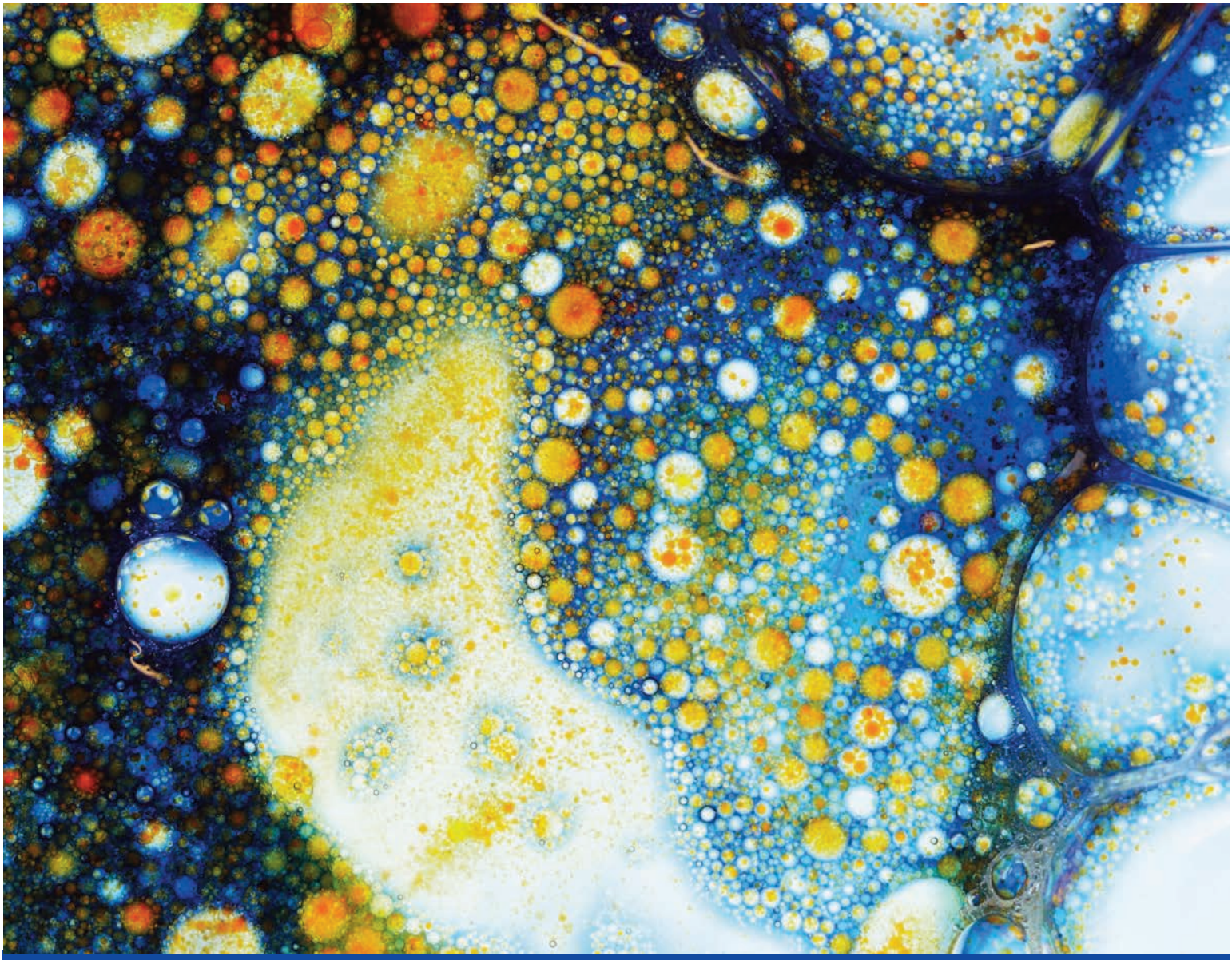

BERGESON & CAMPBELL, P.C.

# Forecast for U.S. Federal and International Chemical Regulatory Policy 2025

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# Forecast 2025

Bergeson & Campbell, P.C. (B&C®), its global consulting affiliate The Acta Group (Acta®), and consortia management affiliate B&C® Consortia Management, L.L.C. (BCCM) are pleased to share with you our Forecast 2025. For all the reasons you might imagine, our seasoned team was especially challenged this year in speculating on what to expect in 2025 regarding global industrial, agricultural, and biocidal chemical regulatory and policy initiatives. Given the European Parliamentary elections this past summer and the right wing shift they brought about, along with the new Trump Administration, change in chemical policy is expected on both sides of the Atlantic. The incoming Trump Administration and Republican congressional dominance portend significant policy changes most pronounced in regulatory and policy initiatives reversing the Biden-Harris climate program and environmental justice (EJ) agenda. How the incoming Administration's focus on deregulation and "right-sizing" the federal bureaucracy may impact more nuanced chemical product law and regulation is unclear. Fears that the now-infamous "Project 2025" document will be an Administration blueprint and not a set of detailed stakeholder suggestions will influence reactions to U.S. Environmental Protection Agency (EPA) decisions both internally and externally.

We do our best in speculating on how things may evolve. At the least, the double whammy of *Loper Bright,* the blockbuster Supreme Court decision overturning the long-standing doctrine of "*Chevron* deference," and a hardened resolve of the environmental non-governmental organization (eNGO) community to challenge judicially attempts to dismantle the Biden-Harris climate gains suggest a great deal of litigation is in our future.

Career staff at EPA will be torn. While a Trump-appointed leadership team can be expected to remain faithful to candidate-Trump's election promises to slow the transition to renewable energy, jump-start fossil fuel extractions, and undo EJ initiatives, career staff may be understandably less motivated if not opposed to these policy changes. Revisiting the Biden-Harris positions on The Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg) implementation, in particular core concepts, including "reasonably foreseen," "to the extent necessary," "systematic review," and "best available science," is expected. What is less clear is whether change will come in the form of legislative amendment, regulatory and policy implementation, or litigation. Probably all the above, suggesting 2025 will be extraordinarily busy and interesting.

The Republicans' razor-thin margin in the U.S. House of Representatives and the equally divided U.S. Senate will be significant impediments to getting any meaningful legislation passed. Toxic Substances Control Act (TSCA) fees are up for reauthorization in **2026** and there is considerable interest within the chemical community to revisit Lautenberg. B&C's multi-year commitment to fixing EPA's deeply flawed new chemicals program, as seen in the extensive work of our two industry coalitions, Coalition for Chemical Innovations and TSCA New Chemicals Coalition, will continue in 2025 with renewed resolve and vigor. Similar policy shifts and uncertainties are expected under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Endangered Species Act (ESA) in the agricultural and biocidal area, but perhaps to less dramatic effect.

The European Union (EU) Parliament's shift to the right also indicates change is afoot. How exactly this change will be expressed is unclear. 2025 marks the first year companies must report under the EU Corporate Sustainability Reporting Directive, an initiative that strengthens reporting on corporate social and environmental information. The new Parliament may have shifted right, but the EU's deeply rooted commitment to sustainability and circularity will continue to influence global corporate behavior. Layered on top of expected regional differences in chemical policies and regulations is the specter of import tariffs and their impact on investments and supply chain predictability, another source of considerable uncertainty.

The EU's proposed ban of per- and polyfluoroalkyl substances (PFAS) will continue to advance. The emphasis is laser-focused on prohibiting PFAS in consumer products. Expect to see essential use criteria emerge in 2025, a much-anticipated element that will generate significant interest. The new European Commissioner for Environment, Water Resilience and a Competitive Circular Economy, Jessika Roswell, Minister for European Union Affairs of Sweden, seems focused on balancing chemical safety with EU competitiveness, but time will tell how this balancing plays out in regulatory and policy initiatives in 2025. Canada's more measured approach to PFAS regulation is underway, with the PFAS survey of some 312 specific PFAS due **January 29, 2025**. Many more PFAS activities are planned by Canada's Minister of the Environment in 2025. With Brazil's REACH law published into law in November 2024, manufacturers and importers of non-exempt chemical substances above one ton per year will now be required to register them. This is a major achievement for the Brazilian government and a game-changing and precedent-setting event for South America, indicating significant change to the year ahead.

Our unique and exceptionally successful business platform and expanding global team of highly skilled professionals are well-suited to offer this 2025 Forecast. Our core business remains laser-focused on the complex intersection of chemical law, science, regulation, and policy. This is what we do, and we love doing it. Our highly acclaimed global team of lawyers; scientists, including toxicologists, chemists, exposure experts, and geneticists; and regulatory and policy experts is deeply versed in chemical law, science, regulation, and policy. We seamlessly leverage the integration of law, science, regulation, and policy to deliver successful outcomes for our clients at every level and in all parts of the globe.

We offer you our best wishes for good health, happiness, and success in what will be a very busy New Year.

## EDITORIAL AND PRODUCTION CONTRIBUTORS

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

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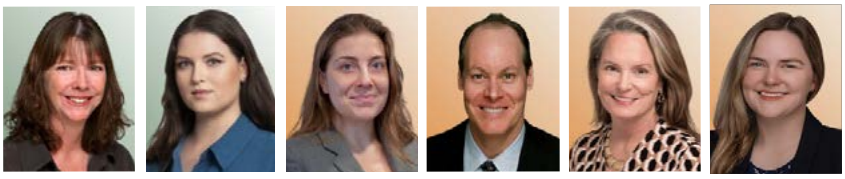

# I. UNITED STATES CHEMICAL MANAGEMENT FORECAST

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## A. Introduction

2025 brings a new Administration to Washington, D.C. Or does it? The return of President-elect Trump for a second term instantly raises important questions — especially about how similar or different the Trump II Administration might be from its first term. Will the Senate defer some of its traditional roles as a separate governing branch of government; will the House, now with a slim retained majority, be more manageable from the view of its leadership; will the new Trump leadership team be more aggressive in its actions to implement its agenda?

In addition to facing stated plans that would fundamentally change the country's climate-related programs, the U.S. Environmental Protection Agency (EPA) might be swept up in designs to reduce significantly federal spending, forced to stare down the looming specter of widespread government agency "reorganization," or weather a potential movement of federal agency offices outside of Washington, D.C., and the relocation of regional offices to make them "more accessible."

How might this affect EPA's chemical and pesticide regulatory programs? This 2025 Forecast outlines what to expect in these program areas in the United States and related regulatory programs and initiatives across the globe.

### 1. Election 2024

Republicans now control what is called the "trifecta" — the White House and party control of both the House and Senate. Before the election, that outcome was less than certain. Now, the expectations and fears of many stakeholders are amplified. Can advocates of change to EPA policies find more success than in the first Trump Administration, or will the forces of inertia — the courts, conflicting priorities, budget limitations, and the grinding gears of the "Administrative State" — stymie plans for fundamental change?

### 2. Congress

The most significant change comes with the switch in party control of the Senate. The committees of jurisdiction for EPA's pesticide and chemical activities are now both led by members seen as more friendly to critics of Biden Administration policies: Senator Shelly Capito (R-WV) of the Senate Environment and Public Works (EPW) Committee and Senator John Boozman (R-AR) of the Senate Committee on Agriculture, Nutrition, and Forestry. Both new Chairs are seen as more open to considering legislation affecting the Toxic Substances Control Act (TSCA) and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) implementation.

In the House, the Republicans have retained control, albeit with an even smaller majority. While that may generally affect the ability of House leadership to achieve legislative success, it will not fundamentally change leadership or agendas in committees beyond those that result from member retirements (and the self-imposed term-limits on committee chairs). There may be some changes to assignments and committee chairs as caucus organization continues in **January 2025**, but no significant shifts are expected.

For Office of Chemical Safety and Pollution Prevention (OCSPP) programs, an early unknown will be the federal budget. Even with current spending levels, part of the critique of present-day program performance is rooted in simple budget limitations. Even with policy changes, EPA programs need to be staffed to provide review of required submissions, which becomes difficult if budget cuts, imposed for whatever reason (be it across the board cuts or punitive budget sanctions), means "no one is home" to review submissions.

OCSPP functions differently from most other EPA activities — submissions are required for evaluation and approval before any pesticide or chemical product can go to market. Both programs have suffered from difficulty in meeting statutory deadlines (premanufacture notice (PMN) submissions in the Office of Pollution Prevention and Toxics (OPPT) and Pesticide Registration Improvement Act (PRIA) submissions in the Office of Pesticide Programs (OPP)), affecting innovation and new products and technologies in both industries. It should be noted that one of the first pieces of legislation House Speaker Johnson (R-LA) introduced on the House floor in 2023 was a bill that approved cutting EPA's budget by 40 percent. In addition to any potential consideration of legislation, results of budget deliberation on EPA or government-wide funding will be among the most impactful congressional actions on both the chemical and pesticide programs.

### 3. Transition

News coverage of the President-elect speculates extensively on the agenda, appointments, and intentions of the incoming Administration. Meanwhile, the incumbent Administration confronts the reality of having a relatively short amount of time to finish work that has been underway. This includes finishing pending rules, issuing policy or other assessment conclusions, and even initiating actions or proposing rules knowing they are likely to never be completed under the incoming leadership. This push can be for a variety of reasons: to settle litigation cases with an agreement that may be different if not concluded now; to build a record on a matter that might help make it harder to reverse; to state clearly a goal or intention that highlights the differences between the two Administrations; or sometimes just to leave a difficult matter for the next team to have to wrestle with.

Each agency is tasked by the White House to select "what really matters" for completion among many suggestions offered across the government. Each cabinet department or program typically has many recommendations, but the process of finishing actions is no easy task, otherwise the task in question would already have been completed (for example, finishing rule development procedures, including White House Office of Management and Budget (OMB) review, and settling inter-agency differences).

The Biden-Harris Administration has been more sensitive to and, as a result, better prepared for the possibility of a return by President-elect Trump, especially compared to the Obama Administration transition team's expectations

**UPCOMING WEBINAR**

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B&C is pleased to announce the launch of the Public Policy and Regulation Blog™ to provide insights on policy developments affecting the manufacturing, use, and regulation of industrial and agricultural chemicals and the products they make possible. This blog goes beyond updates on news and legislation, drawing on B&C's unique blend of expertise to share seasoned perspectives on legislative developments, focusing on what they mean to the chemical and chemical products community.

of an easier hand-off to Hillary Clinton in 2017. The 2017 transition especially affected the then-new TSCA amendments — the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg). In late 2016, there was little time to implement many of the first definitions and operating procedures for the new amendments. The first Trump Administration was then tasked with many of those important precedents, which later were subject to review and reversal by the Biden-Harris Administration.

For the pesticide program, the ticking clock of 2016 was not so impactful, though OCSPP did leave the final decisions on the pesticide chlorpyrifos as an early task for the incoming EPA appointees, with a "final" decision due by the end of March of 2017. Ironically, to this day, nearly eight years later, the registration of some chlorpyrifos products is still an ongoing matter under judicial review.

Additionally, in various agencies, there will be personnel shifts, transfers, and retirements among the many career staff who formed the backbone of agency programs during the current Presidential term. As career staff are not political appointees, most will stay on as part of the permanent staff, although under the second Trump Administration, more significant changes may be in store.

The second Trump term has signaled that new personnel will "hit the ground running," with new cabinet level selections announced well before prior incoming Presidents have selected nominees. Lee Zeldin, a former Representative from Eastern Long Island, New York, has been announced as EPA Administrator-Designate. Mr. Zeldin does not have direct environmental program professional experience on his resume, but as a House member, he did take an interest in issues such as water pollution and the environmental protection of Long Island Sound, and joined the House PFAS Task Force, the bipartisan Climate Solutions Caucus, and the Conservative Climate Caucus. His familiarity with any specifics of the OCSPP program areas is unknown.

**4. Priorities**

In recent years, the publicly declared priorities of each new President have included an explicit promise to reverse major policies and initiatives spearheaded by the departing Administration. It is an unambiguous assurance that they will present "the opposite" position — often by Executive Order (EO) from the incoming President. Candidate Trump was clear-cut about his intentions to reverse positions of importance to the Obama Administration. In turn, Candidate Biden was eager and loud about his ability to undo the policies of President Trump. Washington now awaits what is likely to be a "Day One" spate of decisions and announcements designed to emphasize promised priorities.

For EPA, one such "promised priority" is the focus on climate change initiatives. President Obama signed the Paris Agreement to reduce carbon emissions and combat climate change. President Trump then later withdrew U.S. participation, with President Biden promising to, and then executing, a rejoining on his first day in office. President-elect Trump has now vowed again to withdraw from the Agreement as part of his emphasis on energy production and reduced attention to climate issues.

Another recent presidential trend is the issuance of an EO to both implement and signal priorities. The trendline has accelerated. The Biden Administration set to work immediately by issuing a flurry of EOs and presidential directives to make good on campaign promises and make clear that the then-new President would be the "un-Trump." Over his first 100 days, according to CNN, President Biden issued 60 EOs and directives, most within the first few weeks after the Inauguration. This compares to an estimated 34 such actions taken by President Obama and an estimated 13 undertaken by President Bush in 2001, during their first 100 days. (President Trump's first 100 days in 2017 saw the issuance of 24 EOs, 22 presidential memoranda, and 20 presidential proclamations, with the Administration also introducing 28 bills.) It is not clear how many President-elect Trump will issue this time around, but it will likely be significant.

### 5. Project 2025 — Promise or Prescription?

Late in the 2024 campaign, much attention was given to a Heritage Foundation project that outlined suggested actions and priorities for a potential new Trump Administration — the "Mandate for Leadership: The Conservative Promise" (better known as Project 2025). Regardless of its status within the campaign, the document is now widely viewed as a blueprint for what the second Trump Administration will at least contemplate, if not seek to implement. It was developed by supporters of the Trump campaign, with much of its content drafted by former appointees who worked in various agencies during the first Trump Administration.

Of the 900-page document, the chapter on EPA is relatively short, at only 32 pages. Much of that chapter focuses on EPA's air quality program, especially climate-related actions. The incoming Administration has been clear in its intent to move away from most current climate initiatives and emphasize generally fossil fuel development and production.

OCSPP as a media office is not prominent in the EPA chapter, only accounting for about three pages. Unsurprisingly, related to OCSPP is a focus on topics that will be included in this Forecast. For OPP, development of its Endangered Species Act (ESA) program, along with the program's difficulties in meeting registration decision deadlines, are highlighted. For OPPT, concerns center on the web of definitions underlying risk assessment under the 2016 TSCA amendments, with particular attention given to the impacts on the PMN program reviews of submissions as the program has unfolded during the Biden Administration.

These are not the only concerns raised in the document; many other parts of the EPA chapter have significant recommendations about other parts of EPA that affect OCSPP programs. These include suggestions for significant budget cuts, personnel reductions, restrictions on employee telework, and possibly moving all or part of EPA (among other federal agencies) out of Washington, D.C. Further recommendations include reorganizing EPA regional offices, reassembling EPA's enforcement office, consolidating EPA research labs and its entire research program, measures designed to reduce spending and fundamentally restructure EPA, and ways to "improve" EPA science assessment procedures and policies. One of the most controversial recommendations concerns the re-issuance of an EO affecting the career tenure of federal employees. A proposed "Schedule F" would allow politically appointed managers to fire or otherwise remove federal employees virtually "at will," meaning long-standing protections for career employees might be removed. This could make employees vulnerable to dismissal due to disagreement over regulatory policies, decisions, or interpretations of applicable requirements. Some view this as potentially leading to the large-scale politicization of agency work across all government agencies. It is unclear whether the President has the authority to implement this scheme under current law, but the specter of it alone casts a shadow over the federal workforce.

The document's breadth and depth is so sweeping that it became a separate campaign issue beyond the now seemingly trifling rhetoric of "regulatory reform" or "doing more with less." The Trump campaign disavowed the document as an agenda and said it was among numerous points of view from various stakeholders to be included for consideration during any new term. The fact that many contributors were past agency appointees during the first Trump term (including those involved with penning and brainstorming the EPA chapter) gives the document greater gravitas, especially as it provides much more granular detail than many other issue papers routinely circulated by Washington stakeholders when a new President is due to arrive.

PODCAST:
The Importance of Government Affairs Engagement — A Conversation with Mark Washko

### 6. Operating Environment

New leadership, new Congress, new concerns about budget constraints, employee fears of retribution or dismissal, along with talk of reorganization or relocation — all this now permeates the operating environment of EPA and OCSPP. A new President can appoint new cabinet secretaries and sub-cabinet positions, and Congress can cut budgets and even consider legislative changes, as has been the case after any election year. For EPA, the question of how impactful expected changes may be now takes on a different tone compared to past transitions.

The impact of large federal budget cuts, even outside of climate policy, would ripple across all of EPA. Budget fights among the media programs would ensue over whatever resources are made available. Large staff reductions, not all of which require "Schedule F" authority, can be made under existing law. Even small staffing changes can have outsize


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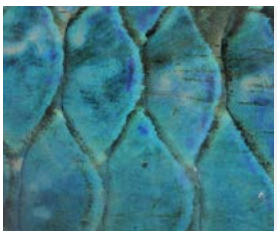
impacts on morale and program efficiency as staff spend time speculating about what might happen instead of focusing on the work at hand.

Much of the potential turmoil at EPA would affect programs other than OCSPP — but EPA-wide blows to budgets, organizational structures, staff size, science policy reviews, and other program management elements would not help OCSPP meet deadlines set under either FIFRA or TSCA. While it may be easy to predict that most staff and their functions are "safe," fear of cuts, retribution, or relocation will affect the staff. These impacts — baseless, speculative, or real — will lead to accelerated retirements of eligible employees, and then to further difficulties recruiting personnel.

In the long term, low morale, difficulties in recruitment, budget constraints, and any level of political interference could further erode public confidence in EPA decision-making. We hope these "worst-case scenarios" do not come to pass.



*In 2024, two court decisions cast a long shadow on EPA's plans for 2025 and beyond:* **Food & Water Watch, Inc. v. EPA *and* Inhance Technologies v. EPA.**

## B. TSCA

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

The Office of Pollution Prevention and Toxics (OPPT) has been working to improve its performance, but was hampered in 2024 by budget cuts. Despite this, the U.S. Environmental Protection Agency's (EPA) pace of reviewing new chemical submissions improved in Fiscal Year (FY) 2024. EPA issued several existing chemicals rules in final and several risk evaluations, but both lagged behind statutory requirements.

EPA also initiated prioritization for five substances and published lists of additional substances to be considered for prioritization. EPA reportedly still intends to complete five risk evaluations and five risk management rules each year. As discussed below, EPA published the update to its risk evaluation framework in May and, on December 18, published in final the update to the new chemicals rules. EPA did not propose the Tiered Data Reporting (TDR) rule, now scheduled for proposal in **January 2025**. On November 19, 2024, EPA issued the final update to the long-anticipated persistent, bioaccumulative, and toxic (PBT) chemicals rules.

In 2024, two court decisions cast a long shadow on EPA's plans for 2025 and beyond. *Food & Water Watch, Inc. v. EPA* and *Inhance Technologies v. EPA*. In *Food & Water Watch, Inc.*, the court held that EPA was obligated to issue a risk management rule to mitigate the potential risk from fluoridation of water. In *Inhance*, the court vacated EPA's orders issued under Section 5(e) and 5(f) in response to Inhance's submissions of Significant New Use Notices (SNUN) for byproducts formed during the fluorination of plastic containers. Both cases are discussed in more detail in Section 2.

2024 also brought legal challenges on the asbestos and methylene chloride (MC) final risk management rules. On May 8, 2024, EPA published in final the risk management rule for MC. In the final MC rule, EPA imposed a Workplace Chemical Protection Program (WCPP) that includes both dermal protection and an Existing Chemical Exposure Limit (ECEL) for inhalation. EPA set the ECEL to 2 parts per million (ppm) as an 8-hour time-weighted average. EPA also extended the ban for consumer uses and banned several other conditions of use (COU) regardless of whether such workplaces could meet the WCPP requirements. The MC rule was also the subject of multiple legal challenges; those cases were consolidated and assigned to the Fifth Circuit.

The final asbestos rule Part 1, published on March 28, 2024, is also the subject of multiple legal challenges. The cases were consolidated and assigned to the Fifth Circuit. These cases will begin to resolve the interpretation of some of the key terms in the Toxic Substances Control Act (TSCA), potentially including what is an unreasonable risk, EPA's requirement to regulate to the "extent necessary," and what COUs are reasonably foreseen. They may also test EPA's obligations to coordinate with the U.S. Occupational Safety and Health Administration (OSHA) on workplace protection.

In December, EPA published in final the risk management rules for perchloroethylene (PCE or PERC), carbon tetrachloride ($CCl_4$), and trichloroethylene (TCE). EPA also proposed risk management rules for 1-bromopropane (1-BP) and N-methylpyrrolidone (NMP). Still to come are proposed rules for Colour Index Pigment Violet 29 (PV29) and the cyclic aliphatic bromide cluster (HBCD). EPA published its final supplement to the risk evaluation for 1,4-dioxane and revised unreasonable risk determination and is proceeding to risk management. On November 19, 2024, the final PBT rule for decabromodiphenyl ether (decaBDE) and phenol, isopropylated phosphate (3:1) (PIP (3:1)) was published. 89 Fed. Reg. 91486. EPA had also expected to publish draft risk evaluations for some of the "Next 20" prioritized chemicals. In October 2024, EPA released a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short list of 15 substances from which EPA will select five on which to focus for its next prioritization candidates. EPA later expanded that list. Recall that for each risk evaluation EPA completes, EPA is required to propose another chemical for prioritization. On December 18, 2024, EPA announced the next five candidates for prioritization — 4-tert-octylphenol, Chemical Abstracts Service Registry Number® (CAS RN®) 140-66-9; benzene, CAS RN 71-43-2; ethylbenzene, CAS RN 100-41-4; naphthalene, CAS RN 91-20-3; and styrene, CAS RN 100-42-5. Comments are due **March 18, 2025**.

OPPT Director Elissa Reaves reorganized OPPT. Shari Z. Barash, Director of the New Chemicals Division (NCD), has been in place for over a year. Reaves brings much-needed management stability to OPPT. We expect significant transitions in management positions through 2025 as OPPT continues to fill permanent positions, senior staff and managers retire, and attrition occasioned by the change in Administration.

Lawsuits filed to force EPA to complete its risk evaluations have led EPA to negotiate specific deadlines for their completion. A coalition of non-governmental organizations (NGO) filed suit on September 18, 2023, in the U.S. District Court for the District of Columbia, regarding EPA's failure to complete risk evaluations for 22 high-priority substances by the statutory deadline. *Cmty. In-Power and Dev. Ass'n v. EPA* (No. 1:23-cv-02715) (*CIDA v. EPA*). The American Chemistry Council (ACC) moved to intervene on behalf of the plaintiffs on October 25, 2023. ACC noted that its High Phthalates Panel requested risk evaluations on two of the 22 chemicals, diisononyl phthalate (DINP) and diisodecyl phthalate (DIDP), and that EPA was required to complete the manufacturer-requested risk evaluations (MRRE) by July 2, 2023, but failed to do so. On April 26, 2024, EPA requested public comment on the proposed consent decrees addressing these lawsuits, which was followed by EPA releasing multiple draft assessments, including 1,1-dichloroethane (1,1-DCE), 1,2-dichloroethane (1,2-DCE), DIDP, and DINP. EPA also issued the final risk evaluation for *tris*(2-chloroethyl) phosphate (TCEP), the first completed risk evaluation for the "Next 20."

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Perspectives from OPP to OPPT — A Conversation with Elissa Reaves, Ph.D

Despite this recent progress, there are recurring concerns with EPA's scientific decision-making on these documents, including EPA's use of a linear low-dose extrapolation for its carcinogenicity assessment of formaldehyde, which contrasts with the threshold approach used by other public health agencies (*e.g.*, World Health Organization (WHO) and the French Agency for Food, Environmental and Occupational Health and Safety (ANSES)). EPA's use of its 2021 draft systematic review protocol has drawn concern by peer reviewers, with one noting "significant limitations with the current literature review approach."

EPA has also demonstrated that it intends on increasing the transparency of its scientific decision-making. For example, EPA released differing scientific opinions (DSO) on its draft risk evaluation for 1,1-DCE and its draft human health hazard technical support document on 1,2-DCE and asked both the public and the Science Advisory Committee on Chemicals (SACC) to weigh in. The release of these DSOs represents a first for EPA's activities under TSCA Section 6.

New funding, new hires, and arrival of scientists from other offices improved EPA's pace of determinations for new chemical substances. In FY 2023, EPA completed 109 determinations; in FY 2024, EPA completed 161, a 50 percent improvement. In FY 2024, EPA received 162 premanufacture notices (PMN), but completed determinations on only 137 — 129 of which are from earlier FYs. An additional 27 were withdrawn or declared invalid, meaning that EPA's queue of PMNs under review grew by only two in FY 2024. This represents the smallest increase in the "backlog" in many years and a welcome improvement. It also represents a significant achievement given the cut in OPPT's FY 2024 budget. We hope to see continued improvements in FY 2025, but additional budget uncertainty and continued lack of final, written policies and procedures may hamper further improvement.

The trend in the number of PMNs that resulted in orders essentially held steady (92 percent in 2024 compared to 90 percent in 2023). Fortunately, the pace of Significant New Use Rule (SNUR) proposals and promulgation improved a bit. EPA proposed five batches of order-based SNURs, representing 162 PMNs during 2024. EPA also proposed three batches of SNURs for 64 substances that EPA had found "not likely" to present unreasonable risk. Unfortunately, the only final SNUR batch that EPA promulgated was one batch of 31 PMNs and the "dead chemical" SNUR prohibiting all manufacture, processing, import, and use of per- and polyfluoroalkyl substances

(PFAS) that are inactive on the TSCA Inventory. 180 additional PMNs with consent orders await SNUR proposal and 151 order-based SNURs await promulgation. Each of these cases represents a possibility that another manufacturer will enter the market without the protective measures established by the order and limit the PMN submitter's ability to commercialize fully the product due to the standard distribution limits in consent orders — limits that do not expire until after the corresponding SNUR is promulgated. For additional discussion, see Section 4.

As we expected, EPA published in final the fee rule in February 2024, with an effective date of April 22, 2024. TSCA fees approximately doubled under the final rule. Despite the thin justification for the increased fees, the final rule was not challenged in court. For more discussion, see Section 7.

In addition to all of the other issues discussed here, the results of the election will also have a profound effect on EPA's implementation of TSCA. As we saw with the previous transition from the previous Trump Administration to the Biden-Harris Administration, we expect the new Administration to seek to reverse or modify many policy decisions. The incoming Administration may again pull back and review risk evaluations, rule proposals, and final rules. For example, the incoming Administration may seek remand of the final asbestos and MC risk management rules rather than continue to defend the rules in the current litigation.

### 2. Significant Court Decisions

2024 brought two significant court decisions that will shape EPA's implementation of TSCA. Other litigation is discussed in Section 9.

#### a. *Inhance Technologies v. EPA*

As we reported previously, on December 19, 2022, EPA filed a complaint in the U.S. District Court for the Eastern District of Pennsylvania, asserting that Inhance was in violation of the 2020 SNUR prohibiting the manufacture, processing, or use of long-chain perfluoroalkyl carboxylates (LCPFAC) in coatings, including as part of articles. *U.S. v. Inhance Technologies*, Civil Action No. 5:22-cv-05055 (E.D. PA). The case kicked off a flurry of litigation relating to Inhance's fluorination processes and EPA's authority to regulate "new" versus "ongoing" uses. As part of its enforcement action, EPA insisted that Inhance submit SNUNs for the production of LCPFAC as byproducts during container fluorination. EPA completed its review of those SNUNs under Section 5 and on December 1, 2023, issued unilateral orders under Section 5(f) banning the production of LCPFACs during fluorination and Section 5(e) banning the production of medium-chain PFACs during fluorination pending testing. The orders effectively prohibited Inhance from continuing its business. Inhance filed promptly a petition for review for those orders in the U.S. Court of Appeals for the Fifth Circuit to challenge EPA's authority to regulate its fluorination processes under the LCPFAC SNUR.

On March 21, 2024, the Fifth Circuit vacated EPA's December 2023 orders, finding that EPA had exceeded its TSCA Section 5 authority and that EPA's underlying interpretation of TSCA presented constitutional concerns. *Inhance Technologies v. EPA*, 96 F.4th 888 (5th Cir. 2024). Following the vacatur, EPA requested a voluntary dismissal of its civil action against Inhance. On May 20, 2024, the Eastern District of Pennsylvania dismissed the case.

EPA and Inhance raised similar arguments in both the Fifth Circuit and D.C. District Court cases. According to EPA, the burden was on Inhance to notify EPA during the rulemaking process that it was engaged in ongoing uses. Otherwise, without such notification, EPA had the authority to regulate "any use 'not previously known to the EPA'" as a "significant new use." Inhance maintained that it had no knowledge at the time of the rulemaking that its fluorination process generated PFAS, lacked fair notice that its processes may become subject to the SNUR, and that its fluorination process could not be considered "new" because it was a "decades-old" process that did not "recently come into existence." Inhance also argued that even if EPA did have the authority to regulate an ongoing use under TSCA Section 5, any PFAS generated are subject to exemptions for impurities and articles.

The Fifth Circuit held that in March 2022, EPA "charged for the first time" that Inhance's fluorination process was subject to the SNUR. The court stated that "[b]ecause the EPA exceeded its statutory authority in doing so, we vacate the orders." The court agreed with Inhance that EPA "exceeded its statutory authority by issuing orders under Section 5 instead of Section 6 because Inhance's forty-year-old fluo-

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rination process is not a 'significant new use' under TSCA." More information is available in our March 25, 2024, memorandum, "Appellate Court Vacates EPA's TSCA Section 5 Orders Prohibiting Inhance from Manufacturing or Processing PFAS during Its Fluorination Process." The decision calls into question whether EPA can foreclose with a SNUR past uses that are not (nor not known to be) ongoing at the time of the rule proposal. For example, EPA's SNURs for inactive PFAS were published in final on January 11, 2024. Each of those PFAS were, at one point in the past, active in commerce. Based on the court's decision, it may be the case that if a company could demonstrate a COU was practiced in the past, then the SNUR does not now preclude that COU. This issue may remain undecided unless and until EPA seeks to enforce the inactive PFAS SNUR.

After the Circuit court's decision and dismissal of the related enforcement case, a group of NGOs announced on April 11, 2024, that the groups had jointly filed a TSCA Section 21 petition asking EPA to use its TSCA authority under Section 6(a) based on EPA's Section 5(f) determinations to prohibit immediately the production of the LCPFACs formed during the fluorination process. EPA announced on July 11, 2024, that it granted the petition. It remains to be seen if the court's vacatur of the orders and mooting of the SNUNs also necessarily moot the determinations. The petition and EPA's response are discussed further in Section 9.

### b. *Food & Water Watch, Inc. v. EPA*

In June 2020, the U.S. District Court for the Northern District of California held a bench trial in a case seeking a rulemaking under TSCA Section 6 to prohibit the addition of fluoridation chemicals to drinking water supplies. *Food & Water Watch, Inc. v. EPA* (No. 3:17-cv-02162-EMC). The plaintiffs filed suit following EPA's denial of a TSCA Section 21 petition requesting it to exercise its Section 6 authority to prohibit the addition of fluoridation chemicals to U.S. water supplies. After the bench trial, the court held the case in abeyance to wait for a final National Toxicology Program (NTP) Monograph that was issued in August 2024.

On September 24, 2024, the court issued its decision, stating that the plaintiffs established by a preponderance of the evidence that the levels of fluoride typical in drinking water in the United States pose an unreasonable risk of injury to the health of the public. The court found that "fluoridation of water at 0.7 milligrams per liter ('mg/L') — the level presently considered 'optimal' in the United States — poses an unreasonable risk of reduced IQ in children." The court notes that its finding "does not conclude with certainty that fluoridated water is injurious to public health; rather, as required by the Amended TSCA, the Court finds there is an unreasonable *risk* of such injury, a risk sufficient to require the EPA to engage with a regulatory response." The order does not dictate how EPA must respond, but states that "[o]ne thing the EPA cannot do, however, in the face of this Court's finding, is to ignore that risk."

It is unclear how the court's order that EPA proceed to rulemaking under Section 6(a) aligns with the statutory requirement that EPA do so only after EPA completes a risk evaluation under Section 6(b) that considers all COUs. The court's decision relates to a single COU, the addition of the fluoridating agent to drinking water, and Section 6 only gives EPA the authority to regulate COUs found to present an unreasonable risk in a risk evaluation. The court's decision might perhaps stand in for the risk evaluation and risk determination, but only for the narrow COU considered in the case.

## 3. Section 6 — Existing Chemical Substances

### a. *Updated Framework Rule*

On May 3, 2024, EPA published the final rule that amends the procedural framework rule for conducting risk evaluations under TSCA Section 6. According to the final rule, EPA reconsidered the procedural framework rule for conducting risk evaluations and revised certain aspects of that framework to align better with the statutory text and applicable court decisions. The rule also reflects EPA's experience implementing the risk evaluation program following enactment of the 2016 TSCA amendments. The rule was effective on July 2, 2024.

EPA codified its policy updates from June 30, 2021, in the final rule, including the "whole chemical approach," rebranded in the final rule as a "single determination," and its assumption that "workers are exposed due to the absence or ineffective use of personal protective equipment…" The final rule also expanded the scope of TSCA risk evaluations, including that no COUs will be excluded. EPA distinguished between its lack of discretion to exclude COUs and its ability to exercise judgment in making its determination as to whether a particular circumstance is intended, known, or reasonably foreseen, and therefore falls within the definition of COU for a particular chemical. According to EPA, the determination of whether a particular circumstance is reasonably foreseen — and therefore an

exposure that must be considered within the scope of the risk evaluation — "is necessarily going to require a fact-specific, chemical-by-chemical analysis." EPA also concluded in the final rule that TSCA "does not authorize the exclusion of relevant exposure pathways from consideration in a risk evaluation" and that "EPA will assess all exposure routes and pathways relevant to the chemical substances under the conditions of use, including those that are regulated under other federal statutes."

EPA's final rule also removed the codified regulatory definitions of "best available science" and "weight of scientific evidence." In the preamble to the final rule, EPA assured the public of its decision to do so by stating that it "can say with confidence that the Agency is fully committed to meeting the requirements in the law, and to being transparent in each risk evaluation…As such, EPA is finalizing the removal of these definitions from the codified regulatory text." In our view, EPA should have revised the definitions of best available science and weight of scientific evidence, thereby providing greater transparency to EPA's decision-making and limiting the susceptibility of EPA's TSCA Section 6 activities to an administration-by-administration, team-by-team, or substance-by-substance interpretation of the scientific standards under TSCA Section 26. More information on EPA's final rule is available in our May 14, 2024, memorandum, "EPA Amends Procedural Framework Rule for Conducting TSCA Risk Evaluations."

### i. *Litigation*

Following publication of the final rule amending the procedural framework rule for conducting TSCA risk evaluations, industry and NGOs filed multiple challenges to the rule in different courts. The International Association of Machinists and Aerospace Workers (IAM) filed suit in the U.S. Court of Appeals for the Fourth Circuit, the Texas Chemistry Council (TCC) and ACC filed suit in the U.S. Court of Appeals for the Fifth Circuit, Worksafe filed suit in the U.S. Court of Appeals for the Ninth Circuit, and United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union (USW) filed suit in the U.S. Court of Appeals for the District of Columbia Circuit. Following a lottery, the U.S. Court of Appeals for the District of Columbia Circuit was selected to hear the consolidated cases. *USW v EPA* (No. 24-1151).

The court granted Olin Corporation's motion to intervene in support of TCC and ACC and granted motions from the Sierra Club and Alaska Community Action on Toxics (ACAT) to intervene to help defend the rule. USW, IAM, and Worksafe challenge EPA's authority to consider the use of personal protective equipment (PPE) when evaluating the risk posed by a chemical to workers. TCC and ACC maintain that EPA's position that TSCA requires review of every possible use of a chemical and that risk determinations must be based on the chemical as a whole mean that EPA is more likely to find unreasonable risk. TCC and ACC also argue that EPA's failure to consider compliance with PPE requirements leads to faulty conclusions on chemical exposure. Briefing in the case will continue into 2025.

## b. *Policy Changes*

### i. *Bans in Absence of Up-front Exposure Data*

On multiple occasions, Dr. Freedhoff has stated that EPA's view is that if EPA does not have data to support that a type of workplace can meet an ECEL, EPA must propose a ban for that COU. In our view, if EPA promulgates an ECEL for a substance, if an entity can demonstrate compliance with that ECEL according to the standards set forth in the rulemaking (standards for methods and timing), that entity should be allowed to continue to operate with the substance in question. While there is value to a workplace having inhalation monitoring data in advance of EPA's rulemaking, it should not be necessary to avert a ban. This issue may be settled in litigation on either the asbestos or MC cases, both of which are discussed in the risk management litigation section below.

### ii. *Systematic Review*

The lack of a final, peer-reviewed Systematic Review method remains a significant issue. TSCA Section 6(b)(4)(C) states: "The Administrator ***shall conduct*** and publish risk evaluations, in accordance with the rule promulgated under subparagraph (B) [reference to Subpart B - Procedures for Chemical Substance Risk Evaluations rule (the Framework Rule)], for a chemical substance…[emphasis added]."

EPA codified the definition of weight of scientific evidence (*i.e.*, TSCA Section 26(i)) in the 2017 Framework Rule as:

> [A] ***systematic review method***, applied in a manner suited to the nature of the evidence or decision, ***that uses a preestablished protocol*** to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of

*In February 2021, the U.S. National Academies of Sciences, Engineering, and Medicine issued a final report on TSCA Risk Evaluations that was quite critical of EPA's approach, concluding that it was not "comprehensive, workable, objective, and transparent."*

> evidence, including strengths, limitations, and relevance of each study and ***to integrate evidence*** as necessary and appropriate based upon strengths, limitations, and relevance [emphasis added].

EPA was placed on notice by a public commenter during the TSCA SACC meeting in July 2019 that the law requires a preestablished protocol. EPA did not have one for its TSCA risk evaluations.

In February 2021, the U.S. National Academies of Sciences, Engineering, and Medicine (NASEM) issued a final report per EPA's request on EPA's 2018 *Application of Systematic Review in TSCA Risk Evaluations* (2018 Guidance Document) that was quite critical of EPA's approach, concluding that it was not "comprehensive, workable, objective, and transparent." The NASEM Committee generally found that "the systematic reviews within the draft risk evaluations considered did not meet the standards of systematic review methodology." In response, EPA began again, publishing a "draft TSCA Systematic Review Protocol" (Draft Protocol). That protocol was reviewed by the SACC in 2022, but EPA has not made any visible progress towards an updated final protocol.

EPA acknowledged in the Draft Protocol that its use of the 2018 Guidance Document resulted in final risk evaluations that are "robust and upholding the standards of best available science and weight of scientific evidence per TSCA sections 26(h) and (i)." Yet EPA also stated it "did not have a complete clear and documented TSCA systematic review (SR) Protocol." EPA further acknowledged that an evidence integration process "was not previously included in the 2018 TSCA [systematic review] SR document [used on the First 10 chemical substances]." This remains a significant legal vulnerability. Time will tell if this issue is raised in the legal challenges to the ongoing litigation on EPA's risk management rules on asbestos and MC.

Here are representative examples of EPA not meeting the TSCA Section 26 standards, each of which occurred in the risk evaluations on NMP. EPA first began evaluating NMP under TSCA in 2012 as a work plan chemical risk assessment. EPA subsequently published the final work plan chemical risk assessment for NMP in 2015. In its subsequent hazard assessment as part of its TSCA Section 6 risk evaluation using the 2018 Guidance Document, EPA departed from its earlier conclusions and stated:

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

EPA did not, however, provide its rationale for reassigning data quality ratings of High for two studies. First, EPA changed its "unreliable" finding of Sitarek and Stetkiewicz (2008) in the 2015 assessment to High in the final risk evaluation for NMP. EPA can change its view of the quality of a study, but to meet the statutory standard, EPA must provide a basis for doing so.

Similarly, EPA increased its data quality rating of a two-generation oral dietary study in rats, designated by EPA as "Exxon (1991)" in the final risk evaluation for NMP and EPA used the data on decreased fertility from this study as the basis for quantifying chronic risks. In 2015, EPA concluded that development effects were the most relevant for quantifying risks because the [decreased fertility] findings "lack[ed] of consistency in findings, when looking at the complete database." Further, EPA evaluated the Exxon (1991) study under the Organisation for Economic Co-operation and Development (OECD) Screening Information Dataset (SIDS) Initial Assessment Report for NMP and assigned a data reliability score of 2 (*i.e.*, reliable with restrictions). In contrast, in the final risk evaluation, EPA assigned a data reliability score of 1 (*i.e.*, reliable without restrictions) to the Exxon (1991) study despite two subsequent two-generation studies that were unable to reproduce the findings of decreased fertility from the Exxon (1991) study.

The discrepancies with EPA's evaluations of Sitarek and Stetkiewicz (2008) and Exxon (1991) in the final risk evaluation for NMP are problematic. EPA has yet to evaluate these studies (and the subsequent studies that sought to reproduce Exxon (1991) using a final, reviewed systematic review method. It is unclear how EPA concluded that these studies warranted higher data quality and reliability ratings

in the final risk evaluation for NMP, recognizing that such a review method should be more, not less, critical of the quality and reliability of the studies.

As noted, EPA's updated 2024 Framework Rule removed the definitions of best available science and weight of scientific evidence, as codified originally in the 2017 Framework Rule. This update may assist EPA with avoiding the apparent procedural errors contained in the First 10 risk evaluations. There are, however, continued concerns about whether EPA's Draft Protocol represents the best available science, which under TSCA Section 26(h) includes "methods, protocols, [and] methodologies." EPA's activities on the draft and final risk evaluation for TCEP provide recent examples.

EPA's 2023 document on TCEP titled "*Systematic Review Supplemental File: Data Quality Evaluation Information for Environmental Hazard*" includes an assigned overall data quality determination of "High" for an aquatic toxicity study performed by Sun *et al.* (2016). During the letter peer review on the draft risk evaluation for TCEP, one of the peer reviewers stated that "these results [*i.e.*, Sun *et al.*, 2016] should have not been given a 'High' rating." EPA was also provided an expert review of Sun *et al.* (2016) shortly after the close of the public comment period on the draft risk evaluation for TCEP. The expert reviewer concluded that "[Sun *et al.*, 2016] does not justify a US EPA Systematic Review rating of 'High' due to a wide range of relevant and consequential weaknesses and errors and should in fact be rated 'Low'." Despite this feedback, EPA retained the "High" data quality rating for Sun *et al.* (2016) in the final risk evaluation for TCEP.

The issues go beyond data quality ratings. For example, one peer reviewer on the draft risk evaluation for TCEP identified several studies that were not cited in the document and commented that:

> The ability to find, without much difficulty, multiple relevant studies that are missing from the document suggests significant limitations with the current literature review approach.

The same peer reviewer further stated:

> This may be because most of the newly identified studies have recently been published. However, the studies cited within the articles and in the European Chemicals Agency (ECHA) database are older and do not appear to have been retrieved with the search strategy that was used.

EPA is using its updated Draft Protocol in more recent risk evaluations (*e.g.*, the "Next 20"). We anticipate that EPA's data quality ratings, identification of studies, and inclusion/exclusion of studies in its risk evaluations will continue to serve as a point of contention in 2025. We do not, however, anticipate that EPA will make meaningful changes to its systematic review methods, unless and until EPA is challenged legally on this point for one of the final risk management rules

#### iii. *Exposures from Pathways Regulated by Other Federal Authorities*

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

### c. *Risk Management*

#### i. *"First 10" Chemicals*

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

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

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

**(a) Asbestos**

On March, 28, 2024, EPA published the final risk management rule for chrysotile asbestos. EPA banned all COUs except the use in brakes for a specialized National Aeronautics and Space Administration (NASA) airplane. Whether EPA can ban asbestos when EPA also concluded that the ECEL is sufficiently protective to mitigate the risk identified is one of the questions that litigation is expected to answer. It also remains to be seen if EPA does not ban all uses of asbestos, will some stakeholders view TSCA reform as having failed since banning asbestos was one of the key political drivers for TSCA reform.

On December 3, 2024, EPA announced the availability of the final TSCA *Risk Evaluation for Asbestos Part 2: Supplemental Evaluation Including Legacy Uses and Associated Disposals of Asbestos* (Asbestos Part 2). Asbestos Part 2 evaluates the risks from legacy uses (*i.e.*, uses without ongoing or prospective manufacturing, processing, or distribution for use) and associated disposal (*i.e.*, future disposal of legacy uses) of chrysotile asbestos, five additional fiber types (*i.e.*, crocidolite, amosite, anthophyllite, tremolite, and actinolite), Libby amphibole asbestos, and asbestos-containing talc. EPA identified unreasonable risks of injury in scenarios for people who handle asbestos-containing materials (ACM) (*e.g.*, during maintenance, renovation, and demolition activities), take-home scenarios for exposed workers (*e.g.*, contaminated clothing), non-professional do-it-yourself (DIY) scenarios (*e.g.*, indoor disturbances [pole or hand sanding and cleaning] of spackle), and the general population located within the vicinity of activities releasing asbestos to the environment. EPA further concluded that "there is no risk of injury to the environment from asbestos that would significantly contribute to the unreasonable risk of asbestos." Based on this determination, EPA stated that it will, consistent with TSCA Section 6(a), "propose a risk management regulatory action to the extent necessary so that asbestos no longer presents an unreasonable risk to human health."

Legacy uses present an interesting challenge because EPA cannot "ban" asbestos that is already in place. For economic reasons, EPA will not be able to order in-place asbestos to be removed by a date certain. Whether EPA can justify more stringent protective measures that must be used during asbestos remediation remains to be seen.

**(b) Methylene Chloride**

On May 3, 2023, EPA published the proposed MC risk management rule. In it, EPA expanded its ban to all consumer uses and expanded the prohibition to commercial uses. Some industrial uses will be allowed to continue if workplaces can meet the WCPP, which includes an ECEL of 2 ppm. EPA's approach was to ban any conditions for which EPA did not have data demonstrating that a workplace could comply with the WCPP and provide certain time-limited exemptions from requirements for uses of MC that EPA determined would otherwise significantly disrupt national security and critical infrastructure. More information regarding EPA's proposed rule is available in our April 25, 2023, memorandum, "EPA Will Propose to Prohibit Most Uses of Methylene Chloride under TSCA Section 6(a)."

**(c) Perchloroethylene**

As readers will recall, on June 16, 2023, EPA published a proposed rule to address the unreasonable risk of injury to human health from PCE (also called PERC) under its COUs as found in EPA's December 2020 risk evaluation for PCE and December 2022 revised risk determination for PCE. At that time, EPA proposed to prohibit most industrial and commercial uses of PCE; the manufacture (including import), processing, and distribution in commerce of PCE for the prohibited industrial and commercial uses; the manufacture (including import),

ARTICLE

"Managing risk: what the EPA's TSCA chemical use bans tell us," *Financier Worldwide*, August 2024

ARTICLE

"EPA Publishes Compliance Guide on Methylene Chloride," *Chemical Processing*, September 9, 2024

processing, and distribution in commerce of PCE for all consumer use; and the manufacture (including import), processing, distribution in commerce, and use of PCE in dry cleaning and related spot cleaning through a ten-year phaseout. For certain COUs that would not be subject to a prohibition, EPA also proposed to require a PCE WCPP that includes requirements to meet an ECEL and prevent direct dermal contact.

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

On December 18, 2024, EPA published the rule in final. The final rule is largely unchanged from the proposal. EPA did provide several key changes, notably the final rule includes a *de minimis* threshold of 0.1 percent for the applicability of the rule. For additional discussion, see our forthcoming memorandum on the final rule.

**(d) Carbon Tetrachloride**

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

On December 18, 2024, EPA published the rule in final. The final rule is largely unchanged from the proposal. For additional discussion, see our forthcoming memorandum on the final rule.

**(e) Trichloroethylene**

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

On December 17, 2024, EPA published the rule in final. The final rule is largely unchanged from the proposal. EPA did, however, provide some key relief in the final rule. The final rule includes a *de minimis* threshold of 0.1 percent for the applicability of the rule. For additional discussion, see our forthcoming memorandum on the final rule.

**(f) N-Methylpyrrolidone**

On June 14, 2024, EPA proposed the risk management rule for NMP. EPA proposed to: prohibit the manufacture (including import), processing, distribution in commerce, and use of NMP in several occupational COUs; require worker protections through an NMP WCPP or prescriptive controls (including concentration limits) for most of the occupational COUs; require concentration limits on a consumer product; regulate certain consumer products to prevent commercial use; and establish recordkeeping, labeling, and downstream notification requirements.

The proposed rule states that pursuant to TSCA Section 6(b), EPA determined that NMP presents an unreasonable risk of injury to health, without consideration of costs or other non-risk factors, including an unreasonable risk to potentially exposed or susceptible subpopulations (PESS) identified as relevant to the 2020 NMP risk evaluation, under the COUs. EPA states that the term "conditions of use" is defined at TSCA Section 3(4) to mean the circumstances under which a chemical substance is intended, known, or reasonably

foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. EPA notes that all TSCA COUs of NMP are subject to the proposed rule.

In addition, EPA proposes to amend the general provisions of 40 C.F.R. Part 751, Subpart A, to define the following terms so that these definitions may be commonly applied to this and other rules under TSCA Section 6 that would be codified under 40 C.F.R. Part 751: "direct dermal contact," "exposure group," and "restricted area." EPA notes that it may codify these definitions in another rule under 40 C.F.R. Part 751 prior to the publication of the final rulemaking for NMP. Comments on the proposed rule were due July 29, 2024. More information on EPA's proposed rule is available in our June 21, 2024, memorandum, "EPA's Proposed NMP Risk Management Rule Includes Requirements to Protect Workers and Consumers."

**(g) 1-Bromopropane**

On August 8, 2024, EPA proposed the risk management rule for 1-BP. EPA states that it proposes to protect the public from exposure to 1-BP by banning all consumer uses except in insulation (because EPA determined that this use did not contribute to the unreasonable risk to people). The ban on consumer uses would begin to go into effect within six months after the final rule is published and would come fully into force within 15 months.

EPA also proposes to ban some industrial and commercial uses of 1-BP for which EPA's analysis identified safer alternatives. The ban on industrial and commercial uses would begin to go into effect six months after the final rule is published and would come fully into effect within 18 months. EPA notes that the proposed rule would also require worker protections for several industrial and commercial uses of 1-BP that would continue but which EPA has determined contribute to the unreasonable risk to human health that must be addressed, including its use in vapor and aerosol degreasing, electronics, and electronic and metal products.

Comments on EPA's proposed rule were due September 23, 2024. More information on EPA's proposed rule is available in our August 13, 2024, memorandum, "Proposed 1-BP Risk Management Rule Would Ban "Numerous" Consumer and Workplace Uses."

**(h) Other of the First 10 Chemicals**

In 2025, EPA will continue to prepare Section 6(a) risk management rules on those of the First 10 for which EPA has completed risk evaluations.

The Fall 2024 Regulatory Agenda includes EPA's plans to publish proposed Section 6 risk management rules for HBCD (2070-AK71) in **June 2025**, PV29 (2070-AK87) in **April 2025**, and 1,4-dioxane (2070-AK88) in **October 2025**. Despite the date stated in the Fall 2024 Regulatory Agenda, on December 20, EPA announced the availability of the proposed risk management rule for PV29. For additional discussion on this rule, see our forthcoming memorandum on the final rule.

On November 14, 2024, EPA published its supplement to the risk evaluation and revised unreasonable risk determination for 1,4-dioxane, clearing the way for EPA to propose a risk management rule. Despite EPA stating in its response to comments for the final framework rule that EPA would better communicate when risks are or are not present under COUs, the final risk determination for 1,4-dioxane includes no such explanation. EPA states quite plainly that "exposures to the general population via drinking water sourced from surface water contaminated with 1,4-dioxane significantly contribute to the unreasonable risk." EPA does not go on to describe what level of contamination is a concern or how common it is that drinking water is contaminated to that level. Instead, EPA's statement implies that all drinking water is contaminated to a level that is a concern. Halfway through the document, EPA explains that it has risk concerns for only 20 public water systems serving about two million people. While it is important for those people to be protected, it is very different to say that less than one percent of the population is at risk than it is to say that 1,4-dioxane presents an unreasonable risk — full stop.

**(i) PV29 Risk Evaluation**

On September 6, 2022, EPA announced the availability of the final revision to the risk determination for the PV29 risk evaluation issued under TSCA. For discussion, see our memorandum dated September 9, 2022. EPA stated that the revision to the PV29 risk determination reflects its announced policy changes to ensure the public is protected from unreasonable risks from chemicals in a way that is supported by science and the law. EPA determined that PV29, as a whole chemical substance, presents an unreasonable risk of injury to health when evaluated under its COUs.

As we wrote last year, EPA's use of the Regional Deposited Dose Ratio (RDDR) software for dosimetric adjustment

***EPA's revised final decaBDE rule includes what appears to be the first instance of EPA requiring a TSCA Section 12(b) export notice for an article.***

across species instead of the multi-path particle dosimetry (MPPD) is questionable for a number of reasons.

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

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

In October 2021, EPA stated that it does not intend to develop an ECEL for PV29. B&C suspects that EPA initially decided not to develop an ECEL because of the inherent scientific issues in the PV29 risk evaluation, namely, using deposited dose as the dose metric for quantifying unreasonable risks. EPA had planned to publish the risk management rule for PV29 in November 2024 (2070-AK87), but is now planning to propose the rule in **April 2025**. On December 20, EPA announced the availability of the proposed risk management rule. We are surprised by the timing since EPA has yet to complete the final peer-reviewed MPPD model, meaning that EPA did not revise the final risk evaluation for PV29 to include an evaluation of unreasonable risks using the proper dose metric (*i.e.*, retained mass).

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

### (j) PBTs

On November 19, 2024, EPA published the final, revised TSCA Section 6 regulations covering two of the five (*i.e.*, decaBDE, Chemical Abstracts Service Registry Number® (CAS RN®) 1163-19-5, and PIP (3:1), CAS RN 68937-41-7) PBT substances. EPA issued the revised rule to address implementation issues and to reduce potential exposures to decaBDE and PIP (3:1). EPA did not revise the chemical-specific provisions for the other three PBT substances addressed in 40 C.F.R. Part 751, Subpart E (*i.e.*, 2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP), CAS RN 732-26-3; hexachlorobutadiene (HCBD), CAS RN 87-68-3; and pentachlorothiophenol (PCTP), CAS RN 133-49-3).

For decaBDE, EPA issued in final revisions to the January 2021 final rule, as proposed in November 2023, to require the use of PPE during certain domestic manufacturing and processing of decaBDE and decaBDE-containing products and articles. EPA did not pursue its original proposal to require labeling on decaBDE-containing plastic shipping pallets, concluding that this requirement would not be practicable. EPA also prohibited releases to water from manufacturing, processing, and distribution in commerce of decaBDE. Additionally, EPA extended the compliance date for the phase-out of processing and distribution in commerce of decaBDE-containing wire and cable insulation for nuclear power generation facilities. The rule also requires an export notification requirement for decaBDE-containing wire and cable for nuclear power generation facilities. This appears to be the first instance of EPA requiring a TSCA Section 12(b) export notice for an article. EPA also included an allowance for unintentional amounts of decaBDE present in products and articles at concentrations less than 0.1 percent by weight. The effective date of the final rule is **January 21, 2025**.

On September 27, 2024, EPA again extended the compliance date for the prohibition on the processing and distribution of decaBDE for use in wire and cable insulation in nuclear power generation facilities in 40 C.F.R. Section 751.405, to bridge until **January 30, 2025**, or the effective date of the final rule, whichever occurs earlier. The effective date is **January 21, 2025**.

For PIP (3:1), EPA issued in final revisions to the January 2021 final rule, as amended in September 2021 and March 2022, and as proposed in November 2023. The final rule requires the use of PPE for the domestic manufacturing and processing of PIP (3:1) and certain PIP (3:1)-containing products and articles. EPA also issued in final phaseouts on processing and distribution for certain uses and new exclusions from the prohibitions on processing and distribution in commerce of PIP (3:1) for use in wire harnesses and electric circuit boards and the processing and distribution in commerce of such PIP (3:1)-containing harnesses and circuit boards. EPA additionally issued an exclusion to allow the distribution in commerce of new and replacement parts containing PIP (3:1). As with the final rule on decaBDE, EPA included an allowance for unintentional amounts of PIP (3:1) present in products and articles at concentrations less than 0.1 percent by weight. EPA did not revise the October 31, 2024, compliance date for articles not otherwise covered by an exclusion from a prohibition or by an existing or newly proposed extension to a phaseout compliance deadline, but did provide a two-year sell-through provision to allow continued distribution of PIP-containing articles that were compliant with the rule as of October 31, 2024.

### d. *Risk Management Litigation*

We expect that 2025 will again see litigation over several TSCA matters, including test orders and final risk management rules. EPA policies implementing TSCA remain in flux, especially as the risk management appeals play out. TSCA stakeholders can expect to seek judicial intervention as they have in the last several years. This is entirely predictable and not necessarily an undesirable outcome; rather, it reflects the back-and-forth between stakeholders and EPA on the interpretation of the new provisions of TSCA occasioned by Lautenberg. The demise of *Chevron* deference incentivizes industry litigants as does an increasingly conservative bench.

#### i. *decaBDE*

EPA published the final TSCA Section 6 PBT rule on January 6, 2021. It prohibits the manufacture, import, and processing of most uses of decaBDE. Two cases were filed in the U.S. Court of Appeals for the Ninth Circuit challenging the rule, and the court has consolidated the cases: *Alaska Community Action on Toxics (ACAT) v. EPA* (No. 21-70168) (Jan. 27, 2021) and *Yurok Tribe, et al. v. EPA* (No. 21-70670) (Mar. 19, 2021). ACAT is concerned about the exemptions for recycled products and decaBDE's use in replacement parts in automotive and aerospace vehicles, arguing that TSCA requires EPA to eliminate exposure to the extent practicable, and the exemptions and failure to regulate how products are disposed or recycled are unlawful.

On June 23, 2022, the court granted EPA's motion for a voluntary remand without vacatur to permit it to reconsider these determinations and conduct reconsideration proceedings. After EPA's publication of the revised rule, litigants on December 12, 2024, have again filed a petition for review. The case is *Yurok Tribe, et al. v. EPA* (9th Cir., No. 24-07497).

#### ii. *PIP (3:1)*

On March 4, 2021, several trade associations that represent heating, ventilation, air-conditioning, and refrigeration (HVACR), home-appliance, consumer technology industries, electrical equipment and medical imaging, and manufacturers from industrial sectors filed a petition for review of EPA's final TSCA Section 6 PBT rule on PIP (3:1) in the U.S. Court of Appeals for the D.C. Circuit. *Air-Conditioning, Heating, and Refrigeration Institute et al. v. EPA* (No. 21-1082). After the petition was filed, EPA issued a temporary No Action Assurance (NAA). In October 2021, EPA proposed to extend the compliance dates applicable to the processing and distribution in commerce of certain PIP (3:1)-containing articles and the PIP (3:1) used to make those articles until October 31, 2024, along with the associated recordkeeping requirements for manufacturers, processors, and distributors of PIP (3:1)-containing articles.

EPA made the October 2021 proposed changes in a March 8, 2022, final rule that has been challenged by petitioners. After filing repeated motions to hold the case in abeyance, on September 18, 2024, EPA filed an unopposed motion to remove the consolidated cases from abeyance and establish briefing deadlines. In its motion, EPA "notes that it would ordinarily prefer to continue to hold these cases in abeyance as it continues to progress toward a relevant final agency action," stating that it "will work expeditiously to publish the final rule upon completion of OMB review." According to EPA, petitioners do not consent to a further

abeyance period, and therefore EPA has elected to file this unopposed motion to govern. More information on the March 2022 PIP (3:1) rule is available in our March 7, 2022, memorandum, "EPA Will Extend Compliance Dates for Articles Containing PIP (3:1)."

After EPA's publication of the revised rule, the group that had petitioned on the original rule for decaBDE included PIP (3:1) in the petition for review of the new, final rule. *Yurok Tribe, et al. v. EPA* (9th Cir., No. 24-07497).

### iii. *Methylene Chloride*

In May 2024, East Fork Enterprises and Epic Paint Company challenged EPA's final risk management rule for MC in the U.S. Court of Appeals for the Fifth Circuit, while the Sierra Club filed suit in the U.S. Court of Appeals for the Ninth Circuit. The Fifth Circuit was selected by lottery to hear the cases. The court granted ACC's July 26, 2024, motion to intervene but denied motions to intervene filed by the Labor Council for Latin American Advancement (LCLAA) and American Federation of Labor-Congress of Industrial Organizations (AFL-CIO). The industry petitioners argue that EPA's risk evaluation and revised risk determination were unlawful; the exposure limits are arbitrary and capricious, lacking substantial evidence; and that EPA's final rule restricts MC more than allowed under TSCA. The Sierra Club claims that although the final rule protects workers and consumers, it leaves fenceline communities exposed to elevated cancer risks and EPA has not determined whether those risks are unreasonable. Key issues that are being litigated include "unreasonable risk," "extent necessary," whether EPA properly considered PESS, the robustness of EPA's economic analysis, and EPA's "whole chemical" (or single determination) approach. The incoming Administration may seek remand so that it can reconsider the rule.

### iv. *Asbestos*

After five separate lawsuits were filed in four separate federal appellate courts challenging EPA's final risk management rule for asbestos, the suits were consolidated on May 7, 2024, in the U.S. Court of Appeals for the Fifth Circuit. *TCC v. EPA*, No. 24-60193. Industry petitioners argue that the rule should be vacated and remanded because EPA's finding that chrysotile asbestos presents an unreasonable risk was not supported by substantial evidence; EPA failed to defer to OSHA's authority to regulate asbestos further; the final rule went further than necessary to eliminate unreasonable risk; and the provision of different compliance deadlines for different companies is unlawful. USW claims that the risk management rule fails to protect workers who will continue to handle asbestos sheet gaskets. Asbestos Disease Awareness Organization (ADAO) maintains that in addition to the sheet gasket provisions, the rule offers no protection for DIY consumers and auto mechanics and fails to address releases to the environment from asbestos-containing waste when disposed. The U.S. Chamber of Commerce, the National Federation of Independent Business, and the Alliance for Automotive Innovation have filed amicus briefs in support of the industry petitioners. The asbestos case will involve many of the same interpretive issues in the MC case. The incoming Administration may seek remand so that it can reconsider the rule.

PODCAST:
A Conversation with Linda Reinstein, President and Cofounder of the Asbestos Disease Awareness Organization (ADAO)

## e. *Risk Evaluations*

### i. *"Next 20"*

The "Next 20" high-priority chemicals are:

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

19. Formaldehyde
20. Phthalic anhydride

EPA has made slow, but continued progress with reviewing the "Next 20" high-priority substances under amended TSCA. EPA's progress in 2024 was prompted, in part, by lawsuits filed against EPA for failing to complete timely its risk evaluations on the "Next 20" high-priority substances, originally designated as such on December 30, 2019. As discussed above, on September 18, 2023, the Community In-Power and Development Association Inc. (CIDA), Learning Disabilities Association of America, Louisiana Environmental Action Network, Sierra Club, and Texas Environmental Justice Advocacy Services (CIDA Plaintiffs) filed suit against EPA in the U.S. District Court for the District of Columbia based on EPA's alleged failure to perform non-discretionary duties under TSCA to complete timely risk evaluations (*CIDA v. EPA*, Case No. 1:23-cv-02715) (the CIDA action). On December 19, 2023, ACC filed suit in the same court over the same alleged failure of EPA to complete MRREs on DIDP and DINP (*ACC v. EPA,* Case No. 1:23-cv-03726) (the ACC action). The court granted EPA's motion to consolidate these cases on January 17, 2024, and, upon consent of the plaintiffs, ordered EPA to complete the following EPA-initiated risk evaluations by the stated deadlines:

- Formaldehyde, 1,1-DCE, and TCEP: *Federal Register* notice of availability of the final risk evaluations no later than **December 31, 2024**;
- 1,3-Butadiene: *Federal Register* notice of availability of the draft risk evaluation no later than **December 31, 2024**;
- Seven of the remaining chemical substances, one of which is 1,3-butadiene: *Federal Register* notices of availability of final risk evaluations no later than **December 31, 2025**; and
- Ten of the remaining chemical substances: *Federal Register* notices of availability of final risk evaluations no later than **December 31, 2026**.

As of December 16, 2024, EPA had published the draft risk evaluation for 1,3-butadiene, but has not published the final risk evaluations for formaldehyde, 1,1-DCE, or 1,2-DCE. Of note, under TSCA Section 26(n), EPA is required to publish an Annual Plan each calendar year that identifies the chemical substances for which risk evaluations are expected to be initiated or completed that year, describes the status of each risk evaluation that has been initiated but not yet completed, and includes an updated schedule for completion of risk evaluations. EPA has not, however, published such a plan since 2021. Whether EPA can get back on track and publish its plan for risk evaluations in 2025, as it did in 2017 through 2021, is unclear. These plans can help the public better anticipate when resources may be required to engage meaningfully in the risk evaluation development process.

**(a) Formaldehyde**

On March 15, 2024, EPA released the draft risk evaluation for formaldehyde and stated that the "SACC will consider and review the draft risk evaluation at a 4-day virtual peer review public meeting that will be held on May 20-23, 2024." In the draft risk evaluation, EPA preliminarily determined that formaldehyde presents unreasonable risks to:

- Non-cancer effects in workers from inhalation and acute dermal exposures;
- Cancer effects for some workers from inhalation exposures under one COU;
- Non-cancer effects in ONUs from inhalation exposures; and
- Non-cancer effects in consumers and bystanders from inhalation and acute dermal exposures.

EPA also stated that "Risk of injury to the environment does not contribute to EPA's preliminary determination of unreasonable risk." More information on EPA's draft risk evaluation is available in our March 21, 2024, memorandum, "EPA Issues Draft Risk Evaluation for Formaldehyde, Preliminarily Finds That Formaldehyde Poses Unreasonable Risk to Human Health."

The TSCA SACC issued its final report on August 1, 2024, and included recommendations and expressions of concern over EPA's draft documents. A few examples include the TSCA SACC's statement that EPA's "reliance on sensory irritation as a [point of departure] POD for the acute inhalation POD requires clearer justification." The TSCA SACC also pointed out that "Sensory irritation is not universally considered an adverse effect, and its selection should be supported with a rationale explaining why it is an appropriate endpoint and what, if any, uncertainty factors should be applied." The TSCA SACC recommended that EPA perform "a review of the literature supporting both threshold and non-threshold models of formaldehyde carcinogenicity to carefully justify the conclusion [emphasis in original]."

As of December 16, 2024, EPA has not released its responses to the TSCA SACC's final report nor the final risk evaluation for formaldehyde. The final risk evaluation was due by December 31, 2024.

### (b) 1,1-Dichloroethane (1,1-DCE) and 1,2-Dichloroethane (1,2-DCE)

On July 2, 2024, EPA announced the availability of the draft risk evaluation for 1,1-DCE and the draft human health hazard technical support document for 1,2-DCE. EPA's draft risk evaluation for 1,1-DCE included its preliminary determination that worker exposures to 1,1-DCE may increase the risk of cancer and non-cancer effects. EPA preliminarily found no unreasonable risk to the general population from breathing air where 1,1-DCE was released from facilities or from ingesting drinking water or surface water or soil from 1,1-DCE disposed to land (*i.e.*, direct disposal to landfills or land applied biosolids from public wastewater treatment works treating 1,1-DCE-containing wastewater). EPA also preliminarily found that chronic, but not acute, exposures to 1,1-DCE contribute to unreasonable risks to aquatic species, including invertebrates and algae. The TSCA SACC peer reviewed the draft documents on 1,1-DCE and 1,2-DCE from September 17 to 19, 2024. On November 27, 2024, the TSCA SACC issued its final report. More information on EPA's draft documents is available in our July 19, 2024, memorandum, "EPA Releases Draft Risk Evaluation for 1,1-Dichloroethane and Draft Hazard Assessment of 1,2-Dichloroethane for Public Comment and Peer Review." On December 17, EPA requested the U.S. District Court for the District of Columbia to grant more time to complete both risk evaluations stating that it needed more time to address comments from the SACC.

### (c) 1,3-Butadiene

On September 18, 2024, EPA called for nominations of peer reviewers to review the draft risk evaluation for 1,3-butadiene, with nominations due by October 18, 2024. EPA stated in the announcement that it was "planning to convene a virtual public meeting of the SACC in early 2025 to review the draft risk evaluation." On December 3, 2024, EPA announced the availability of the draft risk evaluation for 1,3-butadiene with a request for public comments on or before **February 3, 2025**. EPA preliminarily determined that 1,3-butadiene presents an unreasonable risk of injury to workers and the general population, including fenceline communities, from inhalation exposures. EPA stated that the highest risk areas are along the Gulf Coast region from Texas to Louisiana, near 1,3-butadiene releasing facilities. EPA also preliminarily determined that consumer COUs and potential risks to the environment did not contribute significantly to its unreasonable risk determinations. EPA concluded notably that the use of 1,3-butadiene as a monomer in polymer-derived consumer products (*e.g.*, acrylonitrile-butadiene-styrene resins and styrene-butadiene rubber) is stable and not expected to degrade or expose consumers to 1,3-butadiene monomer. The TSCA SACC peer review meeting on the draft risk evaluation for 1,3-butadiene is planned for **February 25-28, 2025**.

### (d) TCEP

On September 26, 2024, EPA released the final risk evaluation for TCEP, a flame retardant and plasticizer. EPA concluded that TCEP presents unreasonable risk of kidney cancer and non-cancer health effects to workers and consumers. EPA determined that seven out of 21 COUs contribute significantly to the unreasonable risk to workers, including:

- Manufacturing imports;
- Paint and coating manufacturing;
- Polymers used in aerospace equipment and products;
- Aerospace equipment and products and automotive articles and replacement parts containing TCEP;
- Paints and coatings for industrial use;
- Paints and coatings for commercial use; and
- Laboratory chemicals.

EPA found unreasonable risk to consumers from three out of 21 COUs: fabric and textile products; foam seating and bedding products; and wood and engineered wood products. EPA also found unreasonable risk for people who eat large amounts of fish contaminated with TCEP and that TCEP presents unreasonable risk to the environment, specifically to fish chronically exposed to TCEP through surface water and sediment. EPA stated that it "is now moving forward on risk management to address the unreasonable risk presented by TCEP." EPA is required to publish the draft risk management rule no later than one year after the final risk evaluation was published. More information on EPA's final risk evaluation is available in our October 2, 2024, memorandum, "EPA Publishes Final Risk Evaluation for TCEP, a Flame Retardant and Plasticizer."

### (e) Phthalates

On December 3, 2024, EPA announced the availability of technical support documents on its risk evaluation of

*If individuals are already violating OSHA requirements or making "a personal choice" to violate existing federal protections and not protect themselves or their family, a Section 6 rule is unlikely to change that behavior.*

phthalates and solicited nominations for peer reviewers. The comment period closed January 2, 2025. This announcement makes it clear that EPA will assess all of the phthalates under a cumulative risk assessment. Presumably, the review panel will assess whether a cumulative risk assessment approach is appropriate for all of the phthalates EPA includes in its grouping. On December 10, 2024, EPA announced its intended schedule in 2025 for releasing draft and final risk evaluations on the individual phthalates and the draft cumulative assessment.

### ii. *Asbestos Part 2 Risk Evaluation*

In August 2023, EPA issued a white paper on its approach to its Asbestos Part 2 risk evaluation. EPA issued its draft risk evaluation for Asbestos Part 2 on November 27, 2024. The risk evaluation was due by December 1, 2024. The deadline was negotiated as a result of the settlement in *Safer Chemicals Healthy Families v. EPA*, 943 F.3d 397 (9th Cir. 2019) in which EPA is obligated to publish a supplemental risk evaluation for asbestos (Part 2) related to legacy uses (*i.e.*, the circumstances associated with activities that do not reflect ongoing or prospective manufacturing, processing, or distribution) of asbestos and associated disposals.

Unsurprisingly, EPA identified risk from unprotected exposures to asbestos during renovation and demolition of buildings that have asbestos. This has been known for decades and EPA has already issued stringent requirements for asbestos remediation. In its assessment of take-home exposures, EPA states "Demolition and asbestos removal workers go to great lengths to avoid asbestos exposure to themselves, those around them, and the environment when they follow National Emission Standards for Hazardous Air Pollutants (NESHAP) rules and regulations, 40 CFR Part 61, subpart M. However, take-home exposures from contaminated clothes/surfaces can occur when asbestos is not handled following NESHAP guidance or when personal protective equipment (PPE, protective clothing) is unavailable." EPA later states "Although current Occupational Safety and Health Administration (OSHA) regulations (29 CFR 1926.1101) prohibit taking contaminated clothing home, this exposure pathway was included to account for workers who may not follow all OSHA guidelines and incur exposures due to lack of knowledge about asbestos identification, removal, handling, and disposal of contaminated clothes or a personal choice." This begs the question how EPA will mitigate against these risks. If individuals are already violating NESHAP or OSHA requirements or making "a personal choice" to violate existing federal protections and not protect themselves or their family, a Section 6 rule is unlikely to change that behavior. EPA cannot "ban" chemicals that are already in place. Furthermore, the assessment states that "EPA concludes asbestos fibers are not to be released from an undisturbed item and hence no exposure is expected," so mandating asbestos removal (even if the expense could be justified) could increase risk, rather than mitigate it. Even with the change of Administration, EPA is still required to mitigate "to the extent necessary" to protect against the risk identified. Stakeholders should watch carefully to see what EPA will propose in its risk management rule.

### iii. *6PPD*

As we reported last year, Earthjustice had filed a citizen petition under Section 21 asking EPA to establish regulations prohibiting the manufacturing, processing, use, and distribution of N-(1,3-Dimethylbutyl)-N′-phenyl-p-phenylenediamine (6PPD) for and in tires. On November 2, 2023, EPA granted the petition and announced that it intends to propose an "advanced notice of proposed rulemaking [ANPRM] under Section 6 of the Toxic Substances Control Act (TSCA) by Fall 2024 in order to gather more information that could be used to inform a subsequent regulatory action." That ANPRM was published on November 19, 2024, with comments due on **January 21, 2025**.

### iv. *Manufacturer-Requested Risk Evaluations*

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

**(a) Di-isononyl Phthalate (DINP)/ Di-isodecyl Phthalate (DIDP)**

The court in the ACC action ordered EPA to complete the MRREs on DINP and DIDP by the following stated deadline:

- DIDP and DINP: *Federal Register* notice of availability of the final risk evaluations no later than December 31, 2024.

On May 17, 2024, EPA released the draft risk evaluation for DIDP and the draft physical chemical, fate, and hazard assessment for DINP. These draft documents were subsequently peer reviewed by the TSCA SACC July 30 - August 1, 2024. The TSCA SACC issued its final report on October 1, 2024, and discussed various aspects of these documents. A few examples include the TSCA SACC stating that "the most significant issue with the current DIDP and DINP assessments is omission of likely exposure scenarios." The TSCA SACC also questioned EPA's occupational exposure assessment for DIDP, noting that "central tendency and 95 centile exposures were evaluated, but only the central tendency conditions were carried through to the risk characterization. EPA should justify why the pivot from past practice, when it is noted that the benchmark was exceeded for some COUs using the 95th centile exposure conditions." EPA did explain that the high-end exposure only applied to a COU (high-pressure spraying) that EPA had not found to be ongoing. The TSCA SACC concurred with EPA's carcinogenicity assessment on DINP, which EPA concluded was "*Not likely to be Carcinogenic to Humans* below levels that do not induce PPARα activation (KE1) [emphasis in original]." The majority of the TSCA SACC supported revising this conclusion to state "'Not likely to be Carcinogenic to Humans' due to the lack of human relevance of the PPARα activation MOA for liver tumors." On September 3, 2024, EPA released the draft risk evaluation for DINP. Comments were due November 4, 2024. As of November 27, 2024, EPA has not released the final risk evaluations for DIDP and DINP. More information on EPA's draft documents on DIDP and DINP is available in our May 24, 2024, memorandum, "EPA Releases Draft Risk Evaluation Documents for DIDP and DINP for Public Comment and Peer Review," and our September 26, 2024, memorandum, "EPA Releases Draft Risk Evaluation for DINP for Public Comment."

**(b) Octamethylcyclotetra-siloxane (D4)**

On October 7, 2020, EPA granted a manufacturer request for risk evaluation of D4. EPA has since held meetings with stakeholders on this substance. In the most recent stakeholder meeting held on March 6, 2024, EPA indicated it was "on track for a draft [risk evaluation] by the end of the year." EPA provided other milestones, including its intent to peer review the draft risk evaluation for D4 in **spring/ summer 2025** and to issue the final risk evaluation by **April 2026**.

**f. *Risk Evaluation Litigation***

**i. *1,4-Dioxane***

On January 26, 2021, the Environmental Defense Fund (EDF), the Sierra Club, and the Environmental Working Group petitioned the U.S. Court of Appeals for the Ninth Circuit for review of EPA's final risk evaluation of 1,4-dioxane and EPA's determination that 1,4-dioxane does not present an unreasonable risk of injury to health or the environment under certain COUs. *EDF et al. v. EPA* (No. 21-70162); consolidated with No. 21-70194, No. 21-70727, No. 21-70684, and No. 21-70930. A coalition of 14 states and three municipalities also filed suit, and the court consolidated the cases. On June 8, 2021, EPA requested voluntary remand without vacatur to allow it to revisit the final risk evaluation. The court granted EPA's motion on August 10, 2021, for the limited purpose of permitting EPA to reconsider the challenged no-unreasonable-risk determinations.

The SACC released on November 17, 2023, its final report on the draft supplement to the risk evaluation for 1,4-dioxane. On July 26, 2023, EPA released the draft revision to the risk determination for 1,4-dioxane. Because EPA proceedings are ongoing, EPA asked that the case stay in abeyance. The next status report was due October 28, 2024. More information on the draft supplement to the risk evaluation and the draft revision to the risk determination is available in our July 31, 2023, memorandum, "Draft Supplement to Risk Evaluation and Draft Revised TSCA Risk Determination for 1,4-Dioxane for Public Comment."

On November 13, 2024, EPA announced the release of its final supplement to the risk evaluation and revised its unreasonable risk determination for 1,4-dioxane. Three weeks later, on December 3, 2024, Union Carbide Corporation (UCC) petitioned the United States Court of Appeals for the Fifth Circuit to review EPA's unreasonable risk determination for 1,4-dioxane, EPA's withdrawal of the TSCA Section 6(i)(1) final order in the final risk evaluation for 1,4-dioxane, and the supplement to the risk evaluation for 1,4-dioxane (*UCC v. EPA*, No. 24-60615). UCC stated

that the court has jurisdiction of these matters pursuant to TSCA Section 19(a)(1)(A), which authorizes judicial review of TSCA Section 6(i)(1) orders and "rules." UCC stated that the unreasonable risk determination and the supplement to the risk evaluation for 1,4-dioxane are rules because their determination and findings underlie the final order.

### ii. *Asbestos*

The ADAO, several scientists, and public health groups filed a petition on January 26, 2021, in the U.S. Court of Appeals for the Ninth Circuit challenging Part 1 of the asbestos risk evaluation. *Asbestos Disease Awareness Organization et al. v. EPA* (No. 21-70160). The petitioners seek review of the final risk evaluation determining the risks of certain COUs of chrysotile asbestos fibers but declining to consider the risks of other asbestos fibers, COUs, health effects, and pathways of exposure that impact public health. The parties filed a joint motion for abeyance on October 13, 2021, pursuant to an agreement with EPA for conducting Part 2 of its risk evaluation of asbestos (Legacy Uses and Associated Disposals of Asbestos). The court granted the parties' motion on October 28, 2021. On October 23, 2024, EPA filed a status report, noting that it released a white paper on August 2, 2023, titled "White Paper: Quantitative Human Health Approach to be Applied in the Risk Evaluation for Asbestos Part 2 – Supplemental Evaluation including Legacy Uses and Associated Disposals of Asbestos." Comments on the white paper were due October 2, 2023.

EPA provided the white paper, final questions identifying the scientific and technical issues on which EPA would like feedback, and public comments received by October 2, 2023, to peer reviewers for consideration. EPA received the peer reviewers' comments on December 26, 2023, and considered them in its development of the Part 2 risk evaluation for asbestos, a draft of which was released for public comment on April 16, 2024. EPA's next status report is due **April 7, 2025**. More information on the Part 2 draft risk evaluation is available in our April 29, 2024, memorandum.

## g. *Prioritization*

In October 2023, EPA issued a list of 15 substances it is considering for prioritization:

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

On December 14, 2023, EPA announced that it is beginning the process to prioritize five of these substances for risk evaluation under TSCA:

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

On July 25, 2024, EPA announced it proposed high-priority substance designations for these five substances. Comments were due by October 23, 2024. More information on EPA's proposed high-priority substance designations is available in our July 29, 2024, memorandum, "EPA Begins 90-Day Comment Period on Proposed High-Priority Substance Designations for Five Chemicals." On December 18, 2024, EPA issued a notice stating "Based on the information provided in the proposed designation documents, . . . and public comments received [on the July 25, 2024, proposed rule], including information pertaining to individual chemical substances, EPA is designating the same five chemicals as High-Priority Substances for risk evaluation under TSCA."

On September 30 and October 1, 2024, EPA held a webinar in which it expanded the list of substances it would consider next for prioritization and sought public comment on which should be among the next five after the five announced on July 25, 2024. The expanded list included the following additional substances beyond those EPA identified in October 2023, and for the first time included metals:

- 1-Hexadecanol;
- 2-Ethylhexyl 2,3,4,5-tetrabromobenzoate (TBB);
- bis(2-Ethylhexyl)-3,4,5,6-Tetrabromophthalate (TBPH);

- Creosote;
- Di-n-octyl phthalate (DnOP);
- N-Nitroso-diphenylamine;
- *p,p'*-Oxybis(benzenesulfonyl hydrazide);
- *m*-Xylene;
- *o*-Xylene;
- *p*-Xylene;
- Antimony & Antimony Compounds;
- Arsenic & Arsenic Compounds;
- Cobalt & Cobalt Compounds;
- Lead & Lead Compounds;
- Long-chain chlorinated paraffins ($C_{18-20}$);
- Medium-chain chlorinated paraffins ($C_{14-17}$); and
- Bisphenol S.

On December 18, EPA announced that it is initiating prioritization for the next batch of five substances:

- 4-tert-Octylphenol;
- Benzene;
- Ethylbenzene;
- Napthalene; and
- Styrene.

We expect EPA to continue to select prioritization targets from among the extended list for prioritization as EPA moves forward. It is a bit of a surprise to see metals and metal compounds on the list. The hazards and potential exposures related to metal compounds often vary significantly depending on the properties of the compound (*e.g.*, water solubility), making a broad categorical approach a significant scientific challenge. It is also a surprise to see the chlorinated paraffins on the list, as those were the subject of PMNs in 2012 and EPA rulemaking in 2015, including a SNUR condition that "[i]t is a significant new use to manufacture the chemical substance more than 5 years." It is not clear why EPA chose those two chlorinated paraffins and not the closely related substances that were submitted at the same time.



Beyond its prioritization activities, EPA expanded use of its information gathering authorities under TSCA Sections 8(c) and 8(d). Under TSCA Section 8(c) and the implementing regulations at 40 C.F.R. Part 717, manufacturers (including importers), processors, and distributors of chemical substances must maintain "records of significant adverse reactions to health or the environment…alleged to have been caused by the substance or mixture." Regulated entities must also provide these records to EPA if requested. On December 26, 2023, EPA published such a request for records on MBOCA with a due date for submission to EPA on or before February 26, 2024. More information on EPA's request is available in our December 27, 2023, memorandum, "EPA Begins TSCA Prioritization Process for Five Chemicals, Requires Reporting on MBOCA."

It is unusual for EPA to require TSCA Section 8(c) reporting for a substance. EPA typically only reviews TSCA Section 8(c) reports during an inspection or audit. In our experience, 8(c) reports rarely provide substantive information on a substance. EPA did not explain why it expects there to be TSCA Section 8(c) reports for MBOCA, but not any of the other substances it has evaluated or intends to consider. As of November 27, 2024, EPA has not issued additional TSCA Section 8(c) requests for the remaining substances considered for prioritization or those proposed as high-priority substances.

EPA's use of its TSCA information gathering authorities provides insight on its future prioritization activities. For example, EPA's intent to initiate prioritization on five chemical substances each year suggests that the 2025 and **2026** lists may contain one or more of the remaining ten chemical substances that EPA evaluated as potential candidates for prioritization and included as part of its proposed TSCA Section 8(d) rule. We note this because entities that have those chemical substances anywhere in their supply chain (not just manufacturers) should be mindful of this and initiate data gathering and generation, as needed, well in advance of EPA's Section 6 activities.

As we discuss in more detail below, EPA intends to ban any COUs that EPA cannot conclude in its risk evaluation based on data are not an unreasonable risk. Companies should expect either to provide exposure data documenting no unreasonable risk or face a ban on the COU. Processors and users need to be mindful of this fact. Manufacturers may be responsible for the hazard data, but EPA will predict risk all the way down the supply chain and manufacturers rarely have release and exposure data related to downstream uses.

*It may be a surprise to some readers, but it is easier to commercialize in the European Union than it is in the United States — a result that negotiations over TSCA reform had hoped to avoid.*

Downstream processors and users cannot simply rely on manufacturers to represent their interests.

**4. Section 5 — New Chemical Substances**

**a. *New Chemicals Procedure Rule***

EPA published the rule in final on December 18, 2024. The final rule was largely as proposed, including EPA's proposal to make PFAS and PBTs ineligible for low volume exemptions (LVE). EPA did not void categorically existing PFAS LVEs. Time will tell if the updated rule will improve the efficiency of EPA's review of new chemicals. The final rule is effective **January 17, 2025**.

**b. *New Chemical Notice Review Case Updates***

EPA received 162 PMNs in FY 2024, down from 173 in FY 2023. Compare this total to FY 2017 (the first full FY after Lautenberg), in which EPA received 437 PMNs, and EPA's workload has dropped by 64 percent. The drop in submissions is undoubtedly partly due to the increased fees, but it is also, in our experience, a result of the unpredictable timeline and high likelihood of receiving a consent order. Our clients are reluctant to commercialize in the United States under TSCA, preferring to commercialize for non-TSCA uses or commercializing outside the United States. It may be a surprise to some readers, but it is easier to commercialize in the European Union (EU) than it is in the United States — a result that negotiations over TSCA reform had hoped to avoid.

On a positive note, EPA's pace of new chemicals reviews picked up in 2024. As we stated above, EPA completed nearly 50 percent more PMN determinations in FY 2024 as it did in FY 2023. EPA again focused on older cases — only 8 of the 137 determinations in FY 2024 were cases submitted in FY 2024. EPA also completed determinations on 6 SNUNs in FY 2024 — all on cases submitted prior to FY 2024. We expect EPA to continue to try to clear older cases. We hope this increased pace of determinations continues into 2025.

As we reported in the past, on August 2, 2023, EPA's Office of the Inspector General (OIG) issued a report on the lack of established policies for TSCA New Chemicals Review. To our knowledge, EPA still does not have written policies that assessors, both new and experienced, can use as a basis for their reviews. Such policies would aid NCD in completing reviews consistently and efficiently.

There has been sustained pressure from across the political spectrum for EPA to restart its Sustainable Futures Program (SF). We are hopeful that this effort will be successful in 2025. New staff within NCD should provide the necessary bandwidth for NCD. Updating the policies and procedures will be a key predicate to EPA updating SF training.

EPA continues to regulate effectively all PMNs that are not low hazard (over 90 percent of all cases) with orders. EPA updated its TSCA Section 5(e) order template to include additional worker notification requirements. We again urge submitters who are waiting for consent orders to review the order template so that you are aware of the bulk of the boilerplate order terms and can focus review on the specific terms for your substance. B&C encourages submitters to avoid letting orders linger.

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

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

| | | | | Determination Made; Regulated[1] | | | Determination Made; Not Regulated | No Determination Made; Completed | |
|---|---|---|---|---|---|---|---|---|---|
| FY | Submitted PMNs | Under Review | Completed PMNs | Consent Order | Not Likely Based on SNUR | Not Likely, Follow-Up SNUR | Not Likely | Invalid | Withdrawal |
| 2016 | 389 | 5 (1%) | 384 (99%) | 152 (39%) | 21 (5%) | 13 (3%) | 39 (10%) | 26 (7%) | 133 (34%) |
| 2017 | 437 | 6 (1%) | 431 (99%) | 252 (58%) | 12 (3%) | 33 (8%) | 40 (9%) | 24 (5%) | 68 (16%) |
| 2018 | 411 | 16 (4%) | 395 (96%) | 91 (22%) | 9 (2%) | 143 (35%) | 56 (14%) | 14 (3%) | 82 (20%) |
| 2019 | 188 | 8 (4%) | 180 (96%) | 72 (38%) | 14 (7%) | 38 (20%) | 28 (15%) | 18 (10%) | 10 (5%) |
| 2020 | 179 | 20 (11%) | 159 (89%) | 52 (29%) | 2 (1%) | 38 (21%) | 23 (13%) | 15 (8%) | 29 (16%) |
| 2021 | 214 | 28 (13%) | 186 (87%) | 121 (57%) | N/A | 4 (2%) | 20 (9%) | 15 (7%) | 26 (12%) |
| 2022 | 191 | 56 (29%) | 135 (71%) | 100 (52%) | N/A | N/A | 10 (5%) | 6 (3%) | 19 (10%) |
| 2023 | 173 | 97 (57%) | 76 (43%) | 59 (34%) | N/A | 1 (1%) | 9 (5%) | 2 (1%) | 5 (3%) |
| 2024 | 162 | 145 (90%) | 17 (10%) | 15 (9%) | N/A | N/A | 1 (1%) | 0 (0%) | 1 (1%) |
| Total | 2344 | 381 (16%) | 1963 (84%) | 914 (39%) | 58 (2%) | 272 (11%) | 226 (9%) | 120 (5%) | 373 (17%) |

Counts based on PMN status posted on EPA's website as of December 18, 2024 (last updated December 12, 2024). FY 2016 cases exclude approximately 249 cases that were completed prior to June 22, 2016. Totals include 122 cases submitted prior to 2016 that were reviewed after June 22, 2016.

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

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

| FY | All PMNs[1] | Under Review[1] | Consent Order | Not Likely Based on SNUR | Not Likely, Follow-Up SNUR | Not Likely | Invalid | Withdrawal |
|---|---|---|---|---|---|---|---|---|
| 2016 | 553 | 3095 | 458 | 953 | 1152 | 308 | 50 | 577 |
| 2017 | 352 | 2723 | 232 | 842 | 854 | 186 | 41 | 466 |
| 2018 | 628 | 2322 | 723 | 634 | 450 | 347 | 19 | 798 |
| 2019 | 275 | 1946 | 235 | 281 | 133 | 154 | 51 | 507 |
| 2020 | 470 | 1595 | 475 | 233 | 143 | 270 | 53 | 502 |
| 2021 | 533 | 1321 | 486 | — | 212 | 216 | 67 | 464 |
| 2022 | 640 | 934 | 572 | — | | 449 | 16 | 434 |
| 2023 | 502 | 594 | 406 | — | 406 | 310 | 29 | 367 |
| 2024 | 241 | 248 | 201 | — | — | 68 | — | 36 |

[1] As of December 18, 2024.

**Table 3. Determinations by Calendar Year**

| Determination Year | Not Likely | Not Likely Based on SNUR | Not Likely, Follow-Up SNUR | Consent Order | Total Restricted | Determinations | Percent Determinations Include Restrictions |
|---|---|---|---|---|---|---|---|
| 2016 | 29 | | | 8 | 8 | 37 | 22% |
| 2017 | 39 | | | 283 | 285 | 324 | 88% |
| 2018 | 24 | 13 | 19 | 150 | 182 | 206 | 88% |
| 2019 | 57 | 27 | 155 | 54 | 236 | 293 | 81% |
| 2020 | 24 | 17 | 88 | 106 | 211 | 235 | 90% |
| 2021 | 28 | 1 | 8 | 50 | 59 | 87 | 68% |
| 2022 | 5 | N/A | 1 | 90 | 91 | 96 | 95% |
| 2023 | 10 | N/A | 1 | 90 | 91 | 101 | 90% |
| 2024 | 11 | N/A | N/A | 124 | 123 | 135 | 92% |

N/A — Not Available. OCSPP ceased using non-order SNURs in 2021. Based on data posted on EPA's PMN website as of December 18, 2024 (last updated December 12, 2024).

### c. *Discussion of Table 1 — PMNs Submitted*

Total PMNs submitted declined again to just 162 submitted in FY 2024 (although the highest PMN case number is P-24-0193, suggesting other cases may be incomplete or additional case numbers were generated as system errors). As discussed above, EPA focused on earlier cases and only 16 FY 2024 cases have received determinations (one was withdrawn). In FY 2024, EPA completed 137 determinations as of December 12: 57 for FY 2023 cases, 59 from FY 2022 cases, and 8 from FY 2021 cases; and five submitted in FY 2018 to FY 2020. EPA will continue to struggle to review PMNs timely for some time to come as it continues to work through older cases (the "backlog").

### d. *Discussion of Table 2 — Length of Review Period*

Table 2 shows the mean number of days between "Day 1" and the final disposition of cases in each FY. EPA's improved output should improve review times, but it will still be some time before EPA has reviewed enough of the languishing cases that new cases will be reviewed timely. The average time that cases wait for a determination (across all years) is over 470 days.

EPA's PMN statistics page lists 407 cases (PMNs, SNUNs, microbial commercial activity notices (MCAN)) awaiting completion as of December 1, 2024. The majority of cases are awaiting EPA action: 219 await risk assessment and another 95 await risk management decisions. An additional 56 cases wait for submitter input during risk assessment/risk management and 56 cases await submitter response on consent orders. It is vitally important that submitters not delay review of consent orders. We urge submitters to review the consent order template in advance of receiving the order from EPA. Nearly every case will lead to an order, so there is no reason to delay review. That way, when the order arrives, you can focus on reviewing the protective conditions rather than the boilerplate and respond promptly to EPA.

### e. *Discussion of Table 3 — PMN Outcomes*

EPA has continued its practice of issuing orders on nearly every PMN. In 2024, of the 135 total determinations, 124 (92 percent) were consent orders. Only 11 were "not likely" determinations. This persistent pattern, along with EPA's justifications in its "not likely" determination documents, supports B&C's view that EPA continues to take an impermissible hazard-based approach: once EPA identifies a hazard other than low hazard for health and aquatic toxicity ("low/low" cases), EPA issues an order. About eight and a half years after enactment of the TSCA amendments, EPA has still not found a limit to what it foresees, nor does it consider how likely an exceedance is. Rather, EPA simply assumes that any uncertainty whether there may be an exceedance in the future is sufficient to conclude that the substance "may present" an unreasonable risk rather than that the substance is "not likely to present" an unreasonable risk.

Even after EPA's update to the New Chemicals regulations, it is unlikely that EPA's approach will change. At most, information provided in a PMN only changes EPA's conclusion from "insufficient information" to "may present an unreasonable risk." In either case, EPA issues an order. In our experience, once EPA identifies a hazard, that precludes a "not likely" determination by EPA.

### f. *SNURs on New Chemicals*

After proposing only one set of SNURs in 2023, NCD proposed eight batches of SNURs in 2024, covering 226 PMNs and one MCAN. Even with this progress, 179 PMNs and SNUNs with consent orders await SNUR proposals, with an average delay of 1,632 days — about three years. Two cases have been waiting since August of 2016 and an additional 40 cases have been waiting over 2,000 days. In addition, 275 cases have proposed SNURs, but await final SNUR publication, including two batches of 2019 SNURs. EPA's inability to propose and promulgate SNURs timely should be a concern for all stakeholders.

While EPA acknowledges the backlog of SNURs required under Section 5(f)(4), EPA does not appear to be prioritizing its obligation to propose order-based SNURs timely. Among the SNURs proposed in 2024, three SNUR batches were so-called "follow-on SNURs," that is SNURs for cases in which EPA did not identify unreasonable risk, but decided that someone, someday might undertake a COU that is an unreasonable risk. It is not clear why EPA prioritized proposing SNURs for those cases when EPA has so many order-based SNURs outstanding, all of which are significantly past the 90-day deadline. Delays in EPA proposing these SNURs increase the likelihood that a competitor will find a substance that is listed on the Inventory and can begin commercialization without the protective measures of an order or SNUR.

### g. *SNURs on Chevron PMNs*

On April 7, 2023, Cherokee Concerned Citizens, a community group in Pascagoula, Mississippi, filed suit in the U.S.

*Among the many uncertainties related to the* Inhance *decision is whether the decision effectively voided the SNURs for inactive PFAS that were published in final on January 11, 2024.*

Court of Appeals for the District of Columbia Circuit for review of an Order for a New Chemical Substance under TSCA Section 5 authorizing Chevron U.S.A. Inc. (Chevron) to manufacture, process, distribute in commerce, use, or dispose of certain new chemical substances. *Cherokee Concerned Citizens v. EPA* (No. 23-1096). According to the non-binding statement of issues, the plaintiffs claim that EPA's issuance of an order is arbitrary, capricious, contrary to TSCA, and not supported by substantial evidence because the new chemicals for which EPA concluded that manufacturing, processing, distribution, use, and/or disposal of the chemical presents unreasonable risk to human health or the environment.

On June 20, 2023, EPA proposed a set of SNURs — those on P-21-0144 to 0147, P-21-0148 to 0150, P-21-0152 to 0154, P-21-155 to 0158, and P-21-0160 to 0163 — the cases that are the subject of *Cherokee Concerned Citizens v. EPA* (discussed above). This set of SNURs appears to have been hastily written and proposed in advance of submission of Notices of Commencement by the PMN submitters as an attempt to prevent the commercialization of those substances by making it impossible for a manufacturer to demonstrate compliance. Among the notable features, EPA proposed voiding the exemption to submitting a SNUN if the COU is allowed in an order. With this order, EPA is effectively voiding the order because the submitter will not be able to document compliance with the SNUR conditions.

On September 20, 2024, EPA filed a motion for a voluntary remand of the *Cherokee Concerned Citizens* case. EPA states that it wishes to withdraw the order and reconsider the 18 PMNs covered by the order. According to EPA, Cherokee Concerned Citizens does not oppose EPA's request for remand but rather supports remand with vacatur. In its September 30, 2024, response, Cherokee Concerned Citizens argue that vacatur is necessary to prevent Chevron from producing the new chemicals during the withdrawal process and that EPA has provided no reason to deviate from the default remedy of vacatur. More information is available in our September 24, 2024, blog item, "EPA Moves for Voluntary Remand, Seeks to Reconsider PMNs in Cherokee Concerned Citizens." Presumably, once EPA revises the orders, EPA will either withdraw and re-propose the corresponding SNURs or issue a supplemental proposal to the current proposed SNURs to bring the SNUR proposal in line with the updated order conditions.

### h. *SNURs on Existing Chemicals*

As discussed in Section 2.a, the *Inhance* court decision in the U.S. Court of Appeals for the Fifth Circuit undermined significantly EPA's ability to regulate existing chemicals with a SNUR. The court concluded that "new" means "new," not simply that the COU is not ongoing at the time the SNUR is proposed. One interpretation of the court's decision is that EPA may not issue a SNUR for any COU that occurred in the past, even if it is not occurring at the time the SNUR is proposed. Among the many uncertainties related to the *Inhance* decision is whether the decision effectively voided the SNURs for inactive PFAS that were published in final on January 11, 2024. The question is whether these SNURs will remain on the books or if a party may find standing to challenge one or more of the rules. We still believe a SNUR for uses that are not ongoing is an appropriate, protective use of EPA's SNUR authority. Time will tell if the Fifth Circuit's decision will be the controlling interpretation or if another case modifies, clarifies, or reverses the decision.

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

COUs that are not ongoing, EPA both protects against the risks that may arise from those COUs and limits the COUs that must be evaluated in the scope of the risk evaluation. EPA plans to issue the final SNURs on the flame retardants TCEP, TBBPA, and TPP in **October 2025**, according to the Fall 2024 Regulatory Agenda (2070-AL07). EPA may defer indefinitely publishing the SNURs in final due to the *Inhance* decision.

Additionally, as reflected in the Fall 2024 Regulatory Agenda, EPA planned to propose SNURs for non-ongoing uses for certain existing chemicals. EPA expects to propose SNURs for phthalates in **February 2025** (2070-AL06), for solvents in **March 2025** (2070-AL08), and certain other chemicals in **March 2025** (2070-AL05). As with the approach taken in the proposed SNURs for the flame retardants discussed above, we expect that the actions will include as significant new uses manufacture (including import) or processing for any use, except for COUs that EPA expects to consider within the scope of the TSCA Section 6 risk evaluations. It is not clear how the *Inhance* decision may affect these plans.

Older SNURs, such as those proposed for nonylphenols and nonylphenol ethoxylates and toluene diisocyanates, remain in the proposal stage. Given EPA's many other priorities and the *Inhance* decision, these SNURs may remain as proposed rules for the foreseeable future.

#### i. *SNURs on Uncommenced PMNs*

On November 29, 2024, EPA issued a Supplemental Notice of Proposed Rulemaking proposing dead-chemical SNURs on 17 uncommenced PFAS PMNs with consent orders. In this set, EPA is proposing any use as a significant new use. As with the Chevron PMNs, EPA proposes voiding the SNUN exemption for companies that hold an order. As a result, the original PMN submitter(s) would be required to submit SNUNs and receive EPA approval prior to any commercial manufacture or import regardless of the terms of the original order. It is not clear how the PMN submitters may respond to this supplemental proposed rule.

### 5. Section 4(a) — Testing and Test Orders

#### a. *High-Priority Substances Undergoing Risk Evaluation*

The TSCA test orders that EPA issued in 2021 and 2022 are likely nearing completion, although EPA has kept the dermal hand wipe sampling testing suspended despite a validated protocol for the testing. Although EPA has not publicized its decisions, some test order recipients report to us that EPA has stated that the ordered testing has been satisfied.

The judicial appeal of a test order from the Vinyl Institute for 1,1,2-trichloroethane resulted in the court remanding the order to EPA to supplement the record (discussed in more detail below). The appeal filed by the TDCE Consortium for the *trans*-1,2-dichloroethylene (TDCE) test order is still pending.

EPA has slowed its pace of issuing test orders. In 2024, EPA only issued orders under its PFAS testing strategy. TSCA test order consortia managed by B&C® Consortia Management, L.L.C. (BCCM) continue to engage with EPA regarding potential testing.

#### b. *National PFAS Testing Strategy*

On February 21, 2024, EPA published its final rule on "*Fees for the Administration of the Toxic Substances Control Act (TSCA)*" and stated that its TSCA Section 4 program costs will include the initiation of approximately ten test orders between FY 2024 and **FY 2026** on PFAS per EPA's implementation of the National PFAS Testing Strategy. B&C notes that EPA's National PFAS Testing Strategy is focused on identifying PFAS that lack toxicity data and have an identifiable manufacturer to whom EPA could issue a test order. We were surprised when EPA subsequently issued test orders on two PFAS with robust data sets on the individual substances or on suitable toxicological analogs/degradants, as discussed below.

#### i. *2-(N-Methylperfluoro-1-octanesulfonamido) ethanol (NMeFOSE) (CAS RN 24448-09-7)*

On March 20, 2024, EPA issued a TSCA Section 4(a)(1) test order on NMeFOSE. The ordered testing focused on physicochemical properties, environmental fate, and health effects. EPA provided background information on NMeFOSE, noting that its expected biotransformation includes *N*-dealkylation of the *N*-methyl group and several subsequent steps that ultimately lead to the formation of perfluorooctane sulfonic acid (PFOS; CAS RN 1763-23-1) and hydroxylamine (CAS RN 7803-49-8).

EPA's position on the expected biotransformation of NMeFOSE is consistent with Health Canada's (HC) findings in its 2006 assessment titled "*Perfluorooctane Sulfonate, Its*

*Salts and Its Precursors that Contain the $C_8F_{17}SO_2$ or $C_8F_{17}SO_3$ Moiety*." HC stated that:

> Since PFOS is likely the ultimate perfluorinated degradation or metabolic product of the group of substances listed in Appendix 1 [including NMeFOSE], the level of this compound [*i.e.*, PFOS] in human tissue provides a useful indicator of exposure to this group of substances from all potential sources.

HC also compared the available toxicity data on PFOS with the identified PFOS precursors and found that:

> Available data indicate that effects associated with the PFOS precursors occur at exposures that are similar to or slightly higher than those for PFOS.

HC provided data tables on a series of PFOS precursors, including N-ethylperfluorooctane sulfonamidoethanol (NEtFOSE, CAS RN 1691-99-2). NEtFOSE is a close analog to NMeFOSE and differs from NMeFOSE only by the presence of an *N*-ethyl group ($-CH_2CH_3$), rather than an *N*-methyl group ($-CH_3$). NEtFOSE also has an extensive toxicological database, including, for example, acute oral and inhalation toxicity studies, subchronic and chronic oral toxicity studies, and reproductive and developmental toxicity studies.

Given that EPA has a close analog to NMeFOSE (*i.e.*, NEtFOSE) and PFOS is a primary degradant of both NMeFOSE and NEtFOSE, it is not clear why EPA issued a test order on NMeFOSE. EPA could have informed its evaluation of the potential hazards for NMeFOSE with the available data on NEtFOSE and its recent in-depth evaluation of PFOS. If EPA had aligned its evaluation in a manner comparable with that of HC, this would have freed up resources within EPA to focus its TSCA Section 4(a)(1) test order activities on those PFAS with limited data sets and no suitable analogs. In addition, there have been no companies that have reported manufacture or import of NMeFOSE to Chemical Data Reporting (CDR) in many years (in 2012, 2016, or 2020), making identifying a target company a significant challenge. More information on EPA's NMeFOSE test order is available in our April 22, 2024, memorandum, "EPA Issues Fourth TSCA Test Order for PFAS."



### ii. *3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl prop-2-enoate (a.k.a., 6:2 fluorotelomer acrylate, 6:2 FTAc; CAS RN 17527-29-6)*

On October 8, 2024, EPA issued a TSCA Section 4(a)(1) test order on 6:2 FTAc. As with the test order on NMeFOSE, EPA ordered testing on physicochemical properties, environmental fate, and health effects. EPA also summarized the anticipated biotransformation of 6:2 FTAc as follows:

> The biotransformation pathway of 6:2 FTAc includes hydrolysis of the ester linkage to form 6:2 fluorotelomer alcohol (FTOH), degradation of 6:2 FTOH to perfluorohexanoic acid (PFHxA) and other short-chain perfluoroalkyl carboxylic acids (PFCAs) as stable transformation products.

There are publicly available robust study summaries on 6:2 FTAc on ECHA's registered substances database that address nearly all of the ordered testing requirements. There is also a toxicological evaluation on 6:2 FTOH published in the peer-reviewed literature (Serex *et al.*, 2014) and EPA's 2023 toxicological review on PFHxA and related salts on EPA's Integrated Risk Information System (IRIS) database (IRIS, 2023). Further, scientists from the U.S. Food and Drug Administration (FDA) have published studies on the pharmacokinetics and biopersistence of 6:2 FTOH and its metabolites (Kabadi *et al.*, 2018) and comparative analyses of the toxicological databases on 6:2 FTOH and PFHxA (Rice *et al.*, 2020). These authors concluded that:

> 6:2 FTOH is significantly more toxic than PFHxA. Use of toxicological studies conducted with PFHxA to assess 6:2 FTOH exposure may significantly underestimate human health risk.

FDA's conclusions have, however, been contested by other scientists (Anderson *et al.*, 2020). EPA did not opine on the comparative toxicity of 6:2 FTAc, 6:2 FTOH, or PFHxA, rather it simply stated that it "identified hazards for potential carcinogenic and toxic effects [for 6:2 FTAc]...and related concerns for health effects from its biotransformation products, including PFHxA."

We mention the availability of this information because it is unclear how EPA made its determination that there

is insufficient information to predict the effects of the chemical substance if EPA did not evaluate the available information on the chemical substance and its potential metabolites/degradation products. For example, EPA does not discuss or cite any of the referenced sources on 6:2 FTOH or PFHxA in the test order and dismissed the ECHA data by stating that:

> While the records retrieved summarized experimental findings, the underlying study reports and data were unavailable for review. Thus, the robust study summaries obtained from ECHA for review were unable to meet the data needs of this Order.

EPA also dismissed two 28-day subacute oral toxicity studies on 6:2 FTAc in rats stating that:

> The robust study summaries reported a 28-day oral exposure to 6:2 FTAc increased Sprague-Dawley rat liver and kidney size with numerous histopathological and hematological effects. Further, this 28-day study in female and male Sprague-Dawley rats, provided as a robust study summary, also reported behavioral effects, specifically reduced spontaneous locomotion in both sexes and more frequent defecation by males following administration of 6:2 FTAc. While the records retrieved summarized experimental findings, the underlying study reports and data were unavailable for review.

B&C reviewed the ECHA robust study summaries on the 28-day subacute oral toxicity studies in rats, which have report dates of 2007 and 2014. We note for comparison that EPA posted sanitized copies of full study reports on two 28-day subacute oral toxicity studies in rats with study completion dates of 2007 and 2014 on its ChemView database. These studies were submitted to EPA on December 7, 2023. EPA does not mention or cite the full study reports from ChemView in the test order, yet it cites other sources from 2024 (*see, e.g.*, Ye *et al.*, 2024). We found this odd given that EPA stated that queried toxicity sources on 6:2 FTAc included EPA's Chemical Information System (CIS), "an internal platform for managing data submissions under TSCA, including toxicity studies."

B&C mentions these issues as cautionary notes to test order recipients. EPA's development of these documents to date support a less-than-robust level of effort by EPA to identify reasonably available information, including information already in EPA's possession and control. Litigation on other TSCA Section 4(a) test orders may hold EPA accountable for a higher level of rigor.

### c. *Section 4(a) Test Order Litigation*

#### i. *1,1,2-Trichloroethane*

On July 5, 2024, the U.S. Court of Appeals for the District of Columbia Circuit issued its decision in *Vinyl Institute v. EPA* (No. 22-1089). In 2022, Vinyl Institute filed suit against EPA, seeking review of EPA's March 2022 test order for 1,1,2-trichloroethane issued under TSCA Section 4(a)(2). In its decision, the court states that "EPA's non-public part of the administrative record is not part of 'the record taken as a whole' subject to our heightened substantial evidence review of TSCA test orders." According to the court, to the extent EPA relies on non-public portions of the administrative record, it "has failed to provide substantial evidence that meets its statutory mandate." The court vacated the test order, remanding to EPA to satisfy that mandate with "substantial evidence in the record taken as a whole." The court also denied Vinyl Institute's motion to supplement the record "with scientific information it could have — and should have — submitted earlier." More information on the court's decision is available in our July 10, 2024, blog item.

#### ii. *6:2 FTSB*

National Foam, Inc. filed suit in the U.S. Court of Appeals for the District of Columbia Circuit on August 15, 2022, seeking review of a TSCA Section 4(a)(2) test order for 6:2 FTSB (6:2 fluorotelomer sulfonamide betaine), a PFAS. *Nat'l Foam v. EPA*, No. 22-1208. According to an August 30, 2024, status report, "[a]s of this filing, Tier 1 testing is now complete. As provided in the Test Order, EPA is currently working to determine whether it is appropriate to proceed to the Tier 2 testing requirements." Because National Foam received an exemption from the test order requirements, National Foam will be required to compensate the data owners and test sponsors for any exempted testing requirements. The next status report was due December 27, 2024.

*EPA expanded its use of new approach methodologies on its assessment of existing chemicals, including the draft risk evaluation for TCEP.*

**iii. *TDCE***

On August 22, 2022, the TDCE Consortium filed a lawsuit challenging the TSCA Section 4(a)(2) test order for TDCE to protect its legal interests while waiting for EPA's conclusion about the need for toxicity testing on sediment-dwelling organisms. The lawsuit, *TDCE Consortium v. EPA*, No. 22-1216, was voluntarily stayed while the TDCE Consortium continued its negotiations with EPA and completed feasibility testing for the ordered sediment-toxicity studies (*i.e.*, OECD 219 "*Sediment-Water Chironomid Toxicity Using Spiked Water*" and OECD 233 "*Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment*"). The TDCE Consortium provided EPA an amended final report of the feasibility testing in September 2024. On November 20, 2024, EPA posted an entry to the docket titled "*Extinguishing memo for OECD 219 and OECD 233 TDCE Test Order requirements*." As of December 16, 2024, EPA has not posted the supporting documents for these entries.

**d. *Section 4(h) — NAMs***

On January 9, 2024, EPA announced the availability of a decision framework for identifying eye irritation or corrosion hazards for new chemicals reviewed under TSCA. EPA states that the "*New Chemicals Program Decision Framework for Hazard Identification of Eye Irritation and Corrosion*" provides a decision framework for use by OPPT's NCD to identify eye irritation or corrosion hazards for new chemical substances based on prioritization of reproducible, human-relevant data.

EPA also expanded its use of new approach methodologies (NAM) on its assessment of existing chemicals, including the draft risk evaluation for TCEP. EPA used for the first time in a TSCA risk evaluation the Web-based Interspecies Correlation Estimation (Web-ICE) to predict acute toxicity values in aquatic species not evaluated in experimental studies. These predictions were then used with empirical data to generate species sensitivity distributions (SSD). The letter peer-reviewers for the draft risk evaluation for TCEP were generally in agreement with EPA's use of Web-ICE. One reviewer noted, however, that "[i]t is likely that TCEP falls into the category of very polar general narcosis toxicants. Thus, models like Web-ICE are likely to underestimate their toxicities."

Finally, EPA has been employing the Open (Quantitative) Structure-activity/property Relationship App (OPERA v2.9) to generate physicochemical property estimates on its PFAS test orders, including NMeFOSE and 6:2 FTAc. EPA has not provided a justification for using OPERA versus its standard software for these estimates (*i.e.*, The Estimation Programs Interface [EPI] Suite™). It may be that EPA concluded internally that OPERA is better at estimating physicochemical properties of PFAS than EPISuite™.

We applaud EPA's commitment to advancing the use of NAMs in its TSCA activities. We urge EPA to update its list of NAMs per TSCA Section 4(h)(2)(C) with its eye irritation and corrosion framework, Web-ICE, or OPERA. EPA last updated the list of NAMs on February 4, 2021, despite its commitment to updating the list of NAMs at least once a year.

**6. Sections 8 and 14 — Reporting and Confidential Information**

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

The TSCA Section 8(a)(7) rule on the PFAS reporting window was set to open after the CDR reporting period closed. The rule requires companies that manufactured and imported PFAS during a 12-year look-back period extending from January 1, 2011, through December 31, 2022, to report identity, quantity, and COU information to EPA. The only exemption provided in the rule was for companies that imported municipal solid waste for disposal. The absence of exemptions makes this reporting rule particularly vexing. Potential

PODCAST:
TSCA Section 8(a)(7) PFAS Reporting Rule — A Conversation with Richard E. Engler, Ph.D.

reporters received some welcome relief when EPA extended the reporting window due to technical difficulties building the reporting tool in the Central Data Exchange (CDX).

EPA delayed the beginning of the reporting period to **July 11, 2025**, and reporting is due by **January, 11, 2026**. Small businesses that only imported articles have an additional six months to report.

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

### b. *Section 8(a) — Asbestos Reporting Rule*

EPA published a final TSCA Section 8(a) rule in 2023 that required reporting and recordkeeping for asbestos by May 24, 2024. Given that the asbestos Part 1 rule is now final, it is not clear how that data will be used. EPA had stated that it and other federal agencies will use reported information in considering potential future actions, including risk evaluation and risk management activities.

### c. *Section 8(a) — Chemical Data Reporting Rule*

On June 22, 2023, EPA announced the start of the 2024 CDR reporting period (88 Fed. Reg. 40816). For the first time in recent history, EPA declined to propose changes to CDR reporting. The 2024 CDR reporting cycle began on June 1, 2024, and was scheduled to close September 30, 2024. This decision relieved EPA of the burden of another rulemaking and will reduce the need for reporters again to adapt their approach to reporting. EPA extended the reporting deadline to November 22, 2024, due to technical difficulties with the CDX CDR portal.

In 2025, we expect that EPA will again review CDR data for significant changes in reporting and may again contact submitters noting such changes. Such contact should not be viewed as EPA alleging CDR violations, although there is such an implication. These contacts are likely meant to be friendly inquiries, but CDR reporters should be cognizant of the implications of amending CDR submissions.

PODCAST:
Asbestos Reporting Rule — A Conversation with Richard E. Engler, Ph.D.

### d. *Procedures for Submitting Confidential Business Information*

On June 7, 2023, EPA published the final confidential business information (CBI) procedure rule. The rule addresses several issues related to TSCA CBI under the Lautenberg amendments to TSCA and has significant implications for submitters and their ability and obligations to make and sustain CBI claims across all types of submissions. On June 20, 2023, EDF filed suit in the U.S. Court of Appeals for the D.C. Circuit, asking the court to review EPA's rule. *EDF v. EPA* (No. 23-1166). EDF's statement of issues, filed on August 21, 2023, includes the following claims for why the final rule is arbitrary, capricious, an abuse of discretion, or otherwise contrary to law: it would allow submitters to assert CBI claims to shield the information from the public that TSCA makes categorically ineligible for CBI protection; it would not require substantiation or EPA review of a CBI claim that was asserted before a chemical's commercialization, for specific chemical identity, once the chemical is commercialized; it unlawfully adopts a regulatory definition of "health and safety study" that is narrower than TSCA's definition, denying TSCA-mandated public access to important information on chemicals; EPA purports to give itself unlawfully broad discretion through its regulations where TSCA imposes a duty on it; and it reduces the transparency previously required under EPA's CBI review procedures without adequate justification. The court consolidated EDF's suit with one filed by ACC and the American Fuel and Petrochemical Manufacturers (AFPM). *ACC v. EPA* (No. 23-1204). The court heard oral argument on September 24, 2024.

### e. *EPA Review of Confidential Business Information*

EPA continued in 2024 its review of CBI. According to EPA's TSCA CBI Review Statistics website, EPA has received 21,544 CBI claims, including 9,105 CBI claims for chemical identity. EPA has completed 9,918 claims, approving 6,243, denying 2,687, and partially approving 988 claims. In addition, EPA found 5,689 cases that did not require review (*e.g.*, all claims were exempt from substantiation or were withdrawn by the submitter). This is an extraordinary level of effort by EPA and we hope that stakeholders appreciate how hard EPA is working. That is not to say that all stakeholders agree with EPA's determinations regarding a CBI claim, but EPA is definitely reviewing CBI claims and taking steps to declassify information that is not eligible for CBI protection.

EPA has also posted an update on its declassification page. On May 23, 2024, EPA published a list of 1,109 substances

that were moved from the CBI portion of the Inventory to the public portion. These declassifications may be due to CBI review during a submission (*e.g.*, a Notice of Activity or CDR report) or from voluntary withdrawals. In any case, it represents a significant increase in transparency for TSCA stakeholders. We expect the 2024 CDR reporting to lead to another substantial batch of declassifications.

### f. *Unique Identifier Implementation*

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

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

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

In addition to the declassification efforts discussed above, EPA continues to issue UIDs for substances on the TSCA Inventory. The confidential portion includes 861 UIDs (some of which include CBI claims approved in 2023), while the public portion includes 81 UIDs. These 81 cases had been assigned a UID when the identity was CBI, but the identity has since been declassified and moved from the confidential portion to the public portion of the Inventory.

Together, these statistics are a good indicator that EPA continues to make progress toward the openness that Congress contemplated in the Lautenberg amendments.

WEBINAR ON DEMAND

There Is More to TSCA Reporting Than CDR: TSCA Sections 8(a), (c), (d), and (e), featuring Dave Turk and Stephanie Griffin from EPA OPPT

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

As we expected, EPA proposed another Section 8(d) data call-in (DCI) to inform EPA's prioritization efforts. On March 26, 2024, EPA issued a proposed rule under TSCA Section 8(d) on the 15 substances it announced in October 2023 as considerations for prioritization, including a transformation product of 6PPD. EPA published the rule in final on December 13, 2024. The final rule requires manufacturers (including importers) of the 16 chemical substances as neat substances, in mixtures, or in articles, at any level to submit to EPA copies and lists of unpublished health and safety studies that contain any of the specified substances at any level. Notable in the rule proposal is that EPA provided no *de minimis* threshold and no exemption if one of the substances was present as an impurity in another test substance. It is not clear to us how a study on a substance that contains, for example, 0.1 percent of benzene, would provide EPA meaningful information on the hazards of benzene (rather than the actual test substance). More information on EPA's proposed rule is available in our April 5, 2024, memorandum, "EPA Proposes to Require Submission of Health and Safety Studies for 16 Chemicals Being Considered for TSCA Risk Evaluation." More information on the final rule is available in our December 23, 2024, memorandum, "EPA Requires Submission of Health and Safety Studies for 16 Chemicals Being Considered for Risk Evaluation under TSCA."

### h. *TSCA Section 8 Tiered Data Reporting Rule*

EPA has again deferred proposing the TDR rule. The Fall 2024 Regulatory Agenda lists the proposal as being planned for **June 2025**, with a final rule in **November 2026** (2070-AK62).

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

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

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

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

Until TDR is in place, we expect EPA to continue to rely upon Section 8(c) and 8(d) rules to gather existing data to inform its prioritization, risk evaluation, and risk management activities.

### 7. Section 26 — Administration of TSCA; Fees Rule

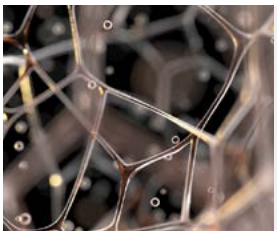
On February 8, 2024, EPA announced its final amendments to the 2018 final rule that established fees for the administration of TSCA. The effective date of the final rule was April 22, 2024.

EPA states that it calculated fees by estimating the total annual costs of carrying out relevant activities under TSCA Sections 4, 5, and 6 (excluding the costs of MRRE) and conducting relevant information management activities under TSCA Section 14; identifying the full cost amount to be defrayed by fees under TSCA Section 26(b) (*i.e.*, 25 percent of those annual costs); and allocating that amount across the fee-triggering events in TSCA Sections 4, 5, and 6. EPA notes that in addition, it affords small businesses an approximately 80 percent discount, in accordance with TSCA Section 26(b)(4)(A).

EPA established the following final fees for small- and non-small businesses:

| Fee Category | Small Business Fees | Non-Small Business Fees |
|---|---|---|
| Test Order | $5,000 | $25,000 |
| Test Rule | $10,000 | $50,000 |
| Enforceable Consent Agreement (ECA) | $10,000 | $50,000 |
| PMN and Consolidated PMN, SNUN, MCAN, and consolidated MCAN | $6,480 | $37,000 |
| Low Exposure/Low Release Exemption (LoREX), LVE, Test-Marketing Exemption (TME), Tier II exemption, TSCA Experimental Release Application (TERA), Film Articles | $2,180 | $10,870 |
| EPA-Initiated Risk Evaluation | $857,400 | Two payments resulting in $4,287,000 |
| MRRE on a Chemical included in the TSCA Work Plan | Reduced fees not available | Two payments of $1,414,924, with final invoice to recover 50% of actual costs |
| MRRE on a Chemical not included in the TSCA Work Plan | Reduced fees not available | Two payments of $2,829,847, with final invoice to recover 100% of actual costs |

It remains unclear whether the statute gives EPA the authority to charge fees greater than 25 percent of its appropriation or actual costs. If EPA's interpretation that it can charge 25 percent of the costs it predicts for its reviews, regardless of how much EPA actually expends (from both fees and appropriated funds) holds, it seems to be a recipe for EPA to set the cost ceiling to nearly any value. It will be some time before the additional revenue will improve EPA's performance because EPA will not collect any risk evaluation fees until EPA completes prioritization and risk evaluation scopes of additional substances (likely in **late 2025** or **early 2026**). The Section 5 submissions received after the fee rule was final represents about an additional $1-$1.5 million dollars (assuming a mix of large and small businesses), but that revenue will take some time to manifest as additional support.



*EPA's exclusion of "other interpretations" or "alternative opinions" is troubling and creates an appearance that EPA had an impermissible "pre-determined desired outcome."*

## 8. Section 26 — Scientific Standards

### a. *Scientific Integrity*

On January 24, 2024, EPA began a 30-day public comment period on the draft updates to its Scientific Integrity Policy (Policy). 89 Fed. Reg. 4606. EPA states that in accordance with the requirements of the 2021 *Presidential Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-based Policymaking*, it is revising its Policy. The updated Policy will adopt a new federal definition of scientific integrity and "meaningfully strengthen several policy elements that will help ensure a culture of scientific integrity at the Agency." EPA notes that it will incorporate the model scientific integrity policy from the National Science and Technology Council's *A Framework for Federal Scientific Integrity Policy and Practice* (2023), lessons learned over the years, and the results of previous surveys of EPA staff on scientific integrity.

The Policy includes multiple intended policy positions for EPA's decision-making, including, for example, "Ensure[ing] peer review charge questions address all relevant scientific questions, including those raised in DSOs, and are free from any interference, especially interference that may inappropriately limit the scope of the review." Public comments on the Policy were due to EPA by February 23, 2024. As of December 19, 2024, EPA has not issued the Policy in final.

There are representative examples under TSCA of how EPA has or has not complied with the intended policy positions in the Policy. For example, on July 1, 2024, EPA announced the release of the draft risk evaluation for 1,1-DCE and the draft human health hazard assessment supporting the draft risk evaluation for 1,2-DCE (also known as ethylene dichloride) prepared under TSCA Section 6. EPA transparently stated in the 1,1-DCE assessment under the Acknowledgements section (lines 996-1010) and as an Additional Note (lines 1131-1145) under the Executive Summary that "there are some significant aspects of the draft 1,1-dichloroethane risk evaluation and the draft 1,2-dichloroethane human health hazard assessment technical support document for which there is not agreement between ECRAD [Existing Chemicals Risk Assessment Division] and senior scientists and technical experts." EPA stated the same concern nearly verbatim under the Summary (lines 232-246) of the 1,2-DCE assessment. EPA also included the DSOs as part of the draft charge questions to the TSCA SACC. Raising the DSOs publicly is vital for EPA to ensure that the public has an opportunity to weigh in on vital scientific issues. Doing so puts EPA in a much more solid footing for its risk evaluations and risk management rules.

The above examples for 1,1-DCE and 1,2-DCE are commendable and supportive of EPA's commitment with meeting the scientific standards under TSCA Section 26 and ensuring the integrity of its scientific decision-making. EPA's activities on formaldehyde are, however, less commendable and appear to involve lapses in scientific integrity. On August 9, 2023, NASEM released its report titled "*Review of EPA's 2022 Draft Formaldehyde Assessment (2023)*." NASEM noted in its report, which EPA sponsored, that:

> The committee…was not charged with commenting on other interpretations of scientific information relevant to the hazards and risks of formaldehyde, nor did its statement of task call for a review of alternative opinions on EPA's formaldehyde assessment.

EPA's exclusion of "other interpretations" or "alternative opinions" is troubling and creates an appearance that EPA had an impermissible "pre-determined desired outcome." EPA's statement of task also suggests that it may have inappropriately limited the scope of NASEM's review. Further, EPA did not take steps to address this apparent lapse when it issued the draft risk evaluation for formaldehyde. For example, EPA stated the following in its charge questions to the TSCA SACC on the draft risk evaluation for formaldehyde:

> Although OPPT is not soliciting comment on the cancer inhalation unit risk (IUR), this value is important in the characterization of risk for occupational, consumer, outdoor and indoor air pathways. As such, the SACC may comment on the use of the cancer IUR value for characterization of risk, including its strengths and uncertainties.

EPA's charge questions did not address all relevant scientific questions. For example, EPA did not solicit input from the TSCA SACC on the carcinogenic mode of action (MOA) for formaldehyde. Rather than soliciting the TSCA SACC's input, which seems warranted given the evaluations of other organizations, such as WHO and ANSES that concluded formaldehyde is a threshold carcinogen, EPA simply adopted the IRIS draft linear low-dose (*i.e.*, non-threshold) approach. EPA's apparent lack of interest in NASEM and the SACC's input on the MOA appears to suggest that EPA has already made a key conclusion about formaldehyde and no longer seeks outside input. This course of action appears to fail to meet the standard in EPA's new (albeit draft) scientific integrity standards.

**b. *Multiple-Path Particle Dosimetry***

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

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

**c. *Scientific Challenges***

On December 14, 2023, the American Cleaning Institute (ACI) and ACC submitted a request for correction of information (RFC) to EPA under the Information Quality Act (IQA) on EPA's final risk evaluation for 1,4-dioxane. The focus of the RFC was on "[EPA's] decision to utilize a linear low-dose extrapolation (*i.e.*, no threshold) for assessing potential carcinogenic risks from exposures to 1,4-DX… [and EPA's conclusion that the] carcinogenic 'mode of action (MOA) is unknown or unclear.'" The submitters expressed concern that EPA failed to meet the IQA requirements and the scientific standards under TSCA Section 26 for best available science and weight of scientific evidence.

On April 16, 2024, EPA unsurprisingly denied the request. EPA's denial response was not substantive, however. EPA concluded that the appropriate mechanism for raising the issues in the RFC was during the public comment period rather than through a separate mechanism under the RFC process. We note, however, that the RFC process is typically pursued by submitters when an agency fails to fulfill its legal obligation to "consider and respond to significant comments received during the period for public comment."

On July 12, 2024, ACI and ACC submitted a request for reconsideration (RFR) of EPA's decision to deny the RFC. As of December 19, 2024, EPA has not posted a response to the RFR. B&C notes that the advantage of filing an RFR is that RFRs are reviewed by an executive panel external to the office that developed the information in question (*i.e.*, OPPT), including the Science Advisor/Assistant Administrator for EPA's ORD, the Chief Information Officer/Assistant Administrator for the Office of Environmental Information, and the Economics Advisor/Assistant Administrator for the Office of Policy, Economics and Innovation.

B&C notes that EPA's response on the above RFC is representative of EPA's responses on previous RFCs on TSCA risk evaluations (*e.g.*, NMP and carbon tetrachloride) and most likely representative of how EPA intends to respond to future RFCs. EPA stated in March 2023 that it will address RFCs during the risk management rulemaking process. We note that EPA's plan contradicts its own IQA guidelines, which state in part, "In cases where the Agency disseminates a study, analysis, or other information prior to the final Agency action or information product, it is EPA policy to consider requests for correction prior to the final Agency action …."

We note also that regulated entities should not be swayed by EPA's sweeping denial responses. We mention this because RFCs represent an important approach for exhausting administrative remedies and building a record if legal challenge is required on EPA's promulgated risk management rules. One possible interpretation of Section 6 is that EPA's risk management rule must be based on the risks identified in the risk evaluation and risk determination. In this case, it would be impermissible for EPA to change its risk evaluation or risk determination as part of its risk management action, so addressing a RFC on a risk evaluation and/or risk determination could not be cured during risk management.

### 9. Section 21 — Petitions and Related Litigation

On June 10, 2024, the U.S. Court of Appeals for the Fourth Circuit affirmed the U.S. District Court for the Eastern District of North Carolina's decision to dismiss a case challenging EPA's response to a TSCA Section 21 petition seeking a test order for 54 PFAS for lack of jurisdiction. *Center for Environmental Health (CEH) v. EPA*, No. 23-1476. The district court granted EPA's motion to dismiss, finding that EPA granted the 2020 petition and that the court lacks jurisdiction to review such a grant. The appellate court affirmed the decision, with one judge concurring in part and dissenting in part. Petitioners claimed that two aspects of EPA's decision make it an effective denial of their petition: EPA chose to test PFAS as a class rather than individually and to use its own testing protocols instead of the program proposed by the petitioners. According to the court, not only did EPA not effectively deny petitioners' petition by not adopting their proposed testing program, "by promptly commencing a proceeding for determining how to best test PFAS, the EPA gave Petitioners all that they were entitled to receive." One judge concurred with the majority opinion's determination that EPA properly granted the petition with respect to the 39 PFAS that fell with the 6,504-member group of PFAS defined by EPA's National PFAS Testing Strategy. The judge stated that EPA's decision not to include within that group 15 of the PFAS set forth in the petition rendered its decision a partial denial subject to de novo review, however, and dissented as to the portion of the majority opinion that concludes EPA granted the TSCA Section 21 petition regarding the 15 excluded chemicals. More information on the decision is available in our June 11, 2024, blog item.

On January 4, 2024, the Washington Department of Ecology (WDOE) submitted a TSCA Section 21 petition seeking a rulemaking to eliminate the current allowances for PCBs in consumer products. WDOE states that its research found that when PCBs are found in consumer products, "they are byproducts known to be associated with pigments, paints, or inks used in the manufacturing process." According to WDOE, "[t]hese inadvertent PCBs currently allowed under TSCA directly expose people and contribute to PCB contamination in the environment."

ARTICLE
"Optimizing TSCA's Potential to Reduce Plastic Waste," *ABA NR&E*, Spring 2024

On April 9, 2024, EPA denied WDOE's petition, stating that "the petitioner has not provided adequate justification — based on the rulemaking process and record for the 1984 final rule and information provided or otherwise available to the Agency — to support reassessing the limits on allowable inadvertent PCBs in consumer products." 89 Fed. Reg. 24824. EPA "finds that the petition is insufficiently specific, and that the petitioner did not meet their burden under TSCA of establishing that it is necessary to amend the 1984 final rule." More information is available in our April 8, 2024, blog item.

Following the Fifth Circuit's March 2024 decision vacating EPA's December 2023 orders prohibiting Inhance Technologies, L.L.C. from manufacturing or processing PFAS during its fluorination process, on April 11, 2024, a coalition of public health groups filed a TSCA Section 21 petition seeking to stop immediately the manufacture and distribution of "hundreds of millions of plastic containers with dangerous levels of per- and polyfluoroalkyl substances (PFAS) that leach from these containers into household products and the environment." Petitioners asked EPA to use its TSCA Section 6 authority to prohibit the production of perfluorooctanoic acid (PFOA), perfluorononanoic acid (PFNA), and perfluorodecanoic acid (PFDA) during this fluorination process. EPA announced on July 11, 2024, that it granted the petition and "will promptly commence an appropriate proceeding under TSCA Section 6."

On September 30, 2024, EPA requested information on the manufacture of PFAS, including PFOA, PFNA, and PFDA, during the fluorination of high-density polyethylene (HDPE) and other plastic containers, including the number, location, and uses of fluorinated containers in the United States; alternatives to the fluorination process that generates PFOA, PFNA, and PFDA; and measures to address risk from PFOA, PFNA, and PFDA formed during the fluorination of plastic containers. 89 Fed. Reg. 79581. Comments were due November 29, 2024. More information on the petition is available in our July 16, 2024, memorandum, "EPA Grants TSCA Section 21 Petition Seeking Section 6 Rule Prohibiting Three PFAS Found in Fluorinated Plastic Containers." More information on the request for information is available in our October 9, 2024, memorandum, "EPA Seeks Public Comment on Manufacture of Certain PFAS during Fluorination of HDPE and Other Plastic Containers."

Although EPA granted the Section 21 petition, on July 25, 2024, CEH and Public Employees for Environmental Responsibility (PEER) filed suit in the U.S. District Court

for the District of Columbia, seeking a rule under TSCA Section 6 to prohibit the production of PFOA during Inhance's fluorination process. *PEER v. Regan* (No. 1:24-cv-02194-JEB). Not surprisingly, Inhance requested that the court allow it to intervene in the suit. On September 28, 2024, EPA filed a motion to dismiss, arguing that petitioners' claims are moot because EPA has initiated the regulatory action sought by requesting information on the manufacture of PFAS during the fluorination of HDPE and other plastic containers. EPA also filed on September 28, 2024, a motion to stay the proceedings pending the resolution of its motion to dismiss. More information is available in our July 30, 2024, blog item, "CEH and PEER File Suit Seeking TSCA Section 6 Rule Prohibiting Production of PFOA During Fluorination of Plastic Containers."

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

On March 13, 2024, EPA published notice of a proposed settlement agreement that would require EPA to: publish an ANPRM concerning lead wheel weights; and by December 31, 2024, either sign a proposed rule regulating lead wheel weights pursuant to 15 U.S.C. Section 2605(a) and sign a final rule or otherwise take final action on the proposed rule by **September 30, 2025**, or sign a determination not to proceed with a rulemaking regulating lead wheel weights. EPA published an ANPRM regarding lead wheel weights on April 3, 2024. 89 Fed. Reg. 22972. On May 23, 2024, the parties filed a joint motion to dismiss the petition without prejudice. More information on the ANPRM is available in our April 9, 2024, blog item, "EPA Publishes ANPRM Regarding Lead Wheel Weights." On December 20, EPA announced that it will not proceed with rulemaking.

Recent Section 21 petition successes (both from EPA and a court granting a petition) may lead to an increase in such petitions. Responding to petitions is a significant burden and if petitions are granted, could expand significantly the number of Section 6 risk evaluation and risk management activities. If so, EPA may lose the ability to manage its workload and could face additional lawsuits for its failure to complete required actions timely.

For more than 30 years, B&C has offered clients an unparalleled level of experience and excellence in matters relating to TSCA. Our TSCA practice group includes seven former senior EPA officials, over a dozen scientists, including seven with Ph.D.s, and a robust and highly experienced team of lawyers and regulatory professionals. Contact Lynn L. Bergeson, lbergeson@lawbc.com, if you would like to discuss how our team can assist you with product approval, product review, and general compliance measures under TSCA.

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

### 1. Endangered Species Act — Under Development Since 1974 and Counting

The Endangered Species Act (ESA) has been, and will continue to be, the most important issue affecting pesticide use and regulation in the United States for the next few years. ESA compliance is arriving at long last — the result of an extensive trail of litigation and false starts on the U.S. Environmental Protection Agency's (EPA) part to find a way to move forward with a credible plan. During the Biden-Harris Administration, EPA has made significant progress in outlining an approach that attempts to integrate fully the requirements of ESA and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Regarding these ambitious plans, there is good news and bad news.

The good news is that the described policies and announced "strategies" address how the Office of Chemical Safety and Pollution Prevention's (OCSPP) Office of Pesticide Programs' (OPP) ecological reviews will be used to fashion mitigation options to protect threatened and endangered species (TES) identified by the U.S. Fish & Wildlife Services (FWS), using mitigation techniques familiar to the pesticide program and pesticide users alike.

The bad news is that the additional requirements, driven by the outlined approach, will impose extensive and complex additional requirements that may be (and many expect to be) too difficult or impossible for pesticide users to implement. This could lead to severe disruption in the user community, continued ESA litigation, and new initiatives to address the issue legislatively, despite how unlikely the prospects for successful legislation about almost anything appear to be at the present time.

#### a. ESA — EPA Actions Since 2022

Before looking forward to 2025, it is important to revisit the significant ESA developments in recent years that brought us to where we are now. During the Biden Administration, EPA issued important and candid assessments of the difficulties of integrating the statutes and developing policy strategies to address the situation. In April 2022, EPA released an ESA Workplan that explained how the ESA implementation efforts in place at that time were effectively impossible to succeed within any reasonable time. For example, under the current approaches, the program would take seven years to evaluate just five percent of pesticide uses, resulting in an ESA program that would take an additional 140 years to complete!

Appreciating the significant problems with these policies and approaches, EPA has continued to release strategies and plans for how to conduct ESA assessments and impose label requirements to protect TES. EPA's ESA website includes links to important documents and updates to its ESA plans, including:

- April 2022 — ESA Workplan;
- November 2022 — Workplan Updated;
- June 2023 — Vulnerable Species Pilot;
- July 2023 — Herbicide Strategy;
- July 2024 — Insecticide Strategy;
- September 2024 — Vulnerable Species Action Plan; and
- Fungicide Strategy (target **January 2025**).

The documents outline the approach EPA will use to protect against potentially adverse pesticide impacts through imposed mitigation strategies on a pesticide's use to prevent or limit expected exposures to the habitat of TES. The strategy is described as "avoidance and minimization," with an emphasis on buffer zones to prevent pesticide exposure outside the treated area and to prevent aerial drift to non-target areas or off-site movement through soil that could reach water sources (groundwater and surface water).

Minimizing off-target and off-site movement to species habitat is intended to prevent or reduce hazards to TES. Milestones for the delivery of these ESA strategy documents are part of a settlement of an ESA lawsuit known as the "Mega-suit," which had been filed more than ten years ago and settled in 2023. The stipulated settlement agreement from that case (*Center for Biological Diversity, et. al., v. United States Environmental Protection Agency, et al.,* No. 3:11-cv-0293 (N.D. Cal.)) can be found here.


Visit and subscribe to B&C's FIFRAblog® to stay abreast of developments in conventional pesticide, biopesticide, antimicrobial, and other pesticide product issues. Find it at https://www.lawbc.com/brand/fifrablog.

*Importantly, in late 2024 and throughout 2025, EPA reportedly plans to issue the first pesticide labels that would capture the result of its strategy documents and mitigation options.*

Label instructions will include Pesticide Use Limitation Areas (PULA), where areas of use restriction will be added to pesticide labels. "Avoidance" appears to mean restrictions where use of a pesticide will be prohibited to ensure that use of that pesticide will not directly (adversely) impact a critical habitat for a species. Minimization strategies will include instructions intended to reduce the estimated potential exposure to species from off-target movement of a pesticide, using extensions of practices EPA already includes on labels to reduce estimated environmental exposures as part of its long-standing review of pesticide labels. These standard practices include establishing buffer zones where use is prohibited around a treated area or requiring certain application methods (*e.g.*, "courser" (heavier) droplet size using different nozzles when spraying the pesticide).

The September 2024 Vulnerable Species Action Plan (VSAP) describes how EPA prepared in final the initial list of vulnerable species to which the framework will apply, the approach EPA plans to use to evaluate potential impacts to these listed species, and any associated mitigations. EPA identifies 27 species listed by FWS in the lower 48 states as "vulnerable species" and within the scope of the VSAP.

The species include various types of plants and animals, adding seven species that were not originally included in the Vulnerable Species Pilot (VSP) and removing another seven species after determining that they did not meet the definition of a vulnerable species. The VSAP also describes how EPA plans to expand the approach to add species to the list in the future. This action fulfills one of EPA's commitments from the 2023 settlement agreement on pesticides and ESA.

In the Herbicide Strategy, EPA outlines a scoring system where certain mitigations qualify for a number of "points," resulting in mitigation credits scored according to an evaluation of how much that mitigation would reduce possible exposure. For example, if using vegetative buffer strips and course (heavier) droplet size to reduce possible migration off-site, the application qualifies for a number of points (*e.g.*, three points for vegetative strips and two points for using course droplet size). The pesticide label would require that to use a certain product, the applicator might need a certain number of mitigation points before it can be used; if the product can be used with enough mitigation measures (points), the use is allowed.

EPA has indicated that the imposition of default strategies will allow the pesticide review process to be manageable in terms of timeliness and budget. These "up-front mitigation strategies" will use the standardized restrictions determined to reduce exposures (*e.g.*, buffer zones, heavier sprays). The strategy is designed to marry the EPA assessments of the required ecological risk studies with the habitat maps and species designations of the relevant sister agencies.

### b. ESA — What to Expect in 2025

Importantly, throughout 2025, EPA reportedly plans to issue the first pesticide labels that would capture the result of its strategy documents and mitigation options. EPA has yet to outline clearly a process that will allow for refinements (hazard and exposure data and other relevant information) responding to ESA-driven mandated label restrictions based on current EPA assessment methods.

For new active ingredients (AI), before any announcement of an approval (new AIs generally have a public comment period), EPA and FWS will have coordinated so that the approval will include EPA's determination of "no effect" for TES.

For pesticides undergoing registration review, proposed re-registration labels will include any new requirements to address ESA issues. These will include restrictions needed to implement EPA's ESA strategies incorporating avoidance and minimization measures to protect species. For many products, including some that will both be very important to crop producers and include stringent species protection requirements, the additional ESA-driven requirements may be "impossible" or very difficult to meet.

EPA has stated there will be a comment period for proposed labels that are part of the registration review process, but it is not clear how proposed label ESA restrictions will incorporate refinements such as data developed by registrants or other information available from stakeholders (*e.g.*, farmers,

crop consultants, applicators). EPA has mentioned, but made no explicit commitment to, incorporating additional information about refined species maps, crop-specific growing conditions, feasibility of compliance, and other "refinements" that historically have been considered before proposed registration review label decisions become effective.

EPA program managers have stated publicly that severe budget restrictions and litigation deadlines impose obstacles to meeting Pesticide Registration Improvement Act (PRIA) deadlines and/or allowing sufficient time for many, if any, refinements to proposed label restrictions or complex use requirements. The statutory deadline for registration review was extended until **October 1, 2026**, but with that deadline applying to hundreds of AIs, EPA likely will not be able to meet the **2026** deadline.

It is unclear how EPA will generally prioritize or otherwise decide which pesticides will be able to meet the **2026** deadline, although there is some guidance from past ESA litigation settlements addressing specific pesticides. EPA's "pilot species" program likely will be another way to determine priorities as a kind of "worst first" (most at risk) approach. Senior program managers at the political level have made more reassuring remarks about incorporating flexibility and allowing refinement data, but there is no clear commitment on the record to allow consideration of refinement data or other important information before new label restrictions are considered mandatory.

The first labels for new AI products where the herbicide and other strategies have been used to assess the product were expected to be submitted for approval by the end of 2024 (and issued thereafter in 2025). These first labels attempting to implement the revised ESA strategies will be closely scrutinized by all stakeholders to see how label restrictions and instructions will be applied to a specific product with intended markets and use in areas where there may be affected species.

Further, where EPA provides its "points options" as mitigation measures, there will be questions as to how they are protective of species. For example: which species; how many; in what area(s) defined as "use limitation area" — where use is prohibited; how practical are any available mitigation options in different areas of intended use and for what crops; and what effect any estimated impact restrictions may have on current production systems and associated costs. These are just a few of the many questions this analysis invites.

EPA's plans and policies have raised several issues. Since many crop production systems in a crop year may require more than one pesticide or pesticide application, and presuming these ESA requirements are on the respective product labels, then the grower would have to comply with the various requirements on each product. There may be conflicts about seasonal timing or conflicting restrictions depending on the species and production areas. It is not clear how such conflicts might be resolved, and in the end, the farm operator will be required to find an alternative crop or production system that can remain compliant.

As EPA outlines new approaches to ESA-FIFRA integration, agricultural stakeholders have expressed concerns about possible impacts on crop production in the affected areas. Since FIFRA has a "risk-benefit" standard, whereby EPA is to consider possible economic and social impacts of its decisions, potential impacts to these stakeholders are relevant to how EPA makes decisions when considering only the FIFRA requirements. Under ESA, however, there is no consideration of economic impacts. If production of soybeans or corn (or anything else) might be reduced in an area (or an individual's farm) due to ESA restrictions, that is not a consideration under ESA. This stark distinction between FIFRA and ESA has been recognized by non-governmental organizations (NGO) and grower group stakeholders from different perspectives, with NGOs stressing the need for greater TES protections versus grower groups expressing concern regarding the loss of essential crop protection products needed to maintain food production (on the nationwide and individual farm level).

EPA's stated plans do not present a clear picture of how EPA will be able to make timely or consistent decisions, or whether compliance with resulting label restrictions will be feasible for users to implement and state officials to enforce. Instead, EPA statements outline an unpredictable picture of how long decisions might take and how initial label restrictions might restrict pesticide use in areas where refined or additional data might show little risk to species. Uncertainty about what restrictions might be necessary to protect species begins with EPA's historic refusal to develop probabilistic models of ecological risk; EPA has, instead, relied on "conservative" models designed intentionally to overestimate risk, which can lead to overly restrictive or complex label instructions.

Conservative models have been used widely across the pesticide program — typically described as "if the product can pass with a conservative screen, then the regulatory analysis

can stop at that point" — with EPA assured of acceptable risk levels. Historically, EPA would allow additional discussion with registrants or other stakeholders to refine pesticide assessments if additional data could refine the EPA assessment conclusions and demonstrate that the regulatory standard will be met. This practice has long been in place to reduce the possibility of "over-regulation" of pesticide uses while continuing to meet the registration standards required by law. In fact, the attempt to not allow time for a refined label that could meet EPA 'final" conclusions was the basis for the Eighth Circuit reversal of EPA's announcement to revoke all chlorpyrifos tolerances while some of the tolerances could meet the required standard with label changes short of a complete prohibition. That decision is available here.

EPA's response to these concerns, raised by stakeholders in comments on EPA's plans, has included patches to the proposed "strategies" with rhetoric referring to consideration of additional data and interaction with users to fashion compliance options that would reduce unnecessary restrictions.

Another subtle impact of revised ESA requirements is the potential for conflict between the interests of pesticide registrants, who may be reluctant, but ultimately likely, to agree to EPA demands (since the alternative is no label — no approval — whatsoever), and the interests of growers who then will have to comply with any restrictions or mitigation requirements. The potential for tension between companies and customers is not new, but the complexity of ESA-driven requirements may exacerbate the potential for conflicting interests.

Recent experience with the new formulations of the herbicide Dicamba, where very complex label requirements for the user has led to enforcement issues, litigation, and intense local controversies (one murder has been reported over allegations of neighboring drift of the herbicide), may foreshadow the difficulty of compliance for at least some of the most widely-used pesticides currently depended upon by agricultural producers.

A vast number of details remain to be determined about enforcement and compliance matters, the ability of EPA to process labels compliant with new requirements (even with electronic labeling), the availability of expertise to help growers comply with identified mitigation options, and a host of other complex issues about use instructions and requirements that will result from ESA program implementation. Resolving these issues will continue well beyond 2025.

## 2. Farm Bill

Every five years, Congress passes legislation that sets national agriculture, nutrition, conservation, and forestry policy, commonly referred to as the "Farm Bill." The 2018 Farm Bill should have been replaced by a 2023 Farm Bill on or before October 1, 2023. With ongoing federal outyear budget disagreements in Congress, new House leadership, and other challenges, the existing 2018 Farm Bill was extended for one year, to October 1, 2024.

Not surprisingly, Congress has continued to be unable to agree on a new Farm Bill. Having missed the October 1 deadline, Congress is now expected to renew the current program for another year and await the arrival of a new Congress and new President in 2025 for any new bill.

The most divisive issue has been a partisan dispute over potential cuts to what are called the "feeding programs" of the U.S. Department of Agriculture (USDA) — the Supplemental Nutrition Assistance Program (SNAP). Republicans have proposed cuts to the program that are flatly opposed by the Democrats. Climate-related spending for USDA programs and the overall cost of the legislation ($1.5 trillion) also remain controversial among and between Democrats and Republicans.

The Farm Bill usually does not contain significant amendments to FIFRA. At various points, there has been discussion of PRIA reauthorization depending on any coincidental need to reauthorize PRIA in a Farm Bill cycle. Generally, it has proven less cumbersome not to include PRIA as part of a Farm Bill, avoiding potential broader pesticide legislative controversies outside the mostly narrow confines of the PRIA fee scheme.

Regarding a 2025 Farm Bill, we expect the pesticide community to continue to look to strengthen the role of the USDA Office of Pest Management Policy (OPMP), particularly OPMP's role in quantifying the risks and benefits to pesticides and OPMP's work with EPA on ESA requirements as part of registration review. This also may include an enhanced role of the FIFRA Interagency Working Group on ESA to make recommendations and implement improvements to the ESA Section 7 consultation process for pesticide registration and registration review.

In recent years, some agricultural stakeholders have lobbied to have the Farm Bill include language to reaffirm state pesticide preemption and the role of states as co-regulators of pesticides, and to promote uniformity in pesticide labeling by reaffirming that EPA is the primary, federal authority under FIFRA for making pesticide findings and decisions. Some groups also have tied climate-positive impacts to Farm Bill support for voluntary adoption of precision agriculture technologies and services, including an emphasis on adjuvants to increase pesticide efficacy and use-efficiency. Advocacy on these issues is expected to continue in 2025.

Other issues that in recent years have been part of the discussion of farm policy and farming practices pertaining to pesticides include support for USDA's Foreign Agricultural Service's engagement in international institutions, especially related to Codex international pesticide residue standards, and calls to eliminate what some consider "duplicative and burdensome" water permits for pesticide applications under the National Pollutant Discharge Elimination System (NPDES). This also may continue in 2025, although the likelihood of success for these issues remains unclear.

### 3. Climate

Addressing climate change was a Biden Administration-wide priority, especially at EPA. President Biden has directed all federal agencies to integrate climate adaptation planning into their missions, programs, and management functions to ensure their success in enhancing preparedness for and resilience to the climate crisis. For EPA, this has included evaluating how climate change might affect efforts to attain environmental standards given heat waves and more intense storms.

OPP is not among the programs most involved in the work of EPA on climate, but pesticide program activities will be affected to some degree. For example, one of the issues stated in EPA's Climate Adaptation Action Plan that implicates FIFRA is: "As pests move into new areas, pest management practices and application of pesticides may expand. This may lead to more chemicals present in soil and water. Chemical safety may be affected by changing chemical use patterns resulting from climate change. An increase in the frequency of new pest problems could trigger requests for emergency exemptions under [FIFRA] if currently registered pesticides are ineffective."

According to EPA, pesticides can also impact climate change throughout their manufacture, transport, and application. Pesticide manufacture emits three main greenhouse gases (GHG): carbon dioxide, methane, and nitrous oxide. To date, these sorts of climate change issues have not yet directly impacted OPP decisions. With the change in Administration, climate issues will be even less relevant.

For 2025, two indirect impacts could affect OPP activity. First, climate changes affecting species habitat could become a consideration in some pesticide ESA assessments. In addition, the budget implications of climate issues as a priority could impact and compete with the funds available among programs. There are reports of impacts on OPP from the competing time and attention available for the recruitment, hiring, and training of new staff given the large increase in funds and needed staff for Agency climate activities.

### 4. Environmental Justice

Environmental justice (EJ) is another original priority announced by the Biden Administration in its first days. Administrator Regan announced EJ as one of two top priorities (along with Climate Change) for EPA across all programs. It has consistently been an important theme and guiding principle across OCSPP program activities. For OPP, pesticide decisions have long been considered a significant EJ concern, resulting in policies and evaluation procedures to ensure protection of farmworkers who apply or work near pesticides. It is widely believed that most if not all EJ initiatives will be dismantled or defunded.

EPA's Agricultural Worker Protection Standard (WPS) aims to reduce pesticide poisonings and injuries among agricultural workers and pesticide handlers. WPS is intended to provide occupational protections to over two million agricultural workers and pesticide handlers who work at over 600,000 agricultural establishments.

The WPS program began in the early 1990s and over 30 years has been expanded to include additional training

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and recordkeeping requirements, as well as explicit label requirements for protective measures to reduce risks to farmworkers and pesticide applicators. In more recent years, EPA added data requirements to better evaluate possible risks to workers and bystanders near areas where pesticides are used, including newer initiatives driven by the emphasizing of EJ concerns.

As part of the revisions to the WPS program, EPA has expanded its Spanish language resources that assist with translating the health and safety portions of pesticide product labels. The Spanish Translation Guide for Pesticide Labeling resource is available for anyone to use, including pesticide manufacturers, to help in displaying parts of their pesticide product labels in Spanish. EPA generally allows pesticide registrants to include on the label other languages optionally in addition to the full English text if the translation is true and accurate. Some pesticide registrants already have their product labels fully translated into Spanish. Many product labels are, however, only available in English. New requirements for bilingual labels were included in PRIA 5 (discussed below), and this will continue to be an important EJ area in 2025.

### 5. PRIA 5 — Pesticide Registration Improvement Act (Fifth Reauthorization)

PRIA remains bedeviled by the simple inability of EPA to meet consistently the deadlines prescribed by the legislative scheme. PRIA fees, along with the registration maintenance fees imposed by the 1988 FIFRA legislation, are designed to generate about one-third of the pesticide program budget. The fundamental problem is that along with the imposed fees, Congress is to appropriate a baseline minimum amount, and in recent years, Congress has been unwilling to provide "their share."

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Specifically, the minimum amount appropriations level is to be $166 million, and for the current year, there is approximately a $35 million shortfall. The result is that the number of personnel in OPP has withered from about 600 staff equivalent positions in Fiscal Year (FY) 2021 to about 530 in FY 2024.

#### a. Background

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

PRIA 5 revised pesticide fees and review times, and included several new provisions, including but not limited to issuing a regulation for bilingual labeling for pesticides, developing ESA guidance, information technology (IT) updates/additions, and establishing a Vector Expedited Review Voucher (VERV).

PRIA 5 provided an increase in fees and funding for OPP from PRIA 4, equal to an increase of $11 million for maintenance fees (average annual collection target raised from $31 million to $42 million), and an across-the-board 30 percent increase for pesticide registration services. PRIA 5 raised minimum appropriation triggers to $166 million (FY appropriations were $138.6 million). And, as provided in the legislation, PRIA fees were increased 5 percent as of October 1, 2024.

#### b. Progress

OPP has made progress on many of these PRIA 5 initiatives, including requirements for bilingual labels, centralized web pages intended to make finding important information easier, increasing transparency about completion of registration actions, establishing the VERV program, and a start on IT upgrades.

Still, the fundamental metric of successfully meeting the target decision deadlines has remained elusive. Over the

years, improvements have been made in earlier identification of problems with a submission (such as missing data or errors in submitted forms), transparency about decisions, IT improvements, providing progress reports, and other accountability measures. In some cases, review of a submission may identify a risk or data issue which may take time to address and understandably require additional time to resolve (or lead to withdrawal of the submission). Historically, however, EPA staff simply report back to the submitter that due to program delays (often not precisely identified), the PRIA deadline "needs" to be renegotiated.

By "renegotiating" the PRIA deadline, EPA acknowledges that the completion of the review process will not meet the prescribed deadline; the submitter could agree to a later deadline, or "get a decision now" — which would be a denial of registration since EPA has not yet completed its review to determine the product meets regulatory standards. With those choices, applicants typically agree to a delay, since a denial is an undesirable outcome — especially since in some cases, the problem is available resources and not a sign of regulatory concerns (withdrawing the submission is an option if there are concerns or if the delay would affect the viability of the product).

Even as EPA attempts to make the progress and process more transparent, missed deadlines have been an increasing source of frustration among registrants who fundamentally seek to understand why fees have gone up 30 percent (and now an additional 5 percent as of October 2024) while performance has declined or otherwise not improved. OPP has recently reported that approximately 70 percent of new AI applications submitted to the Registration Division missed a PRIA deadline.

Uncertain deadlines make product planning difficult for any registrant, with increasing frustration that such deadlines are not met as fees go up. This has led to stakeholders voicing their concerns to allies in Congress, so 2025 may see more direct congressional oversight of PRIA program progress. At the same time, Congress itself is a major part of the problem, since partisan division and overall budget constraints are a major contributor inhibiting EPA's capabilities.

Given the diverging reality of budget constraints with the need for improved predictability, there may be some potential that EPA may invite (or Congress may insist on) new and different ways to address some of the "deadline" issues. Over time, there have been suggestions about whether some part of any evaluative work might be done and submitted by applicants (subject to review by EPA) or how additional "third-party" contractors might be utilized to improve the process.

Since the prospect for significant budget increases are slim, registrants may expect problems or uncertainties regarding PRIA performance, such as:

- Changes to the Renegotiation Process

  One of the most important changes resulting from PRIA 5 was the amendments to the language of FIFRA Section 33(f)(5)(B) and (C), the conditions under which renegotiations for extensions could be conducted. As mentioned, historically EPA has sought to renegotiate PRIA due dates when program delays occur (often resource and staffing related) or when additional data are needed to complete a risk assessment. The subsequent renegotiation rate was high, and the 98 percent on-time completion rate was misleading. Under PRIA 5, there are several important changes to the renegotiation process. First, any renegotiation must be approved by the Office Director of OPP. Secondly, a renegotiation is only permissible in certain circumstances (*i.e.*, new data are needed that cannot be made available within the original review time, or a public comment period generates significant comments that cannot be addressed in time). PRIA renegotiations can no longer be requested based on a lack of OPP resources or late assessments from the science divisions. OPP has acknowledged that this change would result in a reduction in the renegotiation rate but would also likely increase the number of missed PRIA due dates. When the PRIA due date is missed, however, under PRIA 5 the application is to be prioritized. Applicants will be hard pressed to design a market-entry strategy under these conditions where there is no sure regulatory decision date.

- IT Improvements

  In 2024, OPP continued efforts to upgrade its IT systems and provide Salesforce to all office divisions. Thus far, the effectiveness of the platform has not been obvious to those outside of OPP, where PRIA Milestone notifications have been replaced with Salesforce autogenerated e-mails that provide no useful information. Salesforce is to work in conjunction with the new stakeholder portal being developed by OPP. OPP launched its beta phase 1, deployment of the case

management portal, in November 2024, with a larger customer audience planned for early 2025. The case management portal is to provide a real-time, accurate tracking system for all regulatory submissions (the "pizza tracker" approach), and allows for confidential transfer of documents between the applicant and OPP. The portal will pull from and update the Central Data Exchange (CDX). When up and running, these systems should be incredibly useful, but that could be years away, and implementation and integration issues are to be expected with a system upgrade of this magnitude.

During the summer of 2023, there were several periods of major delays in the front-end screening process. The delays were acknowledged by OPP and although rumored as either staffing or IT based, the reason was never made clear. Thousands of applications were held up between submission and the initiation of screening, some for as long as three months. The fallout was an unknown regulatory timeline for those applications affected. Although acknowledging the front-end processing issues and delays, when questioned on whether these applications would be given any special treatment, OPP has referred back to the new PRIA 5 process for missed deadlines. As OPP attempts to implement new IT systems with limited resources and reduced staff numbers, similar delays and missed deadlines are expected.

## 6. Actions on Specific Pesticides

### a. DCPA (Dachtal)

On August 6, 2024, EPA issued an emergency suspension for the registration of the pesticide DCPA or Dachtal. This was significant not only because EPA had determined as part of its registration review that the pesticide no longer met the FIFRA standard for registration, but also because it was the first time in 40 years that EPA had taken "emergency" action against a pesticide. "Suspension" is a statutory term that allows EPA to stop use immediately if EPA believes the risk from continued use of the pesticide warrants immediate cessation of use since the cancellation process (the procedures EPA must follow to cancel a registration) would take too long to prevent an "imminent hazard."

In many cases over the years, EPA's review of new data or new requirements can result in a conclusion that some or all of a pesticide's registrations should be modified or cancelled. In most cases, the registrant will either voluntarily cancel the registration in question or modify its label to EPA's satisfaction under the law.

In this case, even though the registrant stopped sale of the product until a resolution with EPA might be determined, EPA took the highly unusual step of issuing the suspension order. Among the reasons this case is notable is that it signaled very aggressive action on the part of EPA, citing possible risks to farmworkers who might be pregnant and exposed to the pesticide even with voluntary measures to stop use until label changes that might have addressed EPA concerns were agreed upon.

On August 19, 2024, EPA received a letter from the registrant stating its intent to cancel voluntarily the remaining pesticide products containing DCPA in the United States, and subsequently announced it intended to cancel all international registrations as well.

### b. Chlorpyrifos

What would an annual Forecast about pesticides be without at least a brief mention of chlorpyrifos? Since the decision of the U.S. Court of Appeals for the Eighth Circuit in November 2023 that EPA should not have revoked all chlorpyrifos tolerances, EPA has stated its need to sort out what is next for its assessment of the pesticide. *Red River Valley Sugarbeet Growers Ass'n v. Regan*, No. 22-1422 (8th Cir. 2023). The court's decision, as discussed in more detail in our November 16, 2023, memorandum, forced EPA to reinstate the tolerance for residues of the pesticide for all food uses, which was complicated by the fact that the product registrations for the pesticide had been voluntarily cancelled by the respective registrants. On December 2, 2024, EPA proposed a rule to revoke all tolerances for chlorpyrifos, except for those tolerances associated with the 11 food and feed crops that remain registered and for which the court stated should have been allowed to remain in force as compliant with the requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA) — that part of pesticide-related law governing allowable amounts of pesticide residues on food. For more information, see our December 11, 2024, blog.

### c. Dicamba

Another Forecast recidivist is the pesticide Dicamba. Registered many years ago and widely used on a variety of crops, in recent years new formulations have allowed Dicamba to be used "over the top (OTT)" when applied to Dicamba-tol-

erant crops, including soybeans and cotton. These are seeds genetically modified to be tolerant of Dicamba, but OTT use means that the product would be applied when other nearby crops could be susceptible to off-target drift.

The new Dicamba products were designed to minimize drift potential, as the older formulation was known to present a high drift potential. Since the introduction of the new formulations and resistant varieties, hundreds of drift incidents causing damage have been reported to state regulatory agencies. As a result, the registration of the newer Dicamba products have been controversial, and EPA has struggled to balance the need for the newer products to treat weed species that have become resistant to Glyphosate, which has been used on these crops since first being introduced about 20 years ago with the concern raised. Opponents of the new formulation products have judicially challenged EPA's approval of the new Dicamba products, and currently there are no registrations in force for the newer formulations.

EPA has not decided whether to allow continued use of the new formulations, perhaps with additional label requirements about applicator training, geographic restrictions, use conditions (temperature, wind), and calendar windows allowing use. EPA has layered on such additional restrictions before in the attempt to reduce incident reports. States have also added more restrictions in some cases. The basic question facing EPA is whether any set of label restrictions will be enough to prevent reported problems sufficiently with the current "low-volatility" formulation.

### 7. Registration Review — Endocrine Effects

First required to be part of a pesticide registration review as part of the Food Quality Protection Act (FQPA) in 1996, EPA has repeatedly deferred an explicit endocrine effect assessment until completion of designing the program requirements about needed information and assessment methods to be used. EPA developed the Endocrine Disruptor Screening Program (EDSP) over several years since FQPA first required such reviews to be included. Recently, EPA settled litigation on the matter, and in October 2023, EPA issued its new EDSP strategic plan to ensure that its assessments of pesticides more closely, quickly, and effectively evaluate the potential for endocrine effects in humans.

EPA has now agreed to move forward with including the requirement for a review of possible endocrine effects of pesticides as part of registration reviews. As registration review is now required to be completed by **October 1, 2026**, OPP will be under increasing pressure to meet this deadline even if the ESA component of the full and final review remains incomplete.

While the strategic plan was being developed, pesticides undergoing review have been required to include data that EPA has evaluated regarding potential endocrine effects. The court settlement and current plan will make that part of a registration review more explicit about EPA's evaluation of possible endocrine effects.

### 8. VERV Implementation and Process

In 2024, OPP implemented the PRIA 5-mandated VERV program. The program incentivizes companies to develop new, novel, or unique mosquito control products that are intended to prevent the spread of mosquito-borne diseases such as malaria, dengue, and Zika by controlling pyrethroid- or other insecticide-resistant mosquitoes. Under VERV, a voucher may be redeemed to shorten the decision review time for applications that meet certain criteria outlined in PRIA 5. With the record-breaking numbers of dengue, and increased numbers of West Nile and Eastern equine encephalitis in the United States, it is expected that this program will be highly sought in 2025.

To be eligible for a voucher, the application for the new AI must show that the ingredient:

- Demonstrates proven efficacy against pyrethroid- or other insecticide-resistant mosquitoes. On a case-by-case basis, EPA may accept a rationale for efficacy based on the novel mode of action.

- Prevents, kills, mitigates, or repels pyrethroid- or other insecticide-resistant mosquitoes with a novel or unique mechanism that differs from other insecticides already registered by EPA for mosquito control. EPA will consider whether:

    - The mechanism targets new or different receptors;
    - The pesticide is in a new or different chemical;
    - The mechanism uses a special approach such as interrupting behavior, targeting different life stages, or prohibiting reproduction; and if
    - Live release control techniques should target a specific species not controlled by another live-release product.

*EPA states it will use chemical-specific human health spray drift analyses to determine specific label instructions to protect against and reduce the occurrence of spray drift.*

This criteria may be waived, and the repurposing of an existing agricultural pesticide may be allowed, if there is a significant public health benefit; the waiver must be submitted at the time of application.

- Targets mosquitoes that may spread malaria, dengue, Zika, chikungunya, St. Louis encephalitis, eastern equine encephalitis, western equine encephalitis, West Nile encephalitis, Cache Valley encephalitis, La Crosse encephalitis, or yellow fever.

- Is made accessible for use in the United States, including territories or possessions of the United States, and countries where mosquito-borne diseases, such as malaria, are prevalent.

- Broadens the adoption of integrated pest management strategies, such as insecticide resistance management, or makes those strategies more effective.

- Is not contained in any pesticide product registered by EPA as of the date of the enactment of PRIA 5 (December 29, 2022), nor contain an AI approved in the two years preceding the registration by any global authority for the same uses, vectors, and applications.

The application also must include a global access plan that will be made publicly available, including the manufacturing locations and third-party manufacturers; distribution and procurement processes for malaria vector control programs in selected countries (for *Anopheles* mosquitoes); and prices of product.

Prior to redeeming a voucher, an applicant must notify EPA of its intent at least 90 days prior to submitting the application to be eligible for the expedited review process. The applicable registration fees are still required.

The vouchers can only be used for the following New Active Ingredient PRIA Categories: R010 (food use), decision time expedited by six months; R020 (food use, reduced risk), six month expedite; R060 (non-food outdoor), six month expedite; R110 (non-food indoor), six month expedite; R070 (non-food outdoor, reduced risk), four month expedite; and R120 (non-food indoor, reduced risk) two month expedite.

EPA will notify the registrant of the voucher decision and registration decision at the same time.

On December 5, 2024, EPA announced that it has issued its first voucher under its VERV Program as a result of a recent approval by EPA of a new AI, *Wolbachia pipientis w*AlbB strain. For more information on the issuance of the first voucher, please see our December 13, 2024, blog.

### 9. Changes to When EPA Assesses Potential Exposure to Pesticide Spray Drift

On July 15, 2024, EPA announced it is updating its process for determining when it will assess the potential for exposure to pesticide drift when it reviews new AI pesticide registrations or makes decisions on new use directions for existing pesticide registrations. EPA will review potential exposure to drift earlier in the review process.

In its announcement, EPA states that historically it "only conducted a chemical-specific assessment of the potential for people to be exposed to pesticide 'spray drift' during registration review, which happens every 15 years after a pesticide is approved to ensure that it can carry out its intended functions without creating unreasonable adverse effects to human health and the environment." EPA states it will now also complete a chemical-specific spray drift analysis during the initial registration process or the review process for new and amended uses of existing products, to ensure that any needed protections are put in place from the beginning of the pesticide's use, rather than delaying them for 15 years. According to EPA, this change is consistent with its commitment to address EJ concerns from pesticide use in and around farm communities and to comply with the ESA, where EPA is working to improve how it evaluates risk to and protects endangered species.

EPA states it will use chemical-specific human health spray drift analyses to determine specific label instructions to protect against and reduce the occurrence of spray drift, such as droplet sizes and buffer distances, for each pesticide

and use. Additionally, if it identifies spray drift risks for people living or working nearby or non-target species, EPA will protect against those risks.

EPA will now include a chemical-specific human health spray drift analysis for the following:

- ***New active ingredients***: Any new submissions for domestic uses of new AIs;
- ***New uses and amended uses***: Any new use and amended use registration submissions where that AI has previously received a chemical-specific spray drift analysis; and
- ***Currently pending registrations***: Registration actions that are currently under review with EPA, when possible.

For additional information on how EPA will implement this change, *see* *Implementing Chemical Specific Human Health Spray Drift Analysis into Pesticide Registration Actions, July 2024*. For information on the methodology for conducting human health quantitative spray drift analysis, *see* *Residential Exposure Assessment Standard Operating Procedures Addenda 1: Consideration of Spray Drift*. Additional information is also available here.

This announcement reflects the Administration's continued emphasis on EJ considerations as part of EPA's overall mission and program objectives. Pesticide assessments have included consideration of bystander risks from pesticide application for years; this announcement makes such considerations more explicit and prioritized.

After a new pesticide is first brought to market, new uses are added, formulations change, and over time, additional registrants may enter the market for the same AI. Each registration is individually reviewed and must meet FIFRA statutory requirements. This announcement would suggest that some or all of these new uses or formulation changes may receive additional scrutiny moving forward.

## 10. Enforcement

EPA remains focused on reviewing pesticides and devices and initiating enforcement actions for any degree of non-compliance. Every year in recent past, EPA releases a report summarizing its results and accomplishments from the prior year. In EPA's report for FY 2023, EPA provided statistics confirming a recent trend of increased enforcement actions. Enforcement and Compliance Annual Results. These statistics show that EPA:

- Conducted more on-site inspections in FY 2023 than before the pandemic;
- Opened 199 criminal investigations in FY 2023, an increase of 70% over FY 2022;
- Concluded 1,789 civil settlements, over 150 more than in FY 2022; and
- Required companies to pay over $704 million in penalties, fines, and restitution, an increase of 57% over FY 2022.

This increased activity includes EPA Regions expanding their reviews for issues with labels and Notices of Arrival (NOA), as well as reviews of claims on company websites and any related labeling materials (*e.g.*, brochures, patents). Considering EPA's focus and the increased number of inspections, companies should be vigilant in confirming compliance with FIFRA and prepared for inspections that EPA can initiate with no prior notice.

One recent court case that may impact EPA's enforcement authority is *United States v. eBay Inc.* That decision, in part, held that eBay does not "sell" products on its platform since eBay lacks title and possession over the items listed on its site and does not "offer to sell" products on its platform since eBay's actions are not to "offer to transact title in exchange for consideration." eBay thus was found not to be distributing or selling pesticides. The court further found that eBay could not be found in violation of a Stop Sale, Use, and Removal Order (SSURO) because eBay could not have violated a SSURO requesting it to stop selling or distributing pesticides when eBay is not selling or distributing pesticides.

## 11. Pesticide Devices

In 2023, EPA expressed its intent to update its 1976 policy statement regarding how it regulates pesticide devices under FIFRA. EPA's revisions to the policy statement are under review by the Office of General Counsel (OGC) and were to be published for public comment by the end of EPA's FY 2024, a date that passed on September 30, 2024. EPA's stated goal is to improve regulatory consistency by addressing jurisdictional areas that EPA believes are unclear or confusing to the regulated community. Specif-

ically, EPA is expected to propose clarifications regarding common terms (*e.g.*, substance, instrument, contrivance) and clarifications regarding devices that include substances as they relate to the treated article exemption, electrochemical products, generators, and component parts. These clarifications may be potentially useful, especially since the types of pesticide products and devices have expanded greatly since 1976, and the examples of pesticide devices from the 1976 *Federal Register* notice do not include many current devices.

EPA also is developing efficacy test methods for devices with funds provided in PRIA 5 (*i.e.*, up to $500,000 per year FY 2023-**2027**) "… To develop efficacy test methods for antimicrobial pesticide devices making public health claims." EPA's efforts will focus first on test methods to evaluate the efficacy of photocatalytic devices and other air treatment technologies against airborne pathogens. EPA has stated that current testing by device manufacturers can take place under idealized conditions that are not representative of real-world conditions, leading to overstated efficacy claims. EPA's OPP and Office of Research and Development (ORD) will continue efforts in 2025 to develop appropriate test methods. EPA has provided a list of the following reference test methods that have been developed by voluntary consensus standards (VCS) and will be part of EPA's testing and effort to develop draft efficacy test methods.

- AHAM AC-5-2023, "Method for Assessing the Reduction Rate of Key Bioaerosols by Portable Air Cleaners Using an Aerobiology Test Chamber" (published)
- ASHRAE 241, "Control of Infectious Aerosols ~ air cleaning technology testing requirements" (published)
- ASHRAE 185.3P, "Method of Testing In-Room Devices and Systems for Microorganism Removal or Inactivation in a Chamber" (proposed standard authorized May 2021; will be published within the next couple of months)
- ASHRAE 185.5, "Method of Testing HVAC-duct mounted Devices and Systems and In-Room devices for Particle and Microorganism Removal or Inactivation in a Chamber with a Recirculating Duct System" (proposed standard authorized June 2022; standard in development)
- ASTM E3273-21, "Standard Practice to Assess Microbial Decontamination of Indoor Air using an Aerobiology Chamber" (2021)

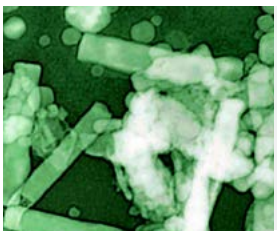
WEBINAR ON DEMAND
FIFRA Hot Topics

The need for clear guidance on efficacy data and related claims is evident in the regulated community, where enforcement across EPA Regions has proliferated in recent years, with inconsistent and overly-rigid results. Industry monitoring and input on EPA's efforts will be critical in 2025 to ensure guidance and test method development meet the needs of pesticide device manufacturers seeking compliance with FIFRA requirements.

### 12. Minimum Risk Pesticides

According to EPA's Regulatory Agenda, EPA is considering comments received for the development of a proposed rule regarding FIFRA Section 25(b) minimum risk pesticides to "establish specific criteria and a petition process related to the minimum risk pesticide exemption, including how the Agency evaluates potential minimum risk active and inert substances and state implementation of the minimum risk program; factors used in classes of exemptions; and the need for any future exemptions or modifications to current exemptions." The comments EPA is reviewing were submitted following an April 2021 advance notice of proposed rulemaking (ANPRM) soliciting public comments and suggestions about the process for petitions and EPA evaluation to add or remove substances from the lists of ingredients for minimum risk pesticides.

During the development of the proposed rulemaking, EPA intends to continue its efforts to engage all stakeholders. In addition to meetings on pesticide-specific actions, EPA states it will sponsor advisory committees that include representatives of pesticide manufacturers, consumer, health, and environmental organizations, academic institutions, and others. EPA also states its headquarters and regional offices will partner with state, territory, and Tribal governments to manage responsibly pesticide regulatory and enforcement programs. According to the Regulatory Agenda, EPA expects to issue a proposed rule in **June 2026**.



*The expansion of the availability of virucidal claims under EPA's interim guidance will facilitate the addition of virus claims to products bearing only food or non-food sanitizer claims.*

**13. Revisions to Pesticide Registration Notice 98-10**

Pesticide Registration Notice (PRN) 98-10, "Notifications, Non-notifications and Minor Formulation Amendments," published in 1998, provides guidance to registrants submitting minor modifications to a registration that do not require extensive EPA review and do not have the potential to cause unreasonable adverse effects to the environment. On September 6, 2017, EPA issued a *Federal Register* notice announcing proposed updates to PRN 98-10, stating that "[s]ince the issuance of PRN 98-10, there have been various statutory and regulatory changes," in particular, certain actions previously covered by PRN 98-10 now fall under PRIA. EPA released a draft revised version of PRN 98-10 in 2017, but it was never issued in final.

The recent non-PRIA back-log renewed interest in revising PRN 98-10. EPA is considering possible changes to the current approach for allowing alternate AI sources to a pesticide confidential statement of formula (CSF). OPP intends to release a new draft revised version of PRN 98-10 for public comment in 2025.

While the new draft will consider the 2017 draft and comments, OPP also intends to consider different approaches, including maintaining CSF notifications and determining if other actions might fall under non-notification. OPP has met with stakeholders to include industry input into the draft.

**14. Antimicrobials Division Programmatic Actions of Note**

In 2023, EPA's Antimicrobials Division (AD) released various draft guidance and proposals related to the registration of antimicrobials, some of those based on needs realized during the pandemic. Preparing and publishing these guidance documents in final were part of AD's FY 2024 priorities. Also included were items that did not yet come to fruition, such as posting draft guidance on chemical air treatment and treated filters and considering the public comments to the Antimicrobial Product Evaluation Program (APEP) strategy provided for comment in 2020. Noted below are topics of importance that registrants of antimicrobial products may find helpful as they navigate the 2025 AD.

**a. Interim Guidance Extending Virus Claims to Sanitizer Products**

On October 10, 2024, EPA announced the release of interim guidance to expand the availability of virucidal claims for antimicrobial pesticides. This new guidance provides the framework for registrants who seek to make virucidal claims for antimicrobial products that meet the criteria for a bacterial disinfectant and/or sanitizer (*e.g.*, household antimicrobial wipes and sprays) consistent with current test guidelines.

This interim guidance reiterates recommended test methods and regulatory guidance discussed in the draft guidance released by EPA on July 17, 2023, for the addition of virucidal claims to products that meet the criteria for hard surface disinfection claims consistent with EPA's *Product Performance Test Guidelines; OCSPP 810.2200: Disinfectants for Use on Environmental Surfaces, Guidance for Efficacy Testing* guideline and provides recommended test methods and regulatory guidance for the addition of virucidal claims to products that meet the criteria for food/non-food contact sanitizer claims consistent with EPA's *Product Performance Test Guidelines; OCSPP 810.2300: Sanitizers for Use on Hard Surfaces — Efficacy Data Recommendations* test guideline.

EPA's interim guidance proposes no change to the test methods or performance standards recommended for a product to meet any of the antimicrobial pesticide product definitions or to fall under the categories of claims on such products; thus, there are no expectations of a reduction of product performance against viruses. The expansion of the availability of virucidal claims under this interim guidance will facilitate the addition of virus claims to products bearing only food or non-food sanitizer claims.

Products that meet the basic criteria to allow for sanitizer claims, as outlined in the current OCSPP 810.2300

test guideline, and have data to support the addition of virucidal label claims, may be used in non-healthcare use sites in residential, commercial, and institutional settings (*e.g.*, cafeterias specifically on hard, non-porous surfaces). Addition of a virucidal claim to a product bearing only sanitizer claims does not imply that the product can be used in healthcare settings, due to the higher level of efficacy against bacteria that is expected in hospital patient care areas.

EPA states that the expansion of the availability of virucidal claims represents a significant policy shift. As such, EPA intends to grant the addition of virucidal claims associated with sanitizer claims for a time-limited period of a maximum of ten years, starting from the date the guidance is finalized for use. Registrants interested in registering sanitizer products with virucidal claims or adding virucidal claims to previously registered sanitizer products should do so within the ten-year period. The time-limited period will expire on **October 10, 2034**. The time-limited registration applies to all products seeking to obtain such registration and is not an individualized time period. For example, if a registrant were to submit an application to add a new virucidal claim to a sanitizer-only product on **September 1, 2029**, that product claim would be valid until **October 10, 2034**.

Products registered under this time-limited registration will receive a registration with terms and conditions. These time-limited registrations will be tracked internally to capture all products under this registration and provide a way for communication with the registrants, as necessary. EPA states that the purpose of the ten-year time-limited registration timeframe is to allow registrants to come forth and use the guidance for registration and for EPA to evaluate the benefits, concerns, and related experience to inform a decision on the permanence of this interim guidance. Prior to the ten-year expiration, EPA will assess implementation, review the record, and may terminate the interim policy, make suggestions for changes to the policy, as necessary, or decide to make the policy permanent.

EPA states that the interim guidance is "intended to allow registrants to provide consumers with additional products that are effective against viruses including SARS-CoV-2." This interim guidance is important for sanitizer registrants seeking to add virucidal claims, although EPA has provided the caveat that this interim guidance has a time-limited period of a maximum of ten years, starting from the date the guidance is finalized for use.

We expect EPA to review and approve sanitizer products with virucidal claims in 2025 as registrants generate the appropriate data and submit the applications to do so.

We expect in 2025 that EPA will be reviewing new or amended registrations to add virus claims to sanitizer labels.

### b. *Legionella pneumophila* Guidance

An OPP priority for 2024, EPA released the final guidance and a test method to evaluate efficacy claims for antimicrobial products against *Legionella pneumophila* (*L. pneumophila*) in cooling tower water on August 28, 2024. Legionnaires' disease (LD) is a serious type of pneumonia (lung infection) acquired by breathing in water droplets contaminated with *L. pneumophila* bacteria. Cooling towers, used in industrial, institutional, and healthcare settings, have been identified as breeding grounds for this bacterium. The U.S. Centers for Disease Control and Prevention (CDC) reports that LD is on the rise. In general, reported cases of LD have been increasing since the early 2000s, with a peak in 2018. While reported cases dropped during the first year of the COVID-19 pandemic, according to the CDC, cases rebounded starting in 2021.

The final guidance follows a public comment period where stakeholders expressed the need for standardized methods. The guidance includes data submission procedures, example pesticide label use directions, and examples of claims for proposed antimicrobial product labels.

### c. Final Framework to Assess the Risk to the Effectiveness of Human and Animal Drugs Posed by Certain Antibacterial or Antifungal Pesticides

On October 9, 2024, EPA announced that it issued in final the framework which was developed to strengthen the assessment of antimicrobial-resistance risks associated with pesticide use. EPA coordinated with the U.S. Department of Health and Human Services (HHS) and USDA, under the oversight of the White House Executive Office of the President, to establish a process for EPA to consider input from the other federal agencies when evaluating whether antibacterial or antifungal pesticides might result in the development or spread of resistance and reduce the effectiveness of some human and animal antibacterial and antifungal drugs. EPA states that framework will strengthen the shared goals of EPA, HHS, USDA, and the

White House in protecting relevant human and animal drugs while ensuring growers can continue to have access to important tools to protect their crops from fungal and bacterial diseases.

EPA states the framework is to provide information and clarification to pesticide applicants, growers, the public, and animal health communities, and inform the public on how EPA will consider resistance issues on regulatory decisions on antibacterial and antifungal pesticides. EPA also states that the framework is not binding on EPA, pesticide registrants, or the public. EPA notes that if circumstances warrant, it will depart from the framework without prior notice. Additionally, pesticide registrants may assert the framework is not applicable and propose an alternative process in its application to EPA.

As outlined in the framework, EPA states it will create a new workgroup, the Interagency Drug and Pesticide Resistance and Efficacy Workgroup (IDPREW). The IDPREW is tasked to provide expert opinion on resistance issues of antifungal and antibacterial pesticides. It will comprise of members from EPA, CDC, the U.S. Food and Drug Administration (FDA), and USDA, and will be chaired by EPA.

According to EPA, the framework also contains a research agenda that outlines the main uncertainties in EPA's ability to assess the resistance risks from antibacterial and antifungal pesticide use. This list highlights areas for scientific development that would assist in (1) informing assessments of the risk to the efficacy of human and animal antibacterial and antifungal drugs posed by certain antibacterial or antifungal pesticides; and (2) clarifying how to mitigate these risks.

### 15. Update to EPA's Safer Choice and Design for the Environment Standard

On August 8, 2024, EPA announced that it made updates to strengthen the Safer Choice and Design for the Environment (DfE) Standard, which identifies the requirements that products and their ingredients must meet to earn EPA's Safer Choice label or DfE logo. EPA states these updates strengthen the criteria that products must meet to qualify for the voluntary Safer Choice label, supporting the use of safer chemicals in the marketplace.

According to EPA, the Safer Choice program was implemented so consumers and purchasers for facilities like schools and office buildings could find cleaners, detergents, and other products made with safer chemical ingredients. It encourages use of chemicals that meet EPA's stringent criteria for human health and the environment and provides opportunities for companies to differentiate their products in the marketplace with the Safer Choice label.

Similarly, the DfE program assists consumers in finding antimicrobial products that meet high standards for public health and the environment. It helps consumers to identify antimicrobial products, like disinfectants, that meet the health and safety standards of the normal pesticide registration process required by FIFRA, as well as meeting the DfE Standard. It is a violation of FIFRA to claim that any pesticide is "safe," so antimicrobial products cannot have a Safer Choice label.

In addition to updated clarifying language, the final updated Standard includes:

- A new certification program for cleaning service providers that use Safer Choice- and DfE-certified products. The Cleaning Service Certification logo is available for organizations and businesses that use cleaners, detergents, disinfectants, and related products as part of their primary operations. The logo distinguishes cleaning service providers who use Safer Choice-certified products for cleaning and DfE-certified products for disinfection either exclusively or to the maximum extent practicable.
- Strengthened criteria that pet care products must meet to ensure they use only the safest possible ingredients for humans, pets, and the environment.
- Updated safer packaging criteria, ensuring primary packaging does not include any unintentionally added per- and polyfluoroalkyl substances (PFAS) or other chemicals of concern.
- Strengthened sustainable packaging requirements for all Safer Choice-certified products to use post-consumer recycled content and be recyclable or reusable.
- Updated criteria for wipe products to ensure certified wipes contain "Do Not Flush" language to help reduce damage to wastewater treatment systems.
- New, optional energy efficiency or use reduction criteria to encourage companies to use less water, use renewable energy, and improve energy efficiency.

This update follows a November 2023 request for public comment on EPA's proposed updates to the Standard. This is EPA's fourth update of the Standard since its inception in 2009 and the first since 2015. EPA states it periodically updates the Standard to keep current with the state of scientific and technological innovation, increase transparency and reduce redundancy, and expand the scope of the program as appropriate.

In 2025, we expect to see the new Cleaning Service Certification logo used by organizations and businesses that use cleaners, detergents, disinfectants, and related products as part of their primary operations.

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

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## D. FDA FOOD AND COSMETICS REGULATIONS

2024 was an interesting year and eventful for the U.S. Food and Drug Administration (FDA) due to the significant reorganization of the Office of Regulatory Affairs (ORA), the official launch of the unified Human Foods Program (HFP), and the continued implementation of major revisions to cosmetic regulations under the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). MoCRA regulatory progress in 2024 was not as efficient as expected as FDA delayed enforcement action until June for the facility registration and product listing requirements. Similarly, FDA showed less progress than anticipated in implementing the MoCRA regulatory obligations addressing Good Manufacturing Practices (GMP).

October 1, 2024, marked the beginning of the implementation of the reorganization establishing the HFP, and building enhanced field operations focusing on inspections, investigations, and imports. FDA did a good job of communicating its plans and issued many updates throughout 2024 communicating its new focus. Expect to see in 2025 continued progress in this regard, and more FDA-initiated chemical and risk-based assessments targeting chemicals of interest.

FDA's progress in promulgating rules proposed years prior remains slow relative to, for example, the U.S. Environmental Protection Agency (EPA), with the notable exception of key food contact rules. The Notice of Proposed Rulemaking (NPRM) on Food Contact Substance Notification That Is No Longer in Effect, expected in 2021, was issued in 2022. The 2024 final rule was effective on May 21, 2024. The Regulatory Agenda remains populated with proposed rules from prior years, and more action is expected in 2025, largely depending on the election outcome. These include a rule intended to clarify changes to the Registration of Food Facilities, rules addressing requirements in hazard analysis and risk-based preventive controls for human and animal food, and rules amending procedural requirements for Color Additive Petitions and Food Additive Petitions. A notable exception is FDA's success in issuing a final rule titled The Revocation of Authorization of Use of Brominated Vegetable Oil in Food. The NPRM was issued in late 2023, the comment period ended in early 2024, and the final rule was issued in July of 2024. FDA inteneded to issue a NPRM for Food Standards Modernization in **spring of 2025,** however, that rulemaking does not appear in the fall agenda. The swiftness of these actions reflects FDA's commitment to advance the HFP, especially for substances that are subject to ongoing risk assessments.

PODCAST:
A Conversation with Deputy Commissioner Jim Jones

James J. Jones, as FDA's first Deputy Commissioner for the unified HFP, spent most of 2024 focused on the reorganization and on promoting the HFP mission as it relates to food safety, chemical safety, and innovative food products. Based on the information made publicly available, and updates throughout 2024, FDA intends to initiate post-market assessments for food ingredients, food additives, color additives, food contact substances (FCS), and contaminants. FDA provided tables to indicate the chemical name, type, and details on where FDA is with its process. FDA held public meetings in September on the "Development of an Enhanced Systematic Process for FDA's Post-Market Assessment of Chemicals in Food." Key themes and concepts discussed during the meeting included:

- The importance of an effective, consistent, transparent, systematic, and science-based post-market food chemical reassessment program that considers all relevant information about the potential risks of chemicals;
- The steps in the process, such as prioritization and assessment, and the order of the steps in the process, as well as the scope of chemicals to include in the process, such as those intentionally added, indirect additives, and/or environmental contaminants;
- The importance of FDA conducting timely assessments and taking timely actions to protect public health;
- The FDA building capacity and expanding FDA's authority for both pre- and post-market programs, including enhancing a program to monitor ingredients considered generally recognized as safe (GRAS); and
- FDA integrating an advisory committee(s) review into the agency's post-market assessment process and the use of peer review to help inform the agency's risk assessments.

### 1. Food and Food Additive Safety

FDA continues building content surrounding its "New Era of Smarter Food Safety" initiative, following announcement of the blueprint in July 2020. FDA's focus on the four core elements: Tech-Enabled Traceability, Smarter Tools and Approaches for Prevention and Outbreak Response, New Business Models and Retail Modernization, and Food Safety Culture, continued in 2024. The Food Safety Modernization Act (FSMA)-based initiative sets deliverables, and tracks accomplishments in each priority area. FDA supplemented the initiative in 2024 with the addition of partnerships, podcasts, webinars, blogs, and related publications. FDA focused in 2024 on core elements related to food safety culture, tech-enabled traceability, and new food delivery models.

FDA continues developing tools for the implementation of various FSMA regulations. During 2024, FDA issued multiple guidance documents focusing on FDA's priorities and efforts to increase transparency. FDA issued the final Food Traceability rule in late 2022, and continues to provide tools to assist impacted parties with compliance of certain recordkeeping requirements mandated by **January 20, 2026**. FDA hosted roundtables in 2024 with industry to discuss the challenges and review strategies for supporting the implementation.

Expect further progress in 2025 with FSMA guidance and the New Era of Smarter Food Safety. With the HFP reorganization complete, we can expect more streamlined approaches to the management of chemical safety in food products.

### 2. Food Contact Substances

FDA issued the long-awaited final rule in 2024 revoking food contact notifications (FCN) determined to no longer be effective. Under this rule, FDA has established a procedural method to remove FCNs that are viewed as no longer effective. FDA will allow the manufacturer or supplier an opportunity to comment prior to issuing its final decision.

As of November 1, 2024, FDA authorized use of 39 FCSs notified via FCNs in 2024, up slightly from the 37 FCNs approved in 2023. In 2024, FDA released updates to the list of substances not considered to be GRAS and more details on its list of chemicals in the food supply currently under FDA review. Of note, FDA specifically addressed Tara flour in 2024, a substance previously noted as "GRAS" and found to have resulted in serious injury to consumers throughout 2022. Additional FCSs currently under post-market review by FDA include FD&C Red No. 3, titanium dioxide, bisphenol A (BPA), per- and polyfluoroalkyl substances (PFAS), and phthalates.

By **year's end in 2025**, FDA seeks to complete implementation of its new Post-Market Assessment of Chemicals in Food. This new approach is intended to increase transparency and expand FDA's authority in both the pre- and post-market programs, including enhancing a program to monitor ingredients considered GRAS.

### 3. Modernization of Cosmetics Regulation Act of 2022

On December 29, 2022, Congress passed and President Biden signed MoCRA into law. MoCRA is the first major amendment to FDA's cosmetics authorities since President Franklin Delano Roosevelt signed the Federal Food, Drug, and Cosmetic Act (FFDCA) into law in 1938. MoCRA seeks to ensure that cosmetic products are safe for their intended use and provides FDA more enforcement authority. MoCRA introduces mandatory facility and product registration, a process that has, until now, been entirely voluntary. MoCRA seeks, through rulemaking, to establish GMPs, another process that has, until now, been entirely voluntary. MoCRA also introduces changes to the labeling and mandates actions on specific ingredients.

FDA's progress in 2024 implementing MoCRA was slow. The only major element enacted in 2024 was the facility registration and product listing provisions. This included newer versions of FDA tools commonly used for other submission processes. FDA provided enforcement discretion until June 2024 to accommodate administrative hiccups and continued in 2024 to refine its systems tools to allow for new user features.

PODCAST:
GRAS: Are Changes in Our Future? — A Conversation with Karin F. Baron

ARTICLE
Chemicals in Food: FDA Steps Up Post-Market Review

MoCRA requires FDA to issue a NPRM to address GMPs **no later than two years from enactment** and publish a final rule **no later than three years of enactment**. No clear progress was made in meeting these requirements in 2024.

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

Two other MoCRA provisions address specific product ingredients. The first relates to talc and requires FDA to propose regulations establishing testing with standardized methods for detecting asbestos in talc-contacting products. In 2024, FDA announced the release of data from its testing. The other provision relates to PFAS. FDA must, **no later than three years after enactment**, publish on its website a summary of an assessment of the uses and safety of uses, including risks for PFAS in cosmetics. No clear progress was made in meeting this goal in 2024.

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

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## E. PFAS

Perfluoroalkyl and polyfluoroalkyl substances (PFAS) are attracting intense global legal, regulatory, commercial, and litigation attention as no other "emerging contaminant" has. This attention will increase in 2025. The regulatory activities are global, from states within the United States to Canada and Europe. Where we have reported on PFAS developments within another chapter, we have provided a link below for readers to follow to obtain more information.

### 1. United States

### a. Federal

#### i. TSCA

In 2024, the U.S. Environmental Protection Agency (EPA) continued to use its authority under Section 4 of the Toxic Substances Control Act (TSCA) to issue test orders for PFAS identified through the PFAS National Testing Strategy, issuing two more test orders. *B. TSCA v. Section 4(a) — Test Orders b. National PFAS Testing Strategy.* EPA's use of its TSCA Section 4 testing authority has led to several challenges to specific orders, with one case still outstanding. *B. TSCA v. Section 4(a) — Test Orders c. Section 4(a) Test Order Litigation ii. 6:2 FTSB.*

To limit the reintroduction of inactive PFAS, in January 2024, EPA issued a final significant new use rule (SNUR) to prevent companies from starting or resuming the manufacture (including import) or processing of 329 PFAS designated as inactive on the TSCA Inventory. The final SNUR provides EPA an opportunity to determine whether the reintroduction of these PFAS presents an unreasonable risk to health or the environment before manufacture (including import) or processing can commence. *B. TSCA iv. Section 5 – New Chemical Substances h. SNURs on Existing Chemicals*.

In September 2024, EPA issued a direct final rule that postpones the data submission period for the TSCA Section 8(a)(7) reporting and recordkeeping rule on PFAS. The direct final rule postpones the data submission period to **July 11, 2025, through January 11, 2026**. For any reporter who is reporting exclusively as an article importer and is also considered a small manufacturer, the submission period will begin on **July 11, 2025**, and last for 12 months, until **July 11, 2026**. The 2023 rule requires all manufacturers (including importers) of PFAS and PFAS-containing articles between 2011 and 2022 to report information related to chemical identity, uses, volumes made and processed, byproducts, environmental and health effects, worker exposure, and disposal to EPA. *B. TSCA. vi. Sections 8 and 14 — Reporting and Confidential Information a. TSCA Section 8(a)(7) Rule on PFAS.*

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

On May 8, 2024, EPA designated perfluorooctanoic acid (PFOA), perfluorooctanesulfonic acid (PFOS), and their salts and structural isomers as hazardous substances under CERCLA. 89 Fed. Reg. 39124. Under the rule, entities are required to report immediately releases of PFOA and PFOS that meet or exceed the reportable quantity (RQ) of one pound within a 24-hour period to the National Response Center (NRC), state, Tribal, and local emergency responders.

In April 2024, EPA issued a separate PFAS Enforcement Discretion and Settlement Policy Under CERCLA (CERCLA Enforcement Discretion Policy) providing direction on how EPA will exercise its enforcement discretion under CERCLA in matters involving PFAS. According to the CERCLA Enforcement Discretion Policy, EPA will focus on holding responsible entities that significantly contributed to the release of PFAS contamination into the environment, including parties that have manufactured PFAS or used PFAS in the manufacturing process, federal facilities, and other industrial parties. EPA notes that it does not intend to pursue entities where equitable factors do not support seeking response actions or costs under CERCLA, including farmers, municipal landfills, water utilities, municipal airports, and local fire departments.

More information on EPA's final rule and the CERCLA Enforcement Discretion Policy is available in our April 23,

WEBINAR ON DEMAND
Determining PFAS Content in Your Supply Chain and Expanding Data Collection Practice

ARTICLE
"EPA Extends PFAS Reporting Deadline to 2026"

2024, memorandum, "EPA Designates PFOA and PFOS as CERCLA Hazardous Substances, Releases CERCLA Enforcement Discretion Policy."

In 2023, EPA stated that it intends to expand its CERCLA authority beyond regulating PFOA and PFOS, but it has yet to issue a proposed rule. EPA published an advance notice of proposed rulemaking (ANPRM) in April 2023 seeking information to assist in the consideration of potential development of future regulations pertaining to PFAS under CERCLA. EPA requested public input on the possible designation of seven PFAS besides PFOA and PFOS (perfluorobutanesulfonic acid (PFBS), perfluorohexanesulfonic acid (PFHxS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA) (sometimes called GenX), perfluorobutanoic acid (PFBA), perfluorohexanoic acid (PFHxA), and perfluorodecanoic acid (PFDA)); precursors to PFOA, PFOS, and the seven PFAS; and categories of PFAS. Implementation of the proposed rule is expected to jump-start extraordinary remediation activities resulting in significant CERCLA-related cleanups, demands for cost recovery, re-opening of "cleaned-up" sites, and private litigation. According to an item in EPA's spring 2024 Unified Agenda , EPA has not determined when it will issue a notice of proposed rulemaking (NPRM). More information is available in our April 13, 2023, memorandum, "EPA Publishes ANPRM Seeking Information to Assist in Consideration of Future CERCLA Regulations Regarding PFAS."

### iii. Emergency Planning and Community Right-to-Know Act (EPCRA)

The National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2020 requires EPA to update annually the list of chemicals covered by the Toxics Release Inventory (TRI) with additional PFAS. EPA issued a final rule in May 2024 identifying seven additional PFAS for TRI Reporting Year 2024 (reporting forms due by **July 1, 2025**). More information is available in our May 22, 2024, blog item, "EPA Issues Final Rule Requiring TRI Reporting for Seven Additional PFAS."

In October 2024, EPA proposed to add 16 individual PFAS and 15 PFAS categories representing more than 100 individual PFAS to the TRI list of chemicals to comply with the NDAA. 89 Fed. Reg. 81776. The proposed rule also addresses how PFAS categories should be treated. Separately, the proposed rule discusses what events may trigger the automatic addition of a PFAS to the TRI pursuant to the NDAA. EPA notes that this discussion does not propose to list chemicals to the TRI pursuant to the NDAA, but rather describes what EPA documents and activities involving PFAS would trigger an automatic addition under the NDAA. Comments were due December 9, 2024. More information on the proposed rule is available in our October 17, 2024, memorandum, "EPA Proposes to Add 16 PFAS and 15 PFAS Categories to the TRI List of Chemicals." According to an item in EPA's fall 2024 Unified Agenda , EPA intends to issue a final rule in **August 2025**.

Facilities in TRI-covered industry sectors should routinely monitor for the addition of PFAS to the TRI list of chemicals. EPA has compiled summaries of existing TRI reporting guidance and gathered links to external technical guidance to address frequently asked questions (FAQ) on PFAS reporting. These resources are available in GuideME.

### iv. Clean Water Act (CWA)

In April 2024, EPA issued the first-ever national drinking water standard for six PFAS. 89 Fed. Reg. 32532. The National Primary Drinking Water Regulation (NPDWR) establishes Maximum Contaminant Levels (MCL) for six PFAS in drinking water: PFOA, PFOS, PFHxS, PFNA, and HFPO-DA as contaminants with individual MCLs, and PFAS mixtures containing at least two or more of PFHxS, PFNA, HFPO-DA, and PFBS using a Hazard Index MCL to account for the combined and co-occurring levels of these PFAS in drinking water. EPA also issued final health-based, non-enforceable Maximum Contaminant Level Goals (MCLG) for these PFAS. More information is available in our May 9, 2024, memorandum, "EPA Issues First-Ever Drinking Water Standards for PFAS."

According to an item in EPA's fall 2024 Unified Agenda, in **June 2025**, EPA intends to issue an NPRM to update requirements for several of the existing National Pollutant Discharge Elimination System (NPDES) permit applications to address monitoring and/or reporting of PFAS. Under the CWA, discharging pollutants from a point source into waters of the United States is prohibited unless the discharge is authorized by an NPDES permit. EPA's NPDES regulations identify requirements that must be included in application forms that are used for different classes of

ARTICLE
"PFAS Risk and the Role of the Corporate Fiduciary"

*EPA issued on February 8, 2024, two proposed rules that will add to its comprehensive approach to tackling PFAS pollution and the commercial bottom line for hundreds of businesses facing costs for cleanup.*

discharges. NPDES permit applicants are required to report to the permitting authority only the pollutants in their discharge that are listed in the application regulations at 40 C.F.R. Section 122.21. The list of pollutants in the application regulations does not currently include PFAS. EPA intends to issue a final rule in **December 2026**.

### v. Resource Conservation and Recovery Act (RCRA)

EPA issued on February 8, 2024, two proposed rules that will add to its comprehensive approach to tackling PFAS pollution and the commercial bottom line for hundreds of businesses facing costs for cleanup. The first proposed rule would modify the definition of hazardous waste as it applies to cleanups at permitted hazardous waste facilities. 89 Fed. Reg. 8598. According to the proposed rule, it "would more clearly provide EPA authority to address, through corrective action for solid waste management units, releases of the full universe of substances that the statute intended — not only hazardous waste and hazardous constituents listed or identified in the regulations, but all substances that meet the definition of hazardous waste in RCRA [S]ection 1004(5) at a facility." The proposed rule would also provide notice of and codify EPA's interpretation of RCRA — "that it provides authority to address releases from solid waste management units of all substances that meet the definition of hazardous waste under the statute." According to an item in EPA's fall 2024 Unified Agenda, EPA intended to issue a final rule in December 2024.

The second proposed rule would amend the RCRA regulations to add nine specific PFAS, their salts, and their structural isomers to its list of hazardous constituents. 89 Fed. Reg. 8606. After EPA issues a final rule, when EPA imposes corrective action requirements at a facility, these PFAS would be among the hazardous constituents expressly identified for consideration in RCRA facility assessments and, where necessary, further investigation and cleanup through the RCRA corrective action process at RCRA treatment, storage, and disposal facilities. According to an item in EPA's fall 2024 Unified Agenda, EPA intends to issue a final rule in **July 2025**.

### vi. PFAS and HDPE Containers

In March 2024, an appellate court vacated EPA's December 2023 TSCA orders prohibiting Inhance Technologies, L.L.C. (Inhance) from manufacturing or processing PFAS during its fluorination process. The court agreed with Inhance that EPA "exceeded its statutory authority by issuing orders under Section 5 instead of Section 6 because Inhance's forty-year-old fluorination process is not a 'significant new use' under TSCA." Just a month later, a coalition of public health groups filed a TSCA Section 21 petition seeking a TSCA Section 6 rulemaking prohibiting the manufacture, processing, use, distribution in commerce, and disposal of three PFAS formed during the fluorination of high-density polyethylene (HDPE) plastic containers. Following its grant of the petition, in September 2024, EPA requested comment on the manufacture of certain PFAS during the fluorination of HDPE and other plastic containers to inform regulations as appropriate under TSCA. Comments were due November 29, 2024. Although EPA promptly granted the petition, on July 25, 2024, the Center for Environmental Health (CEH) and Public Employees for Environmental Responsibility (PEER) filed suit against EPA in the U.S. District Court for the District of Columbia seeking a TSCA Section 6 rulemaking. *B. TSCA. ii. Significant Court Decisions. a. Inhance Technologies v. EPA.*

## b. States

State prohibitions on intentionally added PFAS often first ban the use of PFAS in certain products such as firefighting foams (FFF), food contact materials (FCM), pesticides, and consumer products before eventually banning all products containing intentionally added PFAS that do not have a currently unavoidable use (CUU) determination. Some state consumer product bans are now in effect, while others will take effect in the coming years. Some of these states will also require reporting on intentionally added PFAS in all products sold within the state. These regulations are increasing at a rapid pace, and the scope of PFAS reporting and bans seemingly grow every day.

In 2021, Maine enacted An Act To Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution, but it has since amend-

ed the statute twice, most recently in April 2024. While the 2021 statute required reporting on all products containing intentionally added PFAS, under the April 2024 amendment, reporting will be required only for those products with CUU determinations. In August 2024, the Maine Department of Environmental Protection (MDEP) released new concept draft language to implement the recently amended statute for an informal outreach process. After the informal outreach process, MDEP planned to proceed with rulemaking in fall 2024. More information regarding the 2024 amendment is available in our May 24, 2024, blog item, "Maine Amends Its PFAS Statute, Exempting Certain Product Categories from the Sales Prohibition and Eliminating the General Notification Requirement." More information regarding the concept draft language is available in our August 7, 2024, memorandum, "Maine Seeks Comments on Concept Draft Language for PFAS in Products Rule."


Visit our PFAS News and Information site for a comprehensive and constantly updated library of PFAS resources, including our 26-page booklet PFAS — Bans, Restrictions, Reporting, and Minimizing Liability. Bergeson & Campbell, P.C. (B&C®) has prepared these resources to help those in the chemical and chemical products industry understand what they need to know and what it means to their business.

As of January 1, 2025, Minnesota prohibits intentionally added PFAS in 11 product categories:

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

By **January 1, 2026**, the Minnesota Pollution Control Agency (MPCA) will require a manufacturer of a product sold, offered for sale, or distributed in Minnesota that contains intentionally added PFAS to submit a description and numeric coding of the product; the purpose of any PFAS in the product; the identity of each PFAS present; the amount of each PFAS present; location and contact information for the manufacturer; and any additional information requested. MPCA intended to prepare draft rules and a statement of need and reasonableness in 2024. There will be a public comment period before MPCA adopts the final rules. More information on Minnesota's requirements is available in our October 3, 2024, blog item, "Minnesota Posts Q&As from July 2024 Webinars on PFAS in Products Law; Leaders Mark 100 Days until Law Takes Effect."

The Washington Department of Ecology (WDOE) intends to issue a proposed rule in **summer 2025** and a final rule by **December 2025** that would reduce PFAS in consumer products. The final rule may include reporting requirements or restrictions on the use of intentionally added PFAS in the following product categories:

- Apparel and gear;
- Cleaning products, including products to wash automobiles and boats;
- Cookware and kitchen supplies;
- Firefighting personal protective equipment (PPE);
- Hard surface sealants; and
- Waxes and polishes, including products for floors, automobiles, skis, and snowboards.

In 2024, the state legislatures of California, Colorado, Connecticut, New Hampshire, Rhode Island, and Vermont adopted bills prohibiting intentionally added PFAS in categories ranging from menstrual products (California) to carpets or rugs, cosmetics, textile treatments, feminine hygiene products, food packaging and containers, juvenile products, upholstered furniture, and textile furnishings (New Hampshire). Each year, the number of state bills addressing PFAS increases, and PFAS will continue to be front and center in 2025.

### 2. Canada

Comments on Canada's *Updated Draft State of Per- and Polyfluoroalkyl Substances (PFAS) Report* (Updated Draft Report) and *Revised Risk Management Scope for Per- and Polyfluoroalkyl Substances (PFAS)* (Revised Risk Management Scope) were due in September 2024. Canada proposed to conclude that the class of PFAS, excluding fluoropolymers, meets the criteria of Section 64 of the Canadian Environmental Protection Act, 1999 (CEPA) and that the class, excluding fluoropolymers, be added to Part 2 of Schedule 1 of CEPA. Just two weeks later, Canada issued a mandatory survey to obtain information on the manufacture, import, and use of 312 specific PFAS. Responses to the survey are due **January 29, 2025**. *D. The Americas ii. Canada b. PFAS.*

On October 5, 2024, the Minister of the Environment announced the availability of the proposed plan of priorities. The proposed plan of priorities is a multi-year, integrated plan for the assessment of substances in Canada, as well as other activities that support the management of substances. The substances prioritized for assessment include fluoropolymers. According to Canada, there is evidence to suggest that fluoropolymers may have different exposure and hazard profiles compared with other PFAS. To examine these differences, Canada states that additional work is warranted. Under the CEPA amendments, Canada must publish a final plan of priorities by **June 13, 2025**. According to Canada's workplan, the start date of the assessment of fluoropolymers is **fall 2026**. Comments on the proposed plan of priorities were due December 4, 2024. More information on the proposed plan of priorities is available in our October 11, 2024, memorandum, "Canada Begins Public Consultations on Initiatives Supporting CEPA Amendments."

### 3. European Union (EU)

The European Chemical Agency's (ECHA) Scientific Committees for Risk Assessment (RAC) and for Socio-Economic Analysis (SEAC) continue to work on the 2023 proposal to restrict more than 10,000 PFAS under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation. In September 2024, the committees discussed the following sectors:

- Petroleum and mining;
- Textiles, upholstery, leather, apparel, and carpets; and
- FCM and packaging.

The committees provisionally concluded on the evaluation of the petroleum and mining sector. The committees planned to continue discussing the textiles, upholstery, leather, apparel, and carpets and FCM and packaging sectors in November 2024 and to begin discussing construction products. In 2025, the committees are scheduled to discuss applications of fluorinated gases, transport, and energy sectors.

Although ECHA's work on the PFAS restriction proposal is taking longer than initially predicted, in September 2024, the European Commission (EC) restricted the use of PFHxA and PFHxA-related substances. According to the EC, the PFHxA restriction focuses on uses where the risk is not adequately controlled, alternatives are available, and socioeconomic costs will be limited in comparison to the human health and environmental benefits. The restriction bans the sale and use of PFHxA in consumer textiles, food packaging, consumer mixtures such as waterproofing sprays, cosmetics, and in some FFF applications. The EC notes that the restriction does not affect other applications of PFHxA, for example in semiconductors, batteries, or fuel cells for green hydrogen.

More information is available in our September 19, 2024, blog item, "EC Adopts REACH Restriction for PFHxA and Related Substances." *B. European Union 2. EU REACH.*

**4. United Kingdom (UK)**

The UK REACH work programme for 2023-2024, published in February 2024, states that in 2023/24, the Health and Safety Executive (HSE) will propose and begin an Annex 15 dossier regarding the use and disposal of FFFs where non-PFAS alternatives are available; start evidence gathering and stakeholder engagement regarding other wide dispersive uses, such as the application of coatings or use of cleaning agents; and start evidence gathering and stakeholder engagement regarding the manufacture and placing on the market of consumer articles from which PFAS are likely to be released into air, water, or soil or directly transferred to humans. HSE published a regulatory management option analysis (RMOA) for PFAS in 2023. The RMOA states that based on initial considerations of likely effectiveness and efficiency of options — and considering the Precautionary Principle — HSE concludes that it would be appropriate to consider initiating risk management measures with regard to certain uses of PFAS, including preparing background dossiers to support UK REACH restrictions of PFAS. *C. United Kingdom/Great Britain 2. UK REACH.*

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

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*EPA continues to use consent orders and SNURs to regulate new nanoscale materials under TSCA.*

## F. NANOTECHNOLOGY

### 1. U.S. Environmental Protection Agency

Manufacturers and importers of new nanoscale materials in 2025 should expect to be subject to a consent order or significant new use rule (SNUR), particularly in the absence of data concerning human health and environmental hazards and occupational exposure. As reported in the 2024 Developments in Delegations on the Safety of Manufactured Nanomaterials and Advanced Materials — Tour de Table published by the Organisation for Economic Co-operation and Development (OECD), the U.S. Environmental Protection Agency (EPA) continues to use consent orders and SNURs to regulate new nanoscale materials under the Toxic Substances Control Act (TSCA). Between July 2022 and June 2023, EPA reviewed four low volume exemptions (LVE) that included a graphene material, a titanium dioxide material, and two graphene oxide materials, one of which was a modification to an existing exemption. EPA denied two of the LVEs and granted two under conditions that limited human and environmental exposures to prevent unreasonable risks. Additionally, EPA had under review 17 premanufacture notices (PMN), 16 of which are for multi-walled carbon nanotube chemical substances and one of which is for a graphene material. EPA was still reviewing the 17 nanomaterial substances for potential risks to human health and the environment. EPA completed its review of a significant new use notice (SNUN) for a single-walled carbon nanotube, regulating it with a consent order due to limited available data on nanomaterials. The consent order limits uses and human and environmental exposures to prevent unreasonable risks.

Since January 2005, EPA has received and reviewed more than 275 new chemical notices for nanoscale materials, such as fullerenes and carbon nano-onions, quantum dots, semiconducting nanoparticles, and carbon nanotubes. Because of limited data to assess nanomaterials, EPA has issued consent orders and SNURS containing requirements to limit exposure to workers through the use of personal protective equipment (PPE), limit environmental exposure by not allowing releases to surface waters or direct releases to air, and limit the specific applications/uses to those described in the new chemical notification.

### 2. National Nanotechnology Initiative Environmental, Health, and Safety Research Strategy

The National Nanotechnology Coordination Office (NNCO) requested comments on June 13, 2024, on the "National Nanotechnology Initiative Environmental, Health, and Safety Research Strategy: 2024 Update" (2024 Update). 89 Fed. Reg. 50390. NNCO states that federal agencies participating in the Nanotechnology Environmental and Health Implications Working Group of the Nanoscale Science, Engineering, and Technology Subcommittee of the Committee on Technology, National Science and Technology Council developed the draft 2024 Update and sought comments by the environmental, health, and safety research community and the public "as a final stage of public input that will inform the final strategy." Comments were due July 22, 2024.

According to the 2024 Update, realizing the potential of engineered nanomaterials and nanotechnology-enabled products to solve global challenges while protecting human and environmental health necessitates addressing unmet and new needs in nanotechnology environmental, health, and safety (EHS) through coordinated, collaborative action. Key areas of action could include:


B&C's Nano and Other Emerging Chemical Technologies Blog is the leading source of information on regulatory and legal developments involving nanotechnology and other emerging technologies. Visit and subscribe at https://www.lawbc.com/brand/nanoblog.

- Addressing remaining EHS knowledge gaps for engineered nanomaterials in commerce;
- Monitoring and evaluating emerging nanotechnology applications;
- Investigating emerging nanoscale contaminants of concern;
- Strengthening the collaborative informatics infrastructure;
- Engaging the international nanosafety community; and
- Expanding public engagement in the responsible development of nanotechnology.

A comprehensive, integrated approach will enable responsible nanotechnology innovation to flourish, benefiting human health, the environment, the economy, and society. The 2024 Update should foster collaborations, capabilities, and discoveries that address ethical, legal, and social implications and safety uncertainties and catalyze the field's next decades of achievement. More information on the 2024 Update is available in our June 14, 2024, blog item, "NNI EHS Research Strategy: 2024 Update Available for Public Comment."

### 3. Canada

On October 5, 2024, the Minister of the Environment announced in the *Canada Gazette* publication of a proposed plan of priorities for the assessment of chemical substances. Under the 2023 amendments to the Canadian Environmental Protection Act, 1999 (CEPA), the Minister of the Environment and the Minister of Health are required to "develop, consult on and publish a plan with timelines" by **June 2025.** The proposed list of prioritized substances for assessment and the rationales for priorities include:

- Specific substances:
  - Nanoscale silver: According to the work plan, Canada will begin assessment activities in fall 2024.
  - Nanoscale zinc oxide: According to the work plan, Canada will begin assessment activities on nanoscale zinc oxide in **summer 2026.**
- Certain substances within the following groups:
  - Nanoscale forms of nickel oxide: According to the work plan, Canada will begin assessment activities on substances within the group as early as fall 2024 while it will begin assessment activities on others in **summer 2026**.
  - Nanoscale forms of titanium dioxide: According to the work plan, Canada will begin assessment activities on substances within the group in **summer 2026**.

Comments were due December 4, 2024. More information on the proposed plan of priorities and the prioritized nanomaterials is available in our October 8, 2024, blog item, "Canada's Proposed Plan of Priorities Includes Several Nanoscale Materials; Comments Are Due December 4, 2024."

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## G. BIOTECHNOLOGY

### 1. Coordinated Framework for the Regulation of Biotechnology

Last updated in 2017, the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) outlines a comprehensive U.S. regulatory policy for ensuring the safety of biotechnology products and summarizes the roles and responsibilities of the U.S. Department of Agriculture (USDA), U.S. Environmental Protection Agency (EPA), and U.S. Food and Drug Administration (FDA) with respect to regulating biotechnology products. The agencies intended to release an updated Coordinated Framework in December 2024. The updated Coordinated Framework is expected to clarify better the roles of the agencies and their regulations, improving the Coordinated Framework's transparency, predictability, coordination, and efficiency. More information on the 2017 update to the Coordinated Framework is available in our January 9, 2017, memorandum, "White House Announces Release of Final Update to the Coordinated Framework for the Regulation of Biotechnology."

To update the Coordinated Framework, USDA, EPA, and FDA prepared an ambitious plan to update, streamline, and clarify their regulations and oversight mechanisms for products of biotechnology. Released in May 2024, *The Coordinated Framework for the Regulation of Biotechnology: Plan for Regulatory Reform under the Coordinated Framework for the Regulation of Biotechnology* (Plan for Regulatory Reform) provides a roadmap for actions the agencies will take, individually and collaboratively, to improve regulatory clarity, streamline regulatory oversight, reduce regulatory redundancies and gaps, and increase regulatory coordination for specific product categories and across the Coordinated Framework. The Plan for Regulatory Reform identifies regulations and guidance documents that can be updated, streamlined, or clarified, and identifies potential new guidance or regulations where needed. These actions will focus on the following areas of biotechnology product regulation: modified plants; modified animals; modified microorganisms; human drugs, biologics, and medical devices; and cross-cutting issues. More information on the Plan for Regulatory Reform is available in our May 16, 2024, memorandum, "EPA, FDA, and USDA Issue Joint Regulatory Plan for Biotechnology."

As part of the agencies' efforts to modernize the Coordinated Framework, and in response to stakeholder comments, in October 2024, the agencies announced the release of a new web-based tool on the Unified Website for Biotechnology Regulation for companies that develop microbial biotechnology products. According to EPA, the new tool provides a starting point for researchers and developers, especially those new to biotechnology product development, to navigate the regulatory requirements for genetically modified microorganisms. Through a series of prompts, the tool provides users with information on the regulatory requirements for biotechnology products developed using genetically modified microorganisms and the approval process across agencies.

The following collaborative agency actions that were outlined in the Plan for Regulatory Reform are still outstanding:

- FDA and USDA will consider mechanisms for stewardship of food and crops engineered to produce substances that could cause food safety concerns, or other food crops where stewardship may be important, if they inadvertently enter the food supply;
- EPA and USDA will clarify, and as possible harmonize, regulatory roles, processes, and information, data, and authorization requirements for environmental release of modified microbes; and
- EPA, FDA, and USDA will develop and implement a mechanism for developers to submit information to, and request a meeting with, all three regulatory agencies, early in the product development process.

More information on future actions that the agencies will take individually is provided below.

### 2. U.S. Department of Agriculture

In 2024, multiple bills were introduced to establish an Office of Biotechnology Policy within USDA and to require interagency oversight coordination. Under the Agricultural Biotechnology Coordination Act (H.R. 8539, S. 4421), the Office of Biotechnology Policy would have coordinated work on bio-

technology policies and activities that spans multiple USDA agencies working on research and development (R&D), extension and education, regulation, labeling, and trade. The Biotechnology Oversight Coordination Act (H.R. 8538, S. 4428) would have required interagency coordination by statute. The Synthetic Biology Advancement Act (S. 4413) would have created a Synthetic Biology Center under USDA with a focus on the application of synthetic biology to food security and agriculture. The bills all failed to move out of committee in 2024. Given the complex issues concerning gene editing in agriculture and the more pressing issues facing Congress in 2025, it is unlikely that Congress will take up similar legislation any time soon. More information on the 2024 bills is available in our June 4, 2024, blog item, "National Security Commission on Emerging Biotechnology Announces Introduction of Agricultural Bills."

In 2024, USDA's Animal and Plant Health Inspection Service's (APHIS) Biotechnology Regulatory Services (BRS) announced a new flexibility for BRS importation permits in APHIS eFile that allows permit holders to reuse import labels. According to APHIS, permit holders no longer need to request additional labels if they have used all the import labels received with their permit.

The Plan for Regulatory Reform identifies ways that USDA will update, streamline, and clarify its biotechnology regulations, and USDA will continue to work on implementing these reforms in 2025:

- Modified Plants: USDA will streamline its Regulatory Status Review (RSR) process to provide a regulatory off-ramp for modified plants that do not meet the criteria for exemption. In consultation with EPA and FDA, USDA will explore eliminating interstate movement permits for certain plants or establishing alternative import and interstate movement permit categories for certain plants with streamlined processes and permit conditions. USDA will also consider issuing multi-year permits for all interstate movement and importation permits for plants and for environmental releases for familiar crops (*e.g.*, corn, soybean, cotton, potato, tomato, and alfalfa) and traits. Finally, USDA will streamline Supplemental Permit Conditions to ensure it assigns permit conditions that meet its protection goals, are consistent among developers, and provide concise, plain-language requirements.

- Modified Microorganisms: USDA will clarify the modified microorganisms that are subject to regulation under its authority. USDA will develop, publish, and maintain a list of plant pests. USDA will explore potential pathways to commercialization, including mechanisms for risk-based deregulation, for non-plant organisms that could be proposed in future rulemaking, engaging impacted developers and other stakeholders, and consulting with EPA and FDA.

### 3. U.S. Food and Drug Administration

Under the Coordinated Framework, FDA regulates the safety and effectiveness of intentional genomic alterations in animals produced using biotechnology; the safety and effectiveness of human and animal drugs; and the safety, purity, and potency of human biologics, including drugs and human biologics from plants and animals produced using biotechnology.

To support innovation and more food choices for consumers, FDA issued on February 22, 2024, a guidance entitled "Guidance for Industry: Foods Derived from Plants Produced Using Genome Editing" that describes how firms can voluntarily engage with FDA before marketing food from genome-edited plants. The guidance reaffirms that the risk-based approach FDA has taken for foods derived from new plant varieties also applies to foods from genome-edited plants. In addition, this guidance describes two processes through which companies may voluntarily inform FDA of the steps they have taken to ensure the safety of foods from their genome-edited plant varieties: voluntary pre-market consultations and voluntary pre-market meetings. These processes can help ease the pathway to market for foods from genome-edited plants, while keeping FDA safeguards in place.

According to FDA, one purpose of the guidance is to clarify how its 1992 policy statement, "Statement of Policy: Foods Derived from New Plant Varieties" (NPV policy) (57 Fed. Reg. 22984), applies to foods derived from new plant varieties produced using genome editing. The NPV policy provides scientific and regulatory guidance on foods from new plant varieties. The NPV policy lays out broad, risk-based principles to ensure the safety of foods from new plant varieties. These principles are sufficiently flexible to accommodate foods from new plant varieties developed using a wide range of techniques. The guidance explains that the principles outlined in the NPV policy apply to foods from genome-edited plant varieties. The guidance also reminds developers of new plant varieties of their obligations under Section 403(w) of the Federal Food, Drug, and Cosmetic Act (FFDCA), which was enacted after FDA issued the NPV policy.

In 2025, FDA will continue initiating actions identified in the Plan for Regulatory Reform to update, streamline, and clarify its biotechnology regulations:

- Modified animals: FDA and USDA will clarify and provide guidance on the regulation of cultured animal cell foods. FDA intends to issue draft guidance to help manufacturers and other industry stakeholders understand the types of food safety issues they should consider when producing cultured animal cell foods and how to assemble and organize information that can support a firm's conclusion about the safety of their food.

- Human Drugs, Biologics, and Medical Devices: FDA intends to issue a proposed rule to revise regulations related to post-approval chemistry, manufacturing, and controls (CMC) changes for both drugs and biological products, and intends to issue draft guidance to provide greater clarity on its oversight of post-approval CMC changes for certain biotechnology products. FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) are developing draft guidance on post-approval manufacturing changes to biosimilar and interchangeable biosimilar products to provide clarity on how to make post-approval changes for biosimilar products. In addition, FDA is developing guidance on its oversight of certain genome-editing products, including use of a platform approach to such therapeutics.

**4. U.S. Environmental Protection Agency**

In 2023, EPA issued a final rule exempting two groups of plant-incorporated protectants (PIP) created using genetic engineering from registration requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and from the food or feed residue tolerance requirements under the FFDCA. 88 Fed. Reg. 34756. Under the final rule, EPA exempted the following materials from tolerance requirements in 2024:

- BLB2 and AMR3 proteins in potato when used as a PIP in accordance with the terms of Experimental Use Permit (EUP) No. 8971-EUP-3 (89 Fed. Reg. 31649);

- *Bacillus thuringensis* Cry1B.868 and Cry1Da_7 proteins when used as a PIP in or on the food and feed commodities of corn (89 Fed. Reg. 43328);

- *Ophioglossum pendulum* IPD079Ea protein when used as a PIP in or on the food and feed commodities of corn (89 Fed. Reg. 64807); and

- *Pseudomonas chlororaphis* IPD072Aa protein in or on maize when used as a PIP in or on the food and feed commodities of corn (89 Fed. Reg. 68783).

EPA also received an application for a new PIP, *Bacillus thuringiensis* Cry1A.2 protein and Bacillus thuringiensis Cry1B.2 protein and the genetic material (vector PV-GMIR527237) necessary for their production in corn event MON 94637, which will involve a tolerance exemption. 89 Fed. Reg. 63199. Public comments were due September 3, 2024.

As biotechnology advances further, EPA intends to consider exempting additional categories of PIPs from both FIFRA registration and FFDCA tolerance requirements, as well as adding categories of exempted PIPs to the list of categories that do not require EPA confirmation of eligibility. According to the Plan for Regulatory Reform, EPA is developing guidance documents on common data needs for PIPs for each of the three components of the risk assessment: molecular characterization, human health assessment, and ecological assessment. EPA will also develop internal guidance for PIPs related to technical screen checklists, study evaluation templates, and risk assessment templates to ensure consistency across reviews.

In 2025, EPA will continue initiating actions identified in the Plan for Regulatory Reform to update, streamline, and clarify its regulations regarding pesticides developed through biotechnology:

- Modified Animals: EPA will provide efficacy guidance on genetic modifications in pest animals intended for use as a pesticide. Given the unique parameters involved with field testing of modified mosquito products, EPA will develop efficacy guidance for modified mosquito products for population control.

- Modified Microorganisms: Since biopesticides often have lower toxicity profiles, reduced worker re-entry intervals, and reduced pre-harvest intervals, EPA intends to prioritize review of biopesticide applications, provide technical assistance to biopesticide developers, and seek to collaborate with state lead pesticide agencies to reduce the time to bring new and effective biopesticide tools to farmers, as resources allow and in

alignment with the Pesticide Registration Improvement Act (PRIA 5). On December 22, 2023, EPA granted a three-year registration for a first-of-its-kind biopesticide product containing the new active ingredient Ledprona. More information is available in our December 29, 2023, blog item "EPA Registers Novel Pesticide Technology for Potato Crops."

EPA's review of biotechnology notices continues to shine. EPA received seven Microbial Commercial Activity Notices (MCAN) during fiscal year (FY) 2024 and EPA completed review of all of them in less than 90 days. Because EPA found each to be low concern for health and environmental effects, EPA found each to be "not likely to present" unreasonable risk. EPA also received one Toxic Substances Control Act (TSCA) Environmental Release Application (TERA) in April 2024, and EPA granted it in June.

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## H. BIOBASED AND RENEWABLE CHEMISTRY

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

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

The U.S. Department of Agriculture (USDA) released on March 14, 2024, a report entitled Building a Resilient Biomass Supply: A Plan to Enable the Bioeconomy in America, "a plan that will boost biomass supply chain resiliency for domestic biobased product manufacturing, while also advancing environmental sustainability and market opportunities for small and mid-sized producers." USDA states that the plan finds that U.S. biomass supplies are abundant, positioning the United States to convert biomass into biobased products if improvements to biomass supply chain logistics and materials handling technology are made and farmers are provided with incentives to produce biomass while reducing risk. USDA also published an Implementation Framework identifying how USDA will increase the resiliency of the biomass supply chain in the coming months, including:

- Supporting research on increasing biomass production and developing new biomass crops;
- Funding the infrastructure to process different types of biomass; and
- Developing new biobased products and markets for those products.

More information is available in our March 15, 2024, blog item, "USDA Releases Plan to Strengthen the Bioeconomy through a More Resilient Biomass Supply Chain."

The U.S. Department of Energy's (DOE) Bioenergy Technologies Office (BETO) announced in July 2024 that it selected 13 small businesses to develop innovative biobased products and biomass processing technologies. The companies, located across ten states, were selected to receive up to $206,500 each for this Phase I Small Business Innovative Research (SBIR) award. According to BETO, of the 13 awards, six are first-time awardees, four are located in Historically Underutilized Business (HUB) zones, two are in socially and economically disadvantaged areas, and one is a woman-owned business. The awards under the two BETO topics include:

- Sustainable Biomass Conversion to Biobased Materials — BETO states that regulations are emerging in the United States and worldwide that necessitate sustainable replacements to commonly used materials such as foam, adhesives, resins, and others. BETO supports efforts to decarbonize the industrial sector to produce cost-effective and sustainable chemicals, materials, and processes utilizing biomass and waste resources. This topic is focused on converting sustainable biomass and waste feedstocks to biobased materials.
- Alternative Uses of Commercial Equipment (ACE) — BETO states that as part of the government's


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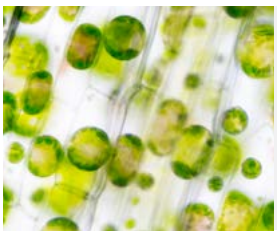
PODCAST
What is Green Chemistry? — A Conversation with Joel A. Tickner, Ph.D.



*In 2025, USDA could at long last propose to codify the Biobased Markets (BioPreferred) Program guidance.*

comprehensive strategy to decarbonize all modes of transportation, it is primarily focused on research, development, and deployment to produce "drop-in" biofuels from renewable biomass and waste resources that are compatible with existing fueling infrastructure and difficult-to-electrify modes of transportation, including aviation, maritime, rail, and medium-to-heavy-duty off-road vehicles. According to BETO, rather than developing new equipment, the intent of this topic is to test commercially available equipment, with minor or major modifications, to demonstrate preprocessing of biomass and waste feedstocks.

More information is available in our July 26, 2024, blog item, "BETO Announces Awards to 13 Small Businesses to Develop Innovative Biobased Products and Biomass Processing Technologies."

On December 9, 2024, USDA at long last issued in final the Biobased Markets (BioPreferred) Program guidance. The Rural Business-Cooperative Service (RBCS), an agency of the Rural Development mission area within USDA, issued a final rule that adopts changes from the Agriculture Improvement Act of 2018 (2018 Farm Bill). 89 Fed. Reg. 97459. The changes include merging the Guidelines for Designating Biobased Products for Federal Procurement (7 C.F.R. Part 3201) and the Voluntary Labeling Program for Biobased Products (7 C.F.R. Part 3202) into one streamlined regulation, the BioPreferred Program. Merging the legacy rules into one streamlined regulation at Part 4270 would facilitate the objective of the BioPreferred Program, which is to encourage the increased use of biobased products in all market sectors. Additionally, RBCS states that it believes these changes will benefit BioPreferred Program stakeholders by implementing process improvements and tying the two initiatives more closely together, making it easier to qualify for both initiatives. The final rule will be effective **January 8, 2025**. More information on the final rule is available in our December 23, 2024, blog item.

On April 22, 2024, the U.S. Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA) issued a final rule amending the Federal Acquisition Regulation (FAR) to restructure and update the regulations to focus on current environmental and sustainability matters and to implement a requirement for agencies to procure sustainable products and services to the maximum extent practicable. 89 Fed. Reg. 30212. The final rule adds several definitions, including defining biobased product as "a product determined by [USDA] to be a commercial product or industrial product (other than food or feed) that is composed, in whole or in significant part, of biological products, including renewable domestic agricultural materials and forestry materials, or that is an intermediate ingredient or feedstock. The term includes, with respect to forestry materials, forest products that meet biobased content requirements, notwithstanding the market share the product holds, the age of the product, or whether the market for the product is new or emerging." More information is available in our May 7, 2024, blog item, "DoD, GSA, and NASA Amend Federal Acquisition Regulation to Require Agencies to Procure Sustainable Products and Services."

In 2024, the U.S. Environmental Protection Agency (EPA) launched enhancements to an online search tool for its Recommendations of Specifications, Standards, and Ecolabels for Federal Purchasing (Recommendations), making it easier to view and sort standards and ecolabels that EPA recommends U.S. federal government purchasers use to meet sustainable acquisition goals and mandates. The search tool allows users to identify the types of products

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

or services covered by an ecolabel or standard, provides information on product and supplier availability, and links to product registries. EPA will continue working in 2025 to expand Recommendations, implementing a September 2024 proposal to add 14 standards and ecolabels to the Recommendations across three new product categories, covering healthcare, laboratories, and clothing and uniforms, and expanding the existing food service ware sub-category. More information is available in our September 24, 2024, blog item, "EPA Proposes Updates to Recommendations of Specifications, Standards, and Ecolabels for Federal Purchasing."

These types of government coordination, policy reform, and dialogue with industry stakeholders will continue to be vital to move the biobased chemicals and renewable products markets forward in 2025.

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## I. PROPOSITION 65

### 1. Short-Form Warning Changes

The California Office of Environmental Health Hazard Assessment's (OEHHA) interest in modifying the short-form warning requirements under Proposition 65 (Prop 65) continues. These changes were first proposed on January 8, 2021, with modifications proposed on December 13, 2021, and April 5, 2022. OEHHA then issued a notice on October 27, 2023, re-proposing these changes (Notice). On June 13, 2024, OEHHA issued a notice proposing additional changes (Notice).

On December 6, 2024, OEHHA issued a notice stating that the Office of Administrative Law approved changes to the Prop 65 Article 6 "clear and reasonable warnings" regulations for "short-form" warnings (Notice). These revisions: (1) require short-form warnings to include at least one chemical name for each applicable endpoint (*i.e.*, cancer and/or reproductive toxicity); (2) include a new provision that would provide Internet retailers a 60-day grace period, commencing from the date they receive a warning or written notice that a product will have new warning content, to update their online short-form warnings during the three-year implementation period; (3) increase the time for implementation of the revised short-form warning content from two years to three years; (4) clarify that the short-form warning can be used on food products; and (5) set forth new tailored safe harbor for passenger or off-highway motor vehicle parts exposure warnings and recreational marine vessel parts exposure warnings. Other changes that had been proposed, including revisions to Internet and catalog warning content and font sizes, were not implemented.

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

Businesses have three years — until **January 1, 2028** — to transition to these revised short-form warning requirements. In addition, any products that were labeled with the short-form warning language as the regulations allowed before this transition period expires (**January 1, 2028**) may continue to be sold indefinitely without the need for relabeling. This unlimited sell-through allowance period is intended to minimize disruption to existing inventory.

The changes to the short-form warning will be a major issue in 2025. Despite the three-year transition period, the new short-form warning text as set forth in Section 25603 and discussed in detail in our December 13, 2024, memorandum results in the near elimination of the short-form warning option. The requirement to specify a Prop 65-listed chemical changes the purpose and advantage of the prior short-form warning. OEHHA states in its Final Statement of Reasons that the short-form warning is now 8-14 words while the full-length warning is 26-44 words. This misses the context, however, and the problems that companies face in attempting to determine, to the parts per million or parts per billion level, whether a product may contain a Prop 65-listed chemical. Industry will need this time to determine how to modify warning language to be compliant with the new requirements. This is particularly true of small businesses that will need to devote time and resources to modifying warnings on labels and elsewhere.

### 2. First Amendment Lawsuits

Legal challenges in 2024 to Prop 65 warning requirements as invalid restrictions on commercial speech in violation of the First Amendment of the Constitution continued and will remain an issue in 2025. In addition to prior successful challenges that found Prop 65 warnings for glyphosate and acrylamide unconstitutional, in 2024, another successful challenge was brought against the titanium dioxide warning requirement. Specifically, on June 11, 2024, the U.S. District Court for the Eastern District of California (District Court) issued an Order granting a preliminary injunction brought by the Personal Care Products Council (PCPC), that alleged that OEHHA's requirement for Prop 65 warnings related to titanium dioxide in cosmetics and the requirement to warn violated the First Amendment. *The Personal Care Products Council v. Bonta*, No. 2:23-cv-01006-TLN-JDP (E.D. Cal. 2024). The court also denied a motion to intervene by Environmental Health Advocates, Inc. (EHA), finding that EHA has not met its burden to demonstrate that OEHHA does not adequately represent EHA's inter-

ests. More information regarding this case is available in our June 20, 2024, memorandum.

While a preliminary injunction is in place preventing enforcement against companies that do not provide warnings for the presence of acrylamide in food and beverages, the underlying case continues in the Eastern District, No. 2:19-cv-02019-DJC-JDP. This is a continuation of the case considered in *California Chamber of Commerce v. Becerra,* 529 F.Supp.3d 1099 (E.D. Cal. 2021) and *California Chamber of Commerce v. Council for Education and Research on Toxics*, 51 F.4th. 1182 (9th Cir. 2022). The U.S. District Court for the Eastern District of California and the Ninth Circuit issued rulings granting and upholding a preliminary injunction. The ruling prohibited the Attorney General and his officers, employees, or agents, and all those in privity or acting in concert with those entities or individuals, including private enforcers, from filing or prosecuting new lawsuits to enforce the Prop 65 warning requirement for cancer as applied to acrylamide in food and beverage products because OEHHA had not demonstrated that the warning is "purely factual and uncontroversial" and thus violated the First Amendment prohibition against compelled commercial speech. This ongoing litigation did not deter OEHHA from issuing on October 15, 2024, a final regulation amending the safe harbor warning language for acrylamide exposure from food. The effective date for the regulation is **January 1, 2025**.

The alternative warning language would require a statement that the International Agency for Research on Cancer (IARC), the U.S. Environmental Protection Agency (EPA), or the National Toxicology Program (NTP) has found that acrylamide is "probably carcinogenic to humans," "likely to be carcinogenic to humans," or "reasonably anticipated to cause cancer in humans," respectively. OEHHA states in its Final Statement of Reasons that it believes the warning language "follows court guidance on businesses' First Amendment rights, promotes compliance by offering businesses enhanced flexibility and safe harbor protection from litigation, and ensures that consumers receive valuable, factual information about acrylamide." OEHHA further states that it has "evaluated the application of recent First Amendment caselaw to the current proposal" and determined the additional safe harbor warning is "purely factual; noncontroversial; does not mislead; and is neither unjustified nor unduly burdensome."

These First Amendment cases are important with potentially significant implications for companies facing Prop 65 warning requirements for other substances where the underlying scientific basis for listing also may be unclear and controversial. OEHHA's acknowledgement of these cases in its most recent rulemaking for acrylamide could be a sign of a new element added to its analysis for Prop 65 warnings. Whether OEHHA's position that these warnings do not violate the First Amendment will be upheld cannot yet be predicted but will be interesting developments to follow in 2025.

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# II. KEY GLOBAL CHEMICAL MANAGEMENT PREDICTIONS

## A. Introduction

Internationally, 2025 will be eventful for all chemical stakeholders. The European Union (EU) will continue to align its chemicals regulatory frameworks with the Green Deal and take measures to achieve net-zero global warming emissions by **2050** while also pursuing aggressive regulatory and policy initiatives in the new year. Introduction of the "essential use" concept in the EU's proposed per- and polyfluoroalkyl substances (PFAS) regulation is expected to be considered and invite considerable attention. Many other initiatives, including EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) revisions, Cosmetic Products Regulation (CPR) revisions, activity under the Ecodesign for Sustainable Products Regulation (ESPR), and the EU Regulation on Deforestation-free Products (EUDR), will all contribute to making 2025 a busy, consequential year. Further progress will be made in 2025 as the EU and United Kingdom (UK) continue to address divergence between EU and UK REACH programs. Globally, the evolution of chemical governance programs generally, especially in South America, will continue to pick up steam.

### 1. EU

The European Commission (EC) expects to consider important revisions to EU REACH, deferred due to the mid-year elections. PFAS restrictions will also be the subject of significant attention in the EU in 2025, with consumer use applications being the primary target of review and prohibition. Broad implementation of the EUDR, including larger operators and micro and small enterprises, is also expected to demand considerable focus in the new year.

### 2. UK

The UK Department for Environment, Food and Rural Affairs (DEFRA) will continue to build the UK REACH program, and address divergence from EU REACH. UK REACH compliance checks may also pick up, given the maturation of the program and need for additional guidance on areas to improve. Look for continued focus on PFAS in the new year and greater detail as to UK priorities in **May 2025**, when the UK Rolling Action Plan (RAP) will be issued.

### 3. Asia/Pacific Rim

As in 2024, expect to see incremental evolution in chemical inventory, reporting, and recordkeeping in Asia for both industrial chemicals and cosmetics. Important changes to the Act on the Registration and Evaluation of Chemicals (K-REACH) in South Korea, effective in 2024, will continue to impact companies that do business there. These and other regulatory measures are all consequential and are discussed below, as are the United Nations (UN) Globally Harmonized System of Classification and Labeling of Chemicals (GHS) implementation in countries in this region. We also summarize initiatives in Turkey, Vietnam, Australia, and New Zealand.

### 4. South and Central America

The big news in Central and South American chemical regulatory matters is Brazil's implementation of Brazil "REACH" in November 2024. This game-changing development will almost certainly inspire implementation of REACH-like programs in other regions in Central and South America. Most Central and South American countries do not yet possess formal chemical inventories and generally have not adopted GHS for their respective Safety Data Sheet (SDS) programs. In 2025, countries will continue to make progress in developing REACH-inspired regulatory programs, Several Central and South American countries are also developing regulatory programs that are expected to have a significant impact on entities doing business in the region, and industrial stakeholders will want to understand these developments to anticipate their impact on their operations.

Chemical management initiatives outside of the United States are evolving at a fast pace. We have every reason to believe 2025 will be eventful.

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## B. EUROPEAN UNION

### 1. Overview

Amending the European Union's (EU) chemicals regulatory frameworks for better alignment with the Green Deal targets of climate neutrality and a competitive circular net-zero economy by **2050** is key to achieving its goals. Significant innovation in the chemicals sector driven by the European Commission's (EC) 2020 EU Chemicals Strategy for Sustainability (CSS), to be implemented through amendments to EU chemicals regulations, is foreseen in 2025 and beyond to achieve the goals of the Green Deal. The amendments will focus on simplifying regulatory processes, improving transparency, and reducing the burden on both the regulators and the regulated community while maintaining a level of human health and environmental protection that is, in the EC's view, second to none and the leading global model for chemical regulation.

EC President Ursula von der Leyen introduced the Clean Industry Deal as part of the Green Deal in her Political Guidelines for 2024-**2029** in response to concerns expressed by EU business leaders in the Antwerp Declaration (2024), and by former European Central Bank President Mario Draghi's report (2024), about the competitiveness of EU industry; it is possible that industry's views may be given greater consideration in upcoming decisions on chemicals legislations and practices. According to the EC's 2024 Work Programme, "The majority of initiatives set out in the 2019 Communication on the European Green Deal have been delivered, and many already agreed into law." Goals for the achievement of zero pollution and protection and restoration of nature will require the EU to legislate proposals on nature restoration, air quality, urban wastewater treatment, and protection of surface and groundwaters. "Swift agreement" on a number of issues, including ecodesign requirements for sustainable products, waste (particularly waste from electrical and electronic equipment) and packaging, shipment of waste, and the repair of goods are deemed necessary by the EC for advancement toward the Green Deal's circular economy goals. 2025 also marks the year the first companies must report under the EU Corporate Sustainability Reporting Directive, an initiative that strengthens reporting on corporate social and environmental information.

WEBINAR ON DEMAND
An Update on the EU Chemicals Strategy for Sustainability

### 2. EU REACH

The EC expects to present the revision of Regulation (EC) 1907/2006 (Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)) to the European Parliament (EP) in 2025, according to the Commissioners responsible for the Chemicals Industry Package. In October 2024, the Council of the European Union (the Council) discussed the CSS and released a Note summarizing the Council's views on the status of the CSS and the path forward. The focus of the REACH revision would include enhancing the compliance of registration dossiers, improving the processes for identification of substances having critical hazard properties and associated risk management activities, and streamlining the authorisation and restriction processes to align with the European Chemicals Agency's (ECHA) Strategy Statement 2024-**2028** and Integrated Regulatory Strategy 2024-**2028**. The REACH revision is also expected to provide clarification of testing requirements to align with the new Classification, Labelling and Packaging (CLP) Regulation hazard classes, particularly for endocrine disruptors.

ECHA's screening activities have progressed successfully and are expected to focus on dossier and substance evaluations for substances registered after the 2018 deadline at greater than 100 metric tons and substances registered at 10-100 metric tons with the highest aggregated tonnage. Risk management activities are also within scope over the coming years, in collaboration with member states (MS), EU agencies, and the EC. Companies having registrations meeting the criteria above are advised to review and update their dossiers. According to the Community Rolling Action Plan (CoRAP), which is updated annually in March, substance evaluation will start for 13 substances in 2025 and for five substances in **2026**. ECHA's per- and polyfluoroalkyl substances (PFAS) restriction proposal is currently under evaluation by ECHA's Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC). A final decision on the proposal is expected in 2025.

The Council also discussed increasing costs and administrative burdens related to changing regulatory roles and responsibilities, with emphasis on the importance of financing the operations of ECHA and the MSs. One tool under discussion is the ongoing proposal for a basic ECHA Regulation, which

would give ECHA more flexibility to use its existing resources and budget. That proposal also suggests new fee types for companies. More details are expected in 2025 when the new Parliament and EC fully start their work.

The EU is committed to animal-free chemical safety evaluation and plans to issue a roadmap with specific actions and milestones to reduce and eventually phase out animal testing by the **end of 2025**. The second workshop, "The Roadmap Towards Phasing Out Animal Testing for Chemical Safety Assessments," was held on October 25, 2024. Concerns remain that currently available scientific methods are inadequate to replace fully animal testing without jeopardizing chemical safety. Ongoing method development and validation are likely to affect testing requirements in the future.

### 3. Cosmetics

The schedule for revision of the Cosmetic Products Regulation (EC) 1223/2009 is currently unknown. Preparation of the revision was put on hold due to the lack of consensus within the EC related to the potential impacts, especially financial, on the cosmetic industry. The issues the revision may address include extension of the generic approach to risk management to ensure that cosmetics do not contain chemicals deemed to be hazardous under other legislations (*e.g.*, ingredients that are classified as bioaccumulative and persistent, reprotoxic, or endocrine disruptors), improvement of safety assessments to include potential effects of interactions between chemicals present in cosmetics, and improvement of cosmetic labeling.

The Green Claim Directive (GCD), EU 2024/825, entered into force on March 26, 2024, and MSs must implement it into national regulations by **March 27, 2026**. The main goal of the GCD is to protect consumers from misleading environmental claims (*i.e.*, "greenwashing") by ensuring that the claims and labels are trustworthy. The GCD defines criteria for companies to substantiate claims, and requires labels and claims to be checked by an accredited verifier. The GCD applies to all goods, which is defined quite broadly under Directive (EU) 2019/771 Article 2, point 5, and includes cosmetic products.

### 4. Biocides

The deadline for the biocides Review Programme has been extended to **December 31, 2030**, by EC Delegated Regulation (EU) 2024/1398, amending the Biocidal Products Regulation, (EU) 528/2012 (BPR). The examination of existing active substances in biocidal products continues in 2025 and beyond, and the work will be accelerated by ECHA giving more support to MSs and the EC. Companies will need resources to update their data submissions and respond to information requests from ECHA.

### 5. Plant Protection Products (PPP)

In March 2024, due to unexpected challenges facing farmers, including extreme weather events, inflation, and changes in international trade due to Russia's war of aggression against Ukraine, the EU modified its goal to reduce the use of chemical pesticides by **2030** and introduce a new regulation on the sustainable use of PPPs. Instead, Regulation (EU) 2024/1468, amending Regulation (EU) 2021/2115, entered into force in May 2024, "to ensure that Member States can better adapt their CAP [Common Agricultural Policy] Strategic Plans to farmers' needs and provide farmers with more flexibility to carry out their agricultural activities taking into account the increasing challenges, the unpredictability of the weather, and economic uncertainties."

A Vision for Agriculture and Food, guided by the report of the Strategic Dialogue on the Future of EU Agriculture, was presented as part of the EC's Political Guidelines 2024-**2029** and work plan for delivery in **March 2025**. The Vision is expected to focus on a shift from conventional pest control to biocontrol and recommend a legislative framework for biocontrol products, including promotion of Integrated Pest Management, production of natural pesticides and low-risk PPPs, reduction of conventional pesticide use, and acceleration of the entry of new applications on the market.

### 6. The Ecodesign for Sustainable Products Regulation (ESPR)

The Ecodesign for Sustainable Products Regulation (EU) 2024/1781 entered into force on July 18, 2024, aiming to improve the circularity, energy performance, and other environmental sustainability aspects of products placed on the EU market. The scope of the ESPR is very broad, including almost all consumer and industrial products, but excluding food, feed, and medicinal products. It will also affect types and possibly quantities of specific chemicals used in products, *i.e.,* REACH substances of very high concern (SVHC), some substances classified under the CLP Regulation, persistent organic pollutants (POP), and substances affecting circularity. The ESPR is the first EU law defining the concept "substance of concern" in detail. The European Chemical Industry Council (Cefic) estimates that about 12,000 of the

approximately 23,000 REACH-registered substances meet the ESPR "substance of concern" definition.

ESPR implementation is in progress. The first step is to prioritize products or product groups, followed by development of specific product rules. The Ecodesign Forum, which includes MS expert groups, gives stakeholders an opportunity to raise concerns and contribute to the development of Ecodesign rules. The first Delegated Act for the first products/product groups is expected in **2026**, followed by the active Digital Product Passport registry. The ESPR will eventually replace the current EU Ecodesign Directive 2009/125/EC.

### 7. EU Regulation on Deforestation-free Products

An area of increased focus in 2024, and continuing in the new year, is the EU Deforestation Regulation (EUDR). This Regulation, enacted on June 29, 2023, is intended to ensure that manufacturers do not produce goods from recently deforested areas or produce their goods in ways that contribute to deforestation. The Regulation explicitly applies to seven commodities (cattle, cocoa, coffee, oil palm, rubber, soya, and wood) and, importantly, to certain byproducts that contain feedstocks from the named commodities, to be "deforestation-free" if they are made available on or exported from the EU market. When effective, the enumerated products will be covered by a due diligence statement. Many regulated entities expressed their support for the EUDR because it is thought to help companies achieve their environmental social governance (ESG) and sustainability goals.

A key concern that many countries and regulated entities have expressed, however, is the lack of the availability of specific guidelines before the effective date of December 30, 2024. For this reason, global partners, including the Biden-Harris Administration, requested that the law's implementation be delayed from December 30, 2024, to **December 30, 2026**. The EC has proposed a delay of 12 months and issued some guidance on the EUDR. On December 3, 2024, the EU Council reached a provisional agreement with the EP on the proposed amendment that would delay implementing EUDR from December 30, 2024, to **December 30, 2025**. The EP voted decisively in favor of implementing the delay on December 17, 2024. The year-long delay will become effective after the publication of the Regulation in the Official Journal of the EU, and is expected to enter into force three days after publication, meaning that if all goes to plan, it will officially pass just days before the EUDR would otherwise go into effect.

Part of EUDR requires the EC to apply an EUDR benchmarking exercise that will classify production countries as low, standard, or high risk. Some worry how these risk categories will be determined and how much this could impact the gross domestic product (GDP) of countries that regularly export these goods to the EU. The EC has stated that


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

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most of the countries will be classified as low risk, which means that the Regulation will help to mitigate deforestation but should not overly burden most of the countries that must comply with the new Regulation.

This initiative may sound exotic and irrelevant. It is neither. Notably, stearic acid and oleic acid are included within the scope of the Regulation. This means that anyone that uses these substances to manufacture a product will need to complete the EUDR's lengthy form for each batch of product they produce in the EU or import into the EU. The only exemptions are for highly recycled products. Of note, vulcanized rubber thread and cord and articles of apparel and clothing accessories (including gloves, mittens, and mitts), for all purposes, made of vulcanized rubber other than hard rubber, are not exempt. For a full list of the regulated commodities, please see Annex 1 of the EUDR. This is a regulation to watch in the new year.

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*Regardless of one's role, whether manufacturer, importer, supplier outside of Great Britain (GB), downstream user, or distributor, all companies doing business as or with a GB-based company are advised to follow the developments in GB closely in 2025.*

## C. UNITED KINGDOM/GREAT BRITAIN

### 1. Overview

Divergence between the United Kingdom (UK) and European Union (EU) regulations pertaining to chemicals will continue in 2025 and beyond. Companies worldwide must be aware of the significant implications for chemical regulatory compliance under several regimes, including the UK REACH regulation, the Cosmetics Products Regulation (CPR), the Biocidal Products Regulation (BPR), and the Plant Protection Products Regulation (PPPR). Regardless of one's role, whether manufacturer, importer, supplier outside of Great Britain (GB), downstream user, or distributor, all companies doing business as or with a GB-based company are advised to follow the developments in GB closely in 2025.

### 2. UK REACH

Revisions of UK REACH will continue in 2025. The Department for Environment, Food and Rural Affairs (DEFRA) published a proposal for a UK REACH alternative transitional registration model (ATRm) in 2023 in response to industry concerns about the costs of accessing EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) data packages to support UK REACH grandfathered registrations. The proposed changes include using available information on the hazards of substances from the international regulatory and scientific communities and industry in combination with enhanced use and exposure information to improve the efficiency and efficacy of the process for assessment and mangement of risks and, as needed, make targeted requests for additional information. The UK's movement toward a more risk-based approach will increase the divergence between UK REACH and the hazard-based EU REACH. The UK's proposed changes also include improvements to the restriction process to enable more rapid responses to identified risks and minimization of animal testing. A public consultation on the proposal was launched on May 16, 2024; the outcome of consultation and the Government's response are expected in 2025.

The UK Rolling Action Plan (RAP) 2023-2025 has focused on per- and polyfluoroalkyl substances (PFAS) in 2024; the next RAP update is expected by **May 31, 2025**. The UK shares the worldwide mission to address concerns related to PFAS. After publishing its Risk Management Option Analysis (RMOA) for PFAS in 2023, the UK Health and Safety Executive (HSE) has continued work on preparing a restriction proposal for PFAS in firefighting foams. The UK approach to PFAS restriction differs from the EU approach, using a more limited definition of PFAS as "[f]luorinated substances that contain at least one fully fluorinated methyl carbon atom (without any hydrogen, chlorine, bromine or iodine atom attached to it), or two or more contiguous perfluorinated methylene groups (–CF2–)." This exclusion of fluorinated substances that contain a single isolated methylene "reduces the number of PFAS in scope to hundreds, maintaining focus on substances that are persistent degradation products of PFAS."

DEFRA has reviewed the UK REACH fees, which are currently aligned with the EU fee structure, and proposes significant changes to align a new fee structure with the costs for performing the regulatory services, per the guidance from His Majesty's Treasury (the UK's finance ministry) for the management of public money. A fixed fee for registrations at all tonnage levels has been proposed, with reduced costs for small and medium enterprises (SME). Fees for an authorisation would increase, as the current fees are not commensurate with the regulatory effort required. The proposal had a public consultation in September 2024 and is expected to be implemented soon.

### 3. Cosmetics

The UK CPR continues to follow closely EU Regulation 1223/2009 on cosmetic products, but differences are developing, particularly with respect to animal testing requirements, safety assessments and safe use levels of cosmetic ingredients, and restrictions applicable to specific ingredients. Assessments of cosmetic ingredients in the UK are performed by the Scientific Advisory Group on Chemical Safety of Non-Food and Non-Medicinal Consumer Products (SAGCS). The UK has banned fewer cosmetic ingredient substanc-

es than are banned in the EU. The UK has stopped issuing licenses for animal testing of substances used solely as cosmetic ingredients, whereas animal testing can be required under EU REACH for specific substances used only as ingredients in cosmetic products. Labeling requirements for cosmetic products also differ between the EU and UK. Companies should consider the emerging differences between UK and EU regulatory requirements when placing or planning to place their cosmetic products on both markets.

### 4. Biocides

Divergence between the regulation of biocidal products in the EU and the UK is ongoing, increasing regulatory compliance complexity in 2025 and beyond. The revision of GB BPR came into force on April 6, 2024, and will be applied to new applications as of **October 6, 2025**. It is notable that the changes will not be applied to existing applications. The revision focused on updating information requirements for active substances and biocidal products in Annexes II and III of the BPR. The changes include the addition of new endocrine disruptor tests; changes in mutagenicity, reproductive toxicity, and generational test requirements; a requirement for developmental neurotoxicity studies after certain triggers; and a requirement to include efficacy data for the active substances. The changes are similar to the updates made to Regulation (EU) No 528/2012 (EU BPR), with minor differences.

Biocidal product authorizations and active substance approvals that were valid in GB at the end of the Brexit transition period remain valid in GB until their normal expiry date, but companies must ensure that they are established in the UK. On **March 3, 2025**, the UK will remove all suppliers from the GB Article 95 List that did not provide confirmation of being established in the UK and did not resubmit a dossier or Letter of Access by November 1, 2024.

### 5. Plant Protection Products

Pesticides are regulated under the Official Controls (Plant Protection Products) Regulations 2020 and maximum residue limits (MRL) under the GB MRL Statutory Register. The UK's direction on the use of pesticides is guided by the UK National Action Plan for the Sustainable Use of Plant Protection Products, but the latest version of this framework document was published in 2013. A new version has been under development for years, including public consultation on the draft version in 2021. The publication date is still unknown, but according to the Agricultural Industries Confederation, publication is expected soon. As the use of pesticides is also part of the EU Commission Political Guidelines 2024-**2029**, it would not be surprising if the UK wishes to follow the EU's progress on this topic, expected in **March 2025**, before proposing its own framework. The UK pesticide policy has been criticized by environmental activists and non-governmental organizations (NGO) for increasing the MRL of pesticides in food and allowing the use of products/active substances that are banned in the EU. The UK approach to pesticide regulation may seem less strict than the EU's, but it is less intrinsically hazard based and more risk based than the EU approach, making the comparison challenging. There is growing divergence between the UK and EU approaches, and it will be interesting to see if the outcome of the UK's 2024 elections changes its approach to pesticide regulation.

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

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## D. THE AMERICAS

### 1. Overview

The 2023 amendments to the Canadian Environmental Protection Act, 1999 (CEPA) were significant and are set to be implemented in 2025. Canada plans to hold stakeholder consultations in 2025 and **2026** regarding its plans to replace the Consumer Chemicals and Containers Regulations, 2001 (CCCR) with a risk-based framework based on the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS), and to eliminate the consumer product exclusion from the Hazardous Products Act (HPA). Canada is also taking regulatory actions on substances of concern to address per- and polyfluoroalkyl substances (PFAS) and plastics. We can expect continued regulatory developments in 2025, as these legislative and regulatory initiatives will have a significant impact on all business sectors.

Chemical substance legislation evolved last year in several Latin America countries. Brazil's draft Industrial Chemicals Regulation was approved by the final committee in the Chamber of Deputies and the Senate is now reviewing. Chile and Colombia implemented chemical control regulatory provisions. With the issuance of Decree 1570/2023 in May 2023, Peru commenced a legislative process for implementing a chemicals management framework. All such efforts are heavily influenced by two factors: trading partners and a desire for membership within the Organisation for Economic Co-operation and Development (OECD). All countries are opting for a notification and/or registration framework like the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) in the European Union (EU).

In 2025, expect this region to be busy. These countries will continue implementing legislative approaches and develop programs expected to impact significantly stakeholders in the region and beyond.

This region operates under key trade blocs, including The Andean Community (Bolivia, Colombia, Ecuador, and Peru) and Mercosur (Argentina, Brazil, Paraguay, and Uruguay). The EU is the third-largest trade partner with the Andean Community. The Andean Community generates resolutions that establish common approaches to regulated products. Stakeholders may wish to consider these approaches when shipping impacted products into the region.

### 2. Canada

#### a. Chemical Control

The 2023 bill amending CEPA was ambitious, requiring that within two years, or by **June 13, 2025,** Canada must develop an implementation framework setting out how the right to a healthy environment will be considered, prepare a multi-year plan of chemicals management priorities, and create a Watch List of substances determined to be capable of becoming toxic under CEPA. Canada is well on its way to meeting this goal. It convened public consultations in fall 2024 on:

- Draft implementation framework for the right to a healthy environment (draft framework): The draft framework notes that the right applies only to the administration of CEPA. According to the draft framework, CEPA defines a healthy environment "as one that is clean, healthy, and sustainable." The draft framework elaborates on the substantive and procedural elements of the right in the context of CEPA, "explain[ing] how CEPA contributes to an environment that is protected from harmful substances, pollutants, and waste and that has clean and healthy air and water, a sustainable climate, and healthy ecosystems and biodiversity." The draft framework notes that the right to a healthy environment may also include the procedural elements of access to information, participation in decision-making, and access to effective remedies in the case of environmental harm.

- Proposed plan of priorities under CEPA (proposed plan): Under CEPA Section 73(1), the plan of priorities will specify the substances to which the ministers are satisfied priority should be given in assessing whether they are toxic or capable of becoming toxic; activities or initiatives in relation to assessing, controlling, or otherwise managing the risks to the environment or to human health posed by substances that are or will be undertaken under an Act of Parliament for whose administration either minister is responsible and which the ministers are of the opinion should be prioritized; and activities or initiatives to promote the development and timely incorporation of scientifically justified alternative methods and strategies in the testing and assessment of substances to replace, reduce, or refine the use of vertebrate animals. The proposed plan includes substances prioritized for assessment.

- Proposed Watch List approach (proposed approach): The proposed approach describes considerations and processes associated with adding and removing substances from the Watch List. The Watch List will include a list of substances that have been assessed as not currently meeting the criteria for toxic substances under CEPA Section 64 and that may be of potential concern if exposure or hazard characteristics were to change in the future. Under the proposed approach, the Minister of the Environment may add a substance to the Watch List when the Minister of the Environment and the Minister of Health have reason to suspect it is capable of becoming toxic or if they have determined it to be capable of becoming toxic.

More information on the draft documents is available in our October 11, 2024, memorandum, "Canada Begins Public Consultations on Initiatives Supporting CEPA Amendments."

In October 2024, Health Canada (HC) announced its planned stakeholder consultation approach regarding potential new health and safety requirements for consumer chemical products under the Canada Consumer Product Safety Act (CCPSA) and the HPA. In July 2023, HC issued a Notice of Intent (NOI) to seek stakeholder input on a proposed regulatory initiative to introduce new requirements to address certain human health hazards of concern (HHHOC) in consumer chemical products regulated under the CCPSA. Following its review of comments on the NOI and the results of a survey regarding safety information on consumer chemical products, HC plans to completely replace the CCCR with a risk-based framework based on GHS. More information on the 2023 NOI is available in our August 17, 2023, memorandum, "Health Canada Begins Consultation on Proposed New Requirements for Consumer Chemical Products under the CCPSA."

In parallel, in December 2022, HC published an NOI regarding potential amendments to remove the consumer product exclusion from the HPA. According to HC, comments indicated overall support for the proposal while noting certain challenges. Given the synergies between the proposals under the CCPSA and the HPA, HC intends to consult with affected stakeholders on the following topics of both proposals:

- Overview of:
  - Stakeholder feedback received on the NOI under the CCPSA;
  - Public opinion research summary; and
  - Analysis for the selected regulatory approach (*i.e.*, a full replacement of the CCCR with a risk-based framework based on GHS).

  HC intends to hold an information session with an opportunity for questions and answers sometime between **January and March 2025**.
- Consumer chemical product scope, exclusions, definitions, recordkeeping requirements, and other general provisions. HC intends to hold consultations from **June to September 2025**.
- Hazard classification and risk characterization of consumer chemical products, including:
  - GHS hazard categories that are relevant to products for non-commercial use (*i.e.*, domestic use); and
  - Consideration of methods for risk assessments for non-commercial use of consumer chemicals products.

  HC intends to hold consultations from **October to December 2025**.
- Information disclosure requirements, including:
  - Labeling;
  - Coexistence of proposed label elements for consumer chemical products and safety data sheets (SDS) for workplace use; and
  - Potential online disclosure requirements.

  HC intends to hold consultations from **January to March 2026**.
- Additional protections (*e.g.*, prohibitions, restrictions, child-resistant containers). HC intends to hold consultations from **April to June 2026**.

HC will use comments obtained during the stakeholder consultations to inform its development of future regulatory proposals.

### b. PFAS

In July 2024, Canada published an *Updated Draft State of Per- and Polyfluoroalkyl Substances (PFAS) Report* (Updated Draft Report) and *Revised Risk Management Scope for Per- and Polyfluoroalkyl Substances (PFAS)* (Revised Risk Management Scope). According to the *Canada Gazette* notice announcing the availability of the documents, Canada proposes to conclude that the class of PFAS, excluding fluoropolymers, meets criteria set out in CEPA Section 64. The ministers propose to recommend that the class of PFAS, excluding fluoropolymers, be added to Part 2 of Schedule 1 of CEPA. The government proposes a separate assessment to examine the exposure and hazard profile of fluoropolymers, which may have different exposure and hazard profiles than other PFAS. The ministers will also consider whether fluoropolymers are possible candidates for the Watch List under CEPA Section 75.1.

According to the Revised Risk Management Scope, Canada is considering:

- As a first step, a regulatory instrument under CEPA to restrict PFAS not currently regulated in firefighting foams (FFF); and
- Additional regulatory instrument(s) under CEPA to prohibit other uses or sectors in relation to PFAS. Prioritization for prohibition may be based on factors such as socioeconomic considerations, the availability of feasible alternatives, and the potential for human and environmental exposure.

The Revised Risk Management Scope states that "[v]oluntary risk management actions are also being considered to achieve early results to reduce releases of PFAS, as a complement to the proposed regulatory instruments." Comments were due September 11, 2024. More information is available in our July 12, 2024, blog item, "Comments on Canada's Updated Draft State of PFAS Report and Revised Risk Management Scope Are Due September 11, 2024."

Less than two weeks after releasing the Updated Draft Report and Revised Risk Management Scope, Canada's Minister of the Environment published a *Canada Gazette* notice announcing a mandatory survey to obtain information on the manufacture, import, and use of 312 specific PFAS. Canada's "Guidance manual for responding to the: Notice with respect to certain per- and polyfluoroalkyl substances (PFAS)" (Guidance Manual) states that the purpose of the notice is to collect information on certain PFAS substances, either alone, in mixtures, products, or manufactured items in Canadian commerce for the calendar year 2023. Canada will use this information to establish baseline commercial use data and support future activities related to the class of PFAS. The list of specific PFAS "is focused on those substances known or anticipated to be in Canadian commerce that have not been recently surveyed." Responses are due **January 29, 2025**.

While companies located outside of Canada are not subject to the notice, companies importing products must respond to the notice if the criteria are met. In the Guidance Manual, Canada "encourages" foreign suppliers to inform their Canadian customers that they import a reportable substance and may meet the reporting criteria of the notice. According to the Guidance Manual, a letter to help Canadian stakeholders obtain data from their foreign suppliers is available for download on the Request for information from foreign suppliers web page. The Guidance Manual notes that if confidential business information (CBI) cannot be shared with Canadian stakeholders to allow them to respond to the notice, foreign suppliers and Canadian importers can submit information together in the form of a blind submission. More information is available in our July 29, 2024, blog item, "Canada Requests Information on 312 PFAS; Responses Due January 29, 2025."

### c. Plastics

Reporting for Canada's Federal Plastics Registry will begin in 2025. On April 20, 2024, Canada published a *Canada Gazette* notice requiring companies (including resin manufacturers, service providers, and producers of plastic products) to report annually on the quantity and types

PODCAST:
Canada Proposes Exclusion of Fluoropolymers from PFAS — A Conversation with W. Scott Thurlow

ARTICLE
"Canada Announces PFAS Mandatory Survey," Chemical Processing, October 2, 2024

of plastic they manufacture, import, and place on the market. The notice applies to all plastic resins and plastic products set out in Parts 1 through 4 of the Schedule that are manufactured in Canada, imported into Canada, or placed on the market in Canada. According to Canada's web page on the Federal Plastics Registry, reporting will start in **September 2025** with Phase 1, requiring reporting on plastic placed on the market in three categories for the 2024 calendar year. In **2026**, Phase 2 adds reporting requirements for resin manufacturers and importers for the three categories that reported during Phase 1, as well as reporting on plastic placed on the market for remaining categories. Phase 2 will also see the introduction of reporting on plastic waste generated at industrial, commercial, and institutional (ICI) facilities and the introduction of reporting for plastic collected and sent for diversion and disposal for some categories. In **2027**, Phase 3 adds additional reporting on plastics collected and sent for diversion and disposal for more categories. Canada notes that reporting requirements for Phase 4 will be covered in a future information gathering notice.

### d. Pest Management Regulatory Agency Developments

Canada's Pest Management Regulatory Agency (PMRA) has been active recently in updating pesticide regulations and guidance, and this is expected to continue in 2025.

Some of the highlights from 2024 that will be relevant in 2025 include the following:

- **Verification of Product Chemistry Information:** PMRA states it is modernizing its pesticide review process by establishing an oversight model and five-year work plan to verify product chemistry information for technical grade AIs. Chemistry verification for each AI will occur every ten years at a minimum and will be separate from the 15-year re-evaluation-based process. Under Step 1, registrants will receive a letter from PMRA requesting, within 90 days from the date of correspondence, chemistry information be provided for each registered source (*i.e.*, Data Code (DACO) 2.11 Manufacturing methods for Technical Grade AI; DACO 2.12 Specifications Form; and DACO 2.13 Preliminary Analysis). Under Step 2, upon review of the chemistry information submitted for verification (Step 1), if PMRA determines that additional chemistry information (for example, batch and/or impurity data) is required, PMRA will issue a notice outlining the requirements and timeframes for submitting the batch and/or impurity data as a condition of registration.

  Companies can find PMRA's five-year schedule for AIs subject to product chemistry verification from 2024-**2029** in PMRA's Notice.

- **New Data Compensation Procedures:** On September 10, 2024, PMRA published two documents for consultation: (1) Regulatory Proposal PRO2024-04, Consultation on guidance for registrants and data holders for use or reliance on test data considered in support of re-evaluation and special review decisions; and (2) Consultation on the Proposed agreement for data compensation under section 66 of the Pest Control Products Act for re-evaluation and special review decisions. These documents are intended to provide guidance regarding the data compensation process for re-evaluation and special review decisions set forth in Pest Control Products Act Regulation (PCPR) amendments issued on December 3, 2023. Registrants should be aware of PMRA developments in establishing and clarifying data compensation procedures, including but not limited to understanding what data may be compensable and the agreement registrants and data holders must enter into under Pest Control Products Act (PCPA) Section 66.

- **PCPR Amendments Addressing Access to Confidential Data:** Since 2022, PMRA has been reviewing PCPA and PCPR to determine what improvements may be needed to increase trust in the federal pesticide regulatory system and address the public's growing expectations to improve environmental risk assessments. As part of that effort, in June 2024, PMRA proposed changes to facilitate access to confidential test data (CTD) (available here) and released Regulatory Proposal PRO2024-02 (available here) with proposed guidance for its proposed policy and procedures for accessing CTD under the proposed PCPR amendments. These amendments and guidance set forth opportunities for certain third parties engaged in "research" or "reanalysis" to access CTD and potentially publish findings or conclusions based on that CTD, provided the

CTD cannot be extrapolated from the published research. CTD could not, however, be used to register or amend a pest control product in Canada or elsewhere. In particular, PMRA states it can deny an application for a person to review CTD if it has "reasonable grounds" to believe that "the individual intends to use the CTD to register a pest control product in Canada or elsewhere or amend a registration." It will be extremely important for companies submitting CTD to ensure that PMRA reviews these applications carefully.

The final amended regulations are expected to be published in the *Canada Gazette, Part II* in **Spring 2025**. Once enacted, applicants, registrants, or other entities submitting data to PMRA will need to ensure that procedures are followed to provide PRMA with sufficient information for it to determine that submitted data is CTD.

## 3. Brazil

### a. Chemical Control

On November 14, 2024, Brazil REACH was officially published into law. The law requires manufacturers and importers to register, in a new system, substances produced or imported at or above one metric ton per year. The government will need to create infrastructure, including technical committees, submission platforms, and details for implementation within the next six months to three years.

Brazil is the largest country in the Americas to adopt a modern chemical control law. Other regional countries are expected to follow Brazil's lead.

In 2025, expect the Brazilian Government to create a national register of chemical substances imported to Brazil. The government has 180 days to prepare regulations to implement the law and three years to establish an online registration system. Companies operating in Brazil have three years to register chemicals manufactured or imported in quantities over one metric ton per year after the launch of the submission platform (*i.e.*, six years from publication of the law). Each substance registration will require data to identify the chemical producer or importer, total amount produced or imported annually, chemical identification, hazard classification, and recommended uses. All substance information will require yearly review with updates before March 31 of the subsequent year.

### b. Personal Hygiene Products, Cosmetics, and Perfumes

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

## 4. Chile

On February 9, 2021, the Ministry of Health (MOH) published Decree No. 57 on the Classification, Labeling and Notification of Hazardous Chemicals and Mixtures (Reglamento de Clasificación, Etiquetado y Notificación de Sustancias Químicas y Mezclas Peligrosas) (Decree No. 57). Decree No. 57 established a national inventory of industrial chemicals, established a method for risk evaluation of priority substances, and implemented GHS. Decree No. 57 implementation is occurring in stages, with the first notification requirement for industrial substances in September 30, 2024. The government planned to publish the first national inventory by December 31, 2024. Notifications for industrial substances contained in mixtures are due **August 30, 2027**. For substances and mixtures for non-industrial use, the first notifications are due **August 30, 2025**, and **August 30, 2029**, respectively. Chilean officials provided industry with details of its online system notifications. The online system malfunctioned in 2024 and officials accepted alternative submission approaches, including using downloadable Excel files. Initially, foreign manufacturers were unable to participate in the notification process. With access to downloadable Excel files, foreign companies were able to assist with completion of the forms to support local customers.

In 2025, industrial substances must comply with GHS, while substances for non-industrial use are subject to notification only. Expect additional progress in 2025 in resolving issues as importers attempt to complete the required notifications. These notifications are tied directly to the hazard classification of the substances, meaning only hazardous substances imported or manufactured at or above one metric ton for the preceding two-year period require notification (*i.e.*, annual volumes for 2022 and 2023).

### 5. Colombia

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

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

### 6. Mexico

Mexico has made no significant progress in implementing a comprehensive chemical law. Mexico embraced in 2019 a National Integrated Policy for the Management of Chemical Substances (La Política Nacional Integral para la Gestión de Sustancias Químicas). The Mexican government's 2019 approach for chemicals regulation would adopt a hazard-based approach, similar to EU REACH. In developing a comprehensive law for managing chemical substances, Mexico is unique among the Latin American countries in that it is part of the United States-Mexico-Canada Agreement (USMCA) that entered into force in July 2020. Its 2019 policy approach is at odds with the USMCA, which supports a risk-based approach for regulating chemicals similar to the Toxic Substances Control Act (TSCA). Given this confusing policy backdrop, it is unclear what, if anything, is expected in 2025.

### 7. Peru

On May 28, 2023, the Ministry of the Environment published Decree No. 1570. The Decree establishes the legal framework for the comprehensive management of chemicals and provides for the standardization of information on hazard classification, labeling, and SDSs; the traceability of information through the creation of a national registry of chemical substances; and the adoption of risk management measures and the evaluation of their impact on health and the environment. In July of 2024, Peru introduced the lengthy draft regulation to implement Decree No. 1570 that initially requested comments within ten business days. The comment period was expanded to October 24, 2024. The regulation will include a list of classifications for hazardous substances; the scope, implementation, and operation of the national registry; technical conditions under which certain activities are exempted from the national registry; a procedure for risk assessment approvals; and risk management measures. The Decree language includes similar exemptions to those that are part of EU REACH. Manufacturers and importers will be responsible for registering substances with the Ministry of Environment (MINAM). Registration deadlines will vary based on classification. Companies will have one year to register substances on the anticipated classification list. If a substance differs from the anticipated list, companies will have 18 months to register. Non-hazardous substances will require registration in two years, and "new" substances not registered will have three years to submit a report in the National Registry of Chemical Substances (RENASQ). After three years, annual reports will be required by all companies to record the covered substance volumes annually manufactured or imported into Peru.

Expect 2025 to be a busy time. The Ministry will establish a new online system and the publication of the list of classifications will provide more insight into regulatory obligations under this Decree. The ability for foreign manufacturers to participate remains unclear. Guidance is expected as the online systems are deployed.

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## E. GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELING OF CHEMICALS

### 1. Overview

2024 began quietly, with several countries continuing to update existing revisions based on the United Nations (UN) Globally Harmonized System of Classification and Labeling of Chemicals (GHS) model. Most countries opted to align with the 7th revised edition of the UN GHS (Rev 7). Early in 2023, Canada issued its update to its existing regulations, followed by an array of initiatives in the Latin American region. In April of 2023, the European Union (EU) proposed major changes to its Classification, Labeling and Packaging (CLP) regulation (*i.e.*, Regulation (EC) 1272/2008), many of which do not align with UN GHS. The UN published its 10th revised edition (Rev 10) in July 2023. In May 2024, the U.S. Occupational Safety and Health Administration (OSHA) finally issued its highly anticipated update to the U.S. Hazard Communication Standard (HCS), aligning the United States with many countries as it opted to adopt Rev 7 and elements of Rev 8. Expect 2025 to be a very busy time as all major parties are in various stages of GHS updates to existing regulations. Changes to CLP resulting in additional labeling requirements on impacted parties were issued December 10, 2024. Companies will continue to face challenges as they consider which revision a country adopts, the scope of the legislation (*i.e.*, worker, consumer, or both), additional elements to the legislation (*e.g.*, additional hazard elements, language requirements), and how those elements influence the content of communication tools (*i.e.*, safety data sheets (SDS) and labels). Revisions to existing GHS implementations will require review of hazard communication tools to ensure continued compliance within regulated timeframes. The UN is expected to publish Rev 11 at some point within 2025, so this will also add to the ever-evolving space of GHS. So much for harmonization!

### 2. United Nations

The 45th session of the UN Sub-Committee of Experts on the Globally Harmonized System of Classification and Labeling of Chemicals convened December 6-8, 2023. Key topics for discussion included concepts related to simultaneous classification of physical hazards and precedence; an approach to address endocrine disruptors, nanomaterials, and hazards to the atmospheric system to address ozone depleting potential not included in the Montreal Protocol; and development of the use of non-animal testing methods for classification of health and environmental hazards.

The 46th session was held July 3-5, 2024. The agenda remained nearly identical to the 45th session, with new discussions on radioisotopes, nitrocellulose mixtures, and the need for ensuring consistency with subcategorization within GHS. The U.S. delegates were invited to consider providing additional information to facilitate future discussions on the elements of consistency with subcategorization.

The 47th session was held December 4-6, 2024. The agenda appears to be relatively similar. Documents of note include the consolidated list of draft amendments adopted at the 44th, 45th, and 46th sessions.

Rev 10 was published as expected in late July 2023. The sub-committee issued minor corrections to several chapters of Rev 10, including mostly changes to translations in 2024. The next update, Rev 11, is expected in 2025.

### 3. U.S. OSHA, HCS 2024

On May 25, 2012, OSHA revised and updated the HCS. On February 5, 2021, OSHA issued a notice of proposed rulemaking (NPRM) to amend HCS 2012 to align with Rev 7 of GHS. The NPRM included many other elements and incorporated some aspects of Rev 8 of GHS.

The final rule, known now as HCS 2024, was published on May 20, 2024, and took effect July 19, 2024.

The final rule adopted many of the proposed elements. Changes to the regulatory text, most significantly in labeling sections, are seen as providing practical accommodations for various supply chain scenarios. Of note, inclusion of small container labeling provides alternatives not previously noted with the regulation, but allowed through various alternative means (*i.e.*, Letters of Interpretation). There are changes to update and revise key definitions, changes to Appendices A – D, and changes to Trade Secret provisions. Most of these changes are to align with Rev 7 and elements of Rev 8 of the UN GHS. OSHA spent most of late 2024

PODCAST
HCS 2024 — A Conversation with Karin F. Baron

*Expect further OSHA HCS progress in 2025 with potential additional corrections, updates to guidance documents, and further clarification on regulatory elements that are not part of the UN GHS approach.*

updating supporting documents and providing guidance. A correction of several inadvertent errors to the final rule was issued on October 9, 2024.

OSHA proposed to stagger implementation dates, similar to its approach in 2012. Substances must be in compliance no later than **January 19, 2026**, with hazard communication programs and training complete by **July 20, 2026**. Mixtures must be compliant by **July 19, 2027**, with hazard communication programs and training completed by **January 19, 2028**. Expect further progress in 2025 with potential additional corrections, updates to guidance documents, and further clarification on regulatory elements that are not part of the UN GHS approach.

WEBINAR ON DEMAND
Harmonizing TSCA Consent Orders with OSHA HCS 2012

### 4. Canada, Health Canada HPR

On December 9, 2020, Health Canada (HC) proposed to update the Hazardous Products Regulation (HPR) from its current approach based on Rev 5 to Rev 7 of GHS in the *Canada Gazette I*. The comment period was to end on February 27, 2021, but was extended to May 19, 2021, to allow all comments to be captured and to align with the U.S. NPRM deadline. HC, on January 4, 2023, published in the *Canada Gazette II* the revisions to the HPR. The changes include updates to the HPR to align with Rev 7 of GHS as expected, but also include elements from Rev 8 to align with the NPRM from the United States. The transition period is **three years** and updates to guidance documents were published in October 2023. There was relatively very little noted about the HPR in 2024. HC did not indicate an intention to delay based on the publication of the final rule by OSHA in May. The two countries remain closely aligned. Expect further joint guidance updates in 2025 as to how specifically to address minor variances between the two regulations.

### 5. Brazil

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

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

On July 3, 2023, ABNT adopted Rev 7 and merged the four-part standard into the "new" NBR 14725:2023. Major revisions include the change in the SDS name to "*Ficha com Dados de Segurança* (FDS)," the allowance of a Quick Response (QR) code on the label to access FDS content, and the requirement that Section 1 of the FDS must include a 24-hour local phone number for emergencies. The remaining changes follow the adoption of Rev 7 and include revisions and additions to hazard and precautionary phrases, and updates on provisions for the labeling of small packages. The two-year transition period to adopt the changes started in 2023, with the transition ending on **July 3, 2025**. The "new" NBR 14725:2023 will become mandatory as of **July 4, 2025**. No further changes are expected in 2025.

### 6. Chile

The Ministry of Health (MoH) and the Ministry of Environment (MoE) published on February 9, 2021, Decree 57, which approved the Regulation on the Classification, Labelling, and Notification of Chemical Substances and Mixtures. The regulation aligns with Rev 7 of GHS and provides transition periods for substances and mixtures for industrial and non-industrial uses. The implementation date for industrial substances was February 9, 2022, and industrial mixtures must comply by **February 9, 2025**. Non-industrial substances had until February 9, 2023, and non-industrial mixtures must comply by **February 9, 2027**.

Companies are allowed to continue using the Standard NCh 2245:2015 during the implementation period.

Chile identified a list of substances, approved by the MoH in Resolution 777, with required classifications to assist with the classification and labeling (C&L) of products. The list contains approximately 4,500 substances, and updates are expected every two years. The list is expected in late 2024 and will be available for use in **early 2025**. The C&L list imposes chemical notification obligations that started in 2024. Stakeholders are urged to review this list prior to developing the SDS, label, and/or verification of compliance with newly enacted notification requirements.

### 7. China

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

On March 12, 2024, MIIT released a draft of the revised GB 30000.1 standard to align with the Rev 8 of the UN GHS. The revised mandatory standard (starting with GB), GB 3000.1-2024, was officially released on July 24, 2024, and will take effect on **August 1, 2025**. The standard includes new categories, terminology, and labeling requirements, and is intended to replace the "General Rules for Classification and Hazard Communication of Chemicals" (GB 13690-2009).

The "Specification for Classification and Labelling of Chemicals Part 31: Precautionary Label for Workplace of Chemicals" (GB/T 30000.31-2023), a recommended national standard (starting with GB/T), was published on November 27, 2023, and implemented on June 1, 2024. This standard aligns with the UN GHS Rev 9 and sets requirements on the preparation and use of precautionary labels for chemicals in workplaces.

To support the "one enterprise, one product, one code" pilot application initiated in 2021 by China's Ministry of Emergency Management (MEM), and to standardize and clarify the coding rules for hazardous chemical information code, China's Chemical Safety Association released a new voluntary Association Standard T/CCSAS 047-2023, "Technical Specification for Coding and Labeling of Hazardous Chemicals," on December 25, 2023. This standard stipulates the coding principles, data storage, and application requirements for QR codes used for hazardous chemicals. It is applicable to the coding and labeling of hazardous chemicals during their production, storage, transportation, operation, and use.

Expect to receive further updates to the GB 30000 series in 2025 to align with China's overarching goal set forth under the "Regulations on the Safety Management of Hazardous Chemicals" (State Council Order No. 591).

### 8. Colombia

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

### 9. CLP

In April 2023, the 19th Adaptation to Technical Progress (ATP) was published in the EU *Official Journal* and contains clarification from the Risk Assessment Committee (RAC) on several substances. Additional clarification was issued May 2, 2023, assumed to be the 20th ATP, which includes the 19th ATP changes now incorporated into Table 3 of Annex VI to CLP, which enter into force **February 1, 2025**.

On October 19, 2023, the 21st ATP was published and includes 27 new entries and 24 amended entries to Annex VI of CLP. Most entries were adopted opinions that occurred in 2021 and includes both updates and new entries. The enforcement of the 21st ATP begins on **September 1, 2025**.

The 22nd ATP was published on June 19, 2024, and includes 27 new entries with 16 modifications and seven deleted harmonized classifications. Most of the entries are from adopted opinions that occurred in 2022. The most relevant entry is the inclusion of multi-walled carbon tubes, silver nano, and updates to formaldehyde. The enforcement date for these updates and revisions is **May 1, 2026**.

The 23rd ATP is expected in **mid-2025** with an enforcement approximately 18 months after publication. The 23rd ATP is expected to have 26 new entries with revisions to about 14 hazard classifications.

The European Commission (EC) made changes to CLP to include new hazard classes currently not addressed within the regulation or as part of the UN GHS as of April 20, 2023. These changes include the addition of hazard classes for endocrine disruptors for human health; endocrine disruptors for the environment; persistent, bioaccumulative, and toxic (PBT); very persistent and very bioaccumulative (vPvB); persistent, mobile, and toxic (PMT); and very persistent and very mobile (vPvM). The transitional periods are divided between substances and mixtures. The transition periods continue into 2025. "For new substances on the market, companies need to comply with the new rules from **1 May 2025**, whereas substances that have already been on the EU market, companies have until **1 November 2026** to comply. Separate transition times apply for mixtures. New hazard classes apply from **1 May 2026** to new mixtures, whereas companies have until **1 May 2028** to update the classification and labelling for existing mixtures." The European Chemicals Agency (ECHA) Guidance, updated in late 2024, includes additional resources, including a webinar provided to assist regulated entities. ECHA views these endpoints as "hazards of highest concern" and indicates that companies need to assess and review if the new classifications apply to substances and mixtures. Expect member states (MS) to continue to propose addition of these endpoints on specific substances through harmonized classification and labeling (CLH) procedures.

The EU continues to champion the proposed inclusion of these endpoints at the UN GHS Sub-Committee. The UN GHS Sub-Committee continues discussions on how best to approach these complex endpoints, with very little movement expected in 2025 due to a myriad of reasons, most importantly resources.

The European Parliament Corrigendum from July of 2024 provided insights into major CLP revisions expected over the next four to five years. On December 10, 2024, the amendments to CLP entered into force. Regulation (EU) 2024/2865 of October 23, 2024, includes many changes to "enhance chemical safety and information transparency." On the good news side, expect a more transparent process for reconciliation of the C&L notification inventory and new approaches to the harmonization of classification by grouping of substances to accelerate the process and avoid unnecessary animal testing.

The publication of the C&L inventory includes provisions for updates to notifications within six months of any decision on CLH. ECHA also notes that to address divergences in the names of notifiers, the reason for diverging from the notified C&L, the reason for introducing a more severe C&L, and the date of the latest update of the C&L will now be required. ECHA intends to flag notifier entries that ECHA believes are incomplete, incorrect, or obsolete. These changes may help harmonize the process.

Table 3 of Annex VI to CLP now specifies the substance form (solid, liquid, and/or gas) that applies to the specific classification. If no form is specified, the classification is relevant for all forms of the substance. The Acute Toxicity Estimates (ATE) will be established for substances by manufacturers, importers, and/or downstream users in notifications to the C&L inventory. Manufacturers, importers, and/or downstream users will not be expected to provide an ATE value if it is already part of a harmonized classification. In addition, EUH statements indicated in Annex VI will apply to all mixtures if relevant regardless of classification.

The CLP revisions include changes to label deadlines and layouts. Impacted individuals are required to update labels within specified timeframes that range from six to no more than 18 months following the update to the SDS. The package size will dictate minimum font size, dimensions of pictogram(s), and the dimensions of the label. Packaging that is less than 10 ml must be easily legible. All text should be black on white background, in a single font (without serifs), and with legible letter spacing. Foldout labels will be more acceptable. Rules for content on the front, inner, and back pages of the foldout label are laid out.

The CLP revisions address the concept of digital labeling. The QR code must be accompanied by the phrase "More hazard information available online," or something similar. The digital label must be accessible within two clicks without using a login and accessible for a period of ten years or for longer as required. The label elements are to be kept together. The label must be accessible by all groups and easily searched.

The dates for implementation vary depending on obligations, with most of industry expected to comply by **July 1, 2026**, with the exception of label formatting. Label formats are applicable from **January 1, 2027**. Substances and mixtures placed on the market within these dates will have until **July 1, 2028**, and **January 1, 2029**, to comply, respectively.

2025 will signal significant changes to the CLP program. Reconciliation of the C&L notification processes is also expected

to invite challenges for companies as they struggle to review and update entries that most made over ten years ago.

### 10. United Kingdom

January 1, 2021, marked the official end of the transition period for the United Kingdom (UK) exit from the EU. The Health and Safety Executive (HSE) continues to be responsible for the UK equivalent to the EU CLP and certain aspects of REACH that impact CLP (*e.g.*, SDS content). The original intent was to incorporate the EU CLP into a Great Britain (GB) CLP Regulation, where GB includes England, Scotland, and Wales. The GB CLP Regulation does include all existing EU CLH in force on December 31, 2020.

2024 regulatory actions were driven by predictable variations between the EU and the UK, as the UK considered ATPs that were not within the scope of the current GB CLP Regulation (*i.e.*, 16th - 22nd). The variations on a substance-by-substance level resulted in the UK aligning with the EU approach for some substances while adopting alternative approaches to C&L for others. The HSE currently captures these substance-level classifications in an Excel spreadsheet that is updated frequently on its website, known as the GB mandatory classification and labeling list (GB MCL list). These changes continue to require considerable diligence for those navigating trade within the region.

In October of 2023, the GB MCL list was amended to adopt 98 substances with a compliance date of **April 20, 2025**. In March of 2024, the list was amended again to adopt 25 substance classifications, some appearing to be portions of the 21st ATP. The transition period ends **September 2, 2025**. Expect further updates to the GB MCL list throughout 2025.

The UK approach to addressing the addition of new hazard classes that are not part of the UN GHS, but added to CLP in 2023, remains unclear. In 2024, the UK did not address the Annex II changes to EU REACH that resulted in changes to the SDS in the EU at the end of 2022. The UK is currently working on revisions to its REACH approach, and it is unclear if these amendments will be addressed in 2025.

### 11. New Zealand

New Zealand was the first country to implement GHS in 2001 by modifying its Hazardous Substances and New Organisms (HSNO) Act of 1996. New Zealand's approach was unique and was originally based on Rev 1 of the UN GHS model.
On October 29, 2019, the New Zealand Environmental Protection Authority (New Zealand EPA) proposed an update to the HSNO classification system by adopting Rev 7 of the UN GHS model. The public consultation period for comments closed on January 9, 2020. On October 15, 2020, New Zealand EPA published a notice to implement the proposed changes. The notice came into force on April 30, 2021, with a four-year transition date for companies to update hazard communication elements, concluding on **April 30, 2025**.

In 2025, companies are urged to complete the changes to the SDS, labels, and packing provisions that have been implemented to meet the enforcement date of **April 30, 2025**.

### 12. South Korea

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

New products placed on the market after January 16, 2021, require submission of the MSDS to MoEL and must comply with certain content requirements, including being translated into Korean. Products that were on the market prior to January 16, 2021, are being phased into this process. Deadlines for submission are tonnage-based by year. The grace period for existing products between 10 and 100 metric tons per year ended January 16, 2024. The grace period for existing substances between 1 and 10 metric tons per year ends **January 16, 2025**. In 2025, the final MSDS deadline for submission for existing substances less than 1 metric ton per year is **January 16, 2026**. Companies are urged to review and ensure all submissions are completed in 2025, as this process does take time with the competent authority review procedures. No further changes are expected in 2025, but compliance checks will result in increased importer scrutiny in **early 2026**.

### 13. Peru

A draft bill was circulated in 2020 that proposed a regulation that would follow UN GHS for C&L of all substances. The draft bill includes provisions for a national registry within one year of the approval of the regulation. On May 28, 2023, the draft bill proceeded to a decree (Decree 1570). The decree process indicates the intention to adopt officially GHS for classification, labeling, and SDSs.

In July 2024, the Peruvian government published a draft regulation on the classification, reporting, and prioritization of hazardous substances. The publication suggests the Peruvian government has opted to implement Rev 6 of the UN GHS model.

The Peruvian SDS must comply with Annex 4 of GHS and include the chemical hazard classification. The SDS must be in Spanish, but manufacturers and importers are able to include additional languages, if required.

### 14. Singapore

First adopted in 2008 under Singapore Standard (SS) 586, GHS became mandatory for manufacturers in 2015 and for workers in 2016. There have been several updates, including one in 2011 to Rev 2 of GHS and one in 2014 to Rev 4. On June 6, 2022, consultation on a draft update to align with many of the requirements outlined in GHS Rev 7 began. On February 6, 2023, the revised relevant editions of the SSs were published to align with Rev 7. There is a 24-month transition period to implement the amended standards. The transition period ends **February 6, 2025**. No further changes are expected in 2025. SSs are for purchase only and updated from time to time.

### 15. Taiwan

Taiwan's Ministry of Economic Affairs (MOEA) is updating the CNS 15030 serial standards, Classification and Labeling of Chemicals, to align with Rev 8 of UN GHS. The comment period for the adoption closed on June 16, 2024, and a virtual seminar was held on September 24, 2024. It is expected that the official standard will be released by the end of 2024.

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

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*Implementation of both KKDIK and BPR continue to drive major chemical regulatory activities, but little actual movement occurred in 2024. 2025 is expected to be more active.*

## F. TURKEY

### 1. Overview

Turkey's efforts to align its chemicals legislative framework with the European Union's (EU) chemicals regulations did not progress significantly in 2024. Chemical regulatory activity had focused on the submission of data by industry to comply with the KKDIK regulation (Kimyasalların Kaydı, Değerlendirilmesi, İzni ve Kısıtlanması), an initiative scheduled to enter into force at the end of 2023. The deadline was extended on December 23, 2023, and efforts by industry stakeholders remain hampered by major delays and a lack of clear communication. Technical glitches with entry by registrants or their Only Representatives (OR) of required information into the KKS IT system proved especially challenging. Amendments to Turkey's 2009 Biocidal Products Regulation (BPR) entered into force on January 1, 2022. Implementation of both KKDIK and BPR continue to drive major chemical regulatory activities, but little actual movement occurred in 2024. 2025 is expected to be more active.

### 2. KKDIK

KKDIK is a hazard-based chemical regulatory framework that requires registration of chemicals manufactured within or imported into Turkey in quantities of one metric ton or more per year. KKDIK data requirements are aligned with those of the EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation.

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

Changes to the KKS IT system to allow registrants or their ORs to claim, subject to a Ministry fee, a registrant's identity and registration number as confidential business information (CBI) were completed in 2023. The system remained largely unavailable for submissions in 2024.

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

A final Revision of KKDİK Regulation Regarding the Extension of Registration Deadlines was published in the *Official Gazette* on December 23, 2023, No:32408.

The registration deadlines are:

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

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

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

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

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

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

The extension of the registration deadline in theory allows for a more measured approach to implement KKDIK for manufacturers, importers, downstream users, and users of Turkey's KKS IT platform. The inability to update complete registrations, or to enter data into KKS IT, however, along with little to no clear communications from the Ministry, made 2024 unproductive in terms of implementing KKDIK. Expect movement in 2025, with at least KKS IT being open again for submissions to allow co-registrants and lead registrants opportunities to meet the **2026** deadlines efficiently and effectively.

### 3. Biocidal Products

Turkey's Ministry of Health proposed several amendments to the BPR, in force since its original publication in *Official Gazette* No. 27449, December 31, 2009. Amendments of several articles entered into force on January 1, 2022, including terms and conditions for placing biocidal products on the market, the testing of active substances, prohibitions for use and sale of biocidal products, the criteria to be used for adding an active substance, and updates or corrections to the biocidal product inventory. Notified products could be placed on the Turkish market until December 31, 2023.

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

No new updates occurred in 2024.

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## G. ASIA/PACIFIC RIM

### 1. Australia

#### a. Industrial Chemicals

In 2024, the Australian Industrial Chemicals Introduction Scheme (AICIS) revised the categorization, reporting, and recordkeeping requirements. For the changes to take effect, the Industrial Chemicals (General) Rules 2019 (Rules) and Industrial Chemicals Categorisation Guidelines were amended. Key changes to the Rules include:

- Written undertakings replaced with records that will make compliance easier;
- Greater acceptance of International Nomenclature of Cosmetic Ingredients (INCI) names for reporting and recordkeeping;
- Changes to the categorization criteria to benefit:
  - Local soap makers;
  - Introducers of chemicals in flavor and fragrance blends; and
  - Introducers of hazardous chemicals where introduction and use are controlled; and
- Strengthening criteria and/or reporting requirements for health and environmental protection.

The Industrial Chemicals Categorisation Guidelines were revised to:

- Refine the requirement to check for hazardous esters and salts of chemicals on the "List of chemicals with high hazards for categorisation" (the List);
- Include highly hazardous chemicals on the List based on an AICIS assessment or evaluation;
- Expand options for introducers to demonstrate the absence of skin irritation and skin sensitization; and
- Include more models for *in silico* predictions and an additional test guideline for ready biodegradability.

In response to industry feedback that more time was needed to prepare for some of the changes, AICIS published a second update to the Guidelines in September 2024. The second update includes:

- For the List: Add chemicals based on current sources and add the European Commission (EC) Endocrine Disruptor List (List I) as a source; and
- Refined requirements for introducers to show the absence of specific target organ toxicity after repeated exposure and bioaccumulation potential.

#### b. Packaging

Australia is reforming its packaging regulations to minimize packaging waste and pollution and build a circular economy for packaging. Under the National Environment Protection (Used Packaging Materials) Measure 2011 (NEPM), businesses with an annual turnover of $5 million or more that produce or sell packaging or packaged products in Australia can meet their obligations two ways:

- Becoming a Signatory to the Australian Packaging Covenant (the Covenant) and becoming a member of the Australian Packaging Covenant Organization (APCO); or
- Reporting to their state or territory government agency under the NEPM.

On September 27, 2024, the Department of Climate Change, Energy, the Environment and Water released a consultation paper, seeking comment on three potential options for reforming the packaging regulations:

- Strengthening administration of the co-regulatory arrangement;
- National mandatory requirements for packaging; or
- An extended producer responsibility scheme for packaging.

Responses were due October 27, 2024.

### 2. China

#### a. Chemical Substances

Many of the regulatory developments initiated in 2020 by

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

The draft Law on Safety of Hazardous Chemicals remains on the State Council of the People's Republic of China's (CSC) 2024 legislation work plan, as announced by CSC on May 6, 2024. Following the CSC announcement, the National People's Congress Standing Committee (NPCSC) states in its 2024 legislative work plan, on May 8, 2024, that the draft of the Law on Safety of Hazardous Chemicals (LSHC) remains on the list for initial deliberation in 2024. The LSHC will replace Decree 591, which establishes a hazardous chemicals information management system, implements electronic identification, and initiates whole lifecycle information management of hazardous chemicals.

While the Ministry of Emergency Management of the People's Republic of China (MEM) continues working on the draft LSHC in 2024, MEE issued a number of related legislative updates on chemical substance regulations and standards. MEE issued a Notice on the Technical Specification for Nomenclature of Chemicals for Environmental Management (Standard HJ 1357-2024) on March 21, 2024, to standardize chemical substance nomenclature for new chemical substance environmental management and registration, and for the management of the Inventory of Existing Chemical Substances in China (IECSC). This is the first time a Technical Standard, which regulates the nomenclature of chemical substances for environmental management, has been published. China continues to update its IECSC. As of May 20, 2024, MEE had released 24 supplemental notices, with a total of 1,399 substances added to the IECSC. China also updated its Restriction of Hazardous Substances (RoHS) regulation by adding four new phthalates to the list of restricted substances, limiting the concentration of each phthalate to be less than 0.1% in electronic information products. The latest lists of "Catalog of Prohibited Import Goods (9th Batch)" and "Catalog of Prohibited Export Goods (8th Batch)," announced by MEE on December 29, 2023, also became effective on January 1, 2024.

To strengthen its new chemical substance management, on February 1, 2024, MEE's Solid Waste and Chemicals Management Center (SCC) notified new chemical substance registrants to submit 2023 annual reports before April 30, 2024, via the online registration system. According to MEE Order No.12, annual reports containing annual production/import volume, environmental release details, the implementation status of environmental risk control measures, and the environmental management requirements, are required for new chemical substances that belong to key environmental management categories and that are registered under Ministry of Environmental Protection (MEP) Order No.7, and those registered under MEE Order No.12 with annual reporting requirements specified in the certificates.

To promote the implementation of the "Law of the People's Republic of China on the Prevention and Control of Environmental Pollution by Solid Wastes (Revised April 29, 2020)," MEE published on January 19, 2024, Solid Waste Classification and Code Catalog to standardize and refine solid waste management, including transfer, information disclosure, pollutant discharge permits, environmental statistics, and other requirements. Measures for the Administration of Pollutant Discharge Permits, approved at the 4th Ministerial Meeting of MEE on December 25, 2023, was published on April 1, 2024, and became effective as of July 1, 2024.

Continuing its implementation of the State Council's Action Plan for New Pollutant Control (2022), MEE published the Standard System Table for New Pollutant Ecological Environment Monitoring (2024 Edition), which consists of a framework diagram and a system project table for the new pollutant ecological environment monitoring standard system, to provide systematic reference in conducting investigation, monitoring, supervision, and management of new pollutants.

### b. Cosmetics and Cosmetic Ingredients

China's National Medical Products Administration (NMPA) made significant progress in 2024 on Cosmetics Supervision and Administration Regulation (CSAR) subsidiary regulations. On April 22, 2024, NMPA published an updated Technical Guidelines for Cosmetic Safety Assessment, based on its 2021 edition, to assist companies prepare for cosmetic product safety reports. This updated Guideline is effective as of May 1, 2024, and it also allows registrants to submit simplified product safety reports meeting the 2021 guideline before **May 1, 2025**, to avoid repeated investment for the same product registration.

To strengthen further the supervision and management of cosmetics and standardize the inspection of cosmetics, on April 29, 2024, NMPA published Measures for the Administration of Cosmetic Inspection, which became effective November 1, 2024. The Measures consist of eight chapters and 47 articles, including general provisions, inspection

***Measures for the Administration of Cosmetic Inspection, which became effective November 1, 2024, is the first regulation in China for the systematic supervision, inspection, and standardization of cosmetic products.***

procedures and requirements, license inspections, routine inspections, inspections with cause, coordination between inspections and audits and cross-regional joint inspections, handling of inspection results, and supplementary provisions. This is the first regulation in China for the systematic supervision, inspection, and standardization of cosmetic products. Detailed processes and requirements regarding implementation of the regulation fall under the responsibility of the newly formed NMPA's Cosmetics Standardization Technical Committee. Following announcement of the committee member list on April 30, 2024, the Technical Committee published its Statutes on August 13, 2024, providing additional information regarding its plan to adhere to scientific, standardized, and practical management to build the most rigorous standard system in China for cosmetic products.

At the same time, the Technical Committee published Provisions on the Working Procedures for the Formulation and Revision of Cosmetics Standards (Trial Version) on August 13, 2024, specifying unified technical requirements and standards for the production, operation, supervision, and management of cosmetic products. On August 7, 2024, the Technical Committee released for public comment its 2024 Plan to establish or amend 55 cosmetic product standards. The standards involve detection methods for restricted and/or prohibited substances and raw materials in cosmetic products.

NMPA has also strengthened its regulations regarding adverse reaction reporting for cosmetic products. Based on Measures for the Administration of Adverse Reactions Monitoring of Cosmetics (2022), on April 19, 2024, NMPA's National Center for Adverse Drug Reaction Monitoring issued a trial Guidelines for Cosmetic Registrants and Filers on the Collection and Reporting of Adverse Reactions to Cosmetics, requiring registrants and filers to establish effective information collection channels for consumers, entrusted production enterprises, cosmetics operators, and medical institutions, to gather and report actively and accurately adverse reactions of their marketed cosmetic products. NMPA reported 173 cases of cosmetic product non-compliance and 29 cases of inclusion of prohibited substances in cosmetic products, between January and September 2024, according to its regional inspection branches. Immediate actions to correct the non-compliant cosmetic products were mandated by the respective Provincial Drug Administration.

On July 8, 2024, NMPA announced the Comprehensive Implementation of Electronic Submission for Cosmetics and New Cosmetic Ingredients, effective September 1, 2024. This significant regulatory change aims to enhance efficiency and facilitate the registration process for companies involved in the cosmetics industry. Beginning September 1, 2024, all relevant entities, including registrants, filers, domestic responsible persons, and manufacturing enterprises, must submit all documents electronically via the Cosmetics Registration and Filing Information Service Platform. Paper documents will no longer be accepted but must be archived by the relevant domestic entities for future reviews or inspections. Original documents, third-party certification materials, and other required paper documents must be signed and confirmed for authenticity by the registrant, filer, or domestic responsible person before being submitted electronically through the Information Service Platform. The NMPA's cosmetic technical institutions and provincial drug supervision departments will adjust their submission procedures to optimize the acceptance, technical review, and management of registration and filing dossiers.

NMPA's National Institute for Food and Drug Control (NIFDC, Center for Medical Device Standards Management of NMPA, National Institute for Drug Control) also released several guidance documents in 2024 to guide the industry to conduct cosmetics safety assessment, standardize the cosmetics safety assessment, and promote implementation of the cosmetics safety assessment system. "Guidelines for Submission of Cosmetic Safety Assessment Materials" and "Technical Guidelines for Identification and Assessment of Cosmetic Risk Substances" were issued on April 30, 2024. Subsequently, on July 8, 2024, NIFDC issued three additional technical guidance documents for cosmetic products: "Technical Guidelines for Cosmetic Stability Testing and Evaluation," "Technical Guidelines for Cosmetic Preservative Challenge Testing and Evaluation," and "Technical Guidelines for Cosmetic and Packaging Material Compatibility Testing and Evaluation." These guidelines aim to

enhance regulatory oversight by ensuring that cosmetic products maintain their safety, effectiveness, and stability; preventing adverse interactions with packaging materials; and preserving the quality and functionality of cosmetic products throughout their shelf life.

In a move to align with the cosmetic regulation, several regulations on toothpaste in China have become effective in 2024. The overarching Regulations on Supervision and Administration of Toothpaste, issued by the State Administration for Market Regulation (SAMR), was implemented on December 1, 2023. This Measure explicitly states that toothpaste should be managed in accordance with provisions related to general cosmetics, and it includes specific guidance on efficacy claims, label requirements, safety monitoring for toothpaste raw materials, accountability, compliance, and legal liabilities. Following that, on September 5, 2023, NMPA announced the Implementation of Toothpaste Regulatory Regulations and Implications of the Filing Requirements for Toothpaste on the Market, providing a simplified filing process for those that are already on the market. Labels for these toothpaste products were required to be updated by July 1, 2024. Registrants must submit and publish the abstracts regarding the basis for product efficacy claims by **December 1, 2025**, except for those only claiming a cleaning function. To assist registrants/filers in this regard, in January 2024, the China Oral Care Products Industry Association (COCIA) published a first national inventory of toothpaste ingredients. This inventory collected 1,026 toothpaste ingredients, providing information on the Chinese ingredient name, INCI name, and maximum historical usage levels.

### c. Food Contact Substances

China continued its work on assessing and regulating food contact materials (FCM) during 2024. On March 12, 2024, China's National Health Commission (NHC) and SAMR announced the publication of 47 new national food safety standards and six amendments. Two important standards for FCM and articles are included in this publication: 1. GB 4806.15-2024 "National food safety standard: Adhesives for Food Contact Materials and Products," and 2. GB 31604.60-2024 "National food safety standard: Determination of solvent residues in food contact materials and products." GB 4806.15-2024 is the first standard for food contact adhesives in China, and GB 31604.60-2024 details the methodology for analyzing 25 organic solvents in food contact composite materials and products. GB 4806.15-2024 introduces controls on FCM, including composite materials and pressure-sensitive adhesives, and also includes in the annexes a list of substances that can be used for direct and/or indirect food contact and the associated use requirements. According to the annexes, 51 raw materials are approved for direct food contacts and 341 substances are permitted for indirect FCMs. Materials approved for direct contact applications are also approved for indirect contact materials. Adhesive products must indicate on the label which category they fall into. Additionally, additives used in adhesives must meet the GB 4806.1-2016 (General Safety Requirements) and GB 9685-2016 (Standards for the Uses of Additives in Food Contact Materials and Articles) requirements and recent updates.

Another key standard included in the March 2024 announcement is GB 2760-2024, "National Food Safety Standards — Food Additives Usage Standard." The updated standard will replace the current standard GB 2760-2014, and enter into force on **February 8, 2025**. GB 2760 specifies the types and names of food additives approved for use in China, as well as the scope and amount of use for each food additive. It also clarifies the principles for the use of food additives, including basic requirements, usage conditions, and principles of introduction.

### 3. New Zealand

Under the Hazardous Substances (Importers and Manufacturers) Notice 2015, importers and manufacturers of hazardous substances must provide the New Zealand Environmental Protection Authority (New Zealand EPA) their business contact information. In 2024, New Zealand EPA amended the reporting requirements, which will take effect in 2025 and **2026**. From January 1, 2025:

- Importers and manufacturers of certain hazardous substances should ensure their recordkeeping supports the annual reporting due in **2026**, reporting on the quantities imported or manufactured during the previous year; and

- New Zealand EPA has the option to issue multi-shipment import certificates for approved explosives, reducing the administrative burden for importers.

From **January 1, 2026**:

- Importers and manufacturers of certain hazardous substances must report annually on the quantities imported or manufactured during the previous

year. The first annual reports, covering substances imported and manufactured in 2025, are due **May 31, 2026**;

- All importers and manufacturers will need to provide their New Zealand Business Number (NZBN) if they have one, and the Hazardous Substances and New Organisms Act (HSNO) approval numbers and/or titles of the group standards for their hazardous substances; and

- Manufacturers of explosives will now need to provide the same information that is already required from importers of explosives.

### 4. South Korea

#### a. K-REACH

On January 9, 2024, the National Assembly passed legislation amending the Act for the Registration and Evaluation of Chemicals (K-REACH) and the Chemical Control Act (CCA). The amendments:

- Increase the threshold to register new chemical substances from 0.1 metric tons per year to one metric ton per year, matching the current standards in the European Union (EU) and Japan;

- Provide new safety responsibilities for manufacturers and/or importers;

- Base the standards for workplaces on the volume and hazards of the chemicals handled; and

- Reorganize toxic substances into three categories — acute human toxic substances, chronic human toxic substances, and ecological toxic substances — according to their hazardous characteristics.

The amendments did not include criteria for classifying toxic substances into the three categories. Although there is still no specific timeline for their development and approval, progress is expected in 2025.

In 2024, the Ministry of the Environment (MOE) published Ordinance No. 1086 and Ordinance No. 1084, amending the K-REACH Enforcement Rules and the CCA Enforcement Rules to adjust certain authorities' chemical management responsibilities. As of April 30, 2024, the following responsibilities were transferred from the National Institute of Environmental Research (NIER) to the National Institute of Chemical Safety (NICS):

- Chemical registration/notification application review;

- Hazard assessment and evaluation;

- Toxic substances designation; and

- Update of the Globally Harmonized System (GHS) Classification List.

Under the reorganization, NICS now oversees the full cycle of safety management, including registration, evaluation, approvals, reporting, and monitoring of chemical substances and products, in addition to its previous responsibilities for chemical accident prevention management plans and related site inspections. Currently, K-REACH, the Consumer Chemical Products and Biocides Safety Act (K-BPR), and CCA have separate information systems, and in 2025, NICS is expected to work to streamline the systems, bringing together related information to improve the efficiency of safety management. NIER will mainly focus on risk and hazard assessments and the development of alternative testing.

#### b. K-BPR

In 2024, MOE announced voluntary agreements with home appliance and automobile manufacturers to comply with K-BPR requirements that will not take effect until **January 1, 2028**. Beginning **January 1, 2028**, only approved biocides can be used in treated articles or parts supplied to or manufactured by the electrical/electronics and automobile industries. At that time, treated articles must also comply with new labeling and advertising rules. The participating manufacturers agree to use only approved biocides and biocidal products; aim to reduce their overall use of biocides; and ensure that their supply chains implement safety management practices for biocides. MOE plans to enter into similar agreements with other sectors.

### 5. Taiwan

Because more than a dozen different regulatory agencies regulate chemical substances under 19 different statutes, the Legislative Yuan requested that regulation be simplified and the management of chemicals of concern be enhanced. Under the Organization Act of the Ministry of the Environ-

ment, the Taiwan Environmental Protection Administration (Taiwan EPA) has been restructured to create a Ministry of Environment (MOENV) and four tertiary agencies, including the Chemicals Administration. According to a spokesperson for the Toxic and Chemical Substances Bureau (TCSB), now the Taiwan Chemical Administration (TCHA), TCHA will act as a "single window" to simplify and harmonize chemicals management. The head of TCHA will be a political affairs officer, appointed by the prime minister, rather than a common affairs officer like the head of TCSB.

On June 11, 2024, MOENV announced the revision of the "Regulations on the Registration and Approval of Toxic and Concern Chemical Substances" to strengthen the safety management of chemical substances. Five new articles, covering environmental monitoring, inspection, timeline regarding certificate issuance, application information transparency and accuracy, and simplified process for export application, are included in the revision.

MOENV's recently revised "Classification and Management of Toxic Chemical Substance" (July 2023 Version) came into effect on April 24, 2024. This guideline specifies the compliance deadlines and control requirements for perfluorohexanesulfonic acid (PFHxS) and its related compounds, starting April 24, 2024, recordkeeping and reporting for perfluorooctane sulfonic acid (concentration not reaching 0.01%), perfluorooctane sulfonyl fluoride (concentration not reaching 0.01%), lithium perfluorooctane sulfonate (concentration not reaching 0.01%), and perfluorooctanoic acid (concentration not reaching 0.01%). Exemptions for per- and polyfluoroalkyl substances (PFAS) contained in substances or mixtures, and measures for PFHxS and its salts and related compounds are also included in the revised guideline, as MOENV announced again on April 24, 2024.

### 6. Vietnam

The Ministry of Industry and Trade (MOIT) has been leading the effort to revise Vietnam's overarching chemical law in Vietnam, "Law on Chemicals" (No 06/2007/QH12). Initially passed in November 2007, the Law on Chemicals regulates chemical handling, safety, and management. MOIT issued final revisions to the Law on Chemicals, and held a workshop on August 1, 2024, to provide input on the updated draft Law. MOIT planned to submit it to the National Assembly for review at the eighth session in October 2024, and hopes to pass it at the ninth session in **May 2025**. This revision includes significant updates, aiming to address issues and deficiencies that have arisen since the law was implemented in 2008 and to comply with international standards to attract more multinational companies' investment and provide more opportunities for Vietnamese enterprises in the global market. The updated draft Law on Chemicals contains ten chapters and 89 articles, covering various regulatory scope such as chemical activities, industry development, items containing hazardous chemicals, chemical activity safety, rights and obligations of organizations and individuals engaged in chemical activities, and state administration of chemicals.

Supporting the chemical law in Vietnam, Decree No. 33/2024/ND-CP, replacing Decree 38/2014/ND-CP, was promulgated on March 27, 2024, and went into effect on May 19, 2024, This decree regulates the production, trade, import/export, processing, and use of designated chemicals (schedule chemicals), discrete organic chemicals (DOC), and DOCs other than schedule chemicals that contain phosphorus [P], sulfur [S], and fluorine [F]) (DOC-PSF), reporting and national control over such chemicals. The decree includes revisions such as clarifying the definition of schedule chemicals, adding and removing schedule chemicals, and introducing new provisions on exemptions from trade licenses and import/export permits.



**CONTRIBUTORS**
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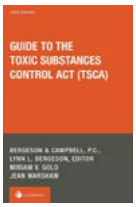
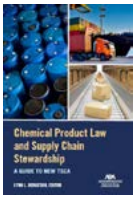
## APPENDIX A: SPEECHES AND WRITINGS

### BOOKS




Lynn L. Bergeson, Christopher R. Blunck, Lisa R. Burchi, Richard E. Engler, Ph.D., Carla N. Hutton, and Todd J. Stedeford, Ph.D., DABT®, ERT, ATS, co-authors, "*Guide to the Toxic Substances Control Act (TSCA),*" LexisNexis (2024).




COMING FEBRUARY 2025: "*Chemical Product Law and Supply Chain Stewardship: A Guide to New TSCA,*" American Bar Association (2025).

### ARTICLES

Recent articles on critical issues:

Lynn L. Bergeson, "EPA Extends PFAS Reporting Deadline to 2026," *Chemical Processing,* November 1, 2024.

Lynn L. Bergeson, "Canada Announces PFAS Mandatory Survey," *Chemical Processing*, October 2, 2024.

Lynn L. Bergeson, "PFAS Risk and the Role of the Corporate Fiduciary," *Corporate Disputes Magazine*, October 2024.

Lynn L. Bergeson, "EPA Publishes Compliance Guide on Methylene Chloride," *Chemical Processing*, September 9, 2024.

Lynn L. Bergeson, "Managing risk: what the EPA's TSCA chemical use bans tell us," *Financier Worldwide*, August 2024.

Lynn L. Bergeson, "EPA Targets But Doesn't Ban N-methylpyrrolidone (NMP)," *Chemical Processing*, August 12, 2024.

Lynn L. Bergeson, "What the EPA's ban on ongoing use of asbestos tells us," *Speciality Chemicals Magazine*, July/August 2024.

Lynn L. Bergeson and Kelly N. Garson, "Loper Bright and TSCA: Will the demise of *Chevron* matter?," *Chemical Watch*, July 22, 2024.

Lynn L. Bergeson, "Chemicals in Food: FDA Steps Up Post-Market Review," *Chemical Processing*, July 16, 2024.

Lynn L. Bergeson, "What Is False and Misleading Is Anyone's Guess," *American College of Environmental Lawyers (ACOEL) Blog*, July 8, 2024.

Lynn L. Bergeson, "EPA Bans Most Uses of Methylene Chloride," *Chemical Processing*, June 10, 2024.

Lynn L. Bergeson and Richard E. Engler, Ph.D., "Optimizing TSCA's Potential to Reduce Plastic Waste," *ABA NR&E*, Spring 2024.

Lynn L. Bergeson, "EPA Issues First Risk Management Rule: What You Need to Know," *Chemical Processing*, April 23, 2024.

Lynn L. Bergeson, "Compliance: Take a Closer Look at EPA's New Air Quality Standards for Particulate Matter," *Chemical Processing*, March 22, 2024.

Lynn L. Bergeson, "OSHA Issues Updated Process Safety Management Enforcement Guidance," *Chemical Processing*, February 7, 2024.

Lynn L. Bergeson, "Global Chemical Regulations: 2024 Will Be a Consequential Year," *Chemical Processing,* January 15, 2024.

Lynn L. Bergeson, "The EPA is undermining the TSCA's potential to reduce plastic waste," *Financier Worldwide*, January 2024.

### PRESENTATIONS

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

"Government Relations: TSCA Special Session," Richard E. Engler, Ph.D., HCPA 2024 Annual Meeting (December 11, 2024).

"It's Been Quite a Year: A Regulatory Overview," Richard E. Engler, Ph.D., HCPA 2024 Annual Meeting (December 10, 2024).

"FIFRA: Registration issues and policy and post-election analysis," James V. Aidala and Heather F. Collins, MS, Biocides The Americas (November 12, 2024).

"The Realities of Risk: A Unique Perspective of the Journey to Deep Supply Chain Sustainability," Lynn L. Bergeson, Evolve 2024 (October 10, 2024).

"TSCA – driver or barrier to sustainable chemistry?," Richard E. Engler, Ph.D., Product Sustainability USA (September 27, 2024).

"Ensuring Data Quality and Compliance to Support Global Antimicrobial Registrations," Lara A. Hall, MS, RQAP-GLP, and Michelle C. Mims, MS, RQAP-GLP, HCPA Antimicrobial Regulatory Frameworks Across the Globe Webinar Series (September 25, 2024).

"Auditing (internal), Inspections, Program Documentation (multi-site and company assessments) – OSHA, EPA, DOT Practical Advice," Karin F. Baron, MSPH, SCHC Annual Meeting (September 25, 2024).

"Navigating the Premanufacture Notice (PMN) Process Under Amended TSCA," Richard E. Engler, Ph.D., SCHC Annual Meeting (September 23, 2024).

"Regulatory Update: Chemical and Product Regulations," Lynn L. Bergeson, Environmental Regulation in Practice 2024 (September 20, 2024).

"Preparing for the future and protecting companies from collateral liability," Lynn L. Bergeson, PFAS Updates USA 2024 (September 18, 2024).

"Legal perspectives including scientific issues and key points in litigation," Lynn L. Bergeson, Regulatory Summit Americas (September 16, 2024).

"*Loper Bright* and TSCA: Will the demise of *Chevron* matter?," Lynn L. Bergeson, Regulatory Summit Americas (September 16, 2024).

"FIFRA Fundamentals," Lisa R. Burchi; Meibao Zhuang, Ph.D.; Heather F. Collins, MS; and Dana S. Lateulere, Chemical Watch (September 12-13, 2024).

"Incorporating Regulatory Burden into Product Design," Richard E. Engler, Ph.D., 28th Annual Green Chemistry & Engineering Conference (June 5, 2024).

"TSCA Fundamentals," Richard E. Engler, Ph.D., Chemical Watch (May 21-22, 2024).

"PFAS Reporting's Silver Linings Playbook: Developing a Strategic Approach to Managing Global Reporting Obligations," Lynn L. Bergeson and Richard E. Engler, Ph.D., HCPA's Mid-Year Meeting (May 10, 2024).

"Impacts of the *Chevron* Decision," James V. Aidala, HCPA's Mid-Year Meeting (May 8, 2024).

"Navigating the Regulatory Landscape," Karin F. Baron, MSPH, Sphera Customer Summit (April 30, 2024).

"New Chemicals," Richard E. Engler, Ph.D., 2024 GlobalChem Conference (March 26, 2024).

"Preparing for 2024 TSCA Chemical Data Reporting," Richard E. Engler, Ph.D., The Alliance for Chemical Distribution (March 6, 2024).

"TSCA Test Order Update: Are we having fun yet?," Lynn L. Bergeson, TSCA Developments 2024 (March 5, 2024).

"Evolving Developments in the Regulation of PFAS and Emerging Contaminants," Lynn L. Bergeson, Environmental Law 2024 (February 23, 2024).

## APPENDIX B: WEBINARS AND PODCASTS

### 2025 COMPLIMENTARY WEBINAR SCHEDULE

Bergeson & Campbell, P.C. (B&C®) and The Acta Group's (Acta®) complimentary webinars feature leading figures from government, industry, and private practice analyzing and advising on pressing chemical policy issues to equip regulatory professionals with the insight to succeed in an ever-changing regulatory environment. More information and registration details are available at www.lawbc. com/media-type/seminars-and-webinars/.

| Topic | Date and Time (subject to change) |
|---|---|
| What to Expect When You Don't Know What to Expect in Chemicals Policy and Regulation and on Capitol Hill in 2025<br>Register now | January 14, 2025<br>11:00 a.m. - 12:00 p.m. (EST) |
| What's New with New Approach Methodologies: A Webinar<br>Register now | February 13, 2025<br>11:00 a.m. - 12:30 p.m. (EST) |
| Consumer Labeling and the Status of GHS<br>Register now | April 1, 2025<br>11:00 a.m. - 12:00 p.m. (EDT) |
| PFAS Updates: What's Happening in the U.S. and EU | April 13, 2025<br>11:00 a.m. - 12:00 p.m. (EDT) |
| *Loper Bright*/Has the demise of *Chevron* Deference Mattered? | July 15, 2025<br>11:00 a.m. - 12:00 p.m. (EDT) |
| EU Hot Topics: REACH and Sustainability | September 16, 2025<br>11:00 a.m. - 12:00 p.m. (EDT) |
| New Developments within the FDA's Human Foods Program | November 11, 2025<br>11:00 a.m. - 12:00 p.m. (EST) |

### WEBINARS AVAILABLE ON DEMAND

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

#### An Update on the EU Chemicals Strategy for Sustainability

The Chemicals Strategy for Sustainability is fundamentally reshaping REACH and CLP regulations in ways that are resetting the global stage for the regulation of chemicals. During this webinar, Meglena Mihova, Managing Partner, EPPA; Jane S. Vergnes, Ph.D., DABT®; Tiina A. Lantto, Ph.D.; and Lynn L. Bergeson discuss the technical, regulatory science, political, and strategic implications of the introduction of new hazard classes under CLP, application of the generic approach to risk assessment and development of the essential use concept, in terms of identifying new hazard classes and NAMs for identifying them.

#### Determining PFAS Content in Your Supply Chain and Expanding Data Collection Practice

The fiscal year 2020 NDAA amended TSCA to require that all manufacturers (including importers) of PFAS and PFAS-containing articles in any year since 2011 report information related to chemical identity, uses, volumes made and processed, byproducts, environmental and health effects, worker exposure, and disposal to EPA. In this webinar, Richard E. Engler, Ph.D., and Lynn L. Bergeson review what PFAS are reportable, what information is due and by when, why finished product importers are on the hook for reporting, why there is a 12-year look-back, and the all-important topic of how much diligence is due before concluding information is "not known or reasonably ascertainable."

#### There Is More to TSCA Reporting Than CDR: TSCA Sections 8(a), (c), (d), and (e), featuring Dave Turk and Stephanie Griffin from EPA OPPT

EPA has been using its TSCA Section 8 authorities in new and different ways. These TSCA reporting obligations have been of interest to stakeholders, raising many good questions

and interest in understanding why EPA is seeking information, how it relies upon the information it receives, and what is in scope under the various reporting obligations. During this webinar, **Dave Turk**, Supervisor for the TRI Regulatory and Policy Branch, EPA OPPT; **Stephanie Griffin**, Acting Supervisor of the Data Collection Branch, EPA OPPT; Richard E. Engler, Ph.D.; and Lynn L. Bergeson address TSCA Sections 8(a), 8(c), 8(d), and 8(e), remind participants about CDR, describe the PFAS data reporting rule, and discuss EPA's consideration of a TDR rule.

### Sponsor's Role in Regulatory Testing — Complying with GLP Standards

Study Sponsors, as defined by GLP regulations and related advisory documents, ensure that non-clinical health and environmental safety studies are conducted in compliance with GLP. During this webinar, Lara A. Hall, MS, RQAP-GLP, Michelle C. Mims, MS, RQAP-GLP, and Lynn L. Bergeson highlight similarities and differences between EPA, FDA, and OECD GLP regulations as they relate to Study Sponsors' roles and responsibilities in GLP-compliant testing to support global regulatory objectives.

### TSCA Reform – Eight Years Later

The Environmental Law Institute (ELI), the George Washington University Milken Institute School of Public Health, and B&C hosted the eighth annual TSCA Reform conference, providing updates and insights regarding the current state of TSCA implementation, ongoing and emerging issues, and related developments. Topics include risk management, risk evaluation and the supporting role Sections 4 and 8 play, new chemicals review, and Section 21 citizens' petitions.

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

### Harmonizing TSCA Consent Orders with OSHA HCS 2012

TSCA consent orders and SNURs are issued under Section 5 for specific chemicals, and often include requirements to add hazard communication language to SDSs. Communicating this language to commercial partners can be challenging, as implementing these measures must be harmonized with requirements under OSHA HCS. In this webinar, Karin F. Baron, MSPH, explores two hypothetical examples and provides guidance on practical approaches to compliance. An industry perspective is presented by Sara Glazier Frojen, Senior Product Steward, Hexion Inc., who discusses the realities of managing this process day-to-day.

### FIFRA Hot Topics

During the Biden-Harris Administration, EPA OPP has focused on long-standing challenges, including efforts to meet ESA consultation requirements and meeting core pesticide registration obligations. During this webinar, James V. Aidala, Lisa R. Burchi, and moderator Lynn L. Bergeson discuss key priorities for EPA OPP and what companies should know to stay on top of new developments in the law and regulation of pesticides.

### What to Expect in Chemicals Policy and Regulation and on Capitol Hill in 2024

2024 saw EPA attempt to complete as many actions on its agenda as possible while tempering its expectations as necessary to avoid any significant pre-election missteps. During this webinar, Lynn L. Bergeson, James V. Aidala, and Richard E. Engler, Ph.D., participate in a lively, timely, and focused discussion on the state of play and how they expect things will shake out in 2024. This conversation covers expected EPA activities, PRIA 5 implementation, proposed existing chemical rules under TSCA, EPA prioritization of additional substances, and more.

## 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, 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.

### Election Outcome — A Conversation with James V. Aidala and Mark J. Washko

Lynn L. Bergeson, James V. Aidala, and Mark J. Washko discuss the results of the 2024 U.S. elections, the transition period between now and Inauguration Day, and speculate on the remainder of 2025, a year that promises to be like

no other. With the Republican trifecta and some surprising Cabinet and EPA-designate picks, there is much to cover.

**GLP Case Studies/Lessons Learned — A Conversation with Lara Hall**
Chemical testing is undertaken for lots of reasons: government mandate, product stewardship, and product defense and support, to name a few. What is under-appreciated is the importance of the standards that apply under GLP, the expertise needed to address novel testing approaches that deviate from GLP, how to manage requests from regulators that may not align with GLP requirements, and many other scenarios that require the expertise of highly trained and experienced testing experts. In this episode, Lynn L. Bergeson and Lara A. Hall discuss just a few of the many testing experiences that have made Lara the consummate testing expert that she is.

**A Conversation with Deputy Commissioner Jim Jones**
Lynn L. Bergeson and FDA Deputy Commissioner for Human Foods, Jim Jones, discuss the Human Foods' priorities and new organizational structure, the recently released proposed systematic post-market review process on which FDA seeks comments, how Jim intends to tackle the many challenges FDA faces with regard to food chemicals, contaminants, and food additives, and much more.

**A Conversation with Linda Reinstein, President and Cofounder of the Asbestos Disease Awareness Organization (ADAO)**
Lynn L. Bergeson and Linda Reinstein, President and Cofounder of the Asbestos Disease Awareness Organization (ADAO), discuss Linda's many years of asbestos disease awareness advocacy. Having lost her husband, Alan, to mesothelioma two decades ago, Linda set out to educate others about the diseases associated with asbestos exposure. Her story is one of grit, perseverance, and devotion.

**Sessions from TSCA Reform — Eight Years Later**
On June 26, 2024, B&C, along with ELI and the George Washington University Milken Institute of Public Health, sponsored the all-day virtual conference, TSCA Reform — Eight Years Later. The quality of the discussion, the caliber of the participants, and the timeliness of the content motivated us to repurpose the substantive sessions to enable our podcast audience to listen to the sessions in this venue.

- Panel 1: Risk Management
- Panel 2: Risk Evaluation and the Supporting Role Sections 4 and 8 Play
- Panel 3: New Chemical Review
- Panel 4: Shaping the Agenda, Section 21 Citizens' Petitions and Other Mechanisms Influencing Priority Setting

**Why are TSCA Citizen Petitions Filed? — A Conversation with Michael Connett** — *transcript available*
Lynn L. Bergeson and Michael Connett, Partner with Siri & Glimstad, LLP, discuss his epic litigation representing Food & Water Watch, a non-profit consumer organization that sued EPA over the fluoridation of drinking water. Lynn and Michael discuss the case, why TSCA citizen petitions in general are filed, Michael's thoughts on how to prepare petitions to maximize their success (as most are denied), and other means of citizen engagement under TSCA.

**Canada Proposes Exclusion of Fluoropolymers from PFAS — A Conversation with W. Scott Thurlow** — *transcript available*
Lynn L. Bergeson and W. Scott Thurlow with Thurlow Law & Public Affairs, discuss Canada's most recent updated draft report on the state of PFAS. The updated draft report defines PFAS to exclude fluoropolymers, an issue in which Scott and his firm are deeply engaged. Scott and Lynn discuss the draft report, Canada's approach to the regulation of PFAS, and Scott's practice as a Canadian lawyer and public affairs specialist.

**Sponsor's Role in Regulatory Testing — A Conversation with Lara Hall** — *transcript available*
Lynn L. Bergeson and Lara A. Hall discuss the critical importance of understanding the role of the study sponsor. As our listeners know, chemical data — testing results, chemical studies, exposure information, environmental fate and monitoring data, to name a few — are the new currency in the chemical community. Lara and Lynn discuss GLP and the rights, duties, and obligations of all the actors involved in chemical testing, and offer some tips and insights in managing this increasingly complicated space.

**HCS 2024 — A Conversation with Karin F. Baron** — *transcript available*
Lynn L. Bergeson and Karin F. Baron, MSPH, discuss the monster final Hazard Communication Standard rule issued on May 20, 2024. This conversation covers the final rule, what in the rule makes us happy, what remains a concern, and how best to read and digest the more than 300 pages of new hazard communication provisions.

**Perspectives from OPP to OPPT — A Conversation with Elissa Reaves, Ph.D.** — *transcript available*
Lynn L. Bergeson and Elissa Reaves, Ph.D., Director, EPA OPPT, discuss Dr. Reaves' recent ascent to this position, her approach to office management, her priorities and goals for OPPT, and some interesting comparisons and contrasts with Dr. Reaves' former stomping ground, EPA's OPP.

**What is Green Chemistry? — A Conversation with Joel A. Tickner, Ph.D.** — *transcript available*
Lynn L. Bergeson and Joel A. Tickner, Ph.D., Professor, Department of Public Health, University of Massachusetts Lowell, and Executive Director of Change Chemistry, discuss green chemistry and Joel's important work at Change Chemistry. They discuss Joel's pioneering work in the green chemistry field, his leadership of Change Chemistry, implementation of the Sustainable Chemistry R&D Act of 2019, EPA's implementation of amendments to TSCA addressing new chemicals review, and much more.

**The Importance of Government Affairs Engagement — A Conversation with Mark Washko** — *transcript available*
Lynn L. Bergeson and Mark J. Washko, discuss the importance of government affairs engagement in the current political environment. Mark has significant experience in engaging with congressional staff and members to ensure his clients' interests are well served. They discuss a few specific examples of how government affairs engagement has helped, Lautenberg and his work on new chemicals, and how best to prepare for the coming November elections.

**A European Perspective on Food Law — A Conversation with Nora von Bergen, LL.M.** — *transcript available*
Lynn L. Bergeson and Nora von Bergen, LL.M., a lawyer with Food Lex AG, discuss her role as an accomplished food practitioner in Bern, Switzerland. Nora and Lynn are both officers of the International Bar Association Agriculture and Food Law Section. They discuss what Nora does at Food Lex and, in that context, recent comprehensive amendments to Swiss food law that went into effect recently, as well as a few of the challenging legal issues Nora and her colleagues are addressing.

**Utility of Consortia Advocacy — A Conversation with Heather J. Blankinship** — *transcript available*
Lynn L. Bergeson and Heather J. Blankinship discuss the value of coalition advocacy, and its essentiality in the chemical space, especially now. Engaging commercial competitors to align on advocacy involving critically important regulatory, testing, and science policy issues is daunting. It involves strong communication skills, strong people skills, a keen understanding of the substantive issues, and endless patience. Heather explains how she does what she does, extolls the virtues of consortia advocacy, discusses some of BCCM's successes, and explains why she and BCCM are as busy as they are these days.

**Asbestos Reporting Rule — A Conversation with Richard E. Engler, Ph.D.** — *transcript available*
Lynn L. Bergeson and Richard E. Engler, Ph.D., discuss EPA's first final risk management rule for chrysotile asbestos, including what it tells us about EPA's approach to risk management under TSCA, why it is relevant to any chemical undergoing review by EPA, why in all probability neither industry nor the NGO community is happy, and why litigation may well be in our future.

**FIFRA Hot Topic Issues — A Conversation with Jim Aidala** — *transcript available*
Lynn L. Bergeson and James V. Aidala discuss the complicated and ever-changing area of agricultural and biocidal products, including what to expect in pesticides when electing (2024 general elections and ag policy), the Endangered Species Act and the regulation of ag chemicals, PRIA 5 issues, new policies relating to "free of" claims, and the regulation of pesticide devices. It's a lot of real estate, but we enjoyed the ride.

**TSCA Section 8(a)(7) PFAS Reporting Rule — A Conversation with Richard E. Engler, Ph.D.** — *transcript available*
Lynn L. Bergeson and Richard E. Engler, Ph.D., discuss the super-hot topic of PFAS reporting under TSCA. This conversation covers what PFAS are reportable, what information is due and by when, why finished product importers are on the hook for reporting, why there is a 12-year look back, and the all-important topic of how much diligence is due before you conclude information is "not known or reasonably ascertainable."

**Environmental, Social, and Governance (ESG) Standards — A Conversation with the Honorable Leo E. Strine, Jr.** — *transcript available*
Lynn L. Bergeson and former Chief Justice of the Delaware Supreme Court, the Honorable Leo E. Strine, Jr., discuss the intense focus on ESG standards and the pressures on corporate directors and managers occasioned by the Caremark decision and its progeny, among other developments. These initiatives have particular relevance to businesses

many of our clients and listeners manage, as they often involve environmentally sensitive chemical products and manufacturing operations.

**TSCA Developments in 2024 — A Conversation with Richard E. Engler, Ph.D.** — *transcript available*
Lynn L. Bergeson and Richard E. Engler, Ph.D., discuss what to expect in 2024 regarding TSCA developments, beginning with the most recent Senate hearing on TSCA on January 24, and then covering Rich's thoughts on key TSCA initiatives for the rest of the year.

**What to Expect on Capitol Hill in 2024 — A Conversation with Jim Aidala** — *transcript available*
Lynn L. Bergeson and James V. Aidala discuss what to expect in 2024 from the Hill and EPA's OCSPP when it comes to key chemical matters. They cover a lot of territory — EPA staffing deficits, a deeply divided Congress, and the many challenging legal, scientific, and policy issues that this OCSPP is tasked with solving, or at least managing, in 2024 as it stares down national elections in about 10 months and all the uncertainty that fact invites.

**GRAS: Are Changes in Our Future? — A Conversation with Karin F. Baron** — *transcript available*
Lynn L. Bergeson and Karin F. Baron, MSPH, discuss an old but evolving concept in FDA circles called GRAS — Generally Recognized as Safe. As listeners may know, "food additives" require pre-market approval by FDA. Substances "generally recognized" as safe under the conditions of a substance's intended use are excluded from the definition of "food additive," are not subject to mandatory pre-market review by FDA, and may be added to human and animal food.

## APPENDIX C: TRAINING COURSES ON DEMAND

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

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

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

### TSCA Tutor®

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

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

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

### FIFRA Tutor®

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

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

F100-series bundle (currently eight modules)
F200-series bundle (currently six modules)
All currently available FIFRA Tutor modules (14 modules)

* Coming Q1 2025

## APPENDIX D: GLOSSARY

**1,1-DCE** — 1,1-Dichloroethane
**1,2-DCE** — 1,2-Dichloroethane
**2,4,6-TTBP** — 2,4,6-tris(tert-butyl)phenol
**6:2 FTAc** — 6:2 Fluorotelomer Acrylate
**6:2 FTOH** — 6:2 Fluorotelomer Alcohol
**6:2 FTSB** — 6:2 Fluorotelomer Sulfonamide Betaine
**6PPD** — N-(1,3-Dimethylbutyl)-N′-phenyl-p-phenylenediamine
**ABNT** — Brazilian Association of Technical Standards
**ACAT** — Alaska Community Action on Toxics
**ACC** — American Chemistry Council
**ACE** — Alternative Uses of Commercial Equipment
**ACI** — American Cleaning Institute
**Acta®** — The Acta Group
**AD** — Antimicrobials Division
**ADAO** — Asbestos Disease Awareness Organization
**AFL-CIO** — American Federation of Labor — Congress of Industrial Organizations
**AFPM** — American Fuel and Petrochemical Manufacturers
**AI - Active Ingredients**
**AICIS** — Australian Industrial Chemicals Introduction Scheme
**ANPRM** — Advance Notice of Proposed Rulemaking
**ANSES** – French Agency for Food, Environmental and Occupational Health and Safety
**Anvisa** — National Health Surveillance Agency
**APCO** — Australian Packaging Covenant Organization
**APEP** — Antimicrobial Product Evaluation Program
**APHIS** — Animal and Plant Health Inspection Service
**ATE** — Acute Toxicity Estimates
**ATP** — Adaptation to Technical Progress
**ATRm** — Alternative Transitional Registration Model
**B&C®** — Bergeson & Campbell, P.C.
**BBP** — Butyl Benzyl Phthalate
**BCCM** — B&C® Consortia Management, L.L.C.
**BETO** — Bioenergy Technologies Office
**1-BP** — 1-Bromopropane
**BPA** — Bisphenol A
**BPR** — Biocidal Products Regulation
**BRS** — Biotechnology Regulatory Services
**C&L** — Classification and Labelling
**CAP** — Common Agricultural Policy
**CAS RN®** — Chemical Abstracts Service Registry Number®
**CBER** — Center for Biologics Evaluation and Research
**CBI** — Confidential Business Information
**CBIC** — Central Board of Indirect Taxes & Customs
**CCA** — Chemical Control Act
**CCCR** — Consumer Chemicals and Containers Regulations, 2001
**$CCl_4$** — Carbon Tetrachloride
**CCPSA** — Canada Consumer Product Safety Act
**CDC** — U.S. Centers for Disease Control and Prevention
**CDER** — Center for Drug Evaluation and Research
**CDR** — Chemical Data Reporting
**CDX** — Central Data Exchange
**Cefic** — European Chemical Industry Council
**CEH** — Center for Environmental Health
**CEPA** — Canadian Environmental Protection Act, 1999
**CERCLA** — Comprehensive Environmental Response, Compensation, and Liability Act
**C.F.R.** — Code of Federal Regulations
**CIS** — Chemical Information System
**CLP** — Classification, Labelling and Packaging
**CMC** — Chemistry, manufacturing, and controls
**CMR** — Carcinogenic, Mutagenic, or Toxic to Reproduction
**COCIA** — China Oral Care Products Industry Association
**CoRAP** — Community Rolling Action Plan
**COU** — Condition of Use
**CPR** — Cosmetics Products Regulation
**CSAR** — Cosmetics Supervision and Administration Regulation
**CSC** — State Council of the People's Republic of China
**CSF** — Confidential Statement of Formula
**CSR** — Chemical Safety Report
**CSS** — Chemicals Strategy for Sustainability
**CTD** — confidential test data
**CUU** — Currently Unavoidable Use
**CWA** — Clean Water Act
**D4** — Octamethylcyclotetra-siloxane
**DACO** — Data Code
**DBP** — Dibutyl Phthalate
**DCI** — Data Call-In
**DCPA** — Dachtal
**decaBDE** — Decabromodiphenyl Ether
**DEFRA** — Department for Environment, Food and Rural Affairs
**DEHP** — Di-ethylhexyl Phthalate
**DfE** — Design for the Environment
**DIBP** — Di-isobutyl Phthalate
**DIDP** – Di-isodecyl Phthalate
**DINP** – Di-isononyl Phthalate
**DnOP** — Di-n-octyl phthalate
**DOC** — Discreate organic chemicals
**DOC-PSF** — Schedule chemicals that contain phosphorus [P], sulfur [S], and fluorine [F]
**DOD** — U.S. Department of Defense
**DOE** — U.S. Department of Energy

**DSO** — Differing Scientific Opinion
**DUIN** — Downstream User Import Notification
**EC** — European Commission
**ECEL** — Existing Chemical Exposure Limit
**ECHA** — European Chemicals Agency
**ECRAD** — Existing Chemicals Risk Assessment Division
**EDF** — Environmental Defense Fund
**EDSP** — Endocrine Disruptor Screening Program
**EHA** — Environmental Health Advocates, Inc.
**EHS** — Environmental, Health, and Safety
**EJ** — Environmental Justice
**eNGO** — Environmental Non-governmental Organization
**EO** — Executive Order
**EP** — European Parliament
**EPA** — U.S. Environmental Protection Agency
**EPCRA** — Emergency Planning and Community Right-to-Know Act
**EPW** — Environment and Public Works Committee
**ESA** — Endangered Species Act
**ESG** — Environmental Social Governance
**ESPR** - Ecodesign for Sustainable Products Regulation
**EU** — European Union
**EUDR** — EU Regulation on Deforestation-free Products
**EUP** — Experimental Use Permit
**EWG** — Environmental Working Group
**FAQ** — Frequently Asked Questions
**FAR** — Federal Acquisition Regulation
**FCM** — Food Contact Material
**FCN** — Food Contact Notification
**FCS** — Food Contact Substance
**FDA** — U.S. Food and Drug Administration
**FDS** – *Ficha com Dados de Segurança*
**FFDCA** — Federal Food, Drug, and Cosmetic Act
**FFF** — Firefighting foams
**FIFRA** — Federal Insecticide, Fungicide, and Rodenticide Act
**FQPA** — Food Quality Protection Act
**FSMA** — Food Safety Modernization Act
**FWS** — U.S. Fish and Wildlife Service
**FY** — Fiscal Year
**GB** — Great Britain
**GBMCL List** — Great Britain Mandatory Classification and Labeling List
**GCD** — Green Claim Directive
**GDP** — Gross Domestic Product
**GenX** — Hexafluoropropylene Oxide Dimer Acid, also known as HFPO-DA
**GHG** — Greenhouse Gas
**GHS** — Globally Harmonized System of Classification and Labelling of Chemicals
**GMP** — Good Manufacturing Practices
**GRAS** — Generally Recognized as Safe
**GSA** — General Services Administration
**HBCD** — Hexabromocyclododecane, also known as Cyclic Aliphatic Bromide Cluster
**HC** — Health Canada
**HCBD** — Hexachlorobutadiene
**HCS** — Hazard Communication Standard
**HDPE** — High-Density Polyethylene
**HFP** — Human Foods Program
**HFPO-DA** — Hexafluoropropylene Oxide Dimer Acid, also known as GenX
**HHCB** — 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[γ]-2-benzopyran
**HHHOC** — Human Health Hazard of Concern
**HHS** — U.S. Department of Health and Human Services
**HPA** — Hazardous Products Act
**HPR** — Hazardous Products Regulation
**HSE** — Health and Safety Executive
**HSNO** — Hazardous Substances and New Organisms
**HUB** — Historically Underutilized Business
**HVACR** — Heating, Ventilation, Air-Conditioning, and Refrigeration
**IAM** — International Association of Machinists and Aerospace Workers
**IARC** — International Agency for Research on Cancer
**ICI** — industrial, commercial, and institutional
**IDPREW** — Interagency Drug and Pesticide Resistance and Efficacy Workgroup
**IECSC** — Inventory of Existing Chemical Substances in China
**INCI** — International Nomenclature of Cosmetic Ingredients
**IQA** — Information Quality Act
**IRIS** — Integrated Risk Information System
**IT** — Information Technology
**K-BPR** — Consumer Chemical Products and Biocides Safety Act
**K-OSHA** — Occupational Safety and Health Act
**K-REACH** — Act on the Registration and Evaluation of Chemicals
**kg** — Kilogram
**KKDIK** — Kimyasalların Kaydı, Değerlendirilmesi, İzni ve Kısıtlanması
**Lautenberg** — Frank R. Lautenberg Chemical Safety for the 21st Century Act
**LCLAA** — Labor Council for Latin American Advancement
**LCPFAC** — Long-chain Perfluoroalkyl Carboxylate
**LD** — Legionnaires' Disease
**LoREX** — Low Release and Low Exposure Exemption
**LSHC** — Law on Safety of Hazardous Chemicals

**LVE** — Low Volume Exemption
**MBOCA** — 4,4′-Methylenebis(2-chloroaniline)
**MC** — Methylene Chloride
**MCAN** — Microbial Commercial Activity Notice
**MCL** — Maximum Contaminant Level
**MCLG** — Maximum Contaminant Level Goals
**MDEP** — Maine Department of Environmental Protection
**MEE** — Ministry of Ecology and Environment
**MEM** — Ministry of Emergency Management
**MEP** — Ministry of Environmental Protection
**MIIT** — Ministry of Industry and Information Technology
**MINAM** — Ministry of Environment
**MINCIT** — Ministry of Commerce
**ml** — milliliter
**MOA** — Mode of Action
**MoCRA**— Modernization of Cosmetics Regulation Act of 2022
**MoE** — Ministry of Environment
**MOEA** — Ministry of Economic Affairs
**MoEUCC** — Ministry of Environment, Urbanization and Climate Change
**MoEL** — Ministry of Employment and Labor
**MOENV** — Ministry of Environment
**MoH** — Ministry of Health
**MOIT** — Ministry of Industry and Trade
**MONRE** – Ministry of Natural Resources and Environment
**MPCA** — Minnesota Pollution Control Agency
**MPPD** — Multiple-Path Particle Dosimetry
**MRL** — Maximum Residue Limit
**MRRE** — Manufacturer-Requested Risk Evaluation
**MS** — Member State
**MSDS** — Material Safety Data Sheet
**NAA** — No Action Assurance
**NASA** — National Aeronautics and Space Administration
**NASEM** — National Academies of Sciences, Engineering, and Medicine
**NCD** — New Chemicals Division
**NDAA** — National Defense Authorization Act
**NEPM** — National Environment Protection (Used Packaging Materials) Measure
**NESHAP** — National Emission Standards for Hazardous Air Pollutants
**NEtFOSE** — N-ethylperfluorooctane sulfonamidoethanol
**New Zealand EPA** — New Zealand Environmental Protection Authority
**NGO** — Non-governmental Organization
**NHC** — National Health Commission
**NICS** — National Institute for Chemical Safety
**NIER** — National Institute of Environmental Research
**NIFDC** — National Institutes for Food and Drug Control
**NIOSH** — National Institute for Occupational Safety and Health
**NMeFOSE** — 2-(N-Methylperfluoro-1-octanesulfonamido) ethanol
**NMP** — N-Methylpyrrolidone
**NMPA** — National Medical Products Administration
**NNCO** — National Nanotechnology Coordination Office
**NOA** — Notice of Arrival
**NOI** — Notice of Intent
**NPDES** — National Pollutant Discharge Elimination System
**NPDWR** — National Primary Drinking Water Regulation
**NPRM** — Notice of Proposed Rulemaking
**NRC** — National Response Center
**NTP** — National Toxicology Program
**NZBN** — New Zealand Business Number
**OCSPP** — Office of Chemical Safety and Pollution Prevention
**OECD** — Organisation for Economic Co-operation and Development
**OEHHA** — Office of Environmental Health Hazard Assessment
**OEM** — Original Equipment Manufacturer
**OGC** — Office of General Counsel
**OIG** — Office of Inspector General
**OMB** — Office of Management and Budget
**ONU** — Occupational Non-user
**OPMP** — Office of Pest Management Policy
**OPP** — Office of Pesticide Programs
**OPPT** — Office of Pollution Prevention and Toxics
**OR** — Only Representative
**ORA** — Office of Regulatory Affairs
**ORD** — Office of Research and Development
**OSHA** — U.S. Occupational Safety and Health Administration
**OTT** - Over The Top
**PBT** — Persistent, Bioaccumulative, and Toxic
**PCE** — Perchloroethylene, also known as PERC
**PCPA** — Pest Control Products Act
**PCPC** — Personal Care Products Council
**PCPR** — Pest Control Products Act Regulation
**PCTP** — Pentachlorothiophenol
**PEER** — Public Employees for Environmental Responsibility
**PERC** — Perchloroethylene, also known as PCE
**PESS** — Potentially Exposed or Susceptible Subpopulation
**PFAS** — Per- and Polyfluoroalkyl Substances
**PFBA** — Perfluorobutanoic Acid
**PFBS** — Perfluorobutanesulfonic Acid
**PFDA** — Perfluorodecanoic Acid
**PFHxA** — Perfluorohexanoic Acid
**PFHxS** — Perfluorohexanesulfonic Acid
**PFNA** — Perfluorononanoic Acid
**PFOA** — Perfluorooctanoic Acid

**PFOS** — Perfluorooctanesulfonic Acid
**PIP** — Plant-Incorporated Protectant
**PIP (3:1)** — Phenol, Isopropylated Phosphate (3:1)
**PMN** — Premanufacture Notice
**PMRA** — Pest Management Regulatory Agency
**PMT** — Persistent, Mobile, and Toxic
**POD** — Point of Departure
**POP** — Persistent Organic Pollutant
**PPE** — Personal Protective Equipment
**ppm** – Part Per Million
**PPP** — Plant Protection Product
**PPPR** — Plant Protection Product Regulation
**PRIA** — Pesticide Registration Improvement Act
**PRIA 5** — Pesticide Registration Improvement Extension Act of 2022
**PRN** — Pesticide Registration Notice
**Prop 65** — Proposition 65
**PULA** – Pesticide Use Limitation Area
**PV29** — Colour Index Pigment Violet 29
**PVA** — Polyvinyl Alcohol, also known as PVOH
**QR Code** — Quick Response Code
**R&D** — Research and Development
**RAC** — Risk Assessment Committee
**RAP** — Rolling Action Plan
**RBCS** — Rural Business-Cooperative Service
**RCRA** — Resource Conservation and Recovery Act
**RDC** — Resolution of the Collegiate Board of Directors
**RDDR** — Regional Deposited Dose Ratio
**REACH** — Registration, Evaluation, Authorization and Restriction of Chemicals
**RENASQ** — National Registry of Chemical Substances
**Rev** — Revised Edition
**RFC** — Request for Comment
**RFC** — Request for Correction
**RFCU** — Reasonably Foreseeable Condition of Use
**RFR** — Request for Reconsideration
**RMOA** — Risk Management Option Analysis
**RoHS** — Restriction of Hazardous Substances
**RQ** — Reportable Quantity
**RSQUI** — National Registry of Industrial Chemical Substances
**RSR** — Regulatory Status Review
**SACC** — Science Advisory Committee on Chemicals
**SAG-CS** — Scientific Advisory Group on Chemical Safety of Non-Food and Non-Medicinal Consumer Products
**SAMR** — State Administration for Market Regulation
**SBIR** — Small Business Innovative Research
**SCC** — Solid Waste and Chemicals Management Center (of the MEE)
**SDS** — Safety Data Sheet
**SDWA** — Safe Drinking Water Act
**SEAC** — Committee for Socio-Economic Analysis
**SF** — Sustainable Futures
**SIDS** — Screening Information Dataset
**SME** — Small and Medium Enterprises
**SNAP** — Supplemental Nutrition Assistance Program
**SNUN** — Significant New Use Notice
**SNUR** — Significant New Use Rule
**SS** — Singapore Standard
**SSD** — Species Sensitivity Distribution
**SSURO** — Stop Sale, Use, and Removal Order
**SVHC —** Substances of Very High Concern
**T-BPR** – Turkey Biocidal Products Regulation
**Taiwan EPA** — Taiwan Environmental Protection Administration
**TBB** — 2-Ethylhexyl 2,3,4,5-tetrabromobenzoate
**TBBPA** — 4,4'-(1-Methylethylidene)bis[2,6-dibromophenol]
**TBPH** — bis(2-Ethylhexyl)-3,4,5,6-Tetrabromophthalate
**TCC** — Texas Chemistry Council
**TCE** — Trichloroethylene
**TCEP** — *tris*(2-Chloroethyl) Phosphate
**TCSB** — Toxic and Chemical Substances Bureau
**TCHA** — Taiwan Chemical Administration
**TDCE** — *trans*-1,2-Dichloroethylene
**TDR** — Tiered Data Reporting
**TERA** — TSCA Environmental Release Application
**TES** — Threatened and Endangered Species
**TME** — Test-Marketing Exemption
**TPP** — Phosphoric Acid, Triphenyl Ester
**TRI** — Toxics Release Inventory
**TSCA** — Toxic Substances Control Act
**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
**USW** — United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union
**VCS** — Voluntary Consensus Standards
**VERV** — Vector Expedited Review Voucher
**vPvB** — Very Persistent and Very Bioaccumulative
**vPvM** — Very Persistent and Very Mobile
**VSAP** — Vulnerable Species Action Plan
**VSP** — Vulnerable Species Pilot
**WCPP** — Workplace Chemical Protection Program
**WDOE** — Washington Department of Ecology
**Web-ICE** — Web-based Interspecies Correlation Estimation
**WHO** — World Health Organization
**WPS** — Worker Protection Standard

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