators who believe their products will help protect against the virus and thus have a sense of urgency that is challenging to align with even accelerated government approval timelines.

A TSCA Retrospective -- A Conversation with Congressman John M. Shimkus

Lynn L. Bergeson speaks with Congressman John M. Shimkus, a Member of the U.S. House of Representatives for the 15th District of Illinois and a senior Member of the House Energy and Commerce Committee. Congressman Shimkus has become a rock star in the industrial chemical community, given his tireless efforts to modernize the Toxic Substances Control Act (TSCA), which of course resulted in passage four years ago of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg). Lynn and Congressman Shimkus address many aspects of Lautenberg's implementation, not just by EPA, but also efforts under way by other industrial chemical stakeholders, including industry, non-government organizations (NGOs), states, and the courts. They discuss the many, many rulemakings EPA has issued since 2016 and survey the next leg of EPA's journey to implement the new law over the next 12 to 24 months, which will be extremely busy.

Checking up on EPA's Office of Pesticide Programs -- A Conversation with Jim Aidala

Lynn L. Bergeson and James V. Aidala, former Assistant Administrator of what is now the Office of Chemical Safety and Pollution Prevention, discuss leadership within OPP, which is transitioning, and a number of high-profile pesticide science policy debates about substances, some of which have been raging literally for years. These substances include dicamba, glyphosate, and chlorpyrifos. The legal and scientific administrative and judicial reviews under way in the United States and internationally are fascinating, precedent setting, and closely watched.

TSCA at Four -- A Conversation with Alexandra Dunn, OCSPP Assistant Administrator

Lynn L. Bergeson and Alexandra Dunn, who heads the Office of Chemical Safety and Pollution Prevention and is responsible for implementing the nation's industrial and agricultural chemical laws, the Toxic Substances Control Act (TSCA) and

the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), discuss implementation of the amendments to TSCA and initiatives under way to introduce safer and greener chemicals.

Back to Work Safely—A Conversation with Larry Sloan, CEO of the AIHA

Lynn L. Bergeson speaks with Larry Sloan, CEO of the American Industrial Hygiene Association (AIHA). Founded in 1939, AIHA is a non-profit organization serving professionals dedicated to the identification, evaluation, control, and confirmation of environmental stressors in or arising from the workplace. Given AIHA's extraordinary institutional expertise in workplace stressors, its role and prominence in getting workers back into a safe and healthful work environment in light of the COVID-19 pandemic has rocketed its Back to Work Safely initiative, one of the subjects of Lynn and Larry's conversation, into national prominence.

What Is the Difference between a Biostimulant and a Pesticide?

Lynn L. Bergeson, Lisa R. Burchi, and Sheryl Lindros Dolan explore the fascinating yet commercially vexing jurisdictional divide between and among biostimulants, biopesticides, and fertilizers as each of these agricultural chemical products is vital to the agricultural community. As big as this market is, there is surprisingly a great deal of confusion in markets globally regarding what exactly is a biostimulant and how it differs from a fertilizer or a pesticide, and importantly how the U.S. Environmental Protection Agency (EPA) goes about regulating the claims made for these products. This podcast focuses on these issues, especially as they relate to how EPA defines and regulates biostimulants, and offers some tips to stakeholders in this commercial space on how to avoid enforcement scrutiny.

EPA's Office of Pesticide Programs and COVID-19 -- A Conversation with Richard Keigwin

Lynn L. Bergeson speaks with Richard Keigwin, Director of the Office of Pesticide Programs (OPP) at the U.S. Environmental Protection Agency (EPA). As OPP Director, Rick leads the EPA office that reviews and approves pesticide products used to combat the spread of SARS-CoV-2, the virus that causes COVID-19. Historically, OPP has consistently been one of the busiest offices in EPA's Office of Chemical Safety and Pollution Prevention (OCSPP). Rick takes listeners through what EPA is doing to accelerate the availability of new tools to combat the spread of the virus, how he has been orchestrating this massive effort from his remote office, and how he has been doing so while simultaneously addressing the usual heavy load of routine pesticide business during this pandemic.

Chemical Distribution in the Time of COVID-19 -- A Conversation with Eric R. Byer, NACD

Lynn L. Bergeson and Eric Byer, President and CEO of the National Association of Chemical Distributors (NACD), discuss uniquely "in the moment" issues such as the extraordinary efforts that NACD member companies are undertaking to distribute much-needed chemical products, including sanitizers and other cleaning products, in response to the pandemic. They also discuss a broad range of federal, state, and international issues on which NACD is focused, including extending the Chemical Facility Anti-Terrorism Standards (CFATS) program, TSCA implementation initiatives, and the impact of tariffs on imports from China on NACD member companies.

EU Classification, Labeling, and Packaging Legislation -- A Conversation with Karin Baron

Lynn L. Bergeson and Karin F. Baron discuss recent European Union enforcement initiatives that have to do with the CLP legislation: Classification, Labeling, and Packaging legislation including the current state of harmonization along the lines of the GHS model, and how this might be more an aspiration than a reality. They also cover a number of different themes that might be of interest to listeners, including why "mixture classifications" can be so varied across different regions, and Karin gives some concrete recommendations and tips for manufacturers, distributors, and exporters that deal with the EU.

APPENDIX C: GLOSSARY

1-BP -- 1-Bromopropane
2,4,6-TTBP -- 2,4,6-Tris(tert-butyl)phenol
µg/m³--- Micrograms per Cubic Meter
ABIQUIM -- Chemical Industry Association (Brazil)
ABNT -- Brazilian Association of Technical Standards
ACA -- American Coatings Association
ACGIH® -- American Conference of Governmental Industrial Hygienists
Acta® -- The Acta Group
AD -- Antimicrobials Division
ADAO -- Asbestos Disease Awareness Association
AEZ -- Application Exclusion Zone
AIA -- Agriculture Innovation Agenda
AICIS -- Australian Industrial Chemical Introduction Scheme
ANDI -- Asociación Nacional de Empresarios de Colombia (Colombia)
ANIQ -- Asociación Nacional de la Industria Química (Mexico)
ANPRM -- Advanced 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
ATP -- Adaptation to Technical Progress
B&C® -- Bergeson & Campbell, P.C.
BAT -- Best Available Techniques
BAT-AEL -- BAT-Associated Emission Level
BAT-AEPL -- BAT Environmental Performance Level
BBP -- Butylbenzylphthalate (BBP)
BCCM -- B&C® Consortia Management, L.L.C.
BE -- Bioengineered
BPG -- Best Practice Guide
BPR -- Biocidal Products Regulation
BRAG® -- Biobased and Renewable Products Advocacy Group
CAA -- Clean Air Act
CARES Act -- Coronavirus Aid, Relief, and Economic Security Act
CAS RN -- Chemical Abstracts Service Registry Number
CBI -- Confidential Business Information
CDC -- Centers for Disease Control and Prevention
CDR -- Chemical Data Reporting
CDX -- Central Data Exchange
CEQ -- Council on Environmental Quality
CIB -- Current Intelligence Bulletin
CLP -- Classification, Labeling and Packaging
CMR -- Carcinogenic, Mutagenic, and Reproductive
CONASQ -- National Chemical Safety Committee (Brazil)
CoRAP -- Community Rolling Action Plan
CPNP -- Cosmetic Product Notification Portal
CPSC -- Consumer Product Safety Commission
CSG -- General Health Council (Mexico)
CSR -- Chemical Safety Report
CWA -- Clean Water Act
D4 -- Octamethylcyclotetra-siloxane
DASS -- Defined Approaches for Skin Sensitization
DBP -- Dibutyl Phthalate
decaBDE -- Decabromodiphenyl Ether
DEHP -- Di-ethylhexyl Phthalate
DENR -- Department of Environment and Natural Resources
DIBP -- Di-isobutyl Phthalate
DIDP -- Di-isodecylphthalate
DINP -- Di-isononylphthalate
DIP -- Data Interpretation Procedure
DIW -- Department of Industrial Works (Thailand)
DOE -- U.S. Department of Energy
dsRNA -- Double-stranded RNA
EAEU -- Eurasian Economic Union
EC -- European Commission
ECHA -- European Chemicals Agency
EDF -- Environmental Defense Fund
EEA -- European Economic Area
EEC -- Eurasian Economic Community
EEE -- Electrical and Electronic Equipment
EPA -- U.S. Environmental Protection Agency
EPFB -- Environmental Protection and Enforcement Bureau
ESA -- Endangered Species Act
EU -- European Union
EUA -- Emergency Use Authorization
F2F -- Farm to Fork Strategy
FAQ -- Frequently Asked Questions
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
FSMA -- Food Safety Modernization Act
FY -- Fiscal Year
GB -- Great Britain
GCC -- Gulf Cooperation Council
GE -- Genetically Engineered
GHS -- Globally Harmonized System of Classification and Labeling of Chemicals

GLP -- Good Laboratory Practice
GSO -- Gulf Standards Organization
HBCD -- Cyclic Aliphatic Bromides Cluster of Flame Retardants
HCBD -- Hexachlorobutadiene
HCS -- Hazard Communication Standard
HFC -- Hydrofluorocarbon
HHCB -- 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran
HMR -- Hazardous Materials Regulations
HPR -- Hazardous Products Regulation
HSE -- Health and Safety Executive
HSIA -- Halogenated Solvents Industry Association
HSNO -- Hazardous Substances and New Organisms
HSNO Act -- Hazardous Substances and New Organisms Act 1996
IARC -- International Agency for Research on Cancer
ICCM5 -- Fifth International Conference on Chemicals Management
IECIC -- Inventory of Existing Cosmetic Ingredients in China
INCI -- International Nomenclature of Cosmetic Ingredients
INSQ -- Inventario Nacional de Sustancias Quimicas (Argentina)
IP -- Intellectual Property
ITC -- International Trade Commission
IUPAS -- International Union of Pure and Applied Chemistry
kg -- Kilogram
K-BPR -- Consumer Chemical Products and Biocides Safety Act
KCMA -- Korean Chemical Management Association (South Korea)
KKDIK -- Kimyasalların Kaydı, Değerlendirilmesi, İzni ve Kısıtlanması
K-REACH – Act on the Registration and Evaluation of Chemicals (South Korea)
Lautenberg -- Frank R. Lautenberg Chemical Safety for the 21st Century Act
LCPFAC -- Long-chain Perfluoroalkyl Carboxylates
MAD -- Mutual Acceptance of Data
MCAN -- Microbial Commercial Activity Notice
MEE -- Ministry of Ecology and Environment
MEP -- Ministry of Environmental Protection
MfE -- Ministry for the Environment (New Zealand)
mg/kg -- Milligram/kilogram
MOA -- Memorandum of Agreement
MoE -- Ministry of Environment (South Korea)
MoEL -- Ministry of Employment and Labor (South Korea)
MoEU -- Ministry of Environment and Urbanization (Turkey)
MoIT -- Ministry of Industry and Trade (Vietnam)
MRL -- Maximum Residue Limit
MS -- Member State
MSCA -- Member State Competent Authority
NAM -- New Approach Methodologies
New Zealand EPA -- New Zealand Environmental Protection Authority
NFSS -- National Food Safety Standards
NGO -- Non-governmental Organization
NI -- Northern Ireland
NICNAS -- National Industrial Chemicals Notification and Assessment Scheme
NIOSH -- National Institute for Occupational Safety and Health
nm -- Nanometer
NMP -- N-methylpyrrolidone
NMPA -- National Medical Products Administration
NNCO -- National Nanotechnology Coordination Office
NNI -- National Nanotechnology Initiative
NPRM -- Notice of Proposed Rulemaking
NRDC -- Natural Resources Defense Council
NSET -- Nanoscale Science, Engineering, and Technology
NSTC -- National Science and Technology Council
NTP -- National Toxicology Program
OCSPP -- Office of Chemical Safety and Pollution Prevention
ODS -- Ozone Depleting Substance
OECD -- Organization for Economic Cooperation and Development
OEHHA -- Office of Environmental Health Hazard Assessment
OEL -- Occupational Exposure Limit
OMB -- Office of Management and Budget
OPP -- Office of Pesticide Programs
OPPT -- Office of Pollution Prevention and Toxics
OR -- Only Representative
OSHA -- U.S. Occupational Safety and Health Administration
OTC -- Over-the-Counter
OTC Monograph Reform -- Over-the-Counter Monograph Safety, Innovation, and Reform Act
OTNE -- Octahydro-tetramethyl-naphthalenyl-ethanone
PANNA -- Pesticide Action Network North America
PBT -- Persistent, Bioaccumulative, and Toxic
PCE -- Perchloroethylene
PCTP -- Pentachlorothiophenol
PEC -- Priority Existing Chemical
PFAS -- Per- and Polyfluoroalkyl Substances
PFOA -- Perfluorooctanoic Acid
PID -- Proposed Interim Decision

PIF -- Product Information Files
PIP -- Plant-incorporated Protectant
PIP (3:1) -- Phenol, Isopropylated Phosphate (3:1)
PMN -- Premanufacture Notice
POP -- UN's Stockholm Convention on Persistent Organic Pollutants
PPE -- Personal Protective Equipment
PPP -- Plant Protection Products
PRIA -- Pesticide Registration Improvement Act
PRIA 4 -- Pesticide Registration Improvement Extension Act of 2018
Prop 65 -- Proposition 65
PSD -- Particle Size Distribution
PTL -- Priority Testing List
PV29 -- Pigment Violet 29
Q1 -- First Quarter
Q2 -- Second Quarter
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
REL -- Recommended Exposure Limit
Rev -- Revised Edition
RFI -- Request for Information
RNAi -- RNA Interference
RoHS -- Restriction of Hazardous Substances Directive
RSR -- Regulatory Status Review
SACC -- Science Advisory Committee on Chemicals
SAICM -- Strategic Approach to International Chemicals Management
SDS -- Safety Data Sheet
SDWA -- Safe Drinking Water Act
SEA -- Turkey Implementation of CLP Regulation
SECURE -- Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient
Services -- U.S. Fish and Wildlife Service and National Marine Fisheries Service
SIA -- Sunscreen Innovation Act
SIEF -- Substance Information Exchange Forum
SNUR -- Significant New Use Rule
SUD -- Safe Use Determinations
Taiwan EPA -- Taiwan Environmental Protection Administration
TBBPA -- 4,4'-(1-Methylethylidene)bis[2,6-dibromophenol]
TCE -- Trichloroethylene
TCEP -- Tris(2-chloroethyl) Phosphate
TCSCA -- Toxic Chemical Substance Control Act (Taiwan)
TCSCCA -- Toxic and Chemical Substances of Concern Control Act (Taiwan)
TLV®-CS -- Threshold Limit Values for Chemical Substances
TPP -- Phosphoric Acid, Triphenyl Ester
TSCA -- Toxic Substances Control Act
TR -- Technical Regulation
TRSCP -- Technical Regulation on the Safety of Chemical Products (Decree No. 1019)
TWA -- Time-Weighted Average
UAE -- United Arab Emirates
UID -- Unique Identifier
UK -- United Kingdom
UN -- United Nations
U.S. -- United States
USDA -- U.S. Department of Agriculture
USMCA -- United States-Mexico-Canada Agreement
VWG -- Virtual Working Group
WHMIS -- Workplace Hazardous Materials Information System
WHS -- Work Health and Safety Laws (Australia)
WPS -- Worker Protection Standard

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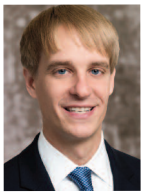

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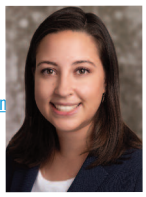

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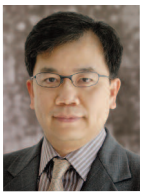

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IN MEMORIAM -- TIMOTHY J. BACKSTROM
(1952 – 2020)

In July 2020, the legal community lost Tim Backstrom, an incredibly gifted lawyer, respected by his peers, loved by his fellow colleagues here at Bergeson & Campbell, P.C., and a wonderful man, husband, and father. Those clients and colleagues who were fortunate to have known or worked with Tim appreciate the enormous void his untimely demise left. Tim's prodigious intellect, his encyclopedic understanding of FIFRA, and his contributions to the law and regulation of fuel and fuel additives under the CAA were very much a part of Tim's many contributions to the legal profession.

Tim knew more about FIFRA law and lore than any person on Earth. For those of us who worked with Tim, we appreciated that Tim was prepared to discuss, at any time, the most obscure aspect of FIFRA law or regulation, and loved every second of it. Tim's passion, intellect, and extraordinary ability to process large amounts of information and prepare beautifully written memoranda, legal briefs, and related documents made him a lawyer's lawyer and his judgment and legal ability were greatly respected.

We will miss Tim's uncompromising commitment to legal excellence, his passion for the law, his exuberance for any work composed by Gustav Mahler, and his unrelenting belief that the rule of law will ultimately prevail over the societal challenges we are now experiencing.