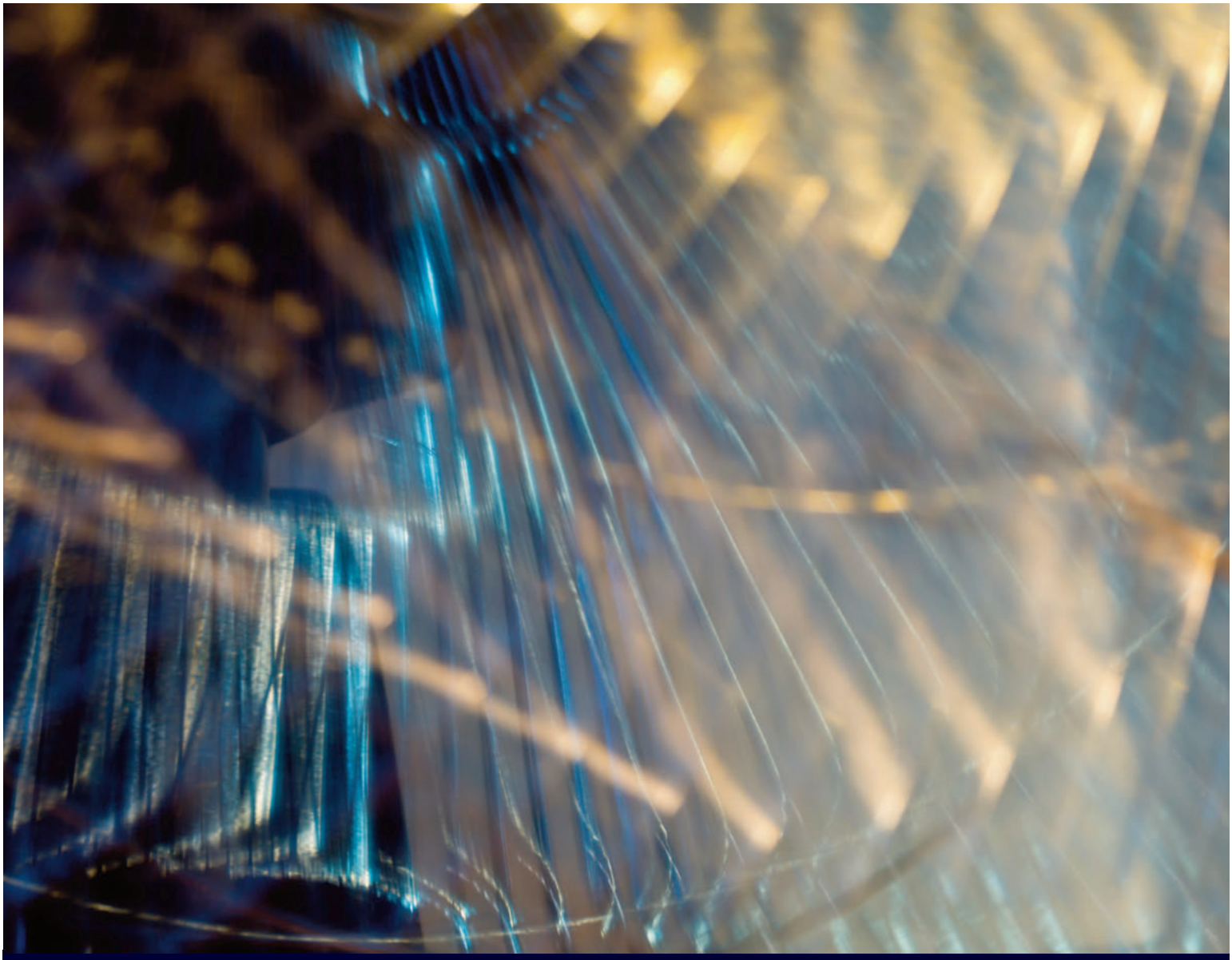

BERGESON & CAMPBELL, P.C.

Forecast for U.S. Federal and International Chemical Regulatory Policy 2026

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Forecast 2026

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 2026. Our distinguished global team of chemical experts worked hard to summarize our collective best guess on what to expect in the New Year regarding global industrial, agricultural, and biocidal chemical regulatory and policy initiatives. This was no easy feat given the general capriciousness of the world in which we live, global geopolitical and trade tensions, and the looming 2026 mid-year elections.

The first year of the second Trump Administration and Republican congressional dominance did not disappoint in terms of shattering the status quo, reconfiguring the federal administrative state, and rolling back Biden Administration initiatives, including climate change, clean energy, and environmental justice and equity commitments. If past is prologue, 2026 could see further legal and regulatory upheaval, perhaps tempered a bit by sagging poll numbers and a reluctant acknowledgement that the business community and the voting public alike really do not like unpredictability and chaos.

We speculated last year that the double whammy of *Loper Bright,* the blockbuster Supreme Court decision overturning the long-standing doctrine of "*Chevron* deference," and the resolve of the environmental non-governmental organization (eNGO) community to challenge judicially attempts to dismantle the Biden-Harris climate gains suggested a great deal of litigation is in our future. We were correct. Whether 2026 is more of the same or a changed political landscape and a likely (if current poll numbers hold) reconfigured Congress blunts some of the Administration's strongest anti-regulation tendencies, giving way to renewed energy for a more balanced approach to chemical policy, remains to be seen. We suspect *Loper Bright* will continue to cast a tall shadow in 2026, and litigation will continue to be both robust and the problem solver of choice.

The Republicans' razor-thin margin in the U.S. House of Representatives and an equally divided U.S. Senate suggest little if any legislation will be considered or passed in 2026. Toxic Substances Control Act (TSCA) fees are up for reauthorization and there remains considerable interest within the chemical community to revisit key provisions in the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The Administration is not a fan, however, nor is the eNGO community, suggesting legislative action may be a stretch. B&C's multi-year commitment to fixing the U.S. Environmental Protection Agency's (EPA) 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 nonetheless continue in 2026 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 fee provisions for FIFRA, known as the

Pesticide Registration Improvement Act of 2022 (PRIA 5) fees, may see an attempt at renewal in 2026. Fees are authorized until **October 2027**, however, and are less controversial relative to TSCA and thus arguably "easier" to authorize. Even "simpler" legislation may not make it through the current legislative maze, however.

The European Union (EU) Parliament's shift to the right has slowed but certainly not extinguished significant European chemical initiatives. While the new Parliament may have shifted right, 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 uncertainty and rancor U.S. import tariffs have inspired and their impact on investments and supply chain predictability is a serious and continuing source of considerable uncertainty.

The European Commission's proposed Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) revision issued in 2025 is expected to be adopted. Implementation will occur in 2026 or **2027**, with efforts focusing on compliance with registration dossiers and other process improvements. The European Union Deforestation Regulation (EUDR) was set to take effect in late December 2025, but was delayed a year for the second time. While businesses are largely delighted with the reprieve, the eNGO community is not. The EU's proposed ban of per- and polyfluoroalkyl substances (PFAS) continues to advance. We expect to see essential use criteria emerge in 2026 and the next phases of the prohibitions of PFAS in consumer applications. Other global PFAS initiatives, and U.S. state programs, are evolving at a brisk pace with no end in sight.

Our Forecast identifies and discusses initiatives well beyond U.S. and European borders. As in years past, we provide in the 2026 Forecast a succinct overview of U.S., European, Great Britain, South and Central America, Asia, Pacific Rim, and Turkey chemical initiatives. Our unique and exceptionally successful business platform and expanding global team of highly skilled professionals are well-suited to offer this 2026 Forecast. Our core business remains laser-focused on the complex intersection of chemical law, science, regulation, and policy, disciplines in which our highly acclaimed global team of lawyers; scientists, including toxicologists, chemists, exposure experts, and geneticists; and regulatory and policy experts is deeply versed. 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 and interesting 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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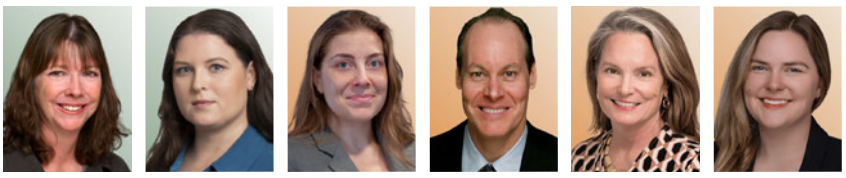

I. UNITED STATES CHEMICAL MANAGEMENT FORECAST

A. INTRODUCTION

Members of the Washington establishment expected big changes coming to Congress and federal agencies as a result of the 2024 election. The morning of January 20 dawns as an exciting day of any new administration, one filled with promise and the anticipation of what might be in store. But with this new (or not so new) Administration, many people (especially federal employees) were nonetheless taken by surprise.

With a Republican trifecta entering the U.S. House of Representatives, United States Senate, and White House, the distant rumbling of change should have been clearly heard. Even with the assurance of "shock and awe" from some, what lay on the horizon was still shocking and extraordinary. A year later, we have seen more Executive Orders come from the Oval Office than ever before, watched entire federal agencies get wiped out, and borne witness to tens of thousands of federal employees losing their jobs (probationary employees among them). That is to say nothing of the trade war with historic adversaries such as China, expanded to somehow now include Canada, Mexico, and all of Europe. And lastly, despite some rhetoric to the contrary, it turns out that Project 2025 really has been a blueprint for action to many.

The U.S. Environmental Protection Agency (EPA) has seen its share of tumult, but compared to other agencies, it remains largely intact. That is not to diminish what has occurred; it is a relative statement when compared to other programs and cabinet departments. Of particular interest to chemical and pesticide industry stakeholders, one part of EPA in line to receive increased staffing is EPA's Office of Chemical Safety and Pollution Prevention (OCSPP). This 2026 Forecast focuses especially on those issues related to the interests of chemical and pesticide industry stakeholders, as well as other associated business issues. It is a cliché to say that past rulebooks have been broken, but it is fair to say that predicting what happens in Washington, D.C., broadly — let alone at EPA in particular — is especially difficult in such unpredictable times. Nonetheless, we will do our best.

1. The First 100 Days +

President Donald Trump, according to the American Presidency Project, eclipsed past presidents by a wide margin with both "Day One" actions as well as the cumulative total of actions over the first 100 days (of this term). "Day One" actions undertaken by President Joe Biden in 2021 totaled 14, while President Trump's 2025 count stands at 41. The number of "First 100-Days" Presidential Memoranda and Executive Orders for President Trump's first term was 54; for President Biden — 56; and now in the second Trump term — 185. Of relevance to EPA is that these actions included many affecting environmental programs and energy production.

EPA's climate-related programs were mostly dismantled, and energy production emphasized. EPA, like many agencies, faced immediate staff reductions within programs linked to anything having to do with diversity initiatives and environmental justice. And even outside of any specific programs, the newly created Department of Government Efficiency (DOGE) bred fear and spread confusion for employees across the government with swinging chainsaw visuals and contradicting instructions about what was required or whether an employee should, could, or must retire.

2. EPA Leadership

The new Administration had learned from President Trump's first term and was thus ready to fill political positions across agencies with nominees or acting personnel. EPA saw an early confirmation for Administrator in Lee Zeldin, a former Representative from Eastern Long Island, New York. For OCSPP, Dr. Nancy Beck, a veteran of Trump's first term, returned to the position as Principal Deputy Assistant

WEBINAR

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Administrator, along with another veteran, Dr. Lynn Dekleva, again appointed as a Deputy Assistant Administrator. These early appointments in 2025 stand in stark contrast to some of the long delays in appointments in 2017. In July 2025, Kyle Kunkler was appointed as Deputy Assistant Administrator for Pesticides. On July 30, 2025, Douglas Troutman was nominated to be the Assistant Administrator of OCSPP. The confirmation hearing for Troutman was before the Senate Environment and Public Works Committee on October 8, 2025, and his confirmation occurred on December 11, 2025. These four appointees, among others, come from backgrounds related to the chemicals and pesticide industries. Although not unusual for appointees in a new administration to represent supportive constituencies that show familiarity with the subject matter, media coverage has been at times critical of this.

On February 4, 2025, Administrator Zeldin announced EPA's "Powering the Great American Comeback Initiative" and the "five pillars" that would guide the Agency's work:

> Pillar 1: Clean Air, Land, and Water for Every American
>
> Pillar 2: Restore American Energy Dominance
>
> Pillar 3: Permitting Reform, Cooperative Federalism, and Cross-Agency Partnership
>
> Pillar 4: Make the United States the Artificial Intelligence Capital of the World
>
> Pillar 5: Protecting and Bringing Back American Auto Jobs

Unsurprisingly, this agenda aligns with the President's own and bears the hallmark of themes repeated during the Presidential campaign. By stressing energy production and the need to enhance and encourage domestic manufacturing jobs (partly via reduced regulatory burdens), much of this agenda is explicitly contrary to the agenda of the Biden Administration, with its emphasis on the need to address climate change programmatically and via multi-billion dollar federal investments. The swap in priorities has already led to significant changes in EPA's workforce and programmatic emphasis but has affected the OCSPP staff operations less drastically.

3. Congress

Congress now has Republican majorities in both the House and Senate, and throughout 2025, leaders of both bodies emphasized supporting President Trump's agenda, including taxes, budget, tariffs, energy production, and federal workforce issues. The majorities in both the House and Senate are small, and partisan rancor is at its highest in recent memory, so little bipartisan agreement has been found on virtually anything during 2025. This is likely to continue into 2026.

The partisan divide and rancor will have an impact on both the Office of Pesticide Programs (OPP) and the Office of Pollution Prevention and Toxics (OPPT). For OPPT, the Toxic Substances Control Act (TSCA) fee provisions expire in **September 2026**, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) fee program authorization expires **September 30, 2027**. Assembling bipartisan support for renewing these fee authorities will not be an easy task but will be on the congressional legislative agenda for 2026 and beyond.

4. Staffing and Budget

As of October 2025, EPA staffing had been reduced from 16,155 when President Trump first took office to 12,448 — a reduction of almost 25 percent. Other agencies saw an even greater reduction in staffing, ranging from almost the entire staff (United States Agency for International Development) to over 40 percent (Small Business Administration). Federal employee unions, among others, are challenging these cuts, but many affected employees may decide

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to not wait for the outcome of those challenges and seek other employment. In the first month of the effort to reduce the federal workforce, over 75,000 federal employees took the offer to leave government service.

As noted in our July 25, 2025, blog item, EPA announced a reorganization of the Office of Research and Development (ORD), including elimination of the Integrated Risk Information System (IRIS), a program that has been the subject of some controversy since President Trump's first term, leading to legislation introduced to eliminate the program entirely. For years, ORD has been the subject of legislation introduced in Congress and advocated by IRIS critics, most recently the "No IRIS" Act, introduced in the House and Senate in February 2025 as H.R. 1415 and S. 623, respectively. The virtual elimination of ORD as a separate office is expected to see a number of ORD scientific and information technology staff reassigned to OCSPP to help meet program assessment deadlines for both OPPT and OPP. Meeting review deadlines in both programs has been difficult to achieve with budget limitations, even with industry-fee contribution. Additional staff, allowing for initiation and training time, should contribute to program outputs.

5. Impacts

Attrition rates and early retirements were on the rise, and with the addition of lower morale, there will be an impact on institutional memory of the affected agencies. The pressures and uncertainty presumably led employees who could transition readily to jobs outside of the government to do so even if they were otherwise satisfied with their federal position. The shock and awe, chainsaw-swinging rhetoric will affect the ability of federal agencies to recruit new employees to fill federal vacancies, which may be impactful, as many new hires will be operating in agencies with reduced staffing. Although OCSPP will see some welcome increases in staffing, the overall budget outlook is expected to be constrained by the lack of agreement over federal spending between the House and Senate.

When it comes to governmental reorganization and staff cuts, there are laws governing how program eliminations or staffing reductions are conducted. In the first days of announcing staff and program reductions, the text of the orders had a familiar "You're fired!" tone. After the smoke of the first announcements — and initial court challenges — cleared, the fine print of the mandates revealed a proviso that incorporated acknowledgment of less-noticed, but crucial requirements when "firing" federal employees.

Regardless of the reason, there are regulations that apply to reducing or eliminating programs and positions within the U.S. government. Known as a reduction in force (RIF), these procedures are arcane, complicated, and could have many unintended impacts if they are imposed to attain targeted reductions in specific parts or programs of the federal workforce. To summarize one possible outcome — staff in eliminated programs who have no experience in pesticide or chemical evaluation procedures might not only find themselves in OCSPP, but their arrival might also "bump out" current staff with years of experience in OCSPP and exemplary performance reviews.

6. States

In recent years, states have taken, or sought to take, more independent actions on chemical and pesticide issues, not wanting to wait for or simply disagreeing with the federal government. The animosity between political parties further sharpens distinctions among state requirements depending on the partisan politics within a particular state. State authority varies under the different laws governing EPA programs, but partisan bitterness that starts in Washington, D.C., can drive actions taken in states by governors, attorney generals, or state legislatures.

Adding to the complexities of current state-federal relationships, the fact that President Trump constitutionally cannot run for reelection means that the **2028** Presidential race is likely to begin exceptionally early, even by modern standards. What that adds to partisan wrangling and the ability of Congress to function effectively will be another unknown for predicting what happens in Washington in 2026.

B&C's Public Policy and Regulation Blog® provides 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.

7. The Day After

It is no surprise that a fresh administration has new and sometimes very different priorities from the one that came before it. But the first year of this Trump Administration, with allied majorities present in both the House and Senate, has had an above average impact already. Separate from how critics or allies may evaluate specific decisions or policies, there is a new question surrounding the role of Congress, the courts, the respective roles of all branches of government, and public acceptance of government decisions.

That broad question will be debated by current and future historians — but for the purposes of this 2026 Forecast, there is a more central question at play, one that looks to what this may mean for EPA and other agencies, the relationship between state and federal governments, and the ability of EPA to function as an agency under current and future conditions. Decisions about tariff policies, agency reorganization, or attempts to expand Executive power may ultimately affect the pesticide and chemical industries far more than any discrete decision about dicamba or trichloroethylene ever could. Either way, it will be important to watch and be aware of developments that could have significant impact on chemical and pesticide issues in the coming year.

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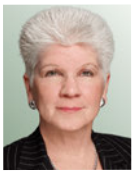
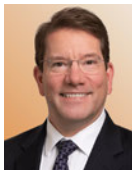


B. TSCA

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

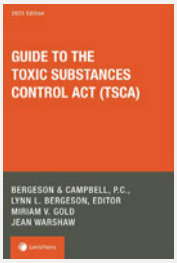
The Office of Pollution Prevention and Toxics (OPPT) has had another turbulent year, with a high volume of new and ongoing legal challenges; the transition between the Biden and Trump administrations and associated changes in U.S. Environmental Protection Agency (EPA)-wide political leadership; an increase in staff retirements and departures, including some key career managers and senior staff; another office reorganization; continued budget and resource challenges; new government-wide efforts and requirements to increase efficiency; and the longest shutdown in federal government history.

The year for the Toxic Substances Control Act (TSCA) has again been dominated by litigation. To a certain extent, this is to be expected. All five of the risk management rules are being litigated, along with the existing chemicals risk evaluation framework rule — all of which raise fundamental questions regarding the purpose and application of TSCA requirements for existing chemicals. Petitioners also challenged the final Section 8(d) reporting rule and recent updates to the new chemicals procedural regulations. Litigation on these issues is a healthy thing as stakeholders wrestle with the meaning of the statutory text. Unsurprisingly, the change of administration led to some predictable changes in approach and priorities. Other issues have also contributed to challenges while EPA has also notched some successes.

The consent decree that resulted from litigation over EPA's missed statutory deadlines for risk evaluations led EPA to commit to completing six risk evaluations by **mid-February 2026**, one by **April 30, 2026**, and ten more risk evaluations by **mid-February 2027**. These milestones have kept staff and management focused on completing this vital work.

As discussed below, EPA also proposed in September to update its risk evaluation framework rule. This rule is foundational to EPA's work under TSCA Section 6. The updated rule is unlikely to satisfy all parties in the litigation related to the 2024 version of the rule. EPA again did not propose the Tiered Data Reporting (TDR) rule and it no longer appears on the Unified Agenda; further work on TDR may have to wait for the dust to settle on the enormous workload of the ongoing risk evaluation and risk management work.

EPA appears to have delayed promulgating final risk management rules on several of the "First 10" risk evaluation substances — possibly in anticipation of the outcome of the ongoing litigation. EPA also appears to have delayed prioritization and risk evaluation work outside of the work necessary to meet the consent decree, both to allow resources to be focused and, we suspect, in anticipation of the litigation and the construction of the final risk evaluation framework rule. *See* Section 3.b. for more discussion on the status of the various risk management rules and Section 3.c. for more discussion of the status of EPA's risk evaluation work.



Guide to the Toxic Substances Control Act (TSCA), published by LexisNexis, is the definitive comprehensive treatise on TSCA, written for lawyers, regulatory affairs specialists, and commercial and business people who need to understand the details of this law. Each yearly edition of Guide to TSCA is thoroughly updated, revised, and expanded by the lawyers, scientists, and regulatory consultants of B&C's renowned TSCA practice group.

In 2024, two court decisions cast a long shadow on EPA's plans and authority. *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. EPA is appealing that decision, based on its disagreement with the court's view of the science but also for the procedural and policy implications that this precedent would set for future citizen petitions under TSCA.

In *Inhance*, the court held that Inhance's process for fluorination of plastic containers that resulted in the formation of chemical byproducts could not be considered "significant new uses" under TSCA because they had been ongoing for years. As a result, the court vacated EPA's orders issued under Section 5(e) and 5(f) that stemmed from EPA's review of Significant New Use Notices (SNUN) submitted by Inhance. Non-governmental organizations (NGO) latched on to the fact that EPA found "unreasonable risk" when reviewing the SNUNs and filed both a Section 21 petition and lawsuit seeking to compel EPA to take action under TSCA Section 6. Although EPA granted the Section 21 petition, it has yet to take any substantive action beyond opening a docket for receipt of information.

The litigation relating to the asbestos and methylene chloride (MC) final risk management rules proceeded. On June 3, 2025, litigants presented oral arguments in the Fifth Circuit case on MC, and although EPA signaled intent to revise the underlying rule, the case is no longer being held in abeyance. The litigants in the asbestos case filed briefs in late 2024 and EPA withdrew its request to hold the case in abeyance in July 2025, conveying plans to provide greater clarity through guidance but not to revise the rule.

Questions about EPA's scientific decision-making for substances remain unresolved. During oral arguments in the MC case, the court questioned why EPA did not rely on human data. EPA has not yet completed its update to its systematic review protocol. It remains unclear whether EPA intends to rely on the draft protocol issued in 2021, the more general guidelines articulated in the 2024 risk evaluation framework rule, or something else as foreshadowed by EPA's requests for comment on the 2025 proposed update to the risk evaluation framework rule.

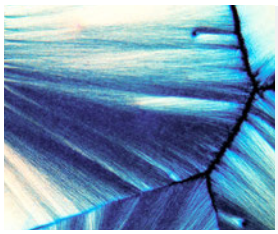
Once the updated framework rule is in place, we expect EPA to press ahead with trying to finish risk evaluations for the remainder of the "Next 20" prioritized chemicals. In December 2024, EPA published final high-priority designations for five chemicals, effectively kicking off the process and deadlines for risk evaluation, but only one (vinyl chloride) had a draft scope published (in January 2025), which has yet to be published in final. The remaining four from that group still await draft scope documents, perhaps on hold until completion of the updated framework rule given expected changes with respect to the level of discretion the Agency may exercise in scoping risk evaluations. Also in December 2024, EPA initiated the prioritization process for five more chemicals. EPA has yet to publish proposed and final high-priority designations for those chemicals. The statute and regulations require final designations by December 2025.

Staff and management turnover has continued. Every division in OPPT, including its front office, lost either its deputy director or director, or both, in 2025. OPPT Director Dr. Elissa Reaves, Shari Z. Barash, Director of the New Chemicals Division (NCD), and Joel Wolf and Jeff Morris, Directors of the Existing Chemicals Risk Management and Risk Assessment Divisions (who are both now working in the OPPT Immediate Office, at least on a temporary basis) have provided some welcome continuity in OPPT and TSCA implementation. It is our understanding that OPPT did not lose any regulatory staff to the Department of Government Efficiency (DOGE) cuts early in the year, but several staff, including some key supervisors and senior staff, elected to take the deferred resignation offers and left EPA around mid-year for retirement or other pursuits. While hiring has been frozen, the Office of Chemical Safety and Pollution Prevention (OCSPP) (both OPPT and the Office of Pesticide Programs (OPP)) saw an influx of scientists from EPA's Office of Research and Development (ORD).

New funding, new hires, and arrival of scientists from other offices did not improve EPA's pace of determinations for new chemical substances. In Fiscal Year (FY) 2025, EPA received 154 Premanufacture Notices (PMN), but completed only 135, including 114 determinations and 21 withdrawn or declared invalid, meaning that EPA's queue of PMNs under review grew by 20 in FY 2025. The current Administration has made new chemicals throughput a priority, having dedicated significant effort to work through a number of backlogged Low Volume Exemptions (LVE) in the first half of the year.

The trend in the number of PMNs that resulted in orders essentially held steady (84 percent in FY 2025, compared to 90 percent in FY 2024 and an average of 85 percent since 2016). We still have concerns with EPA proposing and promulgating Significant New Use Rules (SNUR) timely: EPA proposed four batches of order-based SNURs, representing 142 PMNs. EPA also promulgated four batches of SNURs covering 72 substances, with one batch being promulgated just six months after proposal — a welcome improvement over the typical interval of at least a year. 113 additional PMNs with consent orders await SNUR proposal and 194 order-based SNURs await promulgation. As we have discussed in the past, each case in which an order has been signed, but the SNUR is not final represents a possibility that another manufacturer will enter the market without the protective measures established by the order. The lack of final SNURs also limits the PMN submitter's ability to commercialize fully the product due to the standard distribution limits in consent orders — limits that do not expire until after the corresponding SNUR is promulgated. For additional discussion, see Section 4.e.

For breaking news and expert analysis regarding TSCA developments, visit and subscribe to B&C's TSCAblog®: www.TSCAblog.com.



Oral argument is a notable step in the appeal process that can precede a substantive decision by the reviewing court, potentially directing EPA to take certain immediate actions and setting precedent for future ones.

2. Significant Court Decisions and Updates

Although 2025 was packed with judicial activity in the TSCA space, many of those cases are still active or pending decision. We highlight here several court decisions from 2024 and a few key cases pending decision that will have significant and far-reaching consequences for EPA's future implementation of TSCA. A more in-depth review of ongoing litigation is provided in Section 9.

a. Section 6 Risk Evaluations and Risk Management Rules

Legal challenges remain pending on several TSCA Section 6 risk evaluation and risk management actions, including litigation over EPA's procedural framework rule for conducting risk evaluations, the 1.4-dioxane risk evaluation, and for TSCA Section 6(a) risk management rules like MC, asbestos, trichloroethylene (TCE), perchloroethylene (PCE, also known as PERC), and carbon tetrachloride (CTC). For most cases, EPA has requested the reviewing court to pause the proceedings while the Trump Administration considers the issues and decides what actions are appropriate. In the case of TCE, PCE, and CTC, for example, the litigation proceedings are being held in abeyance while EPA reconsiders approaches taken in the underlying rules. EPA has also signaled to the court that it will reconsider the 1,4-dioxane risk evaluation.

Two of these cases, however, have proceeded to oral argument and may be closer to decision: the consolidated challenges to the MC risk management rule in *East Fork Enterprises Inc. v. EPA*, and the consolidated challenges to the risk evaluation framework rule in *United Steel, Paper, and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO v. EPA*. Oral argument is a notable step in the appeal process that can precede a substantive decision by the reviewing court, potentially directing EPA to take certain immediate actions and setting precedent for future ones. These cases include some significant and overlapping science, policy, and legal issues that will impact OPPT's existing chemicals program and its responsibilities to evaluate and manage risks from tens of thousands of existing chemical substances under TSCA.

Post-oral argument in the risk evaluation framework rule litigation, the D.C. Circuit agreed to hold the case in abeyance while EPA reconsidered the underlying rule, with one judge dissenting. EPA's proposed rule was released in September 2025, reverting to many of the policies and approaches in a 2017 version of the same rule that was previously challenged, while accounting for the court's decision in that case. It is unclear how the D.C. Circuit litigation will proceed and resolve following EPA's "take 3" of the rule, or whether new litigation will follow. The issues addressed in this rule, however, are foundational to the TSCA program.

Post-oral argument in the MC litigation, the Fifth Circuit is no longer holding the case in abeyance after industry petitioners urged the court in February 2025 to reach a more expeditious resolution. EPA has signaled to the court that it will initiate a new rulemaking to address certain issues in the underlying rule. But at oral argument, EPA also defended the science used to reach its unreasonable risk determinations. If the court does reach the merits in this case, it will be the first time since the landmark *Corrosion Proof Fittings* case in 1991 (also in the Fifth Circuit) that a federal appeals court weighs in on EPA's risk management rulemaking authority under TSCA Section 6, and the first time ever since the 2016 Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg) amendments. The decisions will be critical milestones in the implementation of amended TSCA.

The litigation over the asbestos risk management rule in *Texas Chemistry Council, et al. v. EPA* is also active. Interestingly, EPA initially requested that the court hold the case in abeyance while EPA reconsidered the underlying rule, but abruptly withdrew that request in July 2025. EPA noted that instead of pursuing changes through rulemaking, it would "explore whether guidance could provide further clarity to stakeholders as they implement the Rule, particularly with respect to any workplace protection measures." Because the case is not held in abeyance, the Fifth

Circuit could foreseeably schedule oral argument on the merits in the near future.

b. *Inhance Technologies v. EPA* (PFAS)

This 2024 decision regarding EPA's SNUR authority and its application in a SNUR for long-chain per- and polyfluoroalkyl substances (PFAS) created significant new precedent. The disagreement stemmed from EPA's position that the burden was on Inhance to notify EPA during the rulemaking process that Inhance was engaged in ongoing uses that were proposed to be prohibited by the SNUR on the manufacture, processing, and use of long-chain perfluoroalkyl carboxylates (LCPFAC). 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.

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, *U.S. v. Inhance Technologies*, Civil Action No. 5:22-cv-05055 (E.D. PA). On May 20, 2024, the Eastern District of Pennsylvania dismissed the case.

Importantly, the decision calls into question EPA's broader authority to use SNURs as a tool to help manage risks associated with past uses of existing chemicals that have been abandoned or are otherwise no longer ongoing. For example, EPA's SNURs for inactive PFAS were published in final on January 11, 2024, with the intention of ensuring that prospective manufacturers or processors of those chemicals could not simply resume activity — for any use — without first going through an EPA review process as SNUNs under TSCA Section 5. Each of those PFAS were, at one point in the past, active in commerce, however. Based on the court's decision, it could be argued that a company could defeat the SNUR by simply demonstrating that the chemical was manufactured in the past. Alternatively, it could be argued that chemicals on the inactive portion of the TSCA Inventory (*i.e.*, those chemicals no longer actively manufactured in U.S. commerce), or particular chemical uses that the Agency can truly support as not ongoing, can be distinguished from the unknown, but ongoing uses at issue in the *Inhance* litigation. EPA has also promulgated existing chemical SNURs in recent years during Section 6 risk evaluation efforts as a means of narrowing the scope of the risk evaluation without compromising protections.

For example, past — but not currently ongoing — uses of chemicals like asbestos and flame retardants were excluded from the scope of EPA's Section 6 risk evaluations but are also subject to proposed or final SNURs to ensure those uses cannot resume absent further EPA review. It remains to be seen how and whether the Agency will continue to exercise SNUR authorities in the future. In the spring 2025 Unified Agenda, EPA's SNUR actions for existing chemicals were moved to the "Long-Term Actions" stage, suggesting a lower focus and priority.

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. Despite EPA's granting the petition, the NGOs also filed suit seeking a TSCA Section 6 rule in July 2024. The court later dismissed that case in December 2024, citing the fact that EPA had opened a rulemaking docket to facilitate collection of information to inform future regulatory action under TSCA Section 6.

Public Employees for Environmental Responsibility (PEER) has appealed to the D.C. Circuit, oral arguments were held in November 2025, and that case is pending decision. The NGOs have also continued to press for action on PFAS production during container fluorination processes in other ways, like a separate Freedom of Information Act (FOIA) lawsuit to compel release of documents considered confidential business information (CBI), and requests for correction of statements on EPA's PFAS websites. It remains to be seen what actions, if any, EPA will take under TSCA Section 6, and how the judicial process will resolve the issues raised by the NGOs.

c. *Food & Water Watch, Inc. v. EPA* (Citizen Petitions and Fluoride)

As we reported last year, in September 2024, the U.S. District Court for the Northern District of California issued its decision in *Food & Water Watch, Inc. v. EPA* (No. 3:17-cv-02162-EMC), finding 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.

On January 17, 2025, the Biden EPA filed a notice of appeal of the lower court decision. *Food & Water Watch v. EPA* (No. 25-384). At that time, it was unknown how the Trump EPA would proceed. On July 18, 2025, EPA filed its opening brief in the U.S. Court of Appeals for the Ninth Circuit, arguing that the lower court's decision should be reversed. EPA's arguments include:

- Plaintiffs' only relevant standing declarant has water that naturally contains fluoride, and plaintiffs do not ask that the water utility remove naturally occurring fluoride. Thus, according to EPA, plaintiffs' injury is not caused by the addition of fluoride to drinking water, and no available remedy will redress it.

- EPA states that the U.S. District Court for the Northern District of California violated Section 21 of TSCA by "permitting Plaintiffs to rely on evidence not first presented to EPA in the petition and reviewed by EPA in denying the petition." EPA notes that the court's final decision "overwhelmingly relied on voluminous evidence that did not even *exist* at the time of the original petition, and which was therefore not presented in the petition to EPA." According to EPA, "allowing the consideration of new evidence on a rolling basis throughout the proceedings is contrary to statutory text and frustrates the purpose of TSCA Section 21's mandatory exhaustion requirement." The approach "would undermine EPA's ability to meet TSCA's prioritization, risk-evaluation, and risk-management deadlines, and it would require EPA to proceed to risk management with a record insufficient to satisfy TSCA's rigorous scientific and regulatory standards."

- EPA claims that the court "abused its discretion by commandeering the trial and administrative proceedings in violation of the party-presentation principle." Refusing to rule after the close of evidence at the first trial, and "the court's determination to accumulate more evidence that it, rather than the parties, thought proper, transformed the court from a neutral arbiter into an advocate, and transformed TSCA Section 21 from a citizen-petition provision into a license for judicial rulemaking."

EPA states that it "continues to disagree with the district court's merits order purporting to apply TSCA's scientific standards." According to EPA, rather than asking the court to review the district court's factual findings on the "technical, complex scientific issues," it presents "more straightforward legal grounds for reversal." Food & Water Watch's answering brief was due November 17, 2025.

In addition to the potential for EPA regulation of fluoride in drinking water, the outcome of this case will set an important precedent for future use of the citizen petition authority under TSCA Section 21, and the Agency's rationale for granting or denying such petitions. If EPA's appeal is denied, it is unclear how EPA will proceed to rulemaking under Section 6(a) for fluoridation chemicals without the required risk evaluation under Section 6(b) that considers other conditions of use (COU). 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 completed pursuant to Section 6(b). 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. These anomalous results — that a private citizen could compel EPA to do what the Agency could not do on its own volition — namely, undertake a TSCA Section 6(a) rulemaking on an individual chemical use and without a risk evaluation — is presumably not an outcome that Congress intended and one area to consider for potential legislative changes to TSCA. Section 21 was essentially unmodified in the Lautenberg amendments.

More broadly, this decision could embolden citizen petitioners to file more petitions on targeted chemical uses and diminish EPA's ability to deny those petitions on the basis that the petitions fail to meet statutory requirements and evidentiary standards. Because the statute compels EPA to grant or deny these petitions within 90 days, one could easily foresee further increase in the volume of Section 21 petitions as overwhelming OPPT staff and making it even more difficult for the Agency to meet its core statutory requirements for prioritization, risk evaluation, and risk

management of existing chemicals if staff is diverted to focus narrowly on COUs for substances that are the subject of Section 21 petitions.

d. *Environmental Defense Fund v. EPA* (TSCA CBI)

In late December 2024, the D.C. Circuit Court ruled on several aspects of EPA's 2023 updates to its procedural rule regarding assertion, substantiation, and maintenance of CBI claims, which EPA characterized as increasing transparency, modernizing reporting and review procedures for CBI, and aligning the requirements with changes to TSCA in the 2016 Lautenberg amendments. The rule was challenged by both industry and NGO stakeholders.

EPA was ultimately successful in defending several important provisions in this rule. First, the court upheld EPA's narrowed definition of "health and safety study" that is statutorily excluded from CBI protections and therefore effectively limited the types of information that can be claimed as confidential. This court decision affirmed EPA's interpretation in the rule that allows study sponsors to protect the value of studies by redacting information related to the study sponsored and the names of individuals that conducted the study, but not the details of how the study was conducted nor any of the study results. This construct ensures that the public can review and understand the study even if the details of who conducted the study are not available. Readers may recall that the Good Laboratory Practices (GLP) standards are designed to ensure that study sponsors do not interfere inappropriately with the conduct of a study or the study conclusions, so the quality and validity of studies conducted under GLP should never depend on who sponsored the study. Second, the court disallowed EPA from disclosing the specific identity of substances listed on the confidential portion of the Inventory if a submitter fails to seek to protect the identity as CBI. As originally written in the rule, a submitter that does not know the identity of a substance could trigger its disclosure by EPA by submitting something to EPA (such as Chemical Data Reporting (CDR) submission) and not claiming the identity as CBI.

3. Section 6 — Existing Chemical Substances

a. Updated Framework Rule

On September 23, 2025, EPA proposed highly anticipated amendments to the procedural framework rule for conducting existing chemical risk evaluations under TSCA. 90 Fed. Reg. 45690. EPA states that it "proposes to rescind or revise certain 2024 amendments to the procedural framework rule to effectuate the best reading of the statute and ensure that the procedural framework rule does not impede the timely completion of risk evaluations or impair the effective and efficient protection of health and the environment."

As reported in its September 22, 2025, press release, EPA states that the proposed rule includes the following proposed amendments to address targeted changes to EPA's process for conducting TSCA risk evaluations made in the 2024 risk evaluation rule:

- A requirement for EPA to make a determination of unreasonable risk for each of the COUs within the scope of the chemical's risk evaluation as dictated by Congress in TSCA, as amended by Lautenberg, instead of a single risk determination on the chemical substance as a whole;
- Clarifications as to how EPA will consider occupational exposure controls such as personal protective equipment (PPE) and industrial controls when conducting risk evaluations and making risk determinations;
- Clarifications regarding EPA's discretionary authority to determine which COUs, exposure routes, and exposure pathways it will consider in a risk evaluation;
- Revisions to certain regulatory definitions to ensure consistency with Executive Order (EO) 14303 Restoring Gold Standard Science and to ensure transparency and accountability in conducting risk evaluations;
- Revisions to the procedures and requirements EPA would follow when revising or supplementing risk evaluation documents to enable EPA better to meet the statutory deadlines to assess and manage risk; and
- Adjustments to the process and information collection obligations for manufacturers (including importers) for requesting an Agency-conducted TSCA risk evaluation.

EPA proposes to amend the regulations at 40 C.F.R. Section 702.31 (general provisions) so that the changes to the procedures as part of the rulemaking would be applied to

all risk evaluations initiated on or after the date of the final rule (May 3, 2024) and would be applied to risk evaluations that are in process as of the date of the final rule, but not yet final, to the extent practicable. EPA states in the proposed rule that it "is not currently aware of any significant reliance interests in the 2024 amendments to the procedural framework rule at issue in this proposal, which remain fairly recent and apply almost exclusively to internal Agency process." EPA seeks comment on the proposed changes, "including on whether stakeholders have any significant reliance interests on the 2024 amendments at issue and, if so, how such interests should be accounted for in any final action."

ARTICLE
"Defining Risk: EPA Seeks Major TSCA Chemical Evaluation Reforms," *Chemical Processing*, October 13, 2025

We doubt the final rule will satisfy all the parties, so the litigation may proceed after the updated rule is promulgated.

b. Risk Management Rules

i. "First 10" Chemicals

Despite new priorities following the change of administration in January 2025, restructuring of EPA as a whole, and pending litigation against all of the "First 10" TSCA chemicals with final risk management rules, EPA made incremental progress over the last year on proposing and implementing final risk management rules.

(a) Asbestos

In 2024, EPA published the final risk management rule for chrysotile asbestos and announced the availability of the final TSCA *Risk Evaluation for Asbestos Part 2: Supple-*

Table 1: Status of Risk Management for "First 10" TSCA Chemicals

Substance	Rule Status	ECEL[a]	Pending Litigation
1,4-Dioxane	Final risk determination; risk management rule not yet proposed.	n/a	Yes; litigation in abeyance while EPA reconsiders the risk evaluation.
1-BP	Proposed	0.05 ppm (0.25 mg/m^3)	None
Asbestos	Part 1: Final Part 2: Final risk evaluation; risk management rule not yet proposed.	Part 1: 0.005 f/cc Part 2: n/a	Part 1: Yes; ongoing. Part 2: n/a
CCl_4 (CTC)	Final; EPA to reconsider.	0.03 ppm (0.2 mg/m^3)	Yes; litigation in abeyance while EPA reconsiders the rule.
HBCD	Final risk determination; risk management rule not yet proposed.	n/a	n/a
MC	Final; EPA to reconsider.	2 ppm (8 mg/m^3)	Yes; ongoing; pending decision.
NMP	Proposed	None[b]	None
PV29	Proposed	None[c]	None
PCE (PERC)	Final; EPA to reconsider.	0.14 ppm (0.98 mg/m^3)	Yes; litigation in abeyance while EPA reconsiders the rule.
TCE	Final; EPA to reconsider.	0.2 ppm (1.07 mg/m^3)	Yes; some compliance dates postponed; EPA seeking abeyance while EPA reconsiders the rule.

ECEL = Existing Chemical Exposure Limit; ppm = parts per million; f/cc = fibers per cubic centimeter; mg/m^3 = milligram per cubic meter; n/a = not available

[a] All ECEL values listed in the table are based on an 8-hour time weighted average (TWA) for the inhalation route of exposure.

[b] No ECEL is proposed based on unreasonable risk due to dermal contact with liquid NMP and an ECEL addresses risk from inhalation and dermal vapor routes of exposure.

[c] The calculated ECEL for PV29 is 0.014 mg/m^3, which is below the limit of detection for all currently available workplace dust inhalation monitoring methods.

mental Evaluation Including Legacy Uses and Associated Disposals of Asbestos (Asbestos Part 2). 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."

In June 2025, EPA filed a motion with the Fifth Circuit, which was granted, requesting a six-month abeyance of litigation against "Part 1" bans for chrysotile asbestos to allow the Agency to initiate a new rulemaking process, including a formal notice-and-comment rulemaking process, while it considers the assumption of non-use of PPE in the workplace and the feasibility and availability of alternatives. In July 2025, however, EPA abruptly withdrew its motion and asked the court to continue proceedings stating that it had "further reconsidered the challenged rule and no longer intends to conduct notice-and-comment rulemaking to evaluate potential changes at this time." In a supporting declaration, EPA indicated that it "plans to explore whether guidance could provide further clarity to stakeholders as they implement the Rule, particularly with respect to any workplace protection measures." Final briefs were filed by the industry and NGO appellants in September 2025, and the proceeding was subsequently stayed during the federal government shutdown. Once the court has an opportunity to review the briefs, it will likely schedule oral arguments.

TSCA BLOG
"EPA Withdraws Motion to Hold Asbestos Case in Abeyance"

(b) Methylene Chloride

The Fifth Circuit heard oral arguments in June 2025 on EPA's published MC final risk management rule wherein EPA banned all consumer uses, expanded prohibition of commercial uses, and allowed some industrial uses if workplaces can meet the Workplace Chemical Protection Program (WCPP), which includes an ECEL of 2 ppm. EPA indicated that it would not defend two provisions in the final rule regarding EPA's whole chemical approach to risk determination for MC and the assumption of no use of PPE, and that it would initiate new rulemaking to reconsider those issues. In November 2025, EPA extended the initial exposure monitoring deadlines for non-federal laboratories to align with federal laboratories for **November 9, 2026**. Other deadlines are

TSCA BLOG
"EPA Will Publish Final Rule Extending Compliance Dates for Laboratories Using Methylene Chloride"

extended into **2027** for establishing regulated areas and ensuring compliance with exposure limits and developing and implementing an exposure control plan.

(c) Carbon Tetrachloride, Perchloroethylene, and Trichloroethylene

In December 2024, EPA released final risk management rules for TCE, CTC, and PCE with effective dates in January 2025. See B&C's memorandum describing in detail each final risk management rule and providing commentary on each rule. All three risk management rules are the subject of ongoing litigation.

EPA has postponed the effective date of the TCE final rule's requirements for the TSCA Section 6(g) exemptions multiple times. The latest postponement extends to **February 17, 2026**.

In September 2025, EPA requested that the Eighth Circuit hold the CTC final risk management rule cases in abeyance while EPA reconsiders and potentially revises the rule. EPA requested comments in a notice on October 9, 2025, to inform development of any proposed rule to amend the CTC rule as appropriate.

Public comments were accepted in August 2025 on implementation issues associated with the PCE final rule requirements, experiences with the final rule since it went into effect in January 2025, and potential additional measures regarding the final risk management rule for PCE. The litigation remains on hold while EPA evaluates public input and considers developing proposed amendments to the rule.

(d) N-Methylpyrrolidone, 1-Bromopropane, and Color Index Pigment Violet 29

In 2024, EPA proposed risk management rules for N-methylpyrrolidone (NMP) and 1-bromopropane (1-BP) and, in January 2025, a risk management rule for Color Index Pigment Violet 29 (PV29). All three risk management rules are seemingly delayed while EPA awaits outcomes of pending litigation against five of the "First 10"

The timeline for risk management of 1,4-dioxane is on hold due to active litigation against EPA's withdrawal of its risk determination and the related risk assessment.

TSCA chemical risk management rules, although EPA's spring 2025 Unified Agenda indicates EPA's intent to publish a final rule in **April 2026** for NMP (2070-AK85) and 1-BP (2070-AK73).

The PV29 risk management rule may be the most impactful as EPA's conclusion would apply to all poorly soluble, low toxicity (PSLT) particulates — basically anything that can be dust. The PV29 action (2070-AK87) is listed on the "Long-Term Actions" category of EPA's spring 2025 Unified Agenda.

EPA's final rule for NMP may give an indication of how EPA may seek to correct risk evaluations. The NMP Producers Group filed a Request for Correction (RFC) and a Request for Reconsideration (RFR) seeking to have EPA correct the quality rating of two studies. EPA understandably does not want to repeat the risk evaluation process with peer review, but it is not clear that the statute allows EPA to issue a correction during risk management.

(e) 1,4-Dioxane and Cyclic Aliphatic Bromide Cluster

EPA has not yet proposed risk management rules for 1,4-dioxane or hexabromocyclododecane (HBCD, also known as Cyclic Aliphatic Bromide Cluster).

The timeline for risk management of 1,4-dioxane is on hold due to active litigation against EPA's withdrawal of its risk determination and the related risk assessment.

EPA determined that HBCD presents an unreasonable risk of injury to health and the environment under specific COUs, including Manufacturing – Import; Processing: Incorporated into a Formulation, Mixture, or Reaction Products; Processing: Incorporation into Article; Processing: Recycling (of XPS and EPS foam, resin, and panels containing HBCD); Commercial Use: Building/Construction Materials (Installation); and Disposal (Demolition). The spring 2025 Unified Agenda includes EPA's plans to publish a proposed Section 6 risk management rule for HBCD (2070-AK71) in **February 2026**.

ii. PBTs

After years of gyrations on the persistent, bioaccumulative, and toxic (PBT) chemicals rules, we finally had a year in which the rule was not modified and EPA did not need to offer a no-action assurance. The final, updated rule became effective on January 21, 2025. Litigation, however, continues. After EPA's publication of the updated rule, litigants refiled a petition for review of the decabromodiphenyl ether (decaBDE) rule in *Yurok Tribe, et al. v. EPA*, No. 24-07497 (9th Cir., filed Dec. 12, 2024). Plaintiffs in that case filed an opening brief in June 2025, arguing that the final rule was still too weak. EPA filed its answering brief in September 2025, and the case appears to be under consideration for oral argument in **February 2026**.

See B&C's memorandum "EPA Administrator Signs Final Rule Revising PBT Rules for decaBDE and PIP (3:1)."

For decaBDE, EPA is requiring signage in regulated areas, inhalation and dermal PPE for workers during specific uses, TSCA Section 12(b) notice for the export of decaBDE-containing wire and cable for nuclear power generation facilities, and recordkeeping for five years; prohibiting release to water during the manufacturing, processing, and distribution in commerce of decaBDE and decaBDE-containing products; and extending the compliance date for processing and distribution in commerce of decaBDE-containing wire and cable insulation for use in nuclear power generation facilities.

c. Risk Evaluations

i. "Next 20"

The "Next 20" high-priority chemicals refer to the group of chemicals EPA has prioritized for risk evaluation under TSCA following completion of EPA's initial "First 10" chemical risk evaluations post the 2016 Lautenberg amendments to TSCA. The "Next 20" chemicals are:

1. Formaldehyde
2. 1,3-Butadiene

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

EPA has made progress reviewing the "Next 20" high-priority substances under amended TSCA. EPA's progress in 2025 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.

Specifically, the court ordered EPA to complete the certain risk evaluation milestones by deadlines specified in a November 2024 consent decree. Some dates were subsequently modified by the court via minute order in December 2024 and again in March 2025, then automatically extended due to a lapse in federal appropriations, and modified by the court again in December 2025. In January 2025, EPA also published the "2025 Annual Plan for Chemical Risk Evaluations Under TSCA" that outlined the requisite timelines for meeting all court-ordered risk evaluation deadlines per the requirement of TSCA Section 26(n). These plans are crucially important to help the public better anticipate when resources may be required to engage meaningfully in the risk evaluation development process. The consent decree deadlines and status are as follows:

- **Draft risk evaluations for at least five of the subject chemicals by no later than December 31, 2024 - COMPLETE**
  - TCEP (Draft Risk Evaluation — December 2023)
  - Formaldehyde (Draft Risk Evaluation — March 2024)
  - 1,1-DCE (Draft Risk Evaluation — July 2024)
  - 1,3-Butadiene (Draft Risk Evaluation — December 2024)
  - DCHP (Draft Risk Evaluation — January 2025)

- **Final risk evaluations for two of the subject chemicals by no later than December 31, 2024 - COMPLETE**
  - TCEP (Final Risk Evaluation — September 2024)
  - Formaldehyde (Final Risk Evaluation — December 2024)

- **Draft risk evaluations for two more subject chemicals by no later than May 30, 2025 - COMPLETE**
  - DBP (Draft Risk Evaluation — June 2025)
  - DEHP (Draft Risk Evaluation — June 2025)

- **Final risk evaluation for one more of the subject chemicals by no later than June 17, 2025 - COMPLETE**
  - 1,1-DCE (Final Risk Evaluation — June 2025)

- **Final risk evaluations for six of the remaining subject chemicals by no later than December 31, 2025 (*extended 43 days to February 13, 2026*) – IN PROGRESS**
  - 1,3-Butadiene (Draft Risk Evaluation — December 2024; No final yet)
  - DCHP (Draft Risk Evaluation — January 2025; No final yet)
  - DBP (Draft Risk Evaluation — June 2025; No final yet)
  - DEHP (Draft Risk Evaluation - June 2025; No final yet)
  - DIBP (Draft Risk Evaluation — July 2025; No final yet)
  - BBP (Draft Risk Evaluation — August 2025; No final yet)

- **Final risk evaluation for 1,2-DCE by no later than April 30, 2026 – IN PROGRESS**
  - 1,2-DCE (Draft Risk Evaluation — November 2025; No final yet)

- **Final risk evaluations for the remaining ten subject chemicals by no later than Decem-**

ber 31, 2026 (*extended 43 days to February 13, 2027*) – IN PROGRESS

- *o*-Dichlorobenzene (No Draft or Final Risk Evaluation)
- *p*-Dichlorobenzene (No Draft or Final Risk Evaluation)
- 1,2-Dichloropropane (No Draft or Final Risk Evaluation)
- Ethylene dibromide (No Draft or Final Risk Evaluation)
- HHCB (No Draft or Final Risk Evaluation)
- Phthalic anhydride (No Draft or Final Risk Evaluation)
- TBBPA (No Draft or Final Risk Evaluation)
- TPP (No Draft or Final Risk Evaluation)
- TDCE (No Draft or Final Risk Evaluation)
- 1,1,2-Trichloroethane (No Draft or Final Risk Evaluation)

(a) Formaldehyde

EPA released its final risk evaluation for formaldehyde on January 3, 2025. EPA identified unreasonable risk in 58 out of 63 COUs. We note, however, that EPA found TSCA uses to contribute very little of the total exposure of formaldehyde, which is dominated by secondary sources (largely as a combustion byproduct) and biogenic sources (formed by living organisms, including humans).

On December 3, 2025, EPA released an updated draft risk calculation memorandum for formaldehyde and requested public comment. In its updated assessment, EPA proposed a point of departure (POD) of 0.3 ppm (375 μg/m^3) with a benchmark margin of exposure (MOE) of 1. This assessment is responsive to the Science Advisory Committee on Chemicals (SACC) comments and brings EPA's POD closer to other international assessments. It is still below the U.S. Occupational Safety and Health Administration (OSHA) permissible exposure limit (PEL). It also means that secondary and biogenic sources are now not an unreasonable risk for cancer. In the original final risk evaluation, EPA's POD was so low that EPA was effectively concluding that even absent any exposures from the manufacturing, processing, or use of formaldehyde, the population was at an unreasonable risk from exposures to biogenic and secondary sources. Comments are due by **February 2, 2026.**

(b) Tris(2-chloroethyl) Phosphate; 1,1-Dichloroethane; and Asbestos Part 2

EPA completed the final risk evaluation for TCEP in September 2024, but EPA has not yet proposed a risk management rule. See B&C's memorandum from October 2024 for details on EPA's risk determination. As with other pending risk management rules, EPA may be delaying rule proposal until the courts rule on MC and (perhaps) asbestos.

On June 20, 2025, EPA published the final risk evaluation for 1,1-DCE. EPA's final risk evaluation for 1,1-DCE determined that there was unreasonable risk to workers for cancer and non-cancer effects based on inhalation exposures under three COUs, but that these risks could be controlled with appropriate respiratory protection. EPA 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 revised the unreasonable risk findings from the draft risk evaluation risk to a finding of no unreasonable risk to the environment from 1,1-DCE.

In November 2024, EPA released a final "part 2" risk evaluation for asbestos, including legacy uses and associated disposals, and five additional fiber types beyond chrysotile. 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. There are also National Emission Standards for Hazardous Air Pollutants (NESHAP) and OSHA requirements in place to protect workers. EPA cannot "ban" chemicals that are already in place. Because EPA concludes that leaving asbestos undisturbed is lower risk than removal, mandating asbestos removal (even if the expense could be justified) could increase, rather than mitigate risk. How EPA will propose to mitigate risks associated with legacy contamination of asbestos will be instructive. As with other pending risk management rules, we suspect that EPA will not propose a rule until current litigation resolves.

(c) 1,3-Butadiene

EPA published its draft risk evaluation for 1,3-butadiene on December 3, 2024, extended the comment period through March 5, 2025, held the SACC review in April 2025, and released meeting minutes and the final report from the SACC in June 2025. In the draft risk evaluation, EPA preliminarily determined that there was unreasonable risk to workers and the general population (including fenceline communities)

based on potential inhalation exposure for 11 of 28 COUs assessed but found no unreasonable risk to the consumer or the environment. EPA's non-cancer hazard basis is decreased fetal weight in male mice with a human equivalent concentration of 2.5 ppm (5.5 mg/m^3). EPA's cancer hazard basis is leukemia in an occupational epidemiological cohort with a mutagenic mode of action and inhalation unit risk (IUR) of 0.0098 per ppm (4.4E-6 per µg/m^3) for the general population and IUR of 0.0062 per ppm (2.8E-6 per µg/m^3) for chronic occupational scenarios applied to adolescent and adult workers. According to the 2025 Annual Plan, EPA expects to publish the final risk evaluation in December 2025, but the 43-day government shutdown impacted this timeline and will likely bump publication into 2026.

(d) Phthalates

EPA published draft risk evaluations for five phthalates in 2025. The draft risk evaluation for DCHP was published on January 7, 2025, the draft risk evaluations for DEHP and DBP were published on June 5, 2025, and the draft risk evaluations for BBP and DIBP were published on August 6, 2025. EPA's basis for non-cancer health hazard from the five high-priority phthalates is outlined in the table below. EPA preliminarily determined unreasonable risk to workers for DEHP in 13 of 44 COUs, for DBP in 20 of 44 COUs, for DCHP for 9 of 23 COUs, for BBP in 16 of 38 COUs, and for DIBP in 2 of 28 COUs assessed. EPA preliminarily found unreasonable risk to consumers in 4 COUs for DBP only, and unreasonable risk to the environment for DEHP in 20 of 44 COUs, for DBP in 1 of 44 COUs, for BBP in 4 of 38 COUs, and for DIBP in 4 of 28 COUs assessed.

WEBINAR ON DEMAND

Phthalate Risk Evaluation under TSCA and the Potential Impacts to the Plastics Industry

Table 2: EPA's Basis for Non-cancer Health Hazard from the Five High-priority Phthalates

Phthalate	Target Organ System (Species)	Duration	Effect	POD[a]; Human equivalent dose (HED); Human equivalent concentration (HEC)
DEHP	Development/ Reproductive (Rat)	Continuous exposure for 3 generations	↑ total reproductive tract malformations in F1 and F2 males at 14 mg/kg-d	NOAEL = 4.8 mg/kg-day HED = 1.1 mg/kg-day HEC = 6.2 mg/m^3 [0.39 ppm]
DBP	Development/ Reproductive (Rat)	5 to 14 days throughout gestation	↓ FTT	$BMDL_5$ = 9 mg/kg-day; HED = 2.1 mg/kg-day; HEC = 12 mg/m^3 [1.0 ppm]
DCHP	Developmental toxicity (Rat)	10 days during gestation	Phthalate syndrome-related effects (*e.g.*, ↓ FTT; ↓ AGD; Leydig cell effects; ↓ mRNA and/or protein expression of steroidogenic genes; ↓INSL3)	NOAEL = 10 mg/kg-day HED = 2.4 mg/kg-day HEC = 13 mg/m^3 [0.95 ppm]
BBP	Developing male reproductive toxicity (Rat)	Multi-generational or 5-8 days during gestation	Phthalate syndrome-related effects (*e.g.*, ↓AGD; ↓ FTT; ↓ reproductive organ weights; Leydig cell effects; ↓ mRNA and/or protein expression of steroidogenic genes; ↓INSL3)	NOAEL = 50 mg/kg-day HED = 12 mg/kg-day HEC = 64.2 mg/m^3 [5.03 ppm]
DIBP	Developmental toxicity (Rat)	4 days during gestation (GD 14-18)	↓ *ex vivo* FTT production	$BMDL_5$ = 24 mg/kg-day HED = 5.7 mg/kg-day HEC = 30.9 mg/m^3 [2.71 ppm]

[a] Benchmark MOE: UF_A = 3; UF_H = 10; Total UF = 30
POD: Point of departure; FTT: fetal testicular testosterone; AGD: anogenital distance; GD: gestational day; NOAEL: no observed adverse effect level

The draft risk evaluations for DBP, DCHP, and DEHP; draft non-cancer human health and environmental hazard draft technical support documents for BBP and DIBP; and three cross-phthalate technical support documents (*i.e.*, Draft Meta-Analysis and Benchmark Dose Modeling of Fetal Testicular Testosterone, Draft Cancer Human Health Hazard Assessment, and Revised Draft Technical Support Document for the Cumulative Risk Analysis) underwent peer review by the SACC with the public meeting held on August 4-8, 2025.

Due to the stated desire to adhere to the current consent decree, the public comment periods for the DBP and DCHP draft risk evaluations abutted directly the SACC public meeting. This was a challenge for both public and SACC peer reviewers to conduct a concurrent review of multiple draft risk evaluations, draft supporting technical documents, and charge questions for the SACC peer review. EPA must allow adequate time for both public and SACC review of all material. The SACC meeting minutes and final report were published on October 6, 2025.

BBP and DIBP draft risk evaluations were published concurrent with the SACC peer review meeting and EPA intends to forego the statutorily required peer review process. EPA will, instead, consider SACC recommendations for final risk evaluations and unreasonable risk determinations for BBP and DIBP. Final risk evaluations for all five high-priority phthalates were intended to be published in December 2025 to satisfy the consent decree, but the shutdown in October delayed work and automatically extended the consent decree deadlines. We now expect risk evaluations in **early 2026**, with proposed risk management rules **late in the year or in early 2027**.

(e) 1,2-Dichloroethane (or Ethylene Dichloride; EDC)

EPA published a draft risk evaluation for EDC in November 2025 with a comment deadline of **January 20, 2026**. It is not clear how long after the comment period closes EPA will publish the final risk evaluation. EPA has signaled it would view the SACC review of 1,1-dichloroethane as the peer review for EDC.

(f) Substances with Final Risk Evaluation Publication Due by February 2026 and February 2027

2026 will be another busy year for risk evaluations, as the consent decree requires that EPA complete six risk evaluations by **mid-February 2026,** one by **end of April 2026**, and another ten risk evaluations by **mid-February 2027** (nearly one per month). Moreover, EPA has stated its intention to complete the six risk evaluations due **mid-February 2026** by December 31, 2025. We expect that EPA will continue to offer only 60-day comment periods for each. Stakeholders should be prepared to review and comment promptly.

ii. Additional High-Priority Chemical Risk Evaluations Initiated in 2024

The tranche of five chemicals designated as final high-priority substances for risk evaluation in December 2024 has been languishing. EPA published a draft scope of the risk evaluation for vinyl chloride but has yet to propose scopes for the other four (acrylonitrile, acetaldehyde, aniline, and 4,4′-Methylenebis(2-chloroaniline) (MBOCA)). EPA may be delaying further action on these chemicals while it works to meet judicial schedules for completing risk evaluations on the "Next 20" chemicals, until publication of final updates to the procedural framework rule for carrying out TSCA risk evaluations, and/or pending resolution of significant legal challenges that impact risk evaluation approaches.

iii. 6PPD

EPA granted a citizen petition under TSCA Section 21 asking EPA to establish regulations prohibiting the manufacturing, processing, use, and distribution of N-(1,3-Dimethylbutyl)-N′-phenyl-p-phenylenediamine (6PPD) in tires. EPA's announcement in November 2023 indicated that it would 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. EPA extended that comment period for an additional 60 days until March 24, 2025, but has yet to take additional action under TSCA Section 6. Of note, EPA did publish an Agency-wide Action Plan on 6PPD/6PPD-quinone in November 2024, and a final rule in December 2024 under TSCA Section 8(d) requiring manufacturers and importers of 6PPD to report lists and copies of unpublished health and safety studies on 6PPD and 6PPD-quinone to EPA.

iv. Manufacturer-Requested Risk Evaluations

EPA continues to review manufacturer-requested risk evaluations (MRRE) 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. EPA published final risk evaluations for two phthalates in late 2024 and early 2025: di-isodecyl phthalate (DIDP) and di-isononyl phthalate (DINP), both of which were MRREs. EPA also published a draft risk evaluation for octamethylcyclotetra- siloxane (D4) in September 2025, and continues to review the octahydro-tetramethyl-naphthalenyl-ethanone chemical category (OTNE).

(a) Di-isononyl Phthalate/Di-isodecyl Phthalate

Despite completing the DINP and DIDP risk evaluations in December 2024, EPA has yet to propose risk management rules for either. EPA did consider these phthalates in the context of the phthalate cumulative risk assessment, so EPA may seek to align the risk management rules for both with the risk management rules for the other phthalates.

(b) Octamethylcyclotetra-siloxane

On October 7, 2020, EPA granted a manufacturer request for risk evaluation of D4. On September 17, 2025, EPA released the draft risk evaluation for comment and peer review, providing 60 days to comment. On November 13, 2025, EPA announced it would extend the comment deadline for a modest additional 15 days, to December 2, 2025. Depending on EPA's timing for publishing a final rule codifying updates to the procedural framework for TSCA risk evaluations, the final D4 risk evaluation and risk determination may be one of the first to be completed under this updated framework.

d. Risk Evaluation Litigation

i. 1,4-Dioxane

On January 26, 2021, the Environmental Defense Fund (EDF), the Sierra Club, and the Environmental Working Group (EWG) 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. A coalition of 14 states and three municipalities also filed suit, and the court consolidated the cases. *EDF et al. v. EPA* (No. 21-70162); consolidated with No. 21-70194, No. 21-70727, No. 21-70684, and No. 21-70930. 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 U.S. 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.

In May 2025, EPA filed an unopposed motion to extend abeyance in the *UCC* case pending EPA's reconsideration of the 1,4-dioxane risk evaluation. Specifically, EPA stated that it "intends to reconsider certain science issues underlying the risk evaluation for 1,4-dioxane." EPA also stated that the update to the risk evaluation framework rule "may impact the actions challenged" in the litigation. EPA further indicated that it expected the reconsideration process to take between 12 and 24 months. The court granted the motion and has since extended the stay multiple times — most recently until late December 2025.

ii. Asbestos Part 2 Risk Evaluation

The Asbestos Disease Awareness Organization (ADAO), several scientists, and public health groups filed a petition on January 26, 2021, in the U.S. Court of Appeals for the

A draft scope of the risk evaluation for vinyl chloride was released on January 16, 2025. A final scope document or draft risk evaluation for vinyl chloride has not been released.

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. More information on the Part 2 draft risk evaluation is available in our April 29, 2024, memorandum. EPA released the final Part 2 risk evaluation for asbestos on November 27, 2024, and notified the court as required in a December 2024 status report. No further actions have been entered by the court or parties since that time.

e. Prioritization

In October 2023, EPA issued a list of 15 substances it might consider as potential future candidates for prioritization:

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

Shortly thereafter, in December 2023, EPA announced a significant new policy of initiating the prioritization process on five chemicals per year to "create a sustainable and effective pace for risk evaluations." Although TSCA requires EPA to replace each completed risk evaluation with another high-priority substance, EPA's new onboarding policy would apply whether or not a risk evaluation was finished.

In December 2024, and consistent with this policy, EPA published final high-priority designations under TSCA for five of the 15 substances:

- Acetaldehyde;
- Acrylonitrile;
- Benzenamine (or aniline);
- MBOCA; and
- Vinyl chloride.

EPA had only completed two of the "Next 20" risk evaluations by the end of 2024. As a result, these high-priority designations effectively expanded EPA's active risk evaluation workload beyond statutory requirements. A draft scope of the risk evaluation for vinyl chloride only was released on January 16, 2025, with comments due by April 2, 2025. A final scope document or draft risk evaluation for vinyl chloride has not been released. Likewise, no draft or final scope documents have been released for the other four chemicals. While these are nominally overdue, EPA has seemingly focused on completing required risk evaluations for the "Next 20" under the consent decree.

In December 2024, and also consistent with the new policy, EPA initiated the prioritization process for five more chemicals:

- 4-tert-octylphenol, 4-(1,1,3,3-Tetramethylbutyl)-phenol;
- Benzene;
- Ethylbenzene;
- Naphthalene; and
- Styrene.

Since then, EPA has not taken additional action on these substances, including any proposed or final high-priority designations. The one-year statutory deadline for completing the prioritization process for these chemicals was December 2025. EPA may opt to forego establishing new high-priority substances to allow pending litigation on existing risk evaluations and risk management rules to progress and to allow EPA to advance the currently active substances under TSCA Section 6 risk evaluation and risk management.

There has been considerable speculation as to if or when EPA may move forward with the risk evaluation process for these substances, or if EPA will rescind the designations to forestall any required action. Failure to rescind this action could result in legal challenge to complete the high-priority designations, further increasing EPA's workload. As of this writing, EPA has completed only three of the "Next 20" risk evaluations that these five (and the previous five) would replace.

In 2024, EPA also held a webinar in which it expanded the list of substances it would consider next for prioritization. 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.

There has been minimal movement by EPA on this list of substances under consideration for potential prioritization. We wonder if EPA has the bandwidth to initiate additional substances for review under TSCA Section 6. The appearance of metals and metal compounds on the list serves as a reminder that EPA is required by the statute to use the Framework for Metals Risk Assessment to evaluate risk to health and the environment. That document has, however, not been updated since it was published in 2007.

There have been significant advances in our understanding of metals and metal compounds across various conditions (*e.g.*, pH, water hardness, bioavailability). Updates to the approaches for risk evaluation in this framework are urgently needed ahead of EPA considering reviewing this family of substances to enable decisions based on the best available science as the statute requires. The reorganization of ORD may make updating the metals framework significantly more challenging.

4. Section 5 — New Chemical Substances

a. New Chemical Notice Review Case Updates

PMN submissions dropped again. EPA received 154 PMNs in FY 2025, down from 164 PMNs in FY 2024. As readers may remember, this is substantially lower than the 592 PMNs submitted in FY 2015, prior to enactment of Lautenberg and lower than 437 PMNs in FY 2017, the first full FY after Lautenberg. Again, submitters seem to be avoiding commercializing under TSCA — which matches with our experience with our clients.

Unfortunately, EPA's pace of new chemicals reviews dropped in FY 2025. EPA made determinations on 114 PMNs; an additional 21 cases were declared incomplete or were withdrawn by submitters, for a total of 135 cases completed. This means that EPA's "backlog" grew by 19 in FY 2025. In FY 2024, EPA received 164 PMNs and made 138 determinations with an additional 27 cases that were withdrawn, for a total of 165 cases completed, reducing the backlog by one case.

Again, most of EPA's determinations in FY 2025 were older cases: 48 were submitted in FY 2024 and 39 in FY 2023 or earlier. A surprising number of determinations – 15 — were for FY 2025 cases. Thirteen of the 15 cases completed in FY 2025 appear to be Photo Acid Generators (PAG), a category that EPA has worked extensively with a consortium of submitters to develop a robust framework to ensure that PAG use is well-controlled and PAG manufacturers are required by the order to fill key data gaps. EPA continues to try to clear older cases. Under the Trump Administration, OCSPP has resisted advocacy to "prioritize" certain cases. EPA did announce an effort to prioritize new chemicals that will be used in data center projects, but seeking that prioritization requires review by other federal agencies. We do not expect many new chemical notices to qualify.

Table 3 presents statistics on the number of PMNs submitted in each FY since 2016 and the outcomes obtained following completion of EPA's review. Table 4 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 5 shows the determinations made in each FY of the determination (as opposed to the FY of the submission). We discuss below the results shown.

b. Discussion of Table 3 — PMNs Submitted

Total PMNs submitted declined again to just 154 submitted in FY 2025 (although the highest PMN case number is P-25-0163, suggesting other cases may be incomplete or additional case numbers were generated as system errors).

c. Discussion of Table 4 — Length of Review Period

Table 4 shows the mean number of days between "Day 1" and the final disposition of cases in each FY. The PMN determinations that EPA completed on cases received in FY 2025 were, on average, less than six months (124 days for consent order cases and 185 days for the "not likely" cases). This is a promising sign that EPA reviews are getting more efficient; much of this efficiency may be due to EPA's approach to PAGs (discussed above), a class of products that EPA has developed a category approach that allows prompt "may present" determinations and issuing consent orders with the necessary protective measures and tiered, triggered testing requirements. The overall average time for cases completed in FY 2025 (not shown in Table 4) was over 707 days, but this average is skewed significantly by a FY 2016 case that was submitted in March of 2016 and completed nearly nine years later in May 2025.

At the time of this writing, EPA's PMN statistics page lists 446 cases (PMNs, SNUNs, microbial commercial activity notices (MCAN)) awaiting completion as of December 1, 2025. The majority of cases are awaiting EPA action: 241 await risk assessment and another 71 await risk management decisions. An additional 75 cases wait for submitter input during risk assessment/risk management and 59 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, submitters can focus on reviewing the protective conditions, rather than the boilerplate, and respond promptly to EPA.

d. Discussion of Table 5 — PMN Outcomes

EPA continues to focus on older cases: In FY 2025, EPA completed a total of 114 PMN determinations: Of these, 15 were FY 2025 PMNs, 45 FY 2024 PMNs, 22 FY 2023 PMNs, 15 FY 2022 PMNs, and 17 from earlier years. EPA will continue to struggle to review PMNs timely for some time to come as it continues to work through older cases (the "backlog"). To the extent that EPA can leverage categories such as the PAG category, EPA can review and issue timely orders.

EPA continues to seek some restriction for all cases that are not low hazard for health and aquatic toxicity ("low/low" cases). Of the 114 total determinations made in FY2025, 103 (84 percent) were consent orders. Only 11 were "not likely" determinations. Nine 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 to come to a "not likely" conclusion.

Table 3: Number of PMNs Submitted in FYs 2016-2025

				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-On SNUR	Not Likely	Invalid	Withdrawal
2016	389	2 (1%)	387 (99%)	152 (39%)	21 (5%)	13 (3%)	40 (10%)	26 (7%)	135 (35%)
2017	437	5 (1%)	432 (99%)	254 (58%)	12 (3%)	33 (8%)	40 (9%)	24 (5%)	69 (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	17 (9%)	162 (91%)	52 (29%)	2 (1%)	38 (21%)	23 (13%)	15 (8%)	32 (18%)
2021	214	19 (9%)	195 (91%)	127 (59%)	N/A	4 (2%)	22 (10%)	15 (7%)	27 (13%)
2022	191	48 (25%)	143 (75%)	108 (57%)	N/A	0 (%)	10 (5%)	6 (3%)	19 (10%)
2023	176	82 (47%)	94 (53%)	72 (41%)	N/A	1 (1%)	10 (6%)	2 (1%)	9 (5%)
2024	164	97 (59%)	67 (41%)	47 (29%)	N/A	N/A	7 (4%)	0 (%)	13 (8%)
2025	154	136 (88%)	18 (12%)	14 (9%)	N/A	N/A	1 (1%)	3 (2%)	0 (%)
Total	2503	438 (17%)	2170 (83%)	1028 (41%)	58 (2%)	272 (11%)	238 (10%)	123 (5%)	449 (18%)

Counts based on PMN status posted on EPA's website as of November 17, 2025 (last updated October 27, 2025). FY 2016 cases exclude approximately 249 cases that were completed prior to June 22, 2016. Totals include 122 cases submitted prior to 2016 that were re-reviewed after June 22, 2016.

[1] Consent order, "Not Likely Based on SNUR," and "Not Likely, Follow-On 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-On 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).

In its proposal to revise the risk evaluation framework rule (discussed in Section 3.a.), EPA asked stakeholders if EPA should define what it views as reasonably foreseen. If EPA were to do so, it would, presumably, apply that same definition to its review of new chemicals under Section 5. In the meantime, 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.

EPA's update to the new chemicals regulations have not been in place long enough to evaluate whether the requirements for submitters to provide more information in an initial submission will make a meaningful difference in avoiding "rework" — cases in which a submitter provides information after initial submission that requires EPA to re-review the case. Rework is a problem for submitters and EPA. Sometimes rework is a result of a submitter not providing information in the initial submission. It may also result from the company (often a foreign parent company)

Table 4: 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-On SNUR	Not Likely	Invalid	Withdrawal
2016	556	3414	458	953	1152	382	50	616
2017	356	3026	232	842	854	186	41	501
2018	643	2641	734	634	450	347	19	798
2019	289	2265	235	281	133	154	51	507
2020	511	1941	508	233	143	270	53	597
2021	568	1658	532	—	212	318	67	504
2022	722	1251	602	—		449	16	434
2023	661	926	450	—	406	317	29	547
2024	488	554	360	—	—	325		546
2025	174	182	124	—	—	185	16	—

[1] As of November 17, 2025.

Table 5: Determinations by FY

FY of Determination[†]	Not Likely	Not Likely Based on SNUR	Not Likely, Follow-On SNUR	Consent Order	Total Restricted	Determinations	Percent Determinations that Include Restrictions
2016	14			2	2	16	12%
2017	50			270	270	320	84%
2018	16			148	148	164	90%
2019	57	36	138	72		303	81%
2020	30	18	115	93		256	88%
2021	25	4	17	54		100	75%
2022	13	N/A		80		93	86%
2023	7	N/A	1	85		93	93%
2024	15	N/A	1	123		139	89%
2025	11	N/A	N/A	103		114	84%

[†] FY 2016 includes only June 22, 2016, through September 30, 2016.
N/A — Not Available. OCSPP ceased using non-order SNURs in 2021. Based on data posted on EPA's PMN website as of November 17, 2025 (last updated October 27, 2025).

testing undertaken to satisfy obligations for registration in another country becoming available during the protracted PMN review period.

Rework can also result from an error by EPA, or from EPA identifying concerns or relying on analogs that could not be identified or addressed by the submitter in advance. As we have discussed in past years and in our commentary on the new chemicals procedure rule, only rework resulting from a submitter not providing information that was known or reasonably ascertainable at the time of submission will be addressed by that rule. The other sources of rework will continue to be an issue for submitters and EPA to address.

e. SNURs on New Chemicals

After proposing eight batches of SNURs in 2024, covering 194 cases, NCD proposed four batches of SNURs through December 1, 2025, covering 141 cases — welcome progress. Even with this progress, 148 PMNs and SNUNs with consent orders await SNUR proposals. In addition, 194 cases have proposed SNURs, but await final SNUR publication. Consent orders with SNURs present opportunities for significant commercial mischief. For cases that have been commenced, another manufacturer or importer may enter the market without the protective requirements of an order or SNUR. Such a company may also defeat certain aspects of a SNUR if the company undertakes a COU that is defined as a Significant New Use in the proposed SNUR.

On July 9, 2025, EPA withdrew the proposed SNURs for 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. Readers may remember these as the cases that are the subject of *Cherokee Concerned Citizens v. EPA*. While some saw this action as potentially newsworthy, it was a routine procedural step after EPA revoked the corresponding orders for those cases on December 18, 2024.

The proposed SNURs had the intended effect — to disallow the PMN submitter for those PMNs from manufacturing the substances until EPA could address concerns for contaminants that may be present in plastic used to manufacture the PMN substances. We expect that EPA will reissue orders for these cases and then re-propose SNURs, this time with protective measures that match the order(s). Whether the new orders address the concerns raised by the plaintiffs in *Cherokee Concerned Citizens v. EPA* remains to be seen.

f. SNURs on Existing Chemicals

It is unclear how much the *Inhance* court decision in the U.S. Court of Appeals for the Fifth Circuit will dissuade EPA from seeking to issue SNURs on existing chemicals. The court's view that "new" means "new" could undermine the enforceability of any SNUR that EPA proposes that seeks to prohibit a COU that is not "new" even if it is not ongoing at the time the SNUR is proposed. EPA did not propose any new SNURs on existing chemicals in 2025 and may avoid such proposals in 2026.

The proposed SNURs for three flame retardants, TCEP, TBBPA, also known as tetrabromobisphenol A, and TPP, which are all undergoing risk evaluations under TSCA, have been moved to the "Long-Term Actions" category of the spring 2025 Unified Agenda. The proposed SNURs might have the effect of establishing limits under a future, final SNUR. Until the SNUR is final, the SNURs have no protective effect. Given the uncertainty resulting from the *Inhance* decision, EPA may defer indefinitely publishing the SNURs in final, joining older, idle SNURs, such as those proposed for nonylphenols and nonylphenol ethoxylates and toluene diisocyanates, both of which remain in the proposal stage. Given EPA's many other priorities and the *Inhance* decision, these SNURs seem destined to remain as proposed rules for the foreseeable future.

g. Litigation on New Chemicals Procedural Rule

In December 2024, EPA published a final rule updating the procedural regulations for new chemicals with the goal of improving efficiency and better aligning with the 2016 TSCA amendments. Amongst other changes, the final rule made PFAS and other PBT chemicals ineligible for both the low volume exemption (LVE) and the low release and exposure exemption (LoREX); added reference to the five statutory determinations and associated actions; clarified the level of detail needed to support new chemical notices; and modified the procedures with respect to notices EPA deems "incomplete."

In January 2025, several environmental and labor groups filed suit alleging that EPA's new procedures are contrary to statutory mandates for transparency and risk assessment. Claims were consolidated in the U.S. Court of Appeals for the Ninth Circuit in *Alaska Community Action on Toxics v. United States Environmental Protection Agency, et al.* Petitioners argue, for example, that EPA routinely fails to provide information to the public that it is entitled to under TSCA, including publication of notices of receipt of PMNs in the *Federal Register* within five days. Petitioners also allege EPA's approach to PBT chemicals does not go far enough, suggesting that EPA is inappropriately allowing some of these chemicals to be "fast-tracked" for approval via expedited review exemptions. Petitioners' opening briefs were filed in October 2025. In November 2025, EPA requested more time to file its reply briefs.

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

a. Testing to Support TSCA Risk Evaluations

The TSCA test orders that EPA issued in 2021 and 2022 are nearing completion; some test order recipients report

to us that EPA has stated that the ordered testing has been satisfied.

Most of the testing ordered on TDCE has been completed, but EPA has yet to state publicly that all the testing obligations have been satisfied. The appeal filed by the TDCE Consortium for the TDCE test order is still pending.

In general, EPA has slowed its pace of issuing test orders. In 2025, EPA issued no new test orders. EPA may have its hands full with wrapping up the current test orders and trying to keep pace with court-ordered deadlines for ongoing risk evaluations. TSCA test order consortia managed by B&C® Consortia Management, L.L.C. (BCCM) continue to engage with EPA regarding ongoing and potential future testing.

b. National PFAS Testing Strategy

In the final rule on "Fees for the Administration of the Toxic Substances Control Act (TSCA)" published in 2024, EPA 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. In 2025, EPA did not initiate any new test orders. EPA has focused its efforts on its existing PFAS test orders: HFPO (2,3,3,3-tetrafluoro-2-heptafluoropropoxy) propanoyl fluoride, Chemical Abstracts Service Registry Number® (CAS RN®) 2062-98-8), 6:2-FT betaine ester, NMeFOSE (2-(N-Methylperfluoro-1-octanesulfonamido)ethanol, CAS RN 24448-09-7), and 6:2 fluorotelomer acrylate (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl prop-2-enoate (6:2 FTAc), CAS RN 17527-29-6).

The test order for the 6:2-fluorotelomer (FT) betaine ester has been satisfied while testing for HFPO and the 6:2 fluorotelomer acrylate continue. It is not clear whether EPA identified an appropriate order recipient for NMeFOSE (B&C understands that all former manufacturers had ceased production more than ten years ago). Some older studies have been posted to the docket, suggesting that at least one entity is responding to the order, even if further testing is not being conducted.

Once EPA wraps up some of the existing orders, we expect EPA to resume issuing orders for other PFAS.

c. Section 4(a) Test Order Litigation

i. 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. National Foam's argument hinges on the fact that it did not manufacture (including import) or process 6:2 FTSB. According to an August 2025 status report, EPA considers the order satisfied, and EPA will not order additional testing. National Foam filed a motion to continue to hold the case in abeyance until the end of the reimbursement period (likely **November 2029**). In September 2025, EPA opposed the motion for abeyance and moved to dismiss the case as moot, which National Foam has opposed. EPA filed a reply brief in support of its motion to dismiss in November 2025. Both parties also have agreed that all issues are "fully briefed" and "ripe for decisions from the Court." The court will next decide whether to continue to hold the case in abeyance as National Foam seeks or dismiss the petition as moot in favor of EPA.

ii. 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, remains stayed pending EPA's final decisions on the ordered testing. On November 20, 2024. EPA posted an entry to the docket titled "Extinguishing memo for OECD 219 and OECD 233 TDCE Test Order requirements," but withdrew it after the TDCE Consortium pointed out several errors in that memorandum; a corrected version has not been posted.

d. Section 4(h) — NAMs

EPA continues a to develop and integrate new approach methodologies (NAM) into its regulatory programs in 2025, including:

- Training and Promotion: EPA held virtual training sessions in 2025 for key NAM tools like the httk

ARTICLE
"Testing, Testing: why is analysis of new substances so difficult and fraught with legal, regulatory, and commercial challenges?"
Environmental Forum, March/April 2025

A key change of which readers should be aware is that EPA proposed to open the PFAS reporting period 60 days after the date of the final rule and required reporting to be completed in just three months.

R Package (high-throughput toxicokinetics), the CompTox Chemicals Dashboard, and SeqAPASS (a sequence alignment to predict aquatic toxicity), which are all existing NAMs used to help evaluate chemical toxicity and exposure.

- Integrating NAMs into Risk Assessment: Research published in 2025 discusses frameworks and applications, such as for HTTK, intended to guide regulators and risk assessors on when and how to use these NAMs for public health safety decisions.

- Continued Strategy: EPA's overarching strategy, outlined in its New Approach Methods Work Plan, is to reduce and replace vertebrate animal testing by prioritizing the development, evaluation, and application of NAMs.

EPA's public activities in 2025 reflect a focus on expanding the use, confidence, and training of existing and recently developed NAMs as part of a significant, ongoing shift in chemical risk assessment.

The reorganization of EPA's ORD may hamper or delay additional NAM work, but many of the ORD staff responsible for NAMs have been reassigned to OPPT and OPP where they will, we hope, continue their NAM leadership.

6. Sections 8 and 14 — Reporting and Confidential Information

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

As readers likely recall, EPA published a final rule in October 2023 under TSCA Section 8(a)(7) imposing a one-time reporting requirement for manufacturers and importers of PFAS to provide extensive information on their production, use, and environmental and health effects. On May 2, 2025, a coalition of chemical companies filed a Section 21 petition seeking relief on the breadth of the TSCA Section 8(a)(7) reporting rule. On May 13, 2025, EPA again extended the reporting period by issuing an interim final rule extending the reporting period from **April 13, 2026**, to **October 13, 2026**, and extending reporting for small businesses that only import articles to **April 13, 2027**. EPA also agreed to reconsider exemptions available in the rule. On May 16, 2025, the petitioners withdrew the petition.

On November 13, 2025, EPA proposed revisions to the rule. The proposal restores several key exemptions to the reporting requirements, including exemptions for PFAS imported as part of articles, PFAS manufactured or imported as impurities or as byproducts without a separate commercial purpose, and PFAS present below 0.1 percent.

A key change of which readers should be aware is that EPA proposed to open the reporting period 60 days after the date of the final rule and required reporting to be completed in just three months. Unfortunately, this means that the start of reporting will be subject to the speed at which EPA is able to complete its internal rulemaking processes. EPA has yet to provide a target timeframe for publishing the final rule, perhaps to provide sufficient buffer to ensure that its Information Technology (IT) systems are fully developed and functional — a challenge that previously prompted the two rulemakings to extend reporting periods under the prior 2023 final reporting rule. Comments on the proposed rule — including the exemptions and reporting period — were due December 29, 2025.

b. Section 8(a) — Asbestos Reporting Rule

EPA has yet to publish the data it gathered under the final TSCA Section 8(a) asbestos reporting. The deadline for reporting was May 24, 2024. It is not clear what new data EPA received or how those data are being or might be used. The Asbestos Part 1 Risk Management rule was final in March 2024, before the reporting deadline (although the rule is being litigated). The Asbestos Part 2 Risk Evaluation was published in final in November 2024.

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

As readers are likely aware, the 2024 CDR reporting period was extended due to technical difficulties with the Cen-

tral Data Exchange (CDX) CDR portal. EPA extended the reporting deadline to November 22, 2024.

Submitters of 2024 CDR reports may have been contacted by EPA in 2025 if EPA identified significant changes in a company's reported data. 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.

d. Submitting and Protecting Confidential Business Information

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 CBI procedure rule (*EDF v. EPA* (No. 23-1166)). EDF's position was that the rule would allow submitters to assert CBI claims to shield improperly from the public health and safety information that TSCA makes categorically ineligible for CBI protection. The American Chemistry Council (ACC) also challenged the rule; ACC's position was that the rule improperly directs EPA to disclose confidential chemical identities based on submissions by companies that do not know the specific chemical identity.

The court ruled that a submitter may claim and EPA may protect as CBI some information in a health and safety report, as long as the CBI is not the key health and safety information. This allows study sponsors to redact some information related to the conduct of the study (*e.g.*, study sponsor, names of specific people involved in the conduct of the study) and thereby still protect the value of that study without compromising the public's ability to review the actual conduct and results of the study.

The court also ruled that EPA improperly constructed the rule to disclose confidential substance identities if EPA receives a report with an Access Number without a claim to protect that CBI identity when that reporter does not know the specific chemical identity. This court decision maintains the careful balance between CBI protection and the public's right-to-know that Congress crafted in Lautenberg.

e. Confidential Business Information Sunsetting

Readers may recall that under Lautenberg, CBI claims that required substantiation will begin to face the ten-year sunset period for CBI protection under Section 14. Any submission to EPA after June 22, 2016, that included CBI that required substantiation started a ten-year clock. That ten-year period will arrive starting **June 22, 2026**.

EPA has stated that it would publish a list of TSCA submissions with confidentiality claims that are approaching the end of the ten-year period of protection. EPA further stated that it would add TSCA submissions to this list "at least 60 days prior to the end of the ten-year period of protection, along with instructions for reasserting and substantiating expiring claims." EPA's website also notes that "TSCA section 14(e) requires EPA to notify the submitter of a CBI claim at least 60 days prior to the expiration of a claim. Additionally, if EPA denies the claim, TSCA section 14(g)(2) requires that EPA notify the submitter at least 30 days prior to the intended disclosure of the information. EPA has elaborated on the notice, reporting, and EPA review requirements in the CBI procedural rule at 40 CFR 703 and expects to develop an electronic reporting tool to further implement this provision."

To date, EPA has not yet posted a list of soon-to-expire CBI claims, though the 60-day advance notices could foreseeably begin in **April 2026**. The CBI sunset process will be a challenge and learning experience for submitters and EPA. Submitters should begin now to ensure that their older submissions have up-to-date technical contact(s) and consider adding one or more agents to ensure that EPA will be able to communicate confidently with the contact.

Submitters should also monitor the list that EPA posts and watch for updates. Submitters may also wish to consider whether it is necessary to maintain all the CBI claims asserted previously. If the information has since become public (and therefore is not amenable to protection) or is no longer sensitive, submitters may no longer need protections against disclosure.

f. EPA Review of Confidential Business Information

EPA continued to review TSCA CBI in 2025. According to EPA's TSCA CBI Review Statistics website, EPA has received 25,027 CBI claims, including 9,801 CBI claims for chemical

ARTICLE

"Leveraging Chemical Data More Efficiently," *PCB007 Magazine*, July 2025

identity. EPA has completed 10,693 claims, approving 6,483, denying 3,042, and partially approving 1,168 claims. In addition, EPA found 6,814 cases that did not require review (*e.g.*, all claims were exempt from substantiation or were withdrawn by the submitter). While stakeholders may not always agree with the outcome, these statistics clearly reflect an incredible effort by EPA to ensure that information is protected where appropriate and subject to disclosure where not.

EPA did not post an update on its declassification page; the most recent update was May 23, 2024. We expect EPA's processing of the 2024 CDR reporting to lead to another substantial batch of declassifications.

g. Unique Identifier Implementation

Recall that 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. As of the July 2025 version of the Inventory, the confidential portion includes 1,146 UIDs (up to 72 of which may be substances newly added to the Inventory), while the public portion includes 85 UIDs. These 85 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. Of the 1,146 substances on the confidential portion with UIDs, 245 have CBI claims expiring in 2026.

We applaud EPA's continued progress toward the openness that Congress contemplated in the Lautenberg amendments, but those efforts will be complicated by the pending CBI sunset dates.

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

On December 13, 2024, EPA issued a final rule under TSCA Section 8(d) requiring manufacturers (including importers) of 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. EPA provided no *de minimis* threshold and no exemption if one of the substances was present as an impurity in another test substance.

This rule was jointly challenged in February 2025 in the D.C. Circuit Court of Appeals by multiple industry stakeholders. On June 9, 2025, EPA issued a final rule to extend reporting deadlines to **May 22, 2026**, for all 16 chemicals. In November 2025, EPA announced its intent to reconsider the rule, and asked the court to put the ongoing litigation in abeyance. EPA stated that it expected to consider additional exemptions for manufacturers required to report, a regulatory threshold for reporting, and a change to the duration of the lookback period for reporting, but not the 16 chemicals named in the rule. According to the announcement, EPA will issue a proposed rule and provide an opportunity to comment, with a final rule expected in **late 2026 to mid-2027**. EPA also implied forthcoming changes to the **May 2026** reporting deadline associated with the current rule.

i. TSCA Section 8(c) Data Call-in

After issuing a data call-in under TSCA Section 8(c) for MBOCA in 2024, EPA did not issue any additional call-ins under Section 8(c). It is not clear if EPA received any meaningful information from that effort. In our experience, 8(c) records are unlikely to contribute meaningfully to risk evaluations unless the 8(c) records showed a pattern that rose to the level of being reportable under Section 8(e) (in which case, EPA would have received the records in a Section 8(e) submission).

j. TSCA Section 8 Tiered Data Reporting Rule

EPA has once again deferred proposing the TDR rule. The spring 2025 Unified Agenda moved the proposal to "Long-Term Actions" (2070-AK62) with target dates for the notice of proposed rulemaking (NPRM) and final rule now listed as "To Be Determined." This is a clear sign that EPA does

not currently view this rulemaking as a priority amidst other action with statutory and court-ordered deadlines.

7. Section 26 — Administration of TSCA; Fees Rule

The 2016 TSCA amendments provided EPA with expanded authority to collect fees for certain TSCA activities to help defray up to 25 percent of the costs of its TSCA implementation efforts. EPA established its first TSCA fees structure by rule in 2018, and a revised final rule on February 21, 2024. The effective date of the final rule was April 22, 2024, and includes an automatic adjustment of fee amounts for inflation every three years, with the next adjustment set to occur on **October 1, 2026**.

Of note for 2026, however, the statutory provision that provides EPA with authority to collect TSCA fees is set to expire unless reauthorized by Congress. More specifically, TSCA Section 26(b)(6) states that TSCA fee authority "shall terminate at the conclusion of the fiscal year that is 10 years after June 22, 2016, unless otherwise reauthorized or modified by Congress." Negotiations are ongoing in Congress with respect to whether and how to extend TSCA fee authority (amongst other possible revisions), but prospects for timely reauthorization are difficult to predict. In the absence of additional legislative action, this would appear to mean that EPA would no longer be able to collect fees to supplement its appropriated resources after **September 30, 2026**.

EPA will not collect any risk evaluation fees until it completes prioritization and risk evaluation scopes of additional substances. As discussed earlier, EPA appears to be delaying prioritization and risk evaluation work on additional chemicals to focus on completing work on the "Next 20" chemicals for which risk evaluations are already underway.

8. Section 26 — Scientific Standards

a. Scientific Integrity

In January 2025, in the last days of the Biden Administration, EPA released an updated Scientific Integrity Policy with a stated goal of restoring trust in federal science. The policy addressed topics like political interference and suppression of scientific findings, and created a structured process for handling scientific disputes. Not long after, President Trump issued an EO on "Restoring Gold Standard Science" on May 23, 2025, that requires agencies to revert to pre-Biden policies. In August 2025, EPA removed the 2025 policy from its website — without announcement — and reverted to the prior 2012 policy.

The "Gold Standard Science" directive was reminiscent of President Biden's *Presidential Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-based Policymaking*. It is all too true that what is viewed as the best available science is too often biased by a preferred policy outcome. As we reported last year, there was significant scientific disagreement within EPA about using 1,2-DCE as a source for read-across to 1,1-DCE. Despite the significant uncertainties and weakness of such a read-across approach as identified by scientists outside of the Existing Chemicals Risk Assessment Division (ECRAD), including OPP, ORD, and the SACC, the final risk evaluation for 1,1-DCE relies heavily on the PODs for 1,2-DCE without modification.

Even the SACC recommending that OPPT "clarify and improve the description and implementation of the read-across approach such as taking a category approach that would include information from multiple analog compounds" and "incorporating potency differences and adding a general discussion of the potential uncertainties of applying a read-across approach" seems to have had no effect on OPPT's conclusion. Although it was commendable that OPPT sought broad input on its approach, the conclusion in the final risk evaluation appears to ignore largely input from others and does so only with a veneer of scientific rigor, just that 1,2-DCE is the worst-case.

b. Scientific Challenges

We have reported previously on RFCs and RFRs related to 1,4-dioxane, NMP, and CTC. An RFR for NMP is still pending. It is unclear how EPA will respond to the RFR and, if EPA does change its view on the quality of the science underlying the final risk evaluation, how EPA might then address that issue in the final risk management rule.

EPA is understandably reluctant to reopen risk evaluations that have undergone peer review and public comment, potentially delaying substantially a final risk management rule, but the fact that the process is nominally complete does not mean that EPA met the scientific standard in Section 26. Relying on a scientifically flawed risk evaluation undermines the defensibility of a final risk management rule. We hope that all parties agree that ensuring the final risk evaluation is scientifically sound prior to rulemaking avoids the time and expense of rulemaking that may be litigated and found to

be based on flawed science, necessitating repeating the risk determination and subsequent rulemaking.

c. Systematic Review

There remains a lack of clear policy on how OPPT has or will systematically review literature in support of TSCA risk evaluations. In the 2024 version of the framework rule, EPA rescinded the definition of "weight of scientific evidence" that required a systematic review method "***that uses a preestablished protocol*** to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and ***to integrate evidence*** as necessary and appropriate based upon strengths, limitations, and relevance [emphasis added]."

Instead, the rule simply requires that EPA "will apply systematic review methods to assess reasonably available information, as needed to carry out risk evaluations that meet the requirements in TSCA section 26(h) and (i), in a manner that is objective, unbiased, and transparent." In the 2025 proposed update to the risk evaluation framework rule, EPA requested comment on promulgating a definition for systematic review but did not propose a requirement to apply a preestablished systematic review protocol. We note that EPA was placed on notice by a public commenter during the TSCA SACC meeting in July 2019 that the 2017 version of the framework rule required a preestablished protocol. EPA did not — at that time — have a preestablished protocol for its TSCA risk evaluations and has yet to publish an updated, final systematic review process. The outcome of the MC litigation may shed light on whether EPA's lack of a systematic review process is a legal vulnerability.

The lack of a systematic review process has led to some significant weaknesses in EPA's assessments. Notably, a peer reviewer on TCEP stated that "these results [*i.e.*, Sun *et al.*, 2016] should have not been given a 'High' rating." In addition, shortly after the close of the public comment period on the draft risk evaluation for TCEP, EPA received an expert review of that study. 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 comment, EPA retained the "High" data quality rating for Sun *et al.* (2016) in the final risk evaluation for TCEP. Furthermore, EPA seems to have neglected to include several studies that one of the peer reviewers found relatively easily. Unfortunately, once errors become embedded in a final risk evaluation, EPA is reluctant to reopen the evaluation and those errors then become the basis for the risk management rule Both the Biden Administration and the Trump Administration have issued EOs to ensure the identification and use of the best available science. The standard for best available science should not depend on a reader's political views. Study quality must be judged objectively and independent of the policy outcome it may lead to (whether regulatory or deregulatory). Similarly, the weight of scientific evidence must also be judged on objective criteria, not whether the evidence supports a protective or permissive outcome.

9. Section 21 — Petitions and Related Litigation

There has been no visible progress on the Section 21 petition to prohibit the formation of perfluorooctanoic acid (PFOA), perfluorononanoic acid (PFNA), and perfluorodecanoic acid (PFDA) during container fluorination since EPA's request for information in the fall of 2024.

As readers may recall, EPA granted a Section 21 petition seeking EPA to prohibit the production of PFOA, PFNA, and PFDA during a polymer fluorination process. On September 30, 2024, EPA requested information on the formation of and alternatives to processes that form PFAS, including PFOA, PFNA, and PFDA, during the fluorination of high-density polyethylene (HDPE) and other plastic containers. Comments were due November 29, 2024. A cursory review of the comments shows that there is some disagreement among commenters whether there are alternatives to fluorinated HDPE containers for all uses. EPA's delay on progressing this action may be related to the press of other risk evaluation work that is mandated under the consent decree (as discussed in Section 1 of this chapter).

Even though EPA granted the Section 21 petition, on July 25, 2024, Center for Environmental Health (CEH) and 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.

On December 11, 2024, the court granted EPA's motion to dismiss, and denied Inhance's motion to intervene as moot.

CEH and PEER promptly filed a notice of appeal in the U.S. Court of Appeals for the District of Columbia Circuit on December 27, 2024. *PEER v. Zeldin* (No. 24-5294). CEH and PEER argue that the lower court should not have dismissed the complaint as moot because EPA failed to take action to prevent or reduce the risk of fluorinated containers as required by TSCA Section 4(f). The appellants also argue that EPA has an enforceable duty under TSCA Section 7 to file an imminent hazard action against Inhance given EPA's failure to issue a TSCA Section 6(d) rule protecting against the imminent risks.

EPA maintains that the court correctly held the plaintiffs' claim as moot because the court could not award any effective relief and that the court correctly held that it lacked jurisdiction over plaintiffs' Section 7(a)(2) claim. On April 22, 2025, the court granted Inhance's motion to intervene. Inhance states that appellants lack standing to pursue their claims; appellants' claims are moot given EPA's Section 6 action; and appellants' Section 7 claim falls well beyond the purview of TSCA Section 21. The court heard oral argument on November 21, 2025, and two members of the panel expressed skepticism regarding the NGOs' claims and standing. The case is pending decision.

It is not clear if the petitioners might seek additional relief if EPA delays further its review under Section 6. Any action EPA takes under Section 6 will have to comply with the framework rule that is applicable at the time of the risk evaluation. PEER and other NGOs have argued that when performing a risk evaluation under Section 6, EPA must consider all COUs of the substance(s). If that interpretation prevails after EPA revises the framework rule and any potential, subsequent litigation (see Section 3.a for more discussion on the framework rule), EPA will have to expand the scope of its evaluation of PFOA, PFNA, and PFDA well beyond their formation during HDPE fluorination.

EPA also received a significant volume of new TSCA Section 21 petitions in 2025. All but one of these petitions came from industry, and in almost all cases, the industry petitioners withdraw their petitions before EPA published its decision. The only petition not submitted by industry came from a coalition of NGOs on February 11, 2025. Brought by the Natural Resources Defense Council (NRDC), Clean Air Council (CAC), and Communities for a Better Environment (CBE), the petition states that EPA must issue a TSCA Section 6(a) rule prohibiting the use of hydrogen fluoride in domestic oil refining to eliminate unreasonable risks to public health and the environment. According to the petition, "TSCA requires EPA to issue such a rule because this petition identifies (1) a 'chemical substance' ([hydrogen fluoride]) that presents, (2) under one or more 'conditions of use' (the use of HF for alkylation at U.S. refineries, and the rail and truck transportation needed to supply HF to those refineries), (3) an unreasonable risk to health or the environment."

EPA announced on May 15, 2025, that it denied the petition, finding that the petitioners did not meet their burden under TSCA Section 21(b)(1) of establishing that it is necessary to issue a rule under TSCA Section 6(a). 90 Fed. Reg. 20575. After EPA denied their petition, NRDC, CAC, and CBE filed suit on July 8, 2025, in the U.S. District Court for the Central District of California. *CAC v. EPA* (No. 8:25-cv-01473-MWF-DFM). The plaintiffs seek a TSCA Section 6(a) risk management rulemaking, with the proposed rule published within one year of the court's ruling, and a final rule within two years. On August 21, 2025, the parties stipulated to extend the deadline for EPA's response to October 15, 2025. On October 1, 2025, EPA filed a motion for stay of the deadline in light of the lapse of appropriations. The court granted EPA's request on October 2, 2025.

In 2025, EPA received three industry petitions to amend the 2024 final risk management rule for TCE. On March 24, 2025, PPG Industries, Inc. (PPG) submitted a petition seeking an amendment to the final rule's exemption for the

industrial and commercial use of TCE as a processing aid for specialty polymeric microporous sheet materials manufacturing that would allow PPG to meet an interim ECEL of 5 ppm and an action level of 2.5 ppm.

On April 30, 2025, the Alliance for a Strong U.S. Battery Sector (Alliance) and Microporous, LLC submitted a Section 21 petition. It requests that EPA revise the final rule to increase the interim ECEL to 6 ppm and extend the length of the duration from 20 to 25 years to account for the time required to research, develop, test, and obtain approvals for any alternative to TCE in battery-separator manufacturing.

On May 27, 2025, ACC filed a Section 21 petition requesting that EPA reconsider and amend two provisions of the final rule: revise the byproduct exclusion in 40 C.F.R. Section 751.301(c) by removing the "site-limited" restriction that requires byproduct TCE to be reused as a "part of the same overall manufacturing process"; and delete the last sentence from the "regulatory threshold" provision in 40 C.F.R. Section 751.301(b), allowing facilities to continue discharging wastewater that contains TCE at less than 0.1 percent by weight pursuant to their valid, existing Clean Water Act (CWA) National Pollutant Discharge Elimination System (NPDES) permits.

All the TCE petitions have been withdrawn. PPG withdrew its petition on June 11, 2025, via an e-mail to EPA Administrator Lee Zeldin. On July 25, 2025, counsel for the Alliance for a Strong U.S. Battery Sector withdrew its petition via a letter to Zeldin. On September 19, 2025, ACC withdrew its petition.

On May 2, 2025, a coalition of chemical companies petitioned EPA for an amendment of the TSCA Section 8(a)(7) PFAS reporting rule. The petitioners asked that EPA revise the reporting rule to exclude imported articles, research and development (R&D) materials, impurities, byproducts, non-isolated intermediates, and PFAS manufactured in quantities of less than 2,500 pounds (lb.). According to a May 22, 2025, letter from EPA, on May 16, 2025, the coalition withdrew its petition via e-mail to Administrator Zeldin and "EPA now considers this petition closed."

On May 15, 2025, the Center for Environmental Accountability (CEA) filed a Section 21 petition requesting that EPA reconsider the 2024 final rule regarding procedures for chemical risk evaluation under TSCA and initiate a rulemaking to amend certain provisions in 40 C.F.R. Part 702, subpart B. According to CEA, the current process "has led to overly conservative risk conclusions and, in turn, unnecessary risk management rules that force industry to abandon well-studied chemistries that provide beneficial uses in our daily lives." According to an August 13, 2025, letter from EPA, on August 12, 2025, CEA withdrew its petition and EPA now considers the petition closed.

Continued successful use of Section 21 petitions may lead to a further increase in such petitions. Potential overuse or abuse of Section 21 petitions is one of the issues being discussed as part of TSCA reauthorization.

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 five former senior EPA officials, over a dozen scientists, including six 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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Endangered Species Act compliance is arriving at long last, the result of an extensive trail of litigation and false starts on EPA's part to find a way to advance a credible plan.

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

The U.S. Environmental Protection Agency's (EPA) Office of Pesticide Programs (OPP) historically has received significant political attention in past administrations. In recent years, however, the demands of implementing the Toxic Substances Control Act (TSCA) 2016 Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg) amendments have required more attention by political leadership on TSCA issues over administration of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) program. This pattern is expected to continue during the current Administration, but OPP still will have more than its share of difficult issues on its agenda. The Administration's Make America Healthy Again (MAHA) efforts alone will draw more attention to the implications of the current food production system, including pesticide use.

2026 will be the 30th anniversary of the Food Quality Protection Act (FQPA), signed by then-President Clinton on August 3, 1996. FQPA's first years of implementation had its share of growing pains, but in hindsight, its first years led to a smoother path to implementation than the amendments to TSCA after nine years. That said, the pesticide program has its own set of controversies and ongoing implementation challenges, discussed below.

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 EPA's part to find a way to advance a credible plan. During the Biden Administration, EPA made significant progress in outlining an approach that integrates fully the requirements of ESA and FIFRA. In 2025, there was continued progress with the development of EPA "strategies" outlining the approach it plans to use to integrate ESA and FIFRA requirements. EPA also rolled out decisions incorporating the evolving ESA-relevant mitigation requirements for new active ingredients and a few registration review assessments for existing pesticides.

2026 will see "the proof in the pudding" for the planned strategies. During 2025, the Trump Administration has not made fundamental changes to the existing strategies. During 2026, EPA will face decisions about a much larger number of pesticides, which may reveal the impact on pesticide users and the reaction by all stakeholders to EPA's approach.

a. 2025 Activities

EPA's approach to protect against potentially adverse impacts on threatened and endangered species (TES) relies on mitigation requirements related to 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.

Restrictions — "mitigation strategies" — 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. Mitigation strategies will include instructions intended to reduce the estimated potential exposure to species from off-target movement of

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the pesticide. These concepts are 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).

As part of the "strategies," EPA outlines a scoring system where certain mitigations qualify for different numbers 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 various mitigation technique "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 application would require a minimum number of mitigation points before it can be used; if the product can be used with enough mitigation measures (points), the use is allowed.

If the applicator wishes to use a product in a way (time, place, crop — specific use site and conditions), the application needs certain points to be an allowable label use. In some cases, there may not be enough points, meaning there are not sufficient mitigation strategies available for the desired use. In some cases, the options available in a particular use situation may be limited for various reasons, and it is not clear how many pesticides might face insufficient options that would prohibit in the future use patterns that are currently allowed.

EPA has stated generally that under its revised plans, considering comments received and further refinements in the strategies, "most" growers will have sufficient options available to meet the required points expected to be required due to ESA compliance. Little formal analysis has been done, at least not identified publicly by EPA, regarding how many or how few growers may have enough options to avoid significantly disrupting current cropping and pest control activities currently used on their farming operation.

In January 2025, the American Soybean Association (ASA) released an assessment regarding the draft Insecticide Strategy and revised EPA ESA Herbicide Strategy (ASA Survey). The ASA Survey assessed soybean growers regarding their current pesticide practices and what mitigation options appeared available to them (*e.g.,* are contour plowing or buffer strips viable options given the particular farm; do they typically use no-till growing practices).

EPA plans to require zero to nine points from the array of mitigation options to protect species. Farming practices and pest control needs vary widely by region and crop, not to mention variation in the specific geographic area where habitat for a species needs protection. Acknowledging those uncertainties, the ASA Survey found that 36.7 percent of soybean growers, using current practices, would earn nine points (the maximum that might be required for a product). If six points were required, 73.4 percent of soybean farmers would be compliant. One positive result from the 2025 ASA Survey is that compared to an earlier survey, considering EPA refinements and evolving policies, the 36.7 percent number was much greater than the earlier survey estimate of 4.5 percent. Other grower groups (*e.g.,* orchard crops) have commented that in some scenarios their available mitigation options could be limited due to particular growing conditions. The ASA surveys are the only formal surveys of grower group members that are publicly available.

Since there is no prediction of what pesticides for what crops will need what number of mitigation points, the impact of EPA's approach is uncertain at this early stage but may reveal itself more as EPA continues to review labels for new active ingredient submissions and continued registration review decisions. EPA career staff throughout 2025 stated that they expect most growers to have enough options available to them as they continue to further refine specifics about mitigation options and especially refinements to the affected geographic areas needing species protection (*i.e.,* Pesticide Use Limitation Areas (PULA)).

Of note is that one of the senior staff members at ASA who was involved in the surveys was Kyle Kunkler, now appointed as the Deputy Assistant Administrator for Pesticides in the Office of Chemical Safety and Pollution Prevention (OCSPP). Considering his new position and past involvement with ESA issues, the availability of options readily available to affected growers is likely to be an issue to be addressed with continued implementation of the ESA program. Kunkler's former position at ASA has been reported to be of some controversy since he now holds a senior position concerning pesticide issues at EPA.

In 2025, EPA continued work on developing strategies for other categories of pesticides, issuing a final strategy for

insecticides in April 2025, and continued work on rodenticides and disinfectants (due in the next 12-24 months). The April 2025 Insecticide Strategy document is not fundamentally different from the approach outlined in the draft issued during the Biden Administration in July 2024. The April 2025 document outlines the same general approach. Insecticide labels will have requirements for a certain number of mitigation points depending on the OPP evaluation of the data and potential for harm to species from off-site movement of the pesticide.

Thus, unlike other media program activities across EPA, the Trump Administration has not announced nor implemented a fundamental rework or reversal of the Biden Administration's ESA policies. The outline and approach for ESA implementation regarding pesticides appears likely to be maintained through 2026, with one exception for an ESA issue that is more foundational to ESA requirements generally. Specifically, in an April 17, 2025, *Federal Register* notice, the Trump Administration proposed to rescind the current regulatory definition of "harm" at 50 C.F.R. Sections 17.3 and 222.102 (*i.e.,* "Harm in the definition of 'take' in the Act means an act which actually kills or injures wildlife. Such act may include significant habitat modification or degradation where it actually kills or injures wildlife by significantly impairing essential behavioral patterns, including breeding, feeding or sheltering") and instead "rest on the statutory definition of 'take'" (*i.e.,* "to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct"). A "harm" under ESA regulations has been a pivotal term for when steps may be necessary to protect endangered species so if this rule is issued in final and only the statutory definition of "take" is relied upon, activities that could trigger ESA actions will be narrower. Whether these changes are made and if so, withstand likely legal challenge, will affect how EPA implements its pesticide ESA program.

EPA devoted much effort in 2025 on further development of the strategies and developing training and outreach materials and plans to communicate to growers what the program will require. In August 2025, EPA released its Pesticide App for Label Mitigations (PALM) as a "mobile-friendly tool to serve as a one-stop shop that helps farmers and applicators use EPA's mitigation menu."

Pesticide companies and suppliers are also developing compliance assistance materials. In November 2025, pesticide registrants, distributors, and retailers released instructional videos to facilitate understanding and compliance with EPA's ESA requirements. These short videos provide an overview of the EPA ESA program and an explanation of the requirements that pesticide users will face — including an overview of the EPA approach, electronic labels, and mitigation strategies (avoiding off-site drift and soil runoff).

Pesticide registrants are additionally developing materials to help users of their specific products that will have ESA requirements. For example, one of the largest pesticide manufacturers — Syngenta — is collaborating with an environmental consulting firm, Waterborne Environmental™, to develop the Farmer Mitigation Intelligence Tool (FarmMIT) as a user-friendly mitigation tool to explain ESA label requirements and specifics of how to comply for the applicator after identifying the location of the treated field(s) and what products the applicator plans to use.

As new product and registration review assessments are completed, compliance outreach by EPA and industry stakeholders will be an important priority for the future of the ESA program.

b. What to Expect in 2026

Continued progress during 2025 on the long overdue integration of ESA and FIFRA requirements has quieted the previous routine ESA litigation that has characterized many registration decisions in recent years. In 2026, expect to see an operational framework unfold in more detail, addressing questions including: (1) what are any ESA-driven label changes imposed by ESA concern; (2) what level of compliance seems achievable without significant impacts on cropping practices or productivity; (3) are there particularly difficult decisions about a specific pesticide (*e.g.,* where predictions are large impacts on growers and the analyses indicate otherwise wide impacts on species); and (4) how will any emphasis on "permitting reform" or "cooperative federalism" — part of Administrator Zeldin's five pillars — impact decisions about compliance of or enforcement of any ESA decisions.

In the past, where the pesticide program embarked on very significant program changes, the program has used a "pilot program" to test drive the viability of plans behind the change. Another option has seen a delay in full implementation of new requirements, either as a postponement of the requirements altogether or an initial period emphasizing compliance assistance.

Also noticed was a part of the Pesticide Registration Improvement Act of 2022 (PRIA 5) reauthorization at Section 711 extending the deadline for completion of registration reviews for pesticides from October 2022 until **October 2026**. Registration reviews are to include ESA requirements, and EPA is unlikely to complete registration reviews of approximately 1,100 active ingredients before **October 2026**. One question regarding activities in 2026 is whether Congress will consider a further extension due to budget, workload, or ESA reasons. It is possible that the rollout of requirements across the nation might consider some of these past techniques to foster easier implementation and effectiveness of a robust ESA program.

2025 was characterized by a relatively orderly and straightforward continuation of the ESA plans outlined in 2022. Whether stakeholders — both agricultural and environmental — "maintain the peace" during 2026 is among the uncertainties surrounding the immediate future of the ESA pesticide efforts.

2. MAHA — "Make America Healthy Again"

a. The MAHA Assessment

On May 22, 2025, the U.S. Department of Health and Human Services (HHS) announced the release of a new federal report, *Making Our Children Healthy Again* (MAHA Assessment), issued by the MAHA Commission. The MAHA Commission was established by Executive Order (EO) 14212 to study and report on the childhood chronic disease "epidemic" — its causes, scope, and what to do to address the problems across government agencies.

According to HHS, the MAHA Assessment identifies key drivers behind childhood chronic diseases, including poor diet, accumulation of environmental toxins (including pesticide exposure), insufficient physical activity, chronic stress, and overmedicalization. Among other issues, the MAHA Assessment examines pesticide use in agriculture and the perceived negative impacts it has on children. It calls for more research and potential shifts in food and farming policies to improve children's health.

The May MAHA Assessment was to be followed within 180 days by a *Make Our Children Healthy Again Strategy* (MAHA Strategy) based on the findings from the MAHA Assessment. The MAHA Assessment includes a subsection entitled "Why Children Are Uniquely Vulnerable to Environmental Chemicals," where pesticides are mentioned several times. The MAHA Assessment states that children are at heightened risk when exposed to environmental chemicals, including pesticides. The MAHA Assessment states the key factors are the special sensitivities of children, including a developing immune system and sensitive developmental windows (more generally summarized as "children are not little adults").

Children are exposed to hazardous substances in different ways. The MAHA Assessment states several factors, including breastmilk, household dust, the home environment (including the widespread presence of pesticides in the home), and food (noting that "more than over eight billion pounds of pesticides are used each year [globally] in the food system").

The MAHA Assessment specifically names pesticides — chlorpyrifos, atrazine, and glyphosate — as examples presenting notable risks from modern agricultural production methods. The MAHA Assessment highlights many of the problems said to be associated with modern food production as a system — problems due to processed food ingredients, poor nutrition, and typical farming practices. The references to pesticides are generally grouped with other categories or substances, including heavy metals, per- and polyfluoroalkyl substances (PFAS), fluoride, and phthalates.

The MAHA Assessment acknowledges that EPA has a "robust risk-based approach that considers hazard and exposure for assessing the risks of chemicals, including pesticides, to human health and the environment." Throughout the May MAHA Assessment, there are footnotes citing studies that raise concerns about the dangers of the modern food production system, yet the established data about pesticide residues are found to be compliant with FQPA requirements.

Agricultural groups were alarmed and dissatisfied with the rhetoric and claims in the report that appeared to indict the modern agricultural production system as adversely impacting public health, especially the health of children. They pressed the Administration to understand modern agriculture and its benefits. These concerns and efforts became increasingly public as the MAHA Strategy recommendations were expected to be released. The New York Times detailed some of these concerns a few weeks before the Strategy was released in an article entitled "Farmers Are Turning on MAHA."

b. The MAHA Strategy

The May MAHA Assessment was followed by the release on September 9, 2025, of the HHS MAHA Strategy issued

by the MAHA Commission. In its press release announcing the Strategy's release, HHS describes the MAHA Strategy as a "sweeping plan with more than 120 initiatives to reverse the failed policies that fueled America's childhood chronic disease epidemic." HHS states that the MAHA Strategy outlines "targeted executive actions to advance gold-standard science, realign incentives, increase public awareness, and strengthen private-sector collaboration."

In the MAHA Strategy, the Commission again identifies four potential issues it believes are behind the rise in childhood chronic diseases — poor diet, chemical exposure, lack of physical activity and chronic stress, and overmedicalization. The MAHA Strategy discusses the following five key focus areas to address childhood chronic diseases: (1) Advancing Critical Research to Drive Innovation; (2) Realigning Incentives and Systems to Drive Health Outcomes; (3) Process Efficiencies and Deregulation; (4) Increasing Public Awareness and Knowledge; and (5) Fostering Private Sector Collaboration.

What is striking in the MAHA Strategy is how little pesticides are mentioned compared to the earlier Assessment document. The final version of the MAHA Strategy is different in tone than the Assessment released in May and softens many of the sharp points made in the May Assessment. The text is more in keeping with "Presidential Task Force" and general policy announcements of past administrations.

The Strategy lists priorities and directives with only short summaries of the problem and how new actions and initiatives will address the identified issues. The Assessment was more intense in tone and similar to critiques of the modern food production and medical establishment institutions by advocacy groups whose leaders are now in leadership appointments at HHS (including Secretary Kennedy).

For example, the earlier MAHA Assessment repeatedly mentions "corporate capture" of federal agencies and regulatory decision-making, along with a dismal description of current public health policies, food production methods, and medical practices, that lead to a dangerously unhealthy diet for an overmedicated and manipulated public. Many elements of this intense critique remain in the Strategy but are often softened in tone or more obliquely embedded in the list of actions and recommendations. For example, the phrase "ultra-processed" — referring to the modern food production system and ingredients — appears more than 30 times in the May Assessment, and only twice in the September Strategy.

Regarding chemicals and pesticides that were subject to a more negative depiction in the Assessment (especially in the cited research studies), the final Strategy does not mention any pesticides by name. In fact, the section entitled "EPA Process Improvements" cites the need to "reform the approval process" for pesticides to "increase the timely availability of more innovative growing solutions for farmers." Later, there is an explicit mention of EPA's OCSPP using "increased scientific capacity from new hires" as part of "Agency Restructuring" to help improve processing applications. After the release of the Strategy, there were press reports identifying the outreach and advocacy of agricultural stakeholders, including the pesticide industry, to have the Administration better understand what modern agriculture — its methods, its tools, and its productivity — brings to benefit domestic and global consumers.

The final recommendations and initiatives announced in the Strategy can be explained as covering most, if not all, of the MAHA agenda covered in the May Assessment. One broad recommendation that EPA, the U.S. Department of Agriculture (USDA), and the National Institutes of Health (NIH) will develop — "a research and evaluation framework for cumulative exposure across chemical classes" — may lead to new issues of concern regarding chemicals and pesticides. The specific directive — "EPA will focus on pesticides acting through a common mode of action" — includes what will be done "consistent with the statutory obligations" of FIFRA and FQPA. This added proviso is curious since EPA has long-standing requirements to evaluate "cumulative" risks of pesticides as part of registration review, so it is unclear if this directive will lead to new and different policies or simply a restatement of current practices and procedures. More information on the Strategy is available in our September 15, 2025, blog "HHS Announces Release of MAHA Strategy."

c. What to Expect in 2026

The September MAHA Strategy has a much less alarming tone than the May MAHA Assessment. This shift is unlikely to please critics of modern food safety, food production, pharmaceutical, and medical establishments. Critics of pesticide use generally and those who hoped the later Strategy would support greater regulatory controls on pesticide use will have to decide whether to press their agenda as part of the initiatives (or lack thereof) outlined in the current Strategy or press for more fundamental changes.

It appears that 2026 may see a bumper crop of initiatives questioning the adequacy of the federal regulatory controls on pesticide and chemical use in the United States.

In one example, the advocacy group Moms Across America issued a response to the September MAHA Strategy and its lack of calls for greater pesticide restrictions ("Eleven Ways The EPA Fails to Regulate Pesticides"). This group is an important advocate of the MAHA movement, and along with other environmental non-governmental organization (ENGO) critics of EPA's pesticide decisions, is likely to pressure federal and state officials with rhetoric more in line with the May MAHA Assessment. Secretary Kennedy is expected to continue to press many of the concerns he voiced during the 2024 Presidential campaign, separate from the recommendations of the MAHA Strategy document.

By the end of 2025, many states had enacted laws regarding food safety in light of MAHA concerns (*e.g.,* school lunch programs, prohibiting artificial dyes in food). HHS itself has a tracker of state actions characterized as part of the MAHA response. Legislative and regulatory actions regarding chemical and pesticide use and exposures across states have been on the increase for some time. It appears that 2026 may see a bumper crop of initiatives questioning the adequacy of the federal regulatory controls on pesticide and chemical use in the United States.

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

PRIA remains bedeviled by the inability of EPA to meet consistently the deadlines prescribed by the legislative scheme. PRIA was enacted to establish 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 first enacted in 2004 and 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 calling for a third-party review of PRIA performance issues.

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. A significant hindrance to program performance is that appropriations levels have been below the legislatively expected amount of funding "required" in the PRIA legislation. Since Fiscal Year (FY) 2022, the appropriated amount has been $35 million or more below the "minimum" amount expressed in the legislation.

Congress's unwillingness to provide "its share" has contributed to a reduction in staffing available to OPP, which has seen a reduction in staffing (number of Full-Time Equivalent (FTE)) of 50-60 positions since 2021. This number is set to increase during 2026 due to the reorganization of EPA's Office of Research and Development (ORD), with the expectation of 50 or more positions added. Additional staff will be welcome but also will take time for staff training and experience before any real increase in program output is expected.

Congressional appropriations are not expected to be robust generally anytime soon. Relatively flat spending on OPP program activities is a reasonable expectation for 2026 and beyond (if not some cuts).

a. MyPeST Registration Tracking Application

To provide transparency and increase efficiency as mandated by PRIA 5, in January 2025, EPA launched a new web-based registration tracking application, MyPeST. The

intent of the app is to provide registrants accurate, up-to-date information regarding pesticide submissions. At this time, not all aspects of MyPeST are functional but there have been several updates and enhancements this year. The dashboard page now provides information on the registrant's cases and products, with drop-downs and links that enable the user to drill down into a highly detailed view of each application that includes the progress through various milestones, as well as a final projected completion date. MyPeST also provides the ability to communicate with OPP staff directly within the application page.

The potential user must register and pass a multi-step approval process before being assigned access to one or more companies' submissions. So far, over 1,200 registrants have successfully signed up for MyPeST even though the process for gaining access can be a bit tedious (typically managed in about a week). When fully operational, MyPeST should be a beneficial tool for both OPP and applicants.

MyPeST is part of EPA's overall digital transformation strategy to reduce and streamline internal processes. The main goal is to improve the timeliness of pesticide registration decisions but also, as EPA reports, to support Administrator Zeldin's Pillar Three of Powering the Great American Comeback, which is to advance efforts that permit process reform. Insufficient PRIA 5 funding could have the potential to impede EPA's ability to upgrade information and tracking systems like MyPeST that would otherwise help improve meeting program deadlines.

b. Bilingual Labeling Implementation and Tracking

Under PRIA 5, FIFRA was amended to require Spanish language translation for certain sections of end-use pesticide product labels; translations for those sections were made available in EPA's Spanish Translation Guide. PRIA 5 provides a rolling schedule for when labels will be required to be updated either on the label, via scannable technology (Quick Response Code (QR Code)), or other electronic methods readily accessible on the product label. The first registrants required to comply are registrants of end-use Restricted Use Pesticides (RUP) and agricultural use pesticides with the highest toxicity (Category 1); these must incorporate the bilingual language on products released for shipment as of December 29, 2025. EPA provides additional information on its website at Bilingual Labeling Questions & Answers.

PRIA 5 Bilingual Labeling Requirements

PESTICIDE PRODUCT TYPE	BILINGUAL LABELING DUE
Restricted Use Pesticides (RUPs)	December 29, 2025
Agricultural Products (Non-RUPs)	
Acute Toxicity Category I	December 29, 2025
Acute Toxicity Category II	**December 29, 2027**
Antimicrobial and Non-Agricultural Products	
Acute Toxicity Category I	**December 29, 2026**
Acute Toxicity Category II	**December 29, 2028**
All Other Pesticide Products	**December 29, 2030**

PRIA 5 also requires that EPA develop and implement, and make publicly available, a plan for tracking product labels that have included the required bilingual labeling. In July 2025, in an Information Collection Request (ICR), EPA announced its plan to track the adoption of bilingual labeling using the MyPeST application. The ICR was closed for comments on September 19, 2025.

EPA added a voluntary bilingual labeling reporting function to MyPeST. Reporting the adoption of bilingual labeling, however, is currently voluntary. Once the ICR comment process concludes, EPA will provide information on any changes in process and deadlines for mandatory reporting.

c. Progress to Reduce PRIA Backlog

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

Still, the fundamental metric of successfully meeting the target decision deadlines has remained elusive. The changes required by PRIA 5 to the criteria by which a deadline can be renegotiated have added to the number of missed deadlines but also resulted in some improvements made in earlier identification of problems with a submission (*e.g.,* missing data or errors in submitted forms), transparency about decisions, IT improvements, providing progress reports, and other accountability measures.

EPA continues to devote significant effort to save resources and reduce the backlog of notifications and non-PRIA

actions (*i.e.*, actions that do not have a PRIA fee or deadline such as minor label changes or product formulations). Steps have included closing out thousands of older notifications and actions that have stalled in OPP since there were many PRIA backlogged actions that were considered a higher priority for completion. EPA reported in its June 17, 2025, Pesticide Program Dialog Committee (PPDC) meeting that from January 2025 to July 2025, the non-PRIA backlog decreased from 13,270 to 9,798 actions, meeting its goal for FY 2025.

In addition, on October 9, 2025, as required under PRIA 5, EPA announced the availability of two reports prepared from the result of third-party audits that evaluated pesticide registration processes and functions conducted by EPA. According to EPA, the first report entitled "Business Processes Review and Optimization for EPA Office of Pesticides Programs" provides the results of the audit that focused on assessing the operational performance of EPA's OPP and provides recommendations for improvement. The second report evaluates the gaps in OPP's training and education necessary to support its regulatory mission and implementation of PRIA 5. In 2026, expect EPA and stakeholders to review these reports and determine how to best implement the recommendations and whether such actions can be addressed through EPA's ongoing process improvements or will need other action (*e.g.,* congressional action, resource increases). More information is available in our blog "EPA Releases Reports as Part of Agency Efforts to Optimize Pesticide Registration Processes."

d. PRIA 6

Although PRIA 5 is authorized until **September 30, 2027** (the end of FY 2027), work on PRIA 6 will begin as stakeholders evaluate further changes to the current law to make program improvements generally and to incorporate recommendations from the various internal and external reviews for how to address decision backlogs and reduced congressional appropriations. Efforts to formulate PRIA 6 options in 2026 by environmental groups, farmworker advocacy organizations, and registrant groups will aim to keep this broad coalition together to support legislative approval of any proposal. Earlier consideration of PRIA legislation might help avoid a threat of a lapse in authorization that could lead to accumulating a larger backlog and uncertainty about program implementation. As discussed below, if there is movement on a Farm Bill in 2026, which is unlikely, there could be interest in having it incorporate PRIA 6 legislation.

Some uncertainty about program budget and size of the backlog will be affected by the government shutdown at the end of FY 2025.

4. 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 has been annually extended and prospects for a "traditional" Farm Bill — legislation covering a wide range of agricultural activities — continue to diminish.

The most divisive issue has been a partisan dispute over potential cuts to what are called the "feeding programs" of the USDA — the Supplemental Nutrition Assistance Program (SNAP). Republicans have proposed cuts to the program that are flatly opposed by the Democrats.

Congress has continued to be unable to agree on a new Farm Bill. Having missed each FY's deadline, Congress is now expected to renew the current program year-by-year. Budget pressures on farm programs caused by natural disasters, tariffs, and narrow sought-after changes have seen some movement in Congress. Stakeholders interested in more wholesale changes to farm programs keep some pressure on Congress to take on the task of a "normal" Farm Bill.

With the looming 2026 mid-term elections, few expect broad legislative proposals of any sort to be successful during 2026. One possibility is that if there is a change in the majority of the House and/or Senate, there will be interest in changes during the lame-duck period between the November elections and the arrival of new congressional members in **2027**.

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.

Regardless of when and if there is another wide-ranging 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.

Until the Trump Administration stopped support for climate-related programs across the government, there had been some bipartisan interest in suggesting climate-positive impacts of Farm Bill programs. Support for some of these programs may continue, even with less explicit mention of a climate impact. Examples include possible support for voluntary adoption of precision agriculture technologies and services, including an emphasis on adjuvants to increase pesticide efficacy and use efficiency.

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 if there is any serious potential for a Farm Bill in 2026, although the likelihood of success for these issues remains unclear.

5. OPP Reorganization

EPA reorganization efforts have impacted offices throughout EPA, including OCSPP and OPP. EPA will continue to adjust and address these changes in 2026, including the following:

- The termination or transfer of employees previously in the Environmental Justice (EJ) and Diversity, Equity, and Inclusion (DEI) arms of the Agency has been implemented fully.
- On July 18, 2025, EPA announced its "reorganization plan" for ORD. On October 19, 2025, EPA announced that these reorganization efforts have been implemented fully. Bergeson & Campbell, P.C. (B&C®) has discussed in detail the advantages and disadvantages of this reorganization effort (see our blog "EPA's Office of Research and Development — Villain or Victim?") but the practical impact of how this plan plays out will start to show in 2026. One of the issues that ORD was addressing, and whose efforts should be continuing whether at ORD or OSCPP/OPP, is the development of efficacy test methods for pesticide devices. This effort was funded in PRIA 5 (*i.e.*, up to $500,000 per year FY 2023-**2027**) "… [t]o 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.
- Due to federal cutbacks and retirements, EPA has determined that the existing Minor Use and Emergency Response Branch will no longer be a stand-alone Branch but instead will be combined within other Branches of the Registration Division. The work and issues to be addressed are expected to remain the same, and perhaps even improved efficiencies in processing IR-4 tolerance actions and registrations following the assignment for someone to coordinate fungicide, herbicide, and insecticide activities with the Project Management (PM) Teams.
- Speculation continues regarding the reorganization of the Office of Enforcement and Compliance Assurance (OECA) and whether the Good Laboratory Practices Standards Compliance Monitoring Program (*i.e.*, Good Laboratory Practices (GLP) inspectors, downsized from seven to three in 2025) will be moved to the Office of Pollution Prevention and Toxics (OPPT). It is unclear this will happen, but if it does, it will raise questions as to how the loss of senior inspectors with historical knowledge, a possible reorganization, and PRIA budget constraints might impact laboratory inspections and quality compliance.

6. Actions on Specific Pesticides

a. 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, blog, 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. EPA is now reviewing the comments it received in response to the proposed rule, whose comment period ended on March 24, 2025.

b. Organophosphates

Regardless of the status of chlorpyrifos uses, the larger question of how EPA will evaluate the remaining organophosphate (OP) pesticides has presumably changed with the arrival of the Trump Administration. As part of an emphasis on de-regulation or implementation of a more "business-friendly" policy generally, proposals for reductions in the allowable uses to other OP pesticides may be reversed.

Assessments that had proposed use reductions for some OPs may be reversed. "Reversed" in this case means that most, if not all, uses may be maintained as EPA continues to conduct registration review for these pesticides. Under the Biden Administration, the first OP products faced a call for greatly reduced uses using conservative assumptions in risk assessments that registrants challenged in reaction to EPA draft interim registration review decisions. In 2026, expect to see a less challenging path for registration reviews of OP products during the current Administration.

There also will be continued activity in 2026 following the June 30, 2025, filing by the Pesticide Action and Agroecology Network North America (PANNA) and several other non-governmental organizations (together, Petitioner) of a Petition for Writ of Mandamus (Mandamus Petition) in the U.S. Court of Appeals for the Ninth Circuit to seek an order directing EPA to act on a 2021 Petition to revoke all food tolerances and cancel registrations for OP pesticides (OP Petition). Oral arguments were held on December 2, 2025. More information is available in our July 15, 2025, blog "PANNA Files Writ of Mandamus against EPA for Failing to Respond to Petition to Cancel Organophosphate Pesticides."

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-tolerant crops, including soybeans and cotton. These crops have been 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 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 has 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 successfully challenged EPA's 2020 approval of the new dicamba products, and as a result, currently there are no registrations in force for the newer formulations.

On July 23, 2025, EPA proposed the latest approved label for OTT dicamba formulations. Similar to past approvals, EPA has added label requirements about applicator training, geographic restrictions, and certain use conditions (temperature, wind) to allow use and reduce expected incidents of drift. EPA has layered on such additional restrictions before in the attempt to reduce incident reports. States also have added more restrictions in some cases, such as strict calendar cut off dates for their state. The basic

As the October 1, 2026, deadline approaches, EPA is under tremendous pressure to complete the more than 100 remaining pesticide review cases before the statutory deadline.

question facing EPA is whether any set of label restrictions will be enough to prevent reported problems sufficiently with the current "low-volatility" formulation.

The comment period on EPA proposing this new version of a dicamba registration closed on September 5, 2025. EPA will review the comments with an eye to an expected continued legal challenge to any decision to approve if that is the final decision. Growers who may hope for availability of the herbicide will want to have this control tool available for the 2026 growing season.

7. Registration Review and Relevant Pesticide Strategies

As the **October 1, 2026,** deadline for completing the initial reviews of 734 cases of pesticides registered before October 1, 2007, and 65 new active ingredients registered after 2007 approaches, EPA is under tremendous pressure to complete reviewing the remaining cases before the statutory deadline. According to the most recent update provided by OPP during its June 17, 2025, PPDC meeting, of the 799 cases, through September 2024, there were 732 cases (or 92 percent) for which draft risk assessments are completed (70 remain), and 634 cases (or 79 percent) for which final or interim decisions are completed (163 remain). Over 100 of these remaining cases are still pending EPA action as of October 2025, based on EPA's Registration Review Schedules.

Several of EPA's pesticide-related strategies and actions, including its 2023 New EDSP Strategic Plan, ESA Protection Strategies (*e.g.,* Herbicide Strategy and Insecticide Strategy), and EPA's Actions to Protect Pollinators, have caused significant delays in EPA's pesticide registration review.

In January 2025, as part of its 2024 Endocrine Disruptor Screening Program (EDSP) settlement agreement, EPA announced its commitment to several action items to assess the potential effects of conventional pesticide active ingredients (Group 1 chemicals) on human health and uses of its new tracking website for EDSP data call-in (DCI) notices. The website shows the status of DCI notices, including issuance dates and deadlines for data submission, and helps to increase transparency. As of October 2025, the active ingredient dicloran (DCNA) was voluntarily cancelled, and several other chemicals (*e.g.,* acetochlor, fenitrothion, propanil, and zoxamide) were removed from the high-priority list due to sufficient data provided.

Another aspect of EPA's EDSP strategy is to screen a chemical rapidly for bioactivity in several endocrine pathways, using high throughput assays and computational models. EPA last updated in July 2025 that it has partial screening results for over 1,800 chemicals for the estrogen receptor pathway, and that it anticipates additional alternative methods to be available for EDSP chemical screening, based on further advancement of high throughput assays and computational models for other endocrine pathways, in a faster and cheaper manner.

Following release of the Herbicide Strategy in 2024, EPA published its Insecticide Strategy on April 29, 2025, as part of its ongoing workplan to protect federally listed endangered and threatened (listed) species. The Insecticide Strategy identifies practical protections for listed species from the use of insecticides, while providing flexibility for pesticide users and growers. The Strategy also identifies mitigations aimed at protecting more than 900 species listed by the U.S. Fish and Wildlife Service (FWS) that EPA considers when it registers a new insecticide or reevaluates an existing one.

Similar to its 2024 Herbicide Strategy, EPA's 2025 Insecticide Strategy mitigates risks to endangered species from spray drift and runoff through a two-pronged approach: ecological spray drift buffers and a runoff/erosion mitigation points system. These requirements are implemented through an online tool called the Mitigation Menu and apply specifically in areas designated as PULAs. EPA communicates those mitigations and where they apply using a web-based system called Bulletins Live! Two (BLT). For recently completed pesticide cases, EPA has already approved pesticide product labeling that includes BLT reference language through its registration and registration review programs.

In 2026, anticipate EPA racing to meet the **October 1, 2026,** deadline, and continue incorporating these pesti-

cide-related strategies and actions in its registration review decisions. Delays resulting from the government shutdown and delays in receiving data from registrants and the scientific complexity of the remaining cases will continue to be challenges for EPA in 2026.

8. Enforcement

FIFRA enforcement activity has been trending upward over the past several years. In EPA's FY 2024 report summarizing its results and accomplishments from the prior year, EPA provided statistics confirming a recent trend of increased enforcement actions. These statistics show that EPA:

- Conducted 8,500+ on-site inspections in FY 2024, a nearly 10 percent increase from FY 2023;
- Charged 121 criminal defendants in FY 2024, the highest since FY 2019;
- Concluded 1,851 civil cases in FY 2024 — the highest number since FY 2017; and
- Required companies to pay over $1.7 billion in penalties, fines, and restitution, the highest level since FY 2017.

Although it might have been expected that enforcement would decrease with the new Administration, enforcement appears to have remained steady if not on the upswing, with cases ranging from products that were refused entry at the borders, most likely for issues with product labels or Notices of Arrival (NOA), settlements of cases with seven-digit penalties for allegations of the sale/distribution of unregistered or misbranded pesticides, and some "expedited settlement agreements" following EPA's January 17, 2025, release of its new *Expedited Settlement Agreement Pilot Program Under the Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA Settlement Pilot Program or Pilot Program). EPA states that the "purpose of this Pilot Program is to provide an additional enforcement tool that encourages resource prioritization and violation deterrence through expedited resolution of cases involving minor violations that are easily correctible and do not cause significant health or environmental harm."

Although "easily correctible" is not defined, from a timing perspective, it appears that EPA considers a violation easily correctible if FIFRA compliance can be achieved within 30 days, although EPA may, "at its discretion, grant an extension for corrective action in limited circumstances upon submission of a written extension request detailing why achieving compliance within 30 calendar days of receipt of this letter is infeasible or impracticable."

EPA also provides the following "general parameters" that it considers when determining whether a case involves "minor violations" that are suitable for resolution under this Pilot Program, including but not limited to:

- The case involves domestically produced or imported pesticides or device products.
- The case does not require EPA review and approval of registration changes, including but not limited to labeling changes.
- The total proposed penalty should not exceed $24,000, with a penalty matrix provided at Attachment B of the Pilot Program.
- The company is not a "repeat violator" (noting that in the Pilot Program, EPA discusses when a repeat violator may be eligible under the Pilot Program depending on the type of violation and when the violation occurred and provides a hypothetical timeline when an Expedited Settlement Agreement may be permissible).
- The case does not involve criminal or fraudulent behavior (*e.g.*, intentionally falsifying information).

Although the Pilot Program is not referenced specifically, the majority of Expedited Settlement Agreements issued in 2025 relate to the failure of companies to submit their annual pesticide production establishment reports.

9. Revisions to Pesticide Registration Notice 98-10

On December 31, 2025, EPA released a pre-publication version of its notice to revise Pesticide Registration Notice (PRN) 98-10. The 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,

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.

While the new draft considers the 2017 draft and comments, EPA has recently met with stakeholders to include industry input into the draft. EPA intends to consider different approaches, including expanding Confidential Statement of Formula (CSF) notifications and explanatory text regarding graphics, logos, or slogans. EPA is considering if other actions might fall under non-notification, including but not limited to: (1) addition of specific symbols, pictures, logos, and graphics; (2) addition of websites and scannable technology (QR Codes) that link directly to a website; (3) expanding and clarifying permissible typos and corrections; and (4) addition of certain reoccurring language requested by states.

EPA is working with the bilingual labeling team to address potential conflicts between the new guidance and bilingual labeling requirements. After implementation, EPA will allow voluntary withdrawals of pending notifications that meet the criteria as a non-notification amendment per the revised PRN 98-10. For additional discussion on the December 31, 2025, revised version of PRN 98-10, see our forthcoming memorandum.

10. Antimicrobials Division Programmatic Actions of Note — Interim Guidance Extending Virus Claims to Sanitizer Products

In October 2024, EPA announced the release of interim guidance to expand the availability of virucidal claims for antimicrobial pesticides. This 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.

EPA intends to grant the addition of virucidal claims associated with sanitizer claims for a time-limited period of a maximum of ten years. The time-limited period will expire on **October 10, 2034**. 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 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.

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

EPA announced a multi-day in-person workshop in February 2026 to discuss the submission process of human studies conducted to support the registration of skin-applied pesticide repellents.

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.

We expect that in 2026, EPA will review and approve new or amended sanitizer products with virucidal claims, now that registrants have had time to generate the appropriate data and submit the applications to do so.

11. Process Improvement Event for Skin Applied Repellent Human Studies

EPA announced a multi-day in-person workshop in **February 2026** to discuss the submission process of human studies conducted to support the registration of skin-applied pesticide repellents. The event will focus solely on the development of protocols, the submission of the protocols and completed studies for review by EPA, and subsequent consultation with the Human Studies Review Board (HSRB) — these actions are submitted to EPA under the PRIA codes M001 and M002. Conducting human studies for submission to EPA for review and approval by the HSRB is extremely difficult, costly, and lengthy. The process is meticulous, with only a handful of contract research organizations (CRO) in the United States knowledgeable enough, and willing to conduct these studies. A thorough review with the intent to improve the guidelines and processes, which CROs acknowledge are outdated, is warranted during this time of increased vector borne diseases. The number of participants will be limited to only those companies that have previously or are planning to conduct human studies to support a registration for skin-applied repellents.

12. DPR Considering Changes to Enforcement Response Regulations

On November 13, 2025, the California Department of Pesticide Regulation (DPR) held a webinar to discuss potential changes to its Enforcement Response Regulations set forth at 3 C.C.R. Sections 6128 and 6130. DPR also released its Discussion Document explaining the various regulatory "concepts" it is considering and posing questions for public input related to those concepts.

The proposed focus areas are designed to address areas of improvement identified in an EPA audit conducted in 2023, improve statewide consistency, and clarify elements of enforcement processes. The four areas are:

1. Consistently align penalties with the nature of violations. Currently, the regulations classify violations into three categories — Class A, B, and C — based on the severity and nature of the violation. DPR is considering regulatory approaches to align penalties consistently with the nature of violations, including refining the criteria for Class A, B, and C violations, or considering whether additional categories are needed. Among other questions, DPR is seeking input on how "harm" should be defined and what changes should be made for the degree of potential harm and/or actual harm.

2. Increase minimum fine levels. While maximum fines have been updated, minimum fines have not changed since 2002. DPR proposes raising minimum fine levels to better reflect the seriousness of violations, narrowing the currently large fine ranges to support consistency in fine and penalty amounts across counties.

3. Improve statewide consistency in fine amounts. DPR states that a key recommendation from the 2023 EPA audit is to improve consistency in how fines are applied across counties. Currently, County Agricultural Commissioners (CAC) consider county compliance history when determining penalties, but DPR is now considering requiring CACs to consider statewide compliance history when imposing enforcement actions for Class A violations.

4. General processes improvements. DPR is considering several updates to streamline and strengthen enforcement processes, including updating its processes for notification and referrals to District Attorneys, City Attorneys, or Circuit Prosecutors, requiring review of notices of proposed action from reportable investigations, requiring DPR

referrals for multi-jurisdictional reportable incidents (per AB 2113), and clarifying timelines and expectations for reviewing CAC decision reports.

Comments were due by December 13, 2025. A formal regulatory process could be initiated in 2026.

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, or Lisa R. Burchi, lburchi@lawbc.com, to discuss how we can assist you with product registration, reregistration, compliance, and defense.

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D. PFAS

Per- and polyfluoroalkyl substances (PFAS) are attracting intense global legal, regulatory, commercial, and litigation attention as no other "emerging contaminant" has. This attention increased in 2025 and will do so again in 2026. The regulatory activities are global, ranging from the United States to Canada, Europe, and Australia. Where we have reported on PFAS developments within another chapter, we have provided a link for readers to follow to obtain more information.

1. United States

a. Federal

i. TSCA

In May 2025, the U.S. Environmental Protection Agency (EPA) published an interim final rule that postponed the data submission period for the Toxic Substances Control Act (TSCA) Section 8(a)(7) reporting and recordkeeping rule on PFAS. 90 Fed. Reg. 20236. Under the interim final rule, the data submission period will begin **April 13, 2026**, and end **October 13, 2026**. Small manufacturers reporting exclusively as article importers would have until **April 13, 2027**, to report. According to EPA's May 12, 2025, press release, the extension will allow it to develop and test further the software being used to collect data from manufacturers, "thereby providing critical feedback to EPA, including what additional guidance would be useful for the reporting community." 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. See 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)

EPA announced on September 17, 2025, its next steps regarding regulatory efforts to address cleanup of perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS). On May 8, 2024, EPA designated PFOA, PFOS, and their salts and structural isomers as hazardous substances under CERCLA. 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 its September 17, 2025, announcement, EPA states that it is retaining the CERCLA hazardous substance designation for PFOA and PFOS and intends to develop a CERCLA Section 102(a) Framework Rule going forward. According to EPA, the Framework Rule "will provide a uniform approach to guide future hazardous substance designations, including how the agency will consider the costs of proposed designations." When EPA announced its final rule on April 19, 2024, it also announced it was issuing a separate PFAS Enforcement Discretion and Settlement Policy Under CERCLA (CERCLA Enforcement Discretion Policy) "that makes clear that EPA will focus enforcement on parties who significantly contributed to the release of PFAS … into the environment, including parties that have manufactured PFAS or used PFAS in the manufacturing process, federal facilities, and other industrial parties." EPA notes in its September 17, 2025, announcement that "[t]he best, most enduring solution to this issue is a statutory fix to protect passive receivers from liability, which EPA would follow to the letter of the law. EPA stands ready to provide technical assistance to Congress as requested on this issue."

More information on EPA's final rule and the CERCLA Enforcement Discretion Policy is available in our April 23, 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 requesting 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. EPA's list of long-term actions in the spring 2025 Unified Agenda includes an item on "Addressing PFAS in the Environment." According to the item, EPA is now reviewing and evaluating comments on the 2023 ANPRM. EPA has not determined when it will issue a notice of proposed rulemaking (NPRM). The designation of additional PFAS as hazardous substances would jump-start extraordinary remediation activities

resulting in significant CERCLA-related cleanups, demands for cost recovery, re-opening of "cleaned-up" sites, and private litigation. More information on the ANPRM 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 January 2025 identifying nine additional PFAS for TRI Reporting Year 2025 (reporting forms due by **July 1, 2026**). EPA announced on October 7, 2025, the addition of sodium perfluorohexanesulfonate (PFHxS-Na) to the TRI list pursuant to the NDAA for TRI Reporting Year 2026 (reporting forms due by **July 1, 2027**). More information on these additions is available in our January 13, 2025, and October 9, 2025, blog items.

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. 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 spring 2025 Unified Agenda, EPA intends to issue a final rule in **February 2026**.

On January 17, 2025, EPA proposed to clarify the timeframe for when companies must first notify a customer that one of its mixtures or trade name products contains a PFAS listed on the TRI list of toxic chemicals. According to EPA's January 16, 2025, press release, EPA proposed the rule in response to questions from industry regarding the effective date of supplier notifications for PFAS added to the TRI pursuant to the NDAA. An item in EPA's spring 2025 Unified Agenda states that EPA intended to issue a final rule in November 2025. Given that EPA had not yet sent a final rule to the Office of Management and Budget (OMB) before the government shutdown in October 2025, this rulemaking will likely be postponed to 2026. More information on EPA's proposed rule is available in our January 22, 2025, blog item.

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. 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.

In May 2025, the Trump EPA announced that it will keep the NPDWR for PFOA and PFOS, and that it intends to:

- Extend the PFOA and PFOS MCL compliance deadlines; and
- Rescind the regulations and reconsider the regulatory determinations for PFHxS, PFNA, and HFPO-DA, and the Hazard Index mixture of these three PFAS plus PFBS.

An item in EPA's spring 2025 Unified Agenda states that EPA intended to issue an NPRM in October 2025 that would provide additional time for public water systems to meet the compliance deadlines for the MCLs for PFOA and PFOS. Since the government shutdown on October 1, 2025, before EPA could submit a proposed rule to OMB for review, this rulemaking will be delayed, making it unlikely that EPA will issue a final rule in **April 2026** as it intended.

According to an item in EPA's spring 2025 Unified Agenda, EPA intended to issue in September 2025 a proposed rule that would withdraw its regulatory determinations to regulate PFHxS, PFNA, HFPO-DA, and the mixture of these

three PFAS plus PFBS, as well as rescind all associated regulatory provisions associated with the final PFAS NPDWR exclusive to these PFAS. EPA had not submitted a proposed rule to OMB for review before the October 1, 2025, government shutdown, making it unlikely that EPA will meet its goal of issuing a final rule in **February 2026**.

EPA stated in an item in its spring 2025 Unified Agenda that it intended to issue in November 2025 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 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 **May 2027**.

v. Resource Conservation and Recovery Act (RCRA)

EPA issued on February 8, 2024, two proposed rules that would 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 spring 2025 Unified Agenda, after considering public comments on the 2024 proposed rule, EPA plans to take final action and issue a final rule in **April 2026**.

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. 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 spring 2025 Unified Agenda, EPA is considering public comments on the 2024 proposed rule as it develops a final rule. EPA intends to issue a final rule in **April 2026**. More information on the 2024 proposed rules is available in our February 5, 2024, memorandum.

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. *PEER v. Regan* (No. 1:24-cv-02194-JEB). In December 2024, the court granted EPA's motion to dismiss and denied Inhance's motion to intervene as moot.

ARTICLE

"The Cost of Cleanup: Preparing for PFAS remediation battles," *Corporate Disputes*, January – March 2025

Certain states have enacted regulatory programs that first ban the use of PFAS in certain consumer products before eventually banning all products containing intentionally added PFAS that do not have a currently unavoidable use determination.

CEH and PEER appealed to the U.S. Court of Appeals for the District of Columbia Circuit on December 27, 2024, and Inhance moved to intervene. The court was scheduled to hear oral argument on November 21, 2025. *PEER v. Zeldin* (No. 24-5294). *See* B. TSCA. ii. Significant Court Decisions. a. Inhance Technologies v. EPA.

b. States

Certain states, such as Illinois, Maine, Minnesota, and New Mexico, have enacted regulatory programs that first ban the use of PFAS in certain consumer products before eventually banning all products containing intentionally added PFAS that do not have a currently unavoidable use (CUU) determination. Other states have enacted more narrow statutes, targeting products ranging from firefighting foams (FFF) to apparel to food contact materials (FCM). Product bans have taken effect in Alaska, California, Colorado, Connecticut, Hawaii, Illinois, Maine, Maryland, Minnesota, New Hampshire, New Jersey, New York, Oregon, Rhode Island, Vermont, and Washington, although which products are banned varies from state to state. In Minnesota, reports on products containing intentionally added PFAS are due by **July 1, 2026**, and in New Mexico, reports are due **January 1, 2027**. Both Connecticut and New Mexico have begun working to implement labeling requirements. Connecticut's requirement will apply only to certain consumer products and will take effect **July 1, 2026**, while New Mexico has proposed to require labeling for all products containing intentionally added PFAS as of **January 1, 2027**.

With Minnesota's **July 1, 2026**, reporting requirement fast approaching, the Minnesota Pollution Control Agency (MPCA) must quickly revise its proposed reporting and fees rule to address deficiencies noted in an August 2025 administrative law judge's (ALJ) report. The report concluded that MPCA's proposed rule must be disapproved for a procedural reason: MPCA failed to include an assessment of the cumulative effect of the proposed rule with federal TSCA regulations on PFAS reporting. Based on a careful examination of the law, MPCA's explanations, and public comments, the ALJ also found that several provisions of the proposed rule must be disapproved because they are either not rationally related to MPCA's objective or the record does not demonstrate the need or reasonableness of the rule; exceeds, conflicts with, or does not comply with the enabling statute; and is not a rule or is otherwise not an enforceable law. MPCA intends to revise its proposed rule to address the deficiencies noted in the ALJ's report and will include an assessment of the cumulative effect of the proposed rule with the TSCA Section 8(a)(7) reporting rule. After MPCA revises the proposed rule, it will submit it to the Chief ALJ for approval. More information on the ALJ's report is available in our September 26, 2025, blog item. A detailed review of the proposed rule is available in our April 22, 2025, memorandum.

The New Mexico Environment Department (NMED) announced on October 8, 2025, that it has petitioned New Mexico's Environmental Improvement Board (EIB) to adopt a proposed rule to implement the PFAS Protection Act. According to NMED's press release, the proposed rule would "implement the full scope of the PFAS Protection Act, including phasing out and prohibition on the sale of consumer products containing intentionally added PFAS, establishing consumer-facing labels for products which contain intentionally added PFAS, and the reporting requirements for the manufacturers of such products." If passed by EIB, the rule would take effect **July 2026**. Comments on New Mexico's proposed reporting, prohibition, and labeling rule are due **March 31, 2026, by 4:00 p.m. (MST)**. More information on the proposed rule is available in our October 15, 2025, memorandum.

Two bills enacted in 2025, in New Mexico and Illinois, specifically address fluoropolymers. New Mexico's PFAS statute exempts products containing fluoropolymers from its reporting and prohibition requirements. In Illinois, the

PODCAST:
U.S. State PFAS Initiatives — A Conversation with Richard E. Engler, Ph.D. and Carla N. Hutton

Illinois Environmental Protection Agency (IEPA) must submit a report to the General Assembly by **August 1, 2027**, that includes:

- An assessment of statutory and regulatory authority, administrative infrastructure, research capabilities, and funding necessary to develop and implement a program for the review of fluoropolymers used in consumer products and their potential threat to human health and the environment;
- An assessment of available scientific data regarding fluoropolymers, as well as an assessment of other state or federal statutory or regulatory actions taken regarding fluoropolymers; and
- An assessment of potential critical uses of fluoropolymers and their relation to the supply chain.

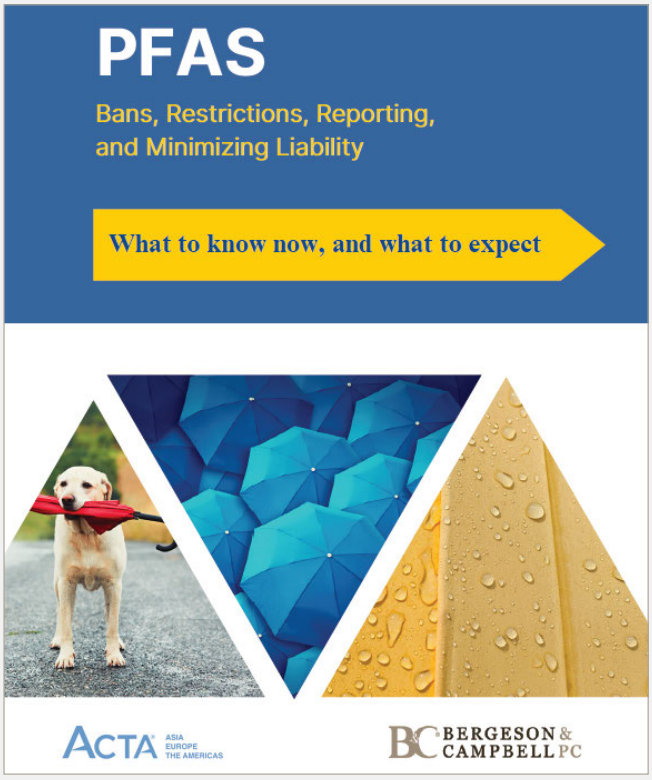
Each year, the number of state bills addressing PFAS increases, and PFAS will continue to be front and center in 2026.

2. Canada

In 2025, Canada released its final *State of Per- and Polyfluoroalkyl Substances (PFAS) Report* (State of PFAS Report) and proposed risk management approach for PFAS, excluding fluoropolymers. The State of PFAS Report concludes that the class of PFAS, excluding fluoropolymers, is harmful to human health and the environment. To address these risks, on March 8, 2025, Canada published a proposed order that would add the class of PFAS, excluding fluoropolymers, to Part 2 of Schedule 1 to the Canadian Environmental Protection Act, 1999 (CEPA). *See* D. The Americas ii. Canada b. PFAS.

3. European Union (EU)

In August 2025, the European Chemicals Agency (ECHA) announced that it published an updated proposal to restrict PFAS under the EU's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation. The authorities from Denmark, Germany, the Netherlands, Norway, and Sweden (Dossier Submitters) submitted the initial proposal in January 2023 and have now completed their evaluation of more than 5,600 scientific and technical comments and prepared an updated restriction proposal (Draft Background Document). In addition to adding sectors to the Draft Background Document, the Dossier Submitters have considered alternative restriction options, beyond a full ban restriction option 1 (RO1) or a ban with time-limited derogations for certain applications (RO2). The Draft Background Document now includes a third restriction option (RO3) that would allow continued use under strict conditions that minimize emissions over the full life cycle, *i.e.*, "regulatory options potentially allowing for adequate control of risks through means other than a ban." ECHA's



Visit our PFAS News and Information site for a comprehensive and constantly updated library of PFAS resources, including our 32-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.

WEBINAR ON DEMAND
PFAS Updates: What's Happening in the U.S. and EU

Scientific Committees for Risk Assessment (RAC) and for Socio-Economic Analysis (SEAC) planned to conclude their discussions on the 14 sectors covered by the 2023 restriction proposal plus PFAS manufacturing and horizontal issues by the end of 2025. ECHA announced on September 15, 2025, that it plans to begin a public consultation on the draft SEAC opinion "shortly after" SEAC's meeting provisionally scheduled for the **first half of March 2026**. ECHA intends to confirm the exact starting date of the consultation in **March 2026**. More information on the Draft Background Document is available in our August 29, 2025, memorandum. *See* B. European Union 2. EU 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.

4. United Kingdom (UK)

The UK REACH Work Programme for 2025-2026, published in July 2025, states that in 2025/26, the Health and Safety Executive (HSE) will consult on the Annex 15 technical report and restriction proposals and undertake relevant work to issue a final opinion for PFAS in FFF. 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. *See* C. United Kingdom/Great Britain 2. UK REACH.

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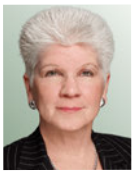
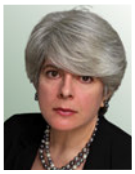
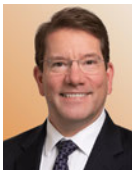


E. FDA FOOD AND COSMETICS REGULATIONS

Under the second Trump Administration, Robert F. Kennedy, Jr., Secretary of the U.S. Department of Health and Human Services (HHS), and his Make America Healthy Again (MAHA) initiative, are driving the focus of the U.S. Food and Drug Administration (FDA) in very focused areas. President Trump's February 13, 2025, Executive Order (EO) 14212, "Establishing the President's Make America Healthy Again Commission," tasked the MAHA Commission with examining potential drivers of childhood chronic disease, including diet, environmental toxins, medical treatments, lifestyle, environmental factors, government policies, food production techniques, electromagnetic radiation, and corporate influence. FDA's work in 2026 and beyond is expected to include policy reforms outlined in the MAHA Commission's September 2025 Make Our Children Healthy Again Strategy (MAHA Strategy). This will include defining ultra-processed foods; improving food labeling by revising the proposed Front-of-Pack nutrition information rulemaking; closing the "Generally Recognized as Safe" (GRAS) loophole by implementing a mandatory GRAS notification program; and removing harmful chemicals from the food supply by developing and implementing an evidence-based systematic process for post-market assessment of chemicals in food, including chemicals present as unintentional contaminants.

Even before the MAHA Strategy was published, on March 10, 2025, Secretary Kennedy directed FDA to explore rulemaking to close the GRAS "loophole," allowing manufacturers to introduce new ingredients into the food supply without notifying FDA. According to an item in FDA's spring 2025 Unified Agenda, FDA intended to release in October 2025 a proposed rule that would amend the GRAS regulations to require the mandatory submission of GRAS notices for the use of human and animal food substances that are purported to be GRAS. Food substances listed or affirmed as GRAS for the intended use by regulation, or for which FDA has already issued a "no questions" letter, would be exempt. The proposed rule would clarify that FDA maintain and update the public-facing GRAS notice inventory for all substances that are the subject of mandatory GRAS notices for their conditions of intended use. The proposed rule would also clarify the process under which FDA would determine that a substance is not GRAS. Removing the self-affirmed GRAS pathway would shift responsibility for demonstrating safety from the manufacturer to FDA, resulting in longer lead times, more supporting data and extensive documentation, and a greater need for transparency and compliance for new products and ingredients. FDA had not submitted a proposed rule to the Office of Management and Budget (OMB) for review before the government shutdown on October 1, 2025, ensuring that FDA would not meet the October 2025 deadline for the rulemaking. While the shutdown may have slowed FDA's rulemaking process, stakeholders should monitor for the proposed rule and be prepared to submit comments promptly.

Although James J. Jones, FDA's first Deputy Commissioner for the unified Human Foods Program (HFP), resigned from FDA in February 2025 because of "indiscriminate" layoffs within HFP, HFP continued to enhance its regulatory approach to food chemical safety. In May 2025, FDA launched a post-market chemical review program. Until now, FDA has conducted post-market reviews on a case-by-case basis, often in response to citizen petitions or new scientific evidence. Under this new program, FDA plans to roll out the following initiatives:

- A modernized, evidence-based prioritization schedule for reviewing existing chemicals. FDA released a draft prioritization framework for ranking food chemicals based on risk on June 18, 2025. This tool uses a multi-criteria decision analysis (MCDA) approach to prioritize chemicals for further review;
- A final, systematic post-market review process shaped by stakeholder input; and
- An updated list of chemicals under review. FDA initially published a list in July 2023, which was updated in March 2024, and then updated on August 19, 2025, following the new review program plan. FDA plans to continue to share information about the status of this work on its public website as part of the agency's push for greater transparency.

1. Food and Food Additive Safety

Under MAHA, FDA took a series of actions to address food chemicals, particularly color additives, in 2025. Specifically,

- On January 16, 2025, FDA revoked its approvals to use the synthetic color additive FD&C Red Dye No. 3 in all food products after **January 15, 2027**, and in ingested drugs after **January 18, 2028**. On January 17, 2025, FDA approved a naturally derived color additive, myoglobin, for use in certain ground meat and poultry analogue products.

- On April 22, 2025, FDA and HHS announced a series of new measures to phase out all petroleum-based synthetic dyes from the nation's food supply. Two synthetic food colorings, Citrus Red No. 2 and Orange B, will be specifically revoked. FDA's September 2025 list of chemicals under FDA review annotates Citrus Red No. 2 as approved only to be used for coloring orange peels and is not intended for use in processed oranges. FDA also proposed revoking authorization for Orange B in food on September 17, 2025. FDA also plans to work with industry to phase out additional food colorings, including FD&C Red No. 40, FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Blue No. 1, FD&C Blue No. 2, and FD&C Green No. 3. FDA is tracking voluntary commitments from the food industry to remove petroleum-based food dyes.

- On May 9, 2025, FDA approved three food color additives derived from natural sources: calcium phosphate (white), butterfly pea flower extract (dark blue), and galdieria extract (blue). FDA published updates to these approvals on August 21, 2025 (calcium phosphate (white), butterfly pea flower extract (dark blue), and galdieria extract (blue)).

- On July 14, 2025, FDA issued a "Dear Manufacturer" letter encouraging voluntary removal of FD&C Red No. 3 "as soon as is practically possible," notwithstanding the **January 15, 2027**, and **January 18, 2028**, regulatory deadlines.

- On August 19, 2025, FDA updated its list of select chemicals under FDA review to provide more insight into the status of FDA's post-market assessments of chemicals in the food supply. In doing so, it added nine additional chemicals: butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), azodicarbonamide (ADA), FD&C Blue No. 1, FD&C Blue No. 2, FD&C Green No. 3, FD&C Red No. 40, FD&C Yellow No. 5, and FD&C Yellow No. 6. FDA also stated that it was expediting its review of chemicals included in previous updates, such as phthalates, propylparaben, and titanium dioxide.

Driven by the MAHA initiative and state-level actions, we anticipate FDA's continued rapid push through 2026 to phase out most petroleum-based synthetic food colorings from the U.S. food supply. The effort will involve a combination of voluntary industry actions, formal rulemaking, and new approvals for natural alternatives.

2. Food Contact Substances

Major regulatory updates by FDA in 2025 related to food contact substances (FCS) centered on the phaseout of certain per- and polyfluoroalkyl substances (PFAS), mandatory pre-market review of new food substances, and the introduction of a new, proactive post-market review framework for food chemicals.

Following the completion of the voluntary phase-out commitments announced by FDA in February 2024, on January 6, 2025, FDA announced its determination that 35 Food Contact Notifications (FCN) related to substances containing PFAS and used as grease-proofing agents in paper and paperboard food packaging are no longer effective. According to FDA, the manufacturers or suppliers have ceased production, supply, or use of the FCSs for their intended use. Industry had until June 30, 2025, to use existing stocks of food paper packaging. FDA has developed a screening method to detect grease-proofing agents containing PFAS in paper and paperboard packaging to allow the agency to monitor the market for these FCSs that are no longer authorized in food packaging.

FDA approved not less than 29 FCNs with effective dates in 2025, which is lower than the number approved in 2024 (48 FCNs) and 2023 (47 FCNs). Approved FCNs include:

- Silicate(2-), hexafluoro-, disodium, reaction products with lithium magnesium sodium silicate (Type 1, containing fluorine) (Chemical Abstracts Service Registry Number® (CAS RN®) 85085-18-3), lithium magnesium sodium silicate (Type 2, without fluorine) (CAS RN 53320-86-8) used as a barrier additive;

- Microfibrillated cellulose pulp (CAS RN 65996-61-4) used in various applications; and

- 2-Methyl-4-isothiazolin-3-one (CAS RN 2682-20-4) and dimethyl dicarbonate (CAS RN 4525-33-1) used as antimicrobials or preservatives.

On July 30, 2025, FDA released its Expanded Decision Tree (EDT) chemical toxicity and risk screening tool. The tool was evaluated through external peer review in March 2024 and FDA plans to engage stakeholders and the public for further feedback on the tool. The tool is intended to provide

a consistent, systematic, and science-based approach to support evaluation of the safety of chemicals in food, based on their structure and estimated toxicity. This tool is one example of FDA's progress regarding its New Approach Methods (NAM) and uses a modernized version of the Cramer Decision Tree tool. FDA expects the EDT tool to be used eventually in both pre- and post-market evaluations of chemicals in food.

3. Modernization of Cosmetics Regulation Act of 2022

On December 29, 2022, Congress passed and former President Biden signed the Modernization of Cosmetics Regulation Act of 2022 (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 Good Manufacturing Practices (GMP), another process that has, until now, been entirely voluntary. MoCRA also introduces changes to the labeling and mandates actions on specific ingredients.

FDA's progress in 2024 implementing MoCRA was slow, and FDA provided enforcement discretion until June 2024 to accommodate administrative hiccups. Cosmetic product facility registrations and cosmetic product listings were due July 1, 2024. Under MoCRA, cosmetic product facilities are required to renew their facility registration every two years, meaning that facilities that registered in 2024 will need to renew their registration in 2026. A responsible person must list each marketed cosmetic product and product ingredients with FDA and update the information annually.

Based on MoCRA, companies must have documented safety substantiation for their cosmetic products, demonstrating their safety under intended conditions of use, by March 2025. Starting in April 2025, facilities were required to report serious adverse effects to FDA within 15 business days and maintain records for six years. FDA launched the FDA Adverse Event Reporting System (FAERS) Public Dashboard for Cosmetic Products, a real-time adverse effect reporting dashboard, on September 12, 2025, to facilitate this mandatory requirement.

FDA's spring 2025 Unified Agenda includes the following cosmetic rules. The dates listed are those in the Unified Agenda items, published on September 4, 2025, but the government shutdown will likely delay them:

- A proposed rule that would prohibit the use of formaldehyde and formaldehyde-releasing chemicals in hair smoothing and straightening products. FDA intended to publish a notice of proposed rulemaking (NPRM) by December 2025;
- A final rule regarding standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products. FDA intends to issue a final rule in **March 2026**;
- A proposed rule that would set forth the minimum current GMP (CGMP) requirements for human drug products compounded by an outsourcing facility. FDA intends to publish an NPRM in **May 2026**; and
- A proposed rule that would identify certain substances as fragrance allergens and would require the disclosure of fragrance allergens on the labels of cosmetic products. FDA intends to issue an NPRM in **May 2026**.

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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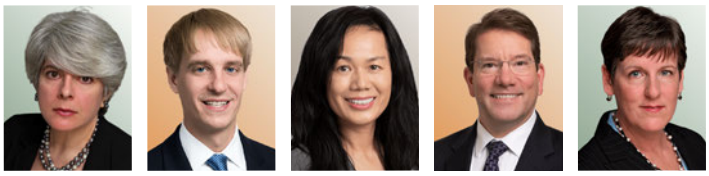

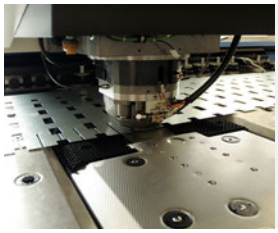

The manufacturer of a product is the most likely candidate for "producer" status, but online retailers, wholesalers, distributors, and others besides the manufacturer may meet the definition depending on the product and the underlying facts.

F. EXTENDED PRODUCER RESPONSIBILITY

1. Overview

Extended producer responsibility (EPR) legislation is intended to incentivize certain "producers" to incorporate environmental considerations into the design of their products by shifting financial and management responsibility to those producers for waste reduction and recycling efforts. EPR for plastic packaging and plastic products, in particular, has taken root in the United States within the last five years and EPR programs are increasingly implemented at the state level.

In 2025, Washington state and Maryland implemented state EPR programs for plastic products and packaging, joining a growing pool of states (Oregon, Colorado, California, Maine, and Minnesota) already placing various requirements onto producers based on jurisdiction. There is not currently a federal framework for EPR. Additional information and commentary on EPR developments in 2025 are included within our July 16, 2025, memorandum, "A Snapshot of Extended Producer Responsibility (EPR) in 2025."

Elements of existing state programs overlap in many ways, but no two programs are the same in form or function. Each respective program's requirements are based on the underlying policy goals associated with plastic end-of-life, such as recycling infrastructure development, accessibility, pollution reduction, and education. As EPR is a funding mechanism to accomplish these goals, the heart of each existing EPR program is the development of private funding sources that are created by shifting the cost burden of plastic waste management from the state onto producers.

EPR regulations consider a range of entities under the definition of "producer." While definitions are nuanced and vary from state to state, "producer" is commonly defined as a person who manufactures a product that uses covered material, and who owns or is the licensee of the brand or trademark under which the product is used in a commercial enterprise, sold, offered for sale, or distributed in the state. Typically, the manufacturer of a product is the most likely candidate for "producer" status, but online retailers, wholesalers, distributors, and others besides the manufacturer may meet the definition depending on the product and the underlying facts.

EPR programs are implemented through a body called a "producer responsibility organization" (PRO), comprised of producers within the respective state. This means that the programs are largely self-governing. PROs have considerable say in how EPR requirements are interpreted and applied, including, in some circumstances, what products fall into the scope of the program and how producers must report information for compliance. While most states have a process through which producers can form a PRO and apply to be the governing entity for that state's EPR program, the PRO Circular Action Alliance (CAA) has taken the lead in most states. CAA offers considerable resources for producers through its website, including information about programmatic deadlines that producers must meet in each state.

2. Implications for Stakeholders

State-level developments in 2025 and years prior are setting the stage for increasingly nuanced and demanding compliance processes in the coming years for producers selling or distributing packaged products in multiple jurisdictions. As noted, each EPR program is built to accomplish state-specific goals. The end result of these state-specific efforts includes a web of different deadlines, program scopes, and reporting requirements. Moving into 2026 and beyond, stakeholders subject to EPR requirements will need to track carefully the myriad of requirements for each jurisdiction that has an EPR approach. More states likely will adopt EPR programs in coming years, almost certainly creating additional red tape and organizational compliance challenges for entities tasked with identifying products and data within the scope of

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these various programs and fulfilling reporting requirements that are inconsistent between states.

Stakeholders that do not themselves manufacture a plastic product should also be aware that different program scopes may be broad enough to encompass certain related items. Any product contained in rigid plastic, film plastic, or other resin types, for example, may be subject to EPR requirements in certain states. As more states implement EPR programs, it is possible that entities not currently subject to EPR requirements may fall under the scope of a future program.

The following comparison illustrates the complexity of determining how EPR programs apply from state to state. California and Oregon's EPR requirements are generally broad and extend to both business-to-business (B2B) transactions and tertiary packaging (including packaging used to protect items during transport). Both California and Oregon's programs contain a process through which producers can seek an exemption from EPR requirements for certain packaging materials.

Colorado does not have a similar process but provides specific B2B, industrial, and commercial use exclusions and exemptions. One Colorado exclusion, for example, requires that the customer is located at a site where the packaging will be disposed of in a residential wastestream. Colorado's exemptions are narrow in scope, however, and most shipments to customers in Colorado are likely to fall under EPR requirements.

As EPR continues to evolve, comprehensive compliance across state programs will become increasingly difficult. Due to the range of stakeholders implicated by these regulations, public interest in EPR, and the complexity of compliance, a federal framework may be on the horizon. Many stakeholders have expressed interest in a federal EPR program to bring national consistency to the compliance process and to remove the complexity associated with navigating many different programs simultaneously. Our November 22, 2024, memorandum, "EPA Releases National Strategy to Prevent Plastic Pollution," includes discussion of a U.S. Environmental Protection Agency (EPA) proposed strategy that would seek, in part, to implement a national EPR program.

Of additional note is action taken by a group of EPR stakeholders, the National Association of Wholesaler-Distributors (NAW) to challenge the legality of Oregon's EPR program. NAW filed its complaint on July 30, 2025, in the U.S. District Court for the District of Oregon against Oregon's Department of Environmental Quality (DEQ), the Oregon Environmental Commission (OEC), and the state Attorney General. The complaint alleges that Oregon's EPR program is unconstitutional on four separate grounds. This is a space that other states implementing similar EPR programs should monitor closely. More information about this ongoing litigation is included in our November 14, 2025, memorandum, "Litigation under Oregon's Packaging EPR Law: What Producers Should Know."

Until and unless a federal program is established or individual state programs are stayed, tracking compliance deadlines across jurisdictions should remain a top priority for stakeholders. 2025 saw effective dates that obligate compliance actions from producers, and producers will face dates associated with other obligations in the future as well. For example, in July 2025, producers subject to Minnesota's EPR program were required to register with a PRO, and Oregon's program officially began the same month.

Other deadlines are more immediate. The first of California's two deadlines for 2023 materials reporting was November 15, 2025. Under Colorado's program, producers registered under CAA were required to pay dues by January 1, 2026. These and other requirements can all be found on CAA's website.

B&C attorneys, scientists, and regulatory specialists assist clients to track emerging trends, evaluate risks, and develop comprehensive compliance plans to stay ahead of evolving EPR requirements. Find out more about B&C's EPR services at https://www.lawbc.com/practices/extended-producer-responsibility-epr/

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G. MICROPLASTICS REGULATION

Microplastics and nano-plastics, generally defined as plastic particles smaller than five millimeters in diameter, increasingly are the subject of significant attention, regulatory action, and litigation. The ramp-up in legislative and regulatory initiatives related to microplastics largely stems from emerging research, resulting public concern, and media interest. A growing body of data correlating microplastic contamination of bodily organs with adverse health effects is fueling the interest.

1. United States

Federal lawmakers are taking steps to build a regulatory framework for microplastics. Two bipartisan federal bills, the Microplastics Safety Act (MSA) and the Plastic Health Research Act (PHRA), introduced July 17, 2025, and August 5, 2025, respectively, seek to gain additional data related to microplastics to assist with regulatory decision-making. The MSA would require the federal government to research potential health impacts of microplastics exposures on children's health, the endocrine system, cancer, chronic illness, and reproductive health. The PHRA would create a funding mechanism for research projects into microplastics exposures and impacts. Currently, the Microbead-Free Waters Act of 2015, implemented by the U.S. Food and Drug Administration (FDA), is the only federal law aimed at regulating and limiting microplastics that are intentionally added to cosmetic products. Lawmakers are no longer focusing only on intentionally added microplastics, however, as both the MSA and the PHRA would cover all microplastics, including unintentionally added microplastics that result from plastic degradation.

Congress is not the only federal body seeking to understand better these particles. Ongoing U.S. Environmental Protection Agency (EPA) and National Oceanic and Atmospheric Administration (NOAA) research seeks to quantify and understand the presence of microplastics in the natural environment and to identify potential causal links between these particles and various environmental and public health concerns. The White House's Make America Healthy Again (MAHA) Report, published on May 16, 2025, notes microplastics as a potential risk to children's health and concludes that additional public and private research is necessary to quantify and understand that risk.

At the state level, dozens of bills were introduced in the 2024 and 2025 legislative sessions that target, restrict, or otherwise regulate microplastics and products that may degrade into microplastics. Many states in previous years have enacted laws banning single-use plastic bags and other products that have the potential to degrade into microplastics and cause contamination. More recent efforts seek to understand public health and environmental risks posed from microplastics.

Current state-level microplastics regulation is a patchwork system of different requirements, start dates, enforcement mechanisms, and scope that varies from jurisdiction to jurisdiction. The following examples illustrate the variety in scope and substance of state microplastics law. New Jersey seeks to limit microfibers entering wastewater streams through regulating washing machine sales. Illinois seeks to restrict hotels and similar establishments from providing small personal care plastic containers (*e.g.*, mini shampoos) to guests. Other states propose to research impacts of microplastics in groundwater and drinking water. In addition to existing state requirements, many states during the 2024-2025 legislative session introduced bills targeting microplastics that did not, ultimately, become law. State interest in microplastics regulation will continue to grow and states are expected to continue to consider legislation and regulations seeking to restrict various products and/or support research on microplastics impacts.

2. Litigation

While microplastics regulation remains nascent, litigation expanded rapidly in 2025 as plaintiffs' attorneys and advocacy groups tested new legal theories. Most early suits have focused on consumer protection, product labeling, and public nuisance rather than direct toxic tort claims, reflecting the current scientific uncertainty around health impacts.

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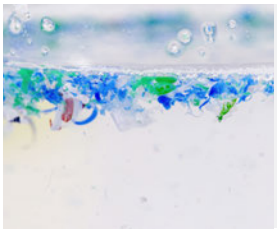
ARTICLE

"Microplastics Regulation Revs Up in 2025, More Action Expected in 2026," *Chemical Processing*, November 10, 2025



Although scientific and regulatory frameworks remain incomplete, microplastics litigation is shifting from speculative to strategic, with early filings already shaping public perception and corporate disclosure practices.

Emerging claims include:

- Consumer deception and greenwashing: Plaintiffs allege that manufacturers falsely market products as "safe," "recyclable," or "biodegradable" despite evidence of microplastic shedding or persistence. Class actions filed against major consumer brands, including bottled water, food packaging, and personal care product companies, challenge these claims. Notable cases include *Miller v. Phillips North America LLC* (claiming that Bisphenol A (BPA) free labels are misleading), *Cheslow v. S.C. Johnson & Son* (alleging that Ziploc® bags are marketed as microwave safe but fail to warn consumers about microplastics leaching into contents when heated), and *Sierra Club v. Exxon Mobil* (claiming that plastic producers created a public nuisance by promoting disposable plastics despite known issues surrounding plastic disposal issues).

- Public nuisance and environmental contamination: Municipalities and non-governmental organizations (NGO) have brought nuisance claims against plastics and packaging producers, asserting that microplastics pollution burdens municipal waste and water systems. A notable example is *Sierra Club v. ExxonMobil Corp.* (N.D. Cal. 2025), which survived a motion to dismiss on nuisance grounds related to microplastics discharges.

- Product liability and exposure claims: A small number of cases allege that food-contact or heat-resistant plastics release microplastics at levels posing health risks. These suits have so far been dismissed for lack of scientific evidence linking specific exposures to injury, but they underscore the growing interest in microplastic toxicology.

Courts have generally been skeptical of these claims, often citing the absence of established causation data and standardized analytical methods. Nonetheless, several dismissals have been without prejudice, allowing refiling as scientific evidence matures. The wave of "testing and labeling" suits closely parallels the trajectory of per- and polyfluoroalkyl substances (PFAS) litigation a decade earlier, suggesting that microplastics could evolve into the next major mass-tort category once analytical and epidemiological tools advance.

Looking ahead to 2026, companies in the packaging, consumer products, and materials sectors should anticipate:

- Heightened scrutiny of environmental marketing claims, particularly around recyclability, compostability, and "microplastic-free" labeling;

- Increasing use of public nuisance and natural resource damage theories by state and municipal plaintiffs; and

- Greater involvement of insurers and investors as risk assessments begin to incorporate microplastics exposure and disclosure obligations.

Although scientific and regulatory frameworks remain incomplete, microplastics litigation is shifting from speculative to strategic, with early filings already shaping public perception and corporate disclosure practices.

3. EU

The European Union's (EU) focus on reducing microplastic releases intensified in 2025, marking a shift from policy ambitions to practical implementation. Building on Commission Regulation (EU) 2023/2055, which restricts *intentionally added* synthetic polymer microparticles under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), the European Commission issued explanatory guidance in April 2025 to help companies interpret borderline cases, including glitter and encapsulated fragrances. The guidance clarified scope, testing criteria for degradability and solubility, and labeling and reporting obligations that began October 17, 2025, when the first supplier information requirements took effect.

At the same time, the European Parliament and Council approved a new regulation on preventing plastic pellet (nur-

dle) losses across the supply chain — addressing a major source of *unintentional* microplastic emissions. The new regulation introduces mandatory risk-management plans, operator training, and certification for large pellet handlers, with phased implementation expected beginning 2026.

Member states (MS) are also moving forward with microplastics regulations. France's filter requirement for new washing machines, effective January 1, 2025, is the first national rule targeting microfibers from textiles. Other MSs, notably the Netherlands, continue to push for EU-wide controls on microplastics released from tires, paints, and textiles, aligning with the Commission's Zero Pollution Action Plan goal of a 30 percent reduction in microplastic emissions **by 2030**.

Taken together, these measures signal that the EU's approach to microplastics is expanding beyond intentionally added particles to encompass entire life-cycle pathways of plastic loss. 2025 marked a transition year from legislative design to early compliance — one likely to shape global standards for microplastic management and reporting.

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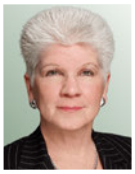

H. NANOTECHNOLOGY

1. U.S. Environmental Protection Agency

Manufacturers and importers of new nanoscale materials in 2026 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 June 2023 and May 2024, EPA reviewed three low volume exemptions (LVE) that included a graphene material, an indium phosphide zinc sulfide quantum dot, and a graphene oxide material. EPA denied two of the LVEs, and at that time, one was pending review. Additionally, EPA had under review 14 premanufacture notices (PMN), 12 of which are for multi-walled carbon nanotube chemical substances and two of which are for silica materials. EPA reported that it was still reviewing the 14 nanomaterial substances for potential risks to human health and the environment. According to EPA, it was also reviewing one significant new use notice (SNUN) for a single-walled carbon nanotube for potential risks to human health and the environment.

Since January 2005, EPA has received and reviewed 300 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.

Although EPA has not yet published any of the data submitted under its January 2017 TSCA Section 8(a) rule requiring one-time reporting on certain nanoscale materials in commerce, according to OECD's *Tour de Table*, EPA continues to receive notifications. Between June 2023 and May 2024, EPA received notification of two nanoscale substances based on metal oxides that met the reporting criteria, bringing the total number of notifications to 89. Under the final rule, nanoscale substances already reported as new chemicals and nanoscale substances that do not have unique or novel properties are exempt from reporting. The *Tour de Table* states that most reporting to date has been for metals or metal oxides. More information on the 2017 reporting rule is available in our January 12, 2017, memorandum, "EPA Promulgates Final TSCA Reporting and Recordkeeping Rule for Nanoscale Materials."

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

In the final weeks of the previous Administration, on December 18, 2024, the National Nanotechnology Initiative (NNI) announced the availability of the *National Nanotechnology Initiative Environmental, Health, and Safety Research Strategy: 2024 Update* (2024 Update). The 2024 Update builds on the initial 2011 strategy, laying out a comprehensive, integrated approach reflecting current opportunities to enable responsible nanotechnology innovation. The 2024 update is organized into two sections:

- Part A, "Progress toward the 2011 Environmental, Health, and Safety (EHS) Research Strategy Goals." This section assesses the progress and current research needs for six core research areas.
- Part B, "Future Directions." This section addresses the scope of the research strategy going forward and expands on the unmet needs from Part A, adding specific actions to support the new needs and challenges identified.

The 2024 Update states that the National Nanotechnology Coordination Office (NNCO), on behalf of NNI, will coordinate the Nanotechnology Environmental and Health

Implications (NEHI) Working Group's efforts to engage stakeholders in organizing "a dynamic and agile response" to the following challenges:

- Addressing the 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;
- Increasing engagement with the international nanosafety community; and
- Expanding public engagement in the responsible development of nanotechnology.

Created in 2003 under the 21st Century Nanotechnology Research and Development Act (Pub. Law No. 108-153), NNI was tasked with establishing the goals, priorities, and metrics for evaluation for federal nanotechnology research, development, and other activities; investing in federal research and development (R&D) programs in nanotechnology and related sciences to achieve those goals; and providing for interagency coordination of federal nanotechnology R&D and other activities. Its future is uncertain, however, given the proposed reduction in its budget for 2026. According to a September 2025 Congressional Research Service (CRS) report entitled *Federal Research and Development (R&D) Funding: FY2026*, the current Administration's fiscal year (FY) 2026 budget requested $131.1 million for NNI, a 63.8 percent decrease from the FY 2024 funding of $231.4 million. The report notes that Congress may consider whether to support the Administration's priorities through specified funding and may also consider what levels of funding are sufficient to support research priorities identified in the statute. Yet without a congressional champion, it is unlikely that NNI will receive funding close to its FY 2024 levels.

3. Canada

On July 23, 2025, Environment and Climate Change Canada (ECCC) announced the release of the *Plan of Priorities*, a multi-year plan that outlines upcoming priorities for the assessment of chemical substances. The Plan includes a list of more than 30 substances and substance groups prioritized for assessment and includes new or expanded activities to help assess, control, and manage risks posed by substances. As reported in our October 8, 2024, blog item, the Proposed Plan includes nanoscale silver, nanoscale zinc oxide, nanoscale forms of nickel oxide, and nanoscale forms of titanium dioxide (nano-TiO_2). The July 2025 Plan includes nanoscale silver, nanoscale zinc oxide, and nano-TiO_2. According to the *Work Plan*, ECCC began working on the assessments for nanoscale zinc oxide and nano-TiO_2 in summer 2025. ECCC plans to begin the assessment for nanoscale silver in **summer 2026**. ECCC will update the Work Plan to adjust expected timelines.

B&C has been at the forefront of the nanotechnology science-policy debate and has been instrumental in the progress of and integration of nanotechnologies. Our involvement includes helping to guide policy, legislative, and regulatory processes. We offer an experienced group of professionals with unique skills, capabilities, and strong relationships with decision-makers. Find out how we can help your company navigate the challenges and benefits posed by current and emerging uses of nanotechnologies and engineered nanoscale materials: B&C's Nanotechnology Practice.

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I. BIOTECHNOLOGY

1. Coordinated Framework for the Regulation of Biotechnology

Due to President Trump's rescission of 19 executive actions, including former President Biden's September 2022 Executive Order (EO) 14081, "Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy," the overall reduced funding for federal agencies, and the current Administration's lack of support for biotechnology, it is unlikely that an update to the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) will be seen any time soon. Last updated in 2017, the 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. 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."

2. National Security Commission on Emerging Biotechnology

Despite the lack of support for biotechnology from the White House, in April 2025, the bipartisan National Security Commission on Emerging Biotechnology (NSCEB) announced the availability of its final report and action plan, "urging Congressional action to bring the full weight of American innovation to improve and maintain U.S. global leadership in biotechnology." Created by the National Defense Authorization Act for Fiscal Year 2022 (Pub. Law No. 117-81), NSCEB was charged with reviewing advancements in emerging biotechnology and related technologies that will shape current and future activities of the U.S. Department of Defense. NSCEB's final report and action plan includes recommendations within the following six pillars for action:

- Pillar 1: Prioritize biotechnology at the national level;
- Pillar 2: Mobilize the private sector to get U.S. products to scale;
- Pillar 3: Maximize the benefits of biotechnology for defense;
- Pillar 4: Out-innovate our strategic competitors;
- Pillar 5: Build the biotechnology workforce of the future; and
- Pillar 6: Mobilize the collective strengths of our allies and partners.

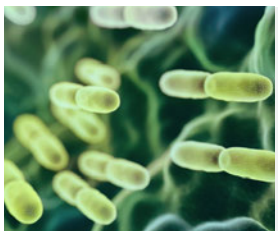
More information on NSCEB's final report and action plan is available in our April 25, 2025, blog item.

As reported in our July 2, 2025, blog item, NSCEB announced on July 1, 2025, two surveys to gather input to modernize U.S. biotechnology product regulation and create simpler, faster, science-based pathways to market. According to NSCEB, the input from the surveys for pharmaceutical products and industrial, food, agricultural, and other products will guide follow-on work to its April 2025 final report. NSCEB sought "concrete, actionable ideas across sectors, including defense, industrial products, food, agriculture, and healthcare."

3. U.S. Department of Agriculture

On December 2, 2024, the U.S. District Court for the Northern District of California granted summary judgment in part to plaintiffs, vacating and remanding the Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient (SECURE) rule to USDA. *Nat'l Fam. Farm Coal., et al. v. Vilsack* (No. 3:21-cv-05695-JD). As reported in our May 18, 2020, memorandum, the SECURE rule shifted the regulatory focus from the process to the end product, exempted certain genetically engineered (GE) plants that could have been developed through conventional breeding techniques, and created a streamlined Regulatory Status Review (RSR) process to create a quicker assessment of plant-pest risks for new GE plants. USDA's Animal and Plant Health Inspection Service (APHIS) announced on December 10, 2024, the re-establishment of the regulatory and nonregulatory processes under the pre-May 2020 framework, "including pathways for authorizing regulated activities, commercializing products, and providing compliance oversight for products of biotechnology." More information on the court's decision is available in our December 5, 2024, blog item.

In keeping with its pre-2020 approach, APHIS restarted the Am I Regulated process. If stakeholders are unsure whether



In 2026, APHIS intends to issue an interim final rule that will create exemptions from USDA's regulations for plants and microbes that are already subject to EPA regulation and products USDA previously reviewed and deregulated.

an organism developed using genetic engineering meets the definition of a "regulated article," they may submit an "Am I Regulated" inquiry. On March 3, 2025, APHIS began accepting petitions for nonregulated status according to APHIS biotechnology regulations at 7 C.F.R. Part 340 (2019). Developers whose modified plant meets the definition of "regulated article" can petition for nonregulated status by providing relevant information, data, and publications that substantiate that the modified plant is unlikely to pose a greater plant pest risk than the unmodified plant from which it was derived. APHIS published a February 2025 "*Petition User Guide with Reference To 7 CFR Part 340 — Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe are Plant Pests*" that provides more information on the specific requirements and instructions on how to apply. APHIS "encourage[s] developers to request a pre-submission consultation to review the information APHIS needs to evaluate a petition and reach a decision." Requests for a pre-submission consult may be sent to BRS.Petitions@usda.gov. More information is available in our February 28, 2025, blog item.

To ensure that the petition process aligns with recent developments related to the National Environmental Policy Act (NEPA) and APHIS' authority in the Plant Protection Act (PPA), in July 2025, APHIS announced updated practices for reviewing petitions seeking a determination of nonregulated status for organisms altered or produced through genetic engineering (modified organisms) under 7 C.F.R. Part 340. Beginning July 9, 2025, when evaluating a petition seeking a determination of nonregulated status that meets the information requirements in 7 C.F.R. Section 340.6, APHIS will first determine whether the modified organism is subject to regulation under 7 C.F.R. Part 340 and the plant pest provisions in the PPA. If APHIS determines that a modified organism is unlikely to pose a greater plant pest risk relative to its comparator and, as such, is not a plant pest, APHIS will end its review. APHIS notes that because it lacks jurisdiction over the modified organism, it must issue a determination that the modified organism is not subject to 7 C.F.R. Part 340. APHIS intends to continue to publish its draft reviews for petitions in the *Federal Register* for public review and comment before making a final determination about a modified organism's regulatory status.

According to the Petition for Determination of Nonregulated Status database, as of September 30, 2025, APHIS' Biotechnology Regulatory Services (BRS) has made a nonregulated status determination for a GE maize and a GE orchid in 2025. Although APHIS had prepared and published draft environmental assessments (EA) for each of these products, consistent with its July 9, 2025, announcement, it terminated work on the EAs.

BRS issued an updated Notification User Guide on June 12, 2025, to include current links to federal and state noxious weed lists, and provided detailed requirements for submitting an electronic notification via the APHIS eFile system. According to APHIS' Biotechnology Permits and Notifications website and APHIS' eFile database, APHIS has received and reviewed over 700 permit applications and notifications between December 3, 2024, and September 2025.

In 2026, APHIS intends to issue an interim final rule that will create exemptions from USDA's regulations for plants and microbes that are already subject to EPA regulation and products USDA previously reviewed and deregulated and provide a permitting exemption for certain modified organisms that are commonly used in laboratory development of products of biotechnology. APHIS intends to issue the interim final rule in **March 2026** with comments due in **May 2026**. Other expected rulemakings in 2026 include:

- National Bioengineered Food Disclosure Standard; Update of the List of Bioengineered Foods: As reported in our April 4, 2024, blog item, consistent with 7 C.F.R. Section 66.7, the Agricultural Marketing Service (AMS) published a request for information (RFI) soliciting comments on new bioengineered crops that have potentially reached the market, including dry edible beans, wheat, cowpea, golden rice, purple tomato, and plums. According to the spring 2025 Unified Agenda item, comment analysis and research would determine which bioengineered foods would be appropriate to add to

the List of Bioengineered Foods in the National Bioengineered Food Disclosure Standard. APHIS intends to publish a notice of proposed rulemaking (NPRM) in **April 2026**.

- National Bioengineered Food Disclosure Standard; Text Message Disclosures: As reported in our April 23, 2024, blog item, in response to a September 2022 U.S. District Court of Northern California order remanding 7 C.F.R. Sections 66.106 and 66.108 to AMS without vacatur for further consideration, AMS published an RFI in April 2024. In accordance with the court's ruling, AMS intended to publish a proposed rule in December 2025 that would amend the National Bioengineered Food Disclosure Standard to remove the standalone text message disclosure option found at 7 C.F.R. Section 66.108 and to add language to the electronic or digital disclosure option found at 7 C.F.R. Section 66.106, requiring an accompanying bioengineered symbol or on-package text as defined in Sections 66.104 and 66.102 when an electronic or digital link disclosure is made. APHIS plans to publish a final rule in **April 2026**.

4. 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.

In 2025, FDA continued reviewing applications regarding foods from cultured cells through a voluntary pre-market consultation process. As of July 24, 2025, FDA has completed three pre-market consultations, including cultivated pork fat cell, cultivated salmon cell, and cultivated chicken cell products. Anticipate FDA to continue this effort in 2026, as well as update its public inventory to complete pre-market consultations for human food made with cultured cells. In accordance with the 2019 formal agreement, this is a joint regulatory oversight between FDA and USDA's Food Safety and Inspection Service (FSIS). FDA oversees the cell collection, growth, and differentiation phases, while USDA FSIS takes over at the harvest stage for livestock and poultry.

In September 2025, as specified in the spring 2025 Unified Agenda, under the guidance of the Make America Healthy Again (MAHA) Commission, FDA proposed a new rule that would require mandatory submission of all Generally Recognized as Safe (GRAS) notices. This action, part of a broader effort to remove self-GRAS determinations, would create a new formal submission process for food ingredients, including those from cultured cells.

Following approval in 2025 of a GE Atlantic salmon (AquaAdvantage salmon), which grows faster than conventional salmon, a genetically altered pig (GalSafe pig) that eliminates a rare allergy triggering sugar molecule in 2020, and a gene-edited beef cattle (PRLR-SLICK) with shorter hair and improved heat-tolerance in 2022, FDA approved in April 2025 a gene-editing pig that creates resistance to porcine reproductive and respiratory syndrome (PRRS) (PRRSV-Resistant pig) for meat production. FDA uses the term Intentional Genomic Alteration (IGA) in animals to describe and categorize changes made to an animal's genomic DNA produced using modern molecular technologies, which may include random or targeted DNA sequence changes, including nucleotide insertions, substitutions, or deletions, and has issued two guidance documents in this regard. In May 2024, FDA Center for Veterinary Medicine (CVM) released Guidance for Industry (GFI) #187A, "Heritable Intentional Genomic Alterations in Animals: Risk-Based Approach," describing FDA's risk-based regulatory approach to the oversight of heritable IGAs in animals. In January 2025, FDA issued GFI #187B, "Heritable Intentional Genomic Alterations in Animals: The Approval Process," detailing how the approval process applies to heritable IGAs in animals.

5. 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 Federal Food, Drug, and Cosmetic Act (FFDCA). 88 Fed. Reg. 34756. Under the final rule, EPA exempted the following materials/residues from tolerance requirements in 2025:

- *Bacillus thuringiensis* Cry1B.34 protein in or on the food and feed commodities of corn when used as a PIP in corn (90 Fed. Reg. 10597);
- *Bacillus thuringiensis* strain EX 297512 when used as an inert ingredient (diluent and/or carrier) in pesticide formulations applied for seed treatment (90 Fed. Reg. 10599);

- *Beauveria bassiana* strain BW149 in or on all food commodities when used in accordance with label directions and good agricultural practices (90 Fed. Reg. 10603);

- *Vadescana* double-stranded RNA (dsRNA) in or on honey and honeycomb when used according to the label and good agricultural practices (90 Fed. Reg. 25155); and

- *Bacillus thuringiensis* Cry1A.2 and Cry1B.2 proteins in or on food and feed commodities of soybean when used as a PIP in soybean (90 Fed. Reg. 37797).

EPA received four new PIP applications between March and May 2025 (90 Fed. Reg. 36433), including a citrus plant expressing three active ingredients (proteins) derived from spinach defensin proteins (CTV-SoD2, CTV-SoD2-1, and CTV-SoD2*) to combat citrus greening disease, a Carrizo Rootstock product CarriCea T1 containing the Cas9 gene and the specific gRNA sequences to knockout three specific gene functions (Accelerated Cell Death 2 (ACD2), Lethal Leaf Spot 1 (Lls1), and Papain-Like Cysteine Protease (PLCP)) to reduce susceptibility to plant pathogens and leaf spot diseases, a soybean plant expressing two new insecticidal proteins (Cry1B.34.1 and Cry1B.61.1) conferring resistance toward lepidopteran pests, and a cotton plant expressing three new insecticidal proteins (Cry1Da_7, Cry1B.3, and Vip3Cb1.1) conferring resistance toward lepidopteran pests. EPA also approved two new corn PIP events, DAS 1131 expressing Cry1Da2 and DP 910521 expressing Cry1B.34, in early 2025.

Regarding GE animal regulation, on August 21, 2025, EPA published a white paper outlining considerations for designing GE mosquitoes and proposed analytical methods for determining the absence of novel proteins in the saliva of GE female mosquitoes. The FIFRA Scientific Advisory Panel (SAP) released the paper for public comment and peer review. Prior to the government shutdown, EPA was scheduled to hold a virtual FIFRA SAP meeting on November 3-5, 2025. Once the meeting is rescheduled, EPA will use the feedback to guide the future regulatory framework for registering GE pest animals under FIFRA. We anticipate that EPA will issue final policies and guidance regarding the risk assessment of GE mosquitoes in 2026.

Following its December 2023 approval of the first sprayable dsRNA product, Calantha, to control the Colorado potato beetle on potato crops, on September 25, 2025, EPA approved the second sprayable dsRNA product, Vedescana, to control Varroa mites, a major threat to honey bees. dsRNA products work by targeting a specific gene in the target pests through RNA interference, a highly specific mechanism that poses minimal risk to humans, bees, and other nontarget organisms. EPA is committed to supporting the development of innovative products that give the agricultural community the tools it needs to ensure a safe and abundant food supply, and we expect that, in 2026, EPA will continue its work on evaluating and approving new biopesticide registrations, including those using dsRNA technology, based on the established frameworks.

Once again, EPA's review of biotechnology notices is a bright spot in the new chemicals review process. EPA received 13 Microbial Commercial Activity Notices (MCAN) during fiscal year (FY) 2025, and EPA completed review of 11 of them, all completed within the statutory 90-day review period. EPA found each to be low concern for health and environmental effects, so 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 FY 2025.

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

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J. BIOBASED AND RENEWABLE CHEMISTRY

Less than two months into the current Administration, President Trump rescinded 19 executive actions, including former President Biden's September 2022 Executive Order (EO) 14081, "Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy." 90 Fed. Reg. 13037. According to the White House's March 14, 2025, fact sheet, EO 14081 "funneled Federal resources into radical biotech and biomanufacturing initiatives under the guise of environmental policy." As reported in our September 13, 2022, blog item, Biden's EO created a National Biotechnology and Biomanufacturing Initiative to accelerate biotechnology innovation and grow America's bioeconomy across multiple sectors in industries such as health, agriculture, and energy.

Revoking the EO and removing federal resources fails to recognize the critical role that the biobased chemicals and renewable products industry plays in building a resilient, dependable, and sustainable system that fosters innovation to develop a circular economy. 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.

While the Executive Branch has pulled back its support of biotechnology and biomanufacturing initiatives, Congress has offered glimmers of hope. In April 2025, the bipartisan National Security Commission on Emerging Biotechnology (NSCEB) announced the availability of its final report and action plan, "urging Congressional action to bring the full weight of American innovation to improve and maintain U.S. global leadership in biotechnology." Following the release of NSCEB's final report and action plan, on June 26, 2025, Representatives Chrissy Houlahan (D-PA) and Stephanie Bice (R-OK) announced the formation of the BIOTech Caucus. According to Houlahan's June 26, 2025, press release, the Caucus' mission "is to advance bipartisan policy solutions to keep the United States at the forefront of global biotechnology leadership, to engage and learn from sector leaders, and to build awareness and bioliteracy among Members of Congress." Joining Co-Chairs Houlahan and Bice on the BIOTech Caucus are Vice-Chairs Representatives Ro Khanna (D-CA), Gus Bilirakis (R-FL), Jake Auchincloss (D-MA), and Pete Sessions (R-TX). The goals of the BIOTech Caucus are to:

- Advance, support, and champion legislation to bolster U.S. biotechnology leadership and strengthen the domestic bioeconomy;
- Convene regular meetings to strategize efforts and learn from key officials and industry leaders; and
- Hold public events in coordination with experts and stakeholders with the goal of building bioliteracy across the U.S. Capitol and calling attention to the urgency of action.

The press release states that the BIOTech Caucus' focus areas include:

- Biosecurity: Federal investments in emerging biotechnology are critical for U.S. national security;
- Innovation: Congress must advance smart policies to elevate bio-innovation among agencies, streamline regulations, and foster a supportive business ecosystem; and
- Opportunity: Congress has a responsibility to help develop and support the bio-workforce of the future, invest across sectors, and encourage a competitive, robust, and growing domestic bioeconomy.

More information on the BIOTech Caucus is available in our June 30, 2025, blog item.

B&C's Biobased and Sustainable Chemicals Blog is the leading source of information on regulatory and legal developments involving renewable chemicals, green chemistry, and efforts to create more sustainable, circular products. Visit and subscribe at https://www.lawbc.com/brand/bioblog.

On August 1, 2025, Senators Elissa Slotkin (D-MI), Amy Klobuchar (D-MN), Joni Ernst (R-IA), and Pete Ricketts (R-NE) reintroduced the bipartisan Biomanufacturing and Jobs Act (S. 2654). According to Slotkin's August 6, 2025, press release, the bill would "create jobs and create new markets for our farmers by strengthening the United States Department of Agriculture (USDA) BioPreferred program, a program designed to promote the use of domestic biobased products." The legislation would:

- Strengthen markets for farmers while also supporting good-paying manufacturing jobs;
- Allow the Secretary of Agriculture to set acceptable price premiums under the BioPreferred program;
- Require each federal agency to increase its procurement of biobased-only contracts or biobased volume purchased under those contracts; and
- Improve reporting of biobased products that are purchased through online federal procurement systems.

Representatives Mark Alford (R-MO), Angie Craig (D-MN), Kristen McDonald Rivet (D-MI), and Mark Messmer (R-IN) introduced companion legislation (H.R. 4832) in the House on August 1, 2025.

Given the difficulty Congress has in passing critical legislation such as appropriations bills, it remains to be seen whether it will provide the resources necessary to carry out NSCEB's action plan or support USDA's BioPreferred program. Please see our Biotechnology Chapter for more information on NSCEB's action plan.

Under the previous Administration, 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 U.S. Environmental Protection Agency (EPA) launched enhancements in 2024 to an online search tool for its Recommendations of Specifications, Standards, and Ecolabels for Federal Purchasing, 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.

Under the current Administration, the FAR will be amended "to ensure that it contains only provisions that are required by statute or that are otherwise necessary to support simplicity and usability, strengthen the efficacy of the procurement system, or protect economic or national security interests," in line with EO 14275, "Restoring Common Sense to Federal Procurement." 90 Fed. Reg. 16447. On May 2, 2025, Russell T. Vought, Director of the Office of Management and Budget (OMB), issued a memorandum to the heads of executive departments and agencies regarding "overhauling" the FAR.

The types of government coordination, policy reform, and dialogue with industry stakeholders supported by previous administrations are vital to move the biobased chemicals and renewable products markets forward in 2026.

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

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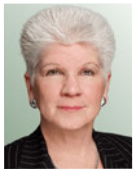
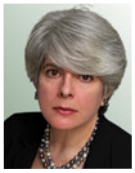
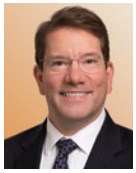


There were two significant decisions issued in 2025, adding to the list of successful challenges to OEHHA's Prop 65 warning requirements because such warnings are invalid restrictions on commercial speech in violation of the First Amendment of the Constitution.

K. PROPOSITION 65

1. Short-Form Warning Changes

The California Office of Environmental Health Hazard Assessment's (OEHHA) changes to the short-form warning requirements under Proposition 65 (Prop 65) were effective as of January 1, 2025. This commenced the three-year implementation period — until **January 1, 2028** — for businesses to transition to these revised short-form warning requirements. 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. Indeed, the new short-form warning text as set forth in Section 25603 and discussed in detail in our memorandum results in the near elimination of the short-form warning option.

To minimize disruption to existing inventory, the regulations allow products labeled with the short-form warning language as the regulations allowed before this transition period expires (**January 1, 2028**) to be sold indefinitely without the need for relabeling. Despite this indefinite sell-through period, companies in 2025 began the process to implement the extensive changes required for the short-form warning and will continue to do so in 2026. Companies that currently use the short-form warning but have not commenced the transition process are encouraged to do so. Time is needed to determine how to modify warning language and the placement of the warning to be compliant with the new requirements and to consider changes that may be needed for online or catalog sales. Companies also can explore options as to why a warning may not be required (*e.g.*, exposure to a Prop 65-listed substance is below a safe harbor level).

PODCAST:
Prop 65 "Short Form" Warning Requirements — A Conversation with Lisa R. Burchi

2. First Amendment Lawsuits

There were two significant decisions issued in 2025, adding to the list of successful challenges to OEHHA's Prop 65 warning requirements because such warnings are invalid restrictions on commercial speech in violation of the First Amendment of the Constitution. On August 12, 2025, the U.S. District Court for the Eastern District of California (District Court) issued an Order granting a permanent injunction and declaratory relief sought by the Personal Care Products Council (PCPC), asserting that OEHHA's requirement for Prop 65 warnings related to titanium dioxide in cosmetics and personal care products violated the First Amendment. *The Pers. Care Prods. Council v. Bonta*, No. 2:23-cv-01006-TLN-JDP (E.D. Cal. 2025).

In reviewing the constitutionality of the Prop 65 warning, the District Court had previously issued a temporary injunction in this case, and found its analysis remained generally the same. In short, the court found that there had been no "sufficient developments in the evidentiary record or to the warning language since [the Court's] prior Order to change the conclusion that the Prop 65 warning for Listed Titanium Dioxide is not purely factual." While the court stated that each sentence of the warning may be true factually, "'the totality of the warning' is nonetheless misleading and [OEHHA's] argument 'ignores the reality that it conveys the core message' that using a cosmetic or personal care product containing Listed Titanium Dioxide poses a risk of cancer in *humans*." The District Court likewise continued to find that the warning language was not "uncontroversial" because there was "robust scientific debate" regarding titanium dioxide's carcinogenicity in humans.

Since the compelled commercial speech was not factual and uncontroversial, an "intermediate" level of scrutiny applied, and the court found OEHHA's needed "substantial interest" in requiring the warning did not meet this higher constitutional standard.

The court also found that the factors it used to grant the temporary injunction were largely the same to grant a permanent injunction, and the court granted declaratory relief by stating the court "DECLARES that Prop 65's warning as applied to Listed Titanium Dioxide is unconstitutional and violative of the First Amendment of the United States Constitution." The result of this case moving forward is to halt all pending or prospective lawsuits and related actions filed against companies for failure to provide the Prop 65 warning.

A similar result and win for industry can be found in the Order issued on May 2, 2025, with regard to Prop 65 warning requirements for acrylamide in certain foods. A different judge from the same District Court as the titanium dioxide case similarly issued a permanent injunction that enjoins enforcement against any person regarding Prop 65 warning requirements with respect to dietary acrylamide, and "DECLARES that Proposition 65's warning requirement is unconstitutional as applied to dietary acrylamide." One point of interest in this Order was the court's response to OEHHA's argument that there is no legal obligation to provide a Prop 65 warning since a business can make a determination that a warning is not required when exposures are below a safe harbor level. In response, the court states:

> The Court disagrees. There is a presumptive burden on all businesses who sell foods containing dietary acrylamide to include a Prop 65 warning unless they can affirmatively establish their product falls below the no significant risk level. *See* Health & Safety Code § 25249.10(c). Even if a business attempts to exempt their product by proving it contains acrylamide levels below the no significant risk level, . . .incurring attendant costs to do so, there is no guarantee they will then be free from litigation challenging their compliance with Prop 65's warning requirements. As other courts in this district have observed, the nature of Prop 65's enforcement scheme creates a constant, credible threat of enforcement by private enforcers because "to bring suit . . . a private plaintiff need only credibly allege that a product has some of the chemical at issue, not that the amount of the chemical is harmful or that it exceeds this level." … *National Ass'n of Wheat Growers v. Becerra* ("*Wheat Growers*"), 469 F. Supp. 3d 1247, 1256 (E.D. Cal. 2020). Indeed, as "one California Court of Appeal has explained," the "instigation of Proposition 65 enforcement actions is 'easy – and almost absurdly easy at the pleading and pretrial stages.'" *Id.* (quoting *Consumer Def. Grp. v. Rental Hous. Indus. Members*, 137 Cal. App. 4th 1185, 1215 (2006)). Thus, the availability of a no significant risk level exemption effectively offers businesses no reprieve from Prop 65's warning requirement, as businesses risk "[f]acing enforcement actions . . . even if a business can prove that its product is not a cancer risk." *Id.* Businesses must either utilize a Prop 65 warning on their products or run the risk of incurring substantial costs in defending against enforcement actions. Given Prop 65's enforcement scheme, a business's decision to adopt a Prop 65 warning is compelled by the State whether or not their product exceeds the no significant risk level. (Footnote omitted.)

The court also found that an alternative Prop 65 warning for acrylamide that OEHHA issued in an October 2024 final regulation and has been in effect since January 1, 2025, was likewise unconstitutional. In issuing the new warning, OEHHA stated in its Final Statement of Reasons 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." The court disagreed, and in its Order, states that the "New Warning is not purely factual and uncontroversial" and continues to "convey the one-sided message that people who consume dietary acrylamide will increase their risk of cancer without sufficient scientific consensus to support that message."

These cases are important and have potentially significant influence and implications for all companies facing Prop 65 warning requirements for other substances where the underlying scientific basis for listing also may be unclear and controversial. These cases also may not yet be over, as the California Attorney General's office has filed an appeal in at least one of these cases so ongoing activity may be expected in 2026.

3. Priority List for New or Updated NSRLs

On June 5, 2025, OEHHA announced it had developed a priority list of substances for which it would be developing

new or updated No Significant Risk Levels (NSRL). An NSRL is a "safe harbor" level for substances listed under Prop 65 as known to California to cause cancer. Companies that can establish that exposure to a chemical in a product is at or below an NSRL are exempt from Prop 65 warning requirements.

OEHHA states that it "focuses development of NSRLs based on public health considerations, coordination with other OEHHA programs that also develop cancer potency values, and availability and quality of scientific data." The four substances on the priority list for NSRL development are:

- Ethylene oxide;
- 1-Bromopropane (1-BP);
- Diethanolamine; and
- Vinyl acetate.

When OEHHA has a proposed NSRL for any of these substances, which could be expected in 2026, it will post a Notice of Proposed Rulemaking (NPRM) and seek public comments. OEHHA states it will update its priority list "as NSRLs are completed or new priorities arise."

OEHHA does not develop NSRLs for all substances listed under Prop 65 so the fact that it has announced it is developing NSRLs for these substances is potentially encouraging. It should be noted that companies are not without options if there is no OEHHA-established NSRL because OEHHA has adopted regulations (Articles 7 and 8) providing guidance for businesses to calculate their own NSRL (or maximum allowable dose levels (MADL) for chemicals listed as causing birth defects or other reproductive harm) in the absence of an OEHHA-established safe harbor level.

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, or Lisa R. Burchi, lburchi@lawbc.com, if you would like to discuss how our team can assist you with Proposition 65 and other U.S. state regulatory compliance measures.

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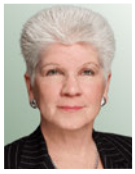
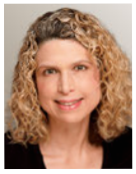


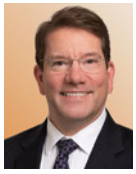


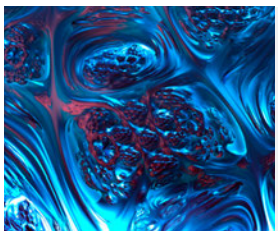

All chemical stakeholders will need to navigate the many uncertainties of policy shifts and global trade in the context of what some are projecting to be sluggish chemical demand and a keen focus on enhancing efficiencies.

II. KEY GLOBAL CHEMICAL MANAGEMENT PREDICTIONS

A. Introduction

2026 will be eventful for chemical stakeholders. Against a backdrop of continued commercial churn, volatility, and geopolitical and trade tensions, all chemical stakeholders will need to navigate the many uncertainties of policy shifts and global trade in the context of what some are projecting to be sluggish chemical demand and a keen focus on enhancing efficiencies. 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 2026. The European Chemicals Agency (ECHA) is expected to issue its opinion on the EU's comprehensive per- and polyfluoroalkyl substances (PFAS) restriction in 2026, with adoption by the European Commission (EC) in **2027**. Many initiatives, including EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) revisions, Cosmetic Products Regulation (CPR) revisions, and activity under the Ecodesign for Sustainable Products Regulation (ESPR), will command attention. While the European Union Deforestation Regulation (EUDR) will not become effective in 2025 as originally expected, actions in anticipation of its effective date in **late 2026** will be closely watched. Further progress will be made in the New Year as the EU and United Kingdom (UK) continue to address divergence between EU and UK REACH programs. Globally, the relentless evolution of chemical governance programs generally, especially in South America, will continue to pick up steam.

1. EU

The EC considered important revisions to EU REACH in 2025 and engaged in public consultations. Final adoption and implementation of revisions is expected in 2026. PFAS restrictions will also be the subject of significant attention in the EU in 2026, with consumer use applications being the primary target of review and prohibition. While broad implementation of the EUDR, including for larger operators and micro and small enterprises, has been delayed a year, its **late 2026** effective date looms large and is 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 are expected to pick up, given the maturation of the program and need for additional guidance on areas to improve. Look for continued intense focus on PFAS in 2026 and agreement on 2026 priority substances in the UK Rolling Action Plan, expected by **May 31, 2026.**

3. Asia/Pacific Rim

In Asia, look for incremental evolution in chemical inventory, reporting, and recordkeeping measures 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, were expected to be implemented in 2025 or **early 2026** and will impact companies that do business there. Similarly, Australia has picked up the pace on regulating PFAS, so look for PFAS initiatives there. These and other regulatory measures are all consequential and are discussed below, as is the United Nations (UN) Globally Harmonized System of Classification and Labelling 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

Evolution of Brazil's implementation of Brazil "REACH" is expected to dominate the industrial chemical scene in 2026. Most Central and South American countries have not established formal chemical inventories and generally have not adopted GHS for their respective Safety Data Sheet (SDS) programs. In 2026, countries will continue to make progress

in developing REACH-inspired regulatory programs. Several Central and South American countries are also developing regulatory programs relating to the regulation and labeling of hazardous chemicals that are expected to have a significant impact on entities doing business in the region. Industrial stakeholders will want to understand these developments to anticipate their impact on their operations.

Chemical management initiatives outside of the United States continue to evolve at a fast pace. Geopolitics and trade tensions, supply chain resilience, and regulatory and political developments make it essential to monitor these initiatives carefully.

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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 2026 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's Clean Industry Deal, introduced in her Political Guidelines for 2024-**2029**, faces challenges from across the political spectrum. Environmental groups view it as deregulation that weakens important Green Deal goals to benefit industry polluters. Industry and conservative politicians continue to raise concerns about unrealistic timelines for implementation of Green Deal measures and adverse effects on the competitiveness of EU industry due to implementation costs.

The European Chemicals Agency (ECHA) is expected to issue its opinion on the EU's comprehensive per- and polyfluoroalkyl substances (PFAS) restriction in 2026, with adoption by the EC anticipated in **2027**.

The Circular Economy Act, which is intended to unlock materials markets and drive circularity in the chemicals industry, is expected to be adopted by **late 2026**.

2. EU REACH

The EC released a significant proposal for the revision of Regulation (EC) 1907/2006 (Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)) to the European Parliament (EP) on April 3, 2025, which was followed by a period of public consultation. Final adoption of the proposal is expected by the end of 2025 with implementation of the revision expected in 2026 or **2027**. The focus of the REACH revision includes 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 authorization and restriction processes to align with ECHA's Strategy Statement 2024-**2028** and Integrated Regulatory Strategy 2024-**2028**. The REACH revision also provides clarification of testing requirements to align with the new Classification, Labelling and Packaging (CLP) Regulation hazard classes, particularly for endocrine disruptors. Polymer notifications, stronger risk controls, more robust enforcement, and accelerated regulatory processes are also being discussed.

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 15 substances in 2026 and for five substances in **2027**. ECHA's PFAS restriction proposal is currently under evaluation by ECHA's Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC). A second public consultation on the RAC and SEAC opinions is expected during the **first half of 2026**, paving the way for adoption of the PFAS restrictions by the EC in **late 2026 or 2027**. ECHA conducted a webinar on October, 30, 2025, "Consultation on PFAS draft opinion – Guidance for respondents."

The EC adopted the revised REACH Fee Regulation. Standard fees and charges for large companies have increased by 19.5 percent. Micro, small, and medium-sized companies

intending to submit REACH registrations or applications for authorization must apply for company size validation at least two months before submitting their dossiers. The verification process will apply from **February 5, 2027**.

The EU is committed to animal-free chemical safety evaluation and plans to issue a roadmap in **early 2026** with specific actions and milestones to reduce and eventually phase out animal testing. Concerns remain that currently available scientific methods are inadequate to replace animal testing completely without jeopardizing chemical safety. Ongoing method development and validation are likely to affect testing requirements in the future.

3. Cosmetics

An omnibus evaluation of the Cosmetic Products Regulation (CPR) (EC) 1223/2009 to reduce administrative burden was announced on July 8, 2025. The public consultation closed on October 14, 2025. A full evaluation of the Regulation is underway and is expected to be complete by the **second quarter of 2026**. The CPR revision is expected to 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.

In June 2025, the EC announced its intention to withdraw the Green Claims Directive (GCD) proposal (EU 2023/0085/COD) due to the EC's inability to reach consensus regarding its applicability to micro-enterprises (*i.e.*, companies with less than ten employees and annual turnover or balance sheet below two million euro). While the GCD proposal has not yet been withdrawn, it is uncertain whether agreement on certain exemptions for micro-enterprises can be reached. Although the fate of the GCD remains uncertain, the broader legislation, Directive (EU) 2024/825 on Empowering Consumers for the Green Transition (ECGT), entered into force on March 26, 2024, and MSs must implement it into national regulations by **March 27, 2026**. While the ECGT provides a level of consumer protection against broad, misleading, or unsubstantiated greenwashing claims, it lacks the GCD's specific measures and the requirement for verification of environmental claims by an independent, accredited third party.

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 (BPR), (EU) 528/2012. In 2026 and beyond, the EU biocides sector will be impacted by expiration of data protection for existing active substances, new requirements for endocrine disruptor data, and enforcement campaigns focused on online sales.

Data protection for existing active substances is set to expire by the end of 2025. Beginning January 1, 2026, companies can enter the EU market with biocidal products containing these existing active substances without purchasing access to the data generated by the companies that originally funded the studies. Companies must also submit all outstanding data on the endocrine disruptive properties of the active product by **December 31, 2026,** or face rejection of its dossier and removal of the product from the EU market.

In addition to the above, in 2026:

- Biocidal product renewals must be in new International Uniform ChemicaL Information Database (IUCLID) format by **July 1, 2026**; and
- Some silicone compounds and formaldehyde face new restrictions.

5. Plant Protection Products

The EU has proposed a new regulation, replacing Commission Regulation (EU) No 547/2011, to enhance plant protection products (PPP) labeling. This Regulation will be effective from January 1, 2026. The updates introduce digital labels, a colored scheme for identifying low-risk products, and harmonized risk communication phrases, aligning with the Farm to Fork Strategy.

Also by January 1, 2026, Regulation (EU) 2023/264 requires that all farmers and spray operators keep detailed records of all uses in electronic, machine-readable format for PPP and update these records within 30 days. These records must include:

- Product name and authorization number;
- Date and time of application, the dosage, and the size of the treated area;

The European Parliament officially extended compliance deadlines for the EUDR for the second time, by another year, making the new reporting deadline for large and medium operators December 30, 2026, and for small and microenterprises June 30, 2027.

- Geospatial identifiers of the application site; and
- Use information using the specified codes.

6. The Ecodesign for Sustainable Products Regulation

The Ecodesign for Sustainable Products Regulation (ESPR) (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.

In February 2025, the first Ecodesign Forum Meeting, which included MS expert groups, gave stakeholders an opportunity to raise concerns, and contributed to the development of Ecodesign rules, was held. The adoption and publication of the first ESPR and Energy Labelling Working Plan occurred on April 16, 2025.

ESPR implementation is in progress. The first step is to prioritize products or product groups, which is expected to continue in 2026, followed by development of specific product 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.

Both industry and environmental groups have expressed concerns regarding the ESPR. Industry is concerned that uncertainty remains regarding implementation, particularly the impact on specific products and the interface with other regulations, such as REACH. While environmental groups generally support the ESPR, there are concerns regarding implementation gaps, enforcement challenges, and scope limitations.

7. European Union Deforestation Regulation

The European Union Deforestation Regulation (EUDR) ((EU) 2023/1115) has been in force since January 1, 2024. On Wednesday, December 17, 2025, the EP officially extended compliance deadlines for the EUDR for the second time, by another year, making the new reporting deadline for large and medium operators **December 30, 2026**, and for small and microenterprises **June 30, 2027**. Additionally, due diligence reporting obligations have been simplified under the language implementing the delays. Bergeson & Campbell, P.C. (B&C®) and The Acta Group (Acta®) have tracked key implementation markers, including the EC's May 22, 2025, publication of low- and high-risk country designations. More information for entities preparing to go live can be found in our August 5, 2025, on-demand webinar, "Regulation Without Borders: The EUDR and the New Era of Global Due Diligence"; in our August 18, 2025, blog item, "The Hidden Risk of Diminished Environmental Data: Could the United States Lose Its 'Low-Risk' Status under the EUDR?"; and our September 18, 2025, podcast on "EUDR Issues — A Conversation with Claire Hansen."

The EUDR mandates that "relevant commodities" linked to deforestation — including cattle, cocoa, coffee, oil palm, rubber, soya, and wood — must not enter the EU market unless documented as "deforestation-free." Commodities are only subject to regulation if they are covered under EUDR Annex I, so companies that produce a product with one of the seven regulated commodities should check the listed relevant products to ensure their products are within

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scope of the Regulation. A central pillar of the EUDR is its Country Classification List, placing nations into low-, standard-, or high-risk categories based on governance quality, deforestation rates, and — critically — data transparency and reliability of operators within that nation.

In fall 2025, the EC signaled via letters and briefings that it would back a potential one-year postponement linked to concerns regarding the capability and readiness of the EUDR information technology (IT) system (built on the TRACES NT digital platform) used to file operators' due diligence statements.

The push to defer potentially has triggered strong reactions. Industry groups and major brands argue that another delay undermines investment certainty after two years of preparation. Others warn reopening the requirements to further reform could dilute the core mission and values of the Regulation. Media and non-governmental organization (NGO) coverage frame the delay as IT-driven, not geopolitically driven, though pressure from trading partners remains part of the backdrop.

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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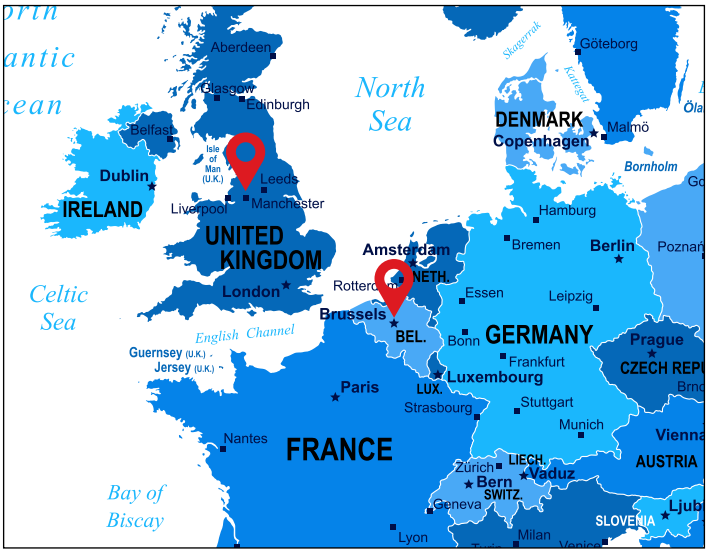

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C. UNITED KINGDOM/GREAT BRITAIN

1. Overview

Divergence between the United Kingdom (UK) and European Union (EU) regulations pertaining to chemicals will continue in 2026 and beyond. Companies worldwide must be aware of the significant implications for chemical regulatory compliance under several regimes, including the UK Registration, Evaluation, Authorisation and Restriction of Chemicals (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 2026.

2. UK REACH

Revisions of UK REACH will continue in 2026. The Department for Environment, Food and Rural Affairs (DEFRA) conducted a public consultation on its proposal to extend the UK REACH transitional registration submission deadlines. Three options were proposed, but DEFRA's preference is to extend the **October 2026**, **October 2028**, and **October 2030** transitional registration deadlines to **October 2029**, **October 2030**, and **October 2031**. 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 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 management 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. The proposal, which underwent public consultation in 2024, is currently under review by the government; implementation of the ATRm is expected to begin in 2026 but is expected to extend beyond the current **October 2026** transitional registration deadline.

Agreement on the 2026 priority substances in the UK Rolling Action Plan (RAP) 2025-**2027** is expected by **May 31, 2026**. Previously, it has focused on per- and polyfluoroalkyl substances (PFAS). The UK shares the worldwide mission to address concerns related to PFAS. The UK approach to PFAS regulation differs from the EU approach, using a more limited definition of PFAS and focusing on substances that are persistent degradation products of PFAS.

DEFRA implemented updated UK REACH fees on April 15, 2025. A fixed fee of £2,222 for registrations at all tonnage levels has been implemented for large enterprises, with reduced costs for small and medium enterprises (SME).

3. Cosmetics

The UK CPR continues to follow closely EU Regulation 1223/2009 on cosmetic products, but differences continue to develop, particularly with respect to animal testing requirements, safety assessments, 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 (SAG-CS). The UK banned 64 substances classified as carcinogenic, mutagenic, or reprotoxic (CMR) in January 2025, and additional bans or restrictions on the use of cosmetic ingredient substances are expected to continue in 2026. 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 UK and EU. 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 2026 and beyond. The revision of GB BPR, focused on updating information requirements for active substances and biocidal products in Annexes II and III of the BPR, went into effect on October 6, 2025. The changes include the addition of new endocrine disruptor tests; changes in mutagenicity, reproductive toxicity, and generational test requirements; a requirement for developmental neuro-

toxicity 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.

Under the UK BPR in 2025, there were 63 non-approvals of biocidal product active substance/product type combinations. As the normal expiry dates for approvals that were valid in GB at the end of the Brexit transition period approach in 2026 and beyond, companies are advised to monitor regulatory actions affecting their products closely.

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 L. Bergeson, lbergeson@actagroup.com, or Christine M. Palermo, Ph.D., DABT, cpalermo@actagroup.com.

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 (NAP), which was updated in 2025. It is important to note that environmental policy, including use of pesticides, is implemented at the country level by each of the four governments in the UK (*i.e.*, by the governments of England, Scotland, Wales, and Northern Ireland). While each government is responsible for and may make different decisions, each works with the Health and Safety Executive (HSE) to seek consistency whenever possible. While the UK approach to pesticide regulation may seem less strict than the EU's, the UK asserts that its efforts to reduce pesticide use outperform those of most countries, and resulted in a 60 percent by weight decrease in pesticide active substance use between 1990 and 2020, whereas global use increased by approximately 90 percent over the same period (https://www.gov.uk/government/publications/uk-pesticides-national-action-plan-2025/uk-pesticides-national-action-plan-2025-working-for-a-more-sustainable-future#annex-3-pesticide-facts-and-figures). Expect the UK to continue its ambitious goals toward further reduction in pesticide use in 2026 and beyond.

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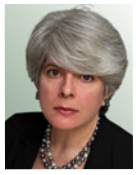
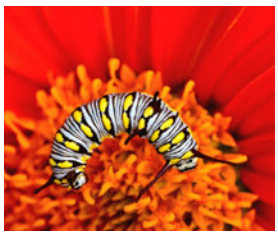


In 2026, the countries in this region will continue implementing legislative approaches and developing programs expected to impact significantly stakeholders in the region and beyond.

D. THE AMERICAS

1. Overview

The 2023 amendments to the Canadian Environmental Protection Act, 1999 (CEPA) were significant and with their implementation in 2025, stakeholders will begin to see what it means to have the right to a healthy environment. Canada published a final Plan of Priorities in 2025, outlining chemicals prioritized for assessment, and has already begun reviewing several substances, including fluoropolymers. It remains to be seen whether Canada will resume work 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), as there was no activity in 2025. Canada continued to address per- and polyfluoroalkyl substances (PFAS), distinguishing between the class of PFAS excluding fluoropolymers and fluoropolymers. We can expect continued regulatory developments in 2026, as these initiatives will have a significant impact on all business sectors.

Chemical substance legislation evolved last year in several Latin America countries. Brazil's Industrial Chemicals Regulation was enacted in November 2024, and the government is now working to implement the new law. In Colombia, manufacturers and importers had until May 2025 to report information regarding hazardous industrial chemical substances. The Colombian government created the National Inventory of Industrial Chemical Substances based on chemicals registered, publishing it in November 2025. In 2026, we anticipate that Colombia will issue a final regulation on the prioritization of chemical substances for risk assessment. With the issuance of Decree 1570/2023 in May 2023, Peru established a chemicals management framework. Publication of the implementing regulation in **early 2026** will establish deadlines for compliance.

In 2026, 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.

2. Canada

a. Chemical Control

The 2023 bill amending CEPA was ambitious, requiring that within two years, Canada 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. On July 23, 2025, Canada announced the release of the following documents implementing the 2023 amendments:

- Implementation Framework for the Right to a Healthy Environment under CEPA: The 2023 legislation, Strengthening Environmental Protection for a Healthier Canada Act (Bill S-5), requires that decisions made under CEPA respect the right to a healthy environment. The Implementation Framework sets out the meaning of the right to a healthy environment and provides guidance on how the Canadian government considers this right in the administration of CEPA. The Framework "provides a new lens for decision-making to support and encourage strong protection of both the environment and people who may be disproportionally impacted by pollution, now and in the future."

- Plan of Priorities: The Plan of Priorities outlines upcoming initiatives to address chemical substances in Canada. It includes a list of more than 30 chemical substances and substance groups prioritized for assessment and includes new or expanded activities to help assess, control, and manage risks posed by substances. In selecting and prioritizing the substances, Canada took into account the following key considerations:

  - Substances that are hazardous to human health and/or the environment, including carcinogens, mutagens, and reproductive toxicants, as well as endocrine disrupting substances;

- Substances impacting populations or environments that may be at increased risk, due to either greater exposure or greater susceptibility;
- Substances with the potential to contribute to cumulative risks;
- Very hazardous substances that are capable of long-range transport;
- Substances with known hazardous properties that are used in products available to consumers; and
- Potential substitutes for substances with known toxicity.

- Strategy to Replace, Reduce or Refine Vertebrate Animal Testing under CEPA: Health Canada (HC) and Environment and Climate Change Canada (ECCC) developed the Strategy to guide efforts toward the replacement, reduction, or refinement of vertebrate animal testing under CEPA.

The work plan on the Plan of Priorities provides timelines for initiating assessments. According to the work plan, in fall 2025, Canada began assessing pharmaceutical substances (testosterones), trichloroethylene, and fluoropolymers. In **fall 2026**, Canada intends to begin assessing terpenes of concern (linalool and citral). Canada will amend the work plan periodically to update its expected timelines.

The CEPA amendments also require the Minister of the Environment to compile and maintain a list that specifies substances that the ministers have reason to suspect are capable of becoming toxic or that have been determined to be capable of becoming toxic (the Watch List). In October 2024, ECCC and HC published the proposed Watch List Approach for a 60-day comment period, outlining how the two agencies would compile and amend the Watch List. The Approach describes the considerations and processes by which substances can be added and removed from the Watch List. ECCC and HC considered public comments and intended to publish the final Watch List Approach in 2025, with Watch List substances to be published in the CEPA Registry soon thereafter. Amendments to the Watch List will be an ongoing activity.

HC's regulatory initiative to address certain human health hazards of concern (HHHOC) in consumer chemical products is delayed. In October 2024, 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 HHHOCs 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 replace the CCCR with a risk-based framework based on GHS. HC announced in September 2025 that the engagement activity planned for this regulatory initiative is delayed and stated that it will provide more information when available. 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 intended to consult with affected stakeholders on certain topics of both proposals. HC's initiative to remove the consumer product exclusions appears to have stalled, however. Given the lack of activity during the past few years, it is unclear whether HC will take action in 2026.

b. PFAS

In March 2025, Canada published its final *State of Per- and Polyfluoroalkyl Substances (PFAS) Report* (State of PFAS Report) and proposed risk management approach for PFAS, excluding fluoropolymers. The State of PFAS Report concludes that the class of PFAS, excluding fluoropolymers, is harmful to human health and the environment and meets one or more of the criteria set out in CEPA Section 64. To address these risks, on March 8, 2025, Canada published a proposed order that would add the class of PFAS, excluding fluoropolymers, to Part 2 of CEPA Schedule 1. Adding the class of PFAS, excluding fluoropolymers, to Part 2 of Schedule 1 requires the Minister of the Environment and the Minister of Health to prioritize pollution prevention actions, which may include total, partial, or conditional prohibition, when managing its risks.

For the purpose of CEPA Section 77(6)(c)(i), ECCC proposed in March 2025 the following new risk management actions through a phased prohibition under CEPA:

- Phase 1: Prohibition of the use of PFAS, excluding fluoropolymers, not currently regulated in firefighting foams (FFF), due to high potential for environmental and human exposure. On September 26, 2025, ECCC began a public consultation on the proposed regulatory approach to prohibit the manufacture, import, use, and sale of PFAS in FFFs for those PFAS that are not already regulated. Comments were due November 25, 2025. EC plans a consultation in **spring 2027** on a proposed instrument for a minimum 60-day public comment period.

- Phase 2: Prohibition of the uses of PFAS, excluding fluoropolymers, not needed for the protection of health, safety, or the environment, which includes consumer applications. ECCC states that prioritization of uses for prohibition is based on, and will take into account, costs and benefits, availability of suitable alternatives, and other socio-economic considerations. Proposed uses to be regulated in Phase 2 include:

  - Cosmetics;
  - Natural health products and non-prescription drugs;
  - Food packaging materials, food additives, and non-industrial food contact products such as paper plates, bowls, and cups;
  - Paints and coatings, adhesives and sealants, and other building materials available to consumers;
  - Consumer mixtures such as cleaning products, waxes, and polishes;
  - Textile uses (including in personal protective equipment (PPE) such as firefighting turnout gear); and
  - Ski waxes.

- Phase 3: Prohibition of the uses of PFAS, excluding fluoropolymers, requiring further evaluation of the role of PFAS for which currently there may not be feasible alternatives and taking into consideration socio-economic factors, including:

  - Fluorinated gas applications;
  - Prescription drugs (human and veterinary);
  - Medical devices;
  - Industrial food contact materials;
  - Industrial sectors such as mining and petroleum; and
  - Transport and military applications.

At each phase of risk management, ECCC will consider exemptions, when necessary, with attention to feasible alternatives and socio-economic factors. Stakeholders will need to monitor for developments and provide detailed comments promptly as ECCC proposes to prohibit uses of PFAS, excluding fluoropolymers.

The State of PFAS Report notes that there is evidence to suggest that fluoropolymers may have significantly different exposure and hazard profiles when compared with other PFAS in the class. ECCC states that given information suggesting their differences from the other PFAS in the class, additional work on fluoropolymers is warranted. According to the work plan on the Plan of Priorities, Canada began assessing fluoropolymers in fall 2025. More information on the Final State of PFAS Report and proposed risk management approach is available in our March 24, 2025, memorandum.

c. Plastics

Reporting for Canada's Federal Plastics Registry began 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 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. Canada 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 2026. Some of the highlights from 2025 that will be relevant in 2026 include the following:

- Regulations Amending the Pest Control Products Regulations (Antimicrobial-Treated Class I Medical Devices): In 2025, PMRA held a public consultation on NOI2025-01, "Regulations Amending the Pest Control Products Regulations (Antimicrobial-treated Class I Medical Devices)." HC sought feedback on a proposed amendment to the Pest Control Products Regulations that would exempt Class I medical devices (*i.e.*, wheelchairs, manual toothbrushes, compression stockings) treated with antimicrobial preservatives, as well as the corresponding antimicrobials when used to treat those devices, from the Pest Control Products Act, as it has been determined that the risks of these products are adequately addressed under the Food and Drugs Act and the Medical Devices Regulations. The proposed amendment would expand the existing exemption for antimicrobial-treated Class II, III, and IV medical devices.

- Revised procedures for the registration of pesticides for emergency use: PMRA held a public consultation in 2025 on Regulatory Proposal PRO2025-03, "Consultation on Revised Procedures for the Registration of Pesticides for Emergency Use." PRO2025-03 contains proposed guidance for registering pesticides or amending registrations for emergency control of seriously detrimental pest infestations. Where currently registered pesticides and non-chemical control methods or practices are insufficient to address the pest outbreak, PMRA will consider requests for registration of pesticides for emergency use. PMRA intends the information proposed in PRO2025-03 to replace the current DIR2017-03, "Registration of Pesticides for Emergency Use: Revised Procedures," dated August 31, 2017.

- Policy on continuous oversight of pesticides: In October 2025, PMRA published a document describing its continuous oversight policy for pesticides registered in Canada, which builds on its existing surveillance and monitoring systems. According to PMRA, continuous oversight is a complementary process that supports but does not replace the requirements outlined in the Pest Control Products Act, including applications for registration, amendment, re-evaluation, and special review. Continuous oversight begins upon the initial registration of a pesticide active ingredient and continues throughout its regulatory lifecycle. PMRA notes that relevant information collected and retained could support major reviews such as re-evaluations or special reviews or could trigger earlier regulatory action based on an emerging risk, ensuring that new information is being considered between, and during, review activities.

3. Mercosur Bans CMR Substances in Cosmetics, Personal Hygiene, and Perfumes

In 2025, Mercosur, the trading bloc comprised of Brazil, Argentina, Paraguay, and Uruguay, issued a new resolution that revises the list of substances that cannot be used in cosmetics, personal hygiene, and perfume products once adopted into the national law of each member state (MS). MERCOSUR/GMC/RESOLUTION N° 07/25 (modifying Mercosul Resolution GMC N° 62/14) revises the list from 2014 to include bans on substances that are classified as carcinogenic, mutagenic, or reprotoxic (CMR) by European Union (EU) standards. The ban on substances would apply to products already on the market — not only new ones. Existing products would have 12 months to reformulate — except for those containing butylphenyl methylpropional and hydroxyisohexyl 3-cyclohexene carboxaldehyde, which would get 18 months.

As with all Mercosur technical resolutions, the requirements are not applicable to anyone until they are enacted into local law by each MS. Per the resolution, MSs are supposed to enact the resolution into local law by December 2025. In practice, the four countries in the bloc do not always meet Mercosur deadlines. It will be important to monitor national adoption in each of the four countries in 2026.

4. Argentina

On June 26, 2025, Argentina published Resolution 458/2025 approving the new Manual of Procedures, Criteria, and Scope for the authorization of establishments and/or individuals or legal entities involved in the chain of production in the local market, import, and/or export of phytosanitary products. The new measure went into effect on November 3, 2025.

The resolution's aim is to reduce red tape by creating a new system to bring crop-protection products to market based on sworn statements for companies that manufacture, import, or market such products. The scope is broad, covering registration and field trials, granting indefinite product authorizations (instead of requiring renewals), and allowing entry of products that already have approval from a select list of countries.

The resolution eases the regulatory pathway for both technical products and formulations that have been approved in the following jurisdictions:

- Australia;
- Canada;
- Swiss Confederation;
- EU;
- United States;
- Japan;
- New Zealand;
- United Kingdom; and
- Brazil.

The resolution expands application of the GHS to all phytosanitary products. Companies with registered or new products will have three years to adapt to the GHS. The resolution grants government agencies 90 days from the date the resolution goes into effect (*i.e.*, from November 3, 2025) to issue the new labeling rules for covered products based on the GHS. In 2026, expect the continued roll out of Resolution 458/2025, including these new labeling rules.

5. 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 to facilitate compliance with the new law.

Although not the first, Brazil is the largest country in the Americas to adopt a modern chemical control law. Brazil's adoption further cements the trend toward greater chemical regulation.

In 2026, expect the Brazilian government to continue with two key aspects of implementation: (1) enactment of the implementing regulation called for in the law; and (2) creation of the information technology (IT) system for the registration platform. Under the law, the government has 180 days to prepare regulations to implement the law and three years to establish an online registration system.

Brazil's multidisciplinary National Chemical Safety Commission (Comissão Nacional de Segurança Química (CONASQ)) met the deadline to produce a draft of the implementing regulation by May 2025. The work then moved back to the federal government for continued refinement before its expected publication in the coming months. The draft regulation sets out many of the important details left pending by the law, including the definition of exempt "low priority polymers," the criteria for prioritization, and the fees companies will need to pay to comply with the new obligations.

Under the law, companies operating in Brazil have three years after the launch of the submission platform to register chemicals manufactured or imported in quantities over one metric ton per year. 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

Brazil's ban on animal testing in cosmetics, personal care, and perfumes took effect on July 31, 2025, upon publication of Law 15.183/2025, amending two existing laws that regulate scientific use of animals for testing. Brazil now bans the use of live vertebrate animals in tests of personal hygiene products, cosmetics, and perfumes, or in testing of ingredients intended for those products, including in tests aimed at determining product hazards, efficacy, or safety.

Data from animal testing conducted after the ban went into effect cannot be used to authorize the marketing of personal hygiene products, cosmetics, perfumes, or their ingredients, except in cases where they were obtained to comply with national or foreign non-cosmetic regulations. Companies that used data from animal testing after the ban cannot label their products or packaging with statements, logos, or seals of "not tested on animals," "cruelty-free," or other similar expressions. Products and ingredients that were manufactured before the law came into effect can continue to be sold. The ban on animal testing will apply to new products.

c. PFAS

Brazil's Congress is considering the region's first national PFAS control bill, PL 2726/2023. First presented in 2023, the bill is moving through three committees in the Chamber of Deputies. As of October 1, 2025, the proposal was still in the first of these committees, the Environment and Sustainable Development Committee. The original text has been replaced by a substitute text sponsored by the Environment Committee's rapporteur. The substitute text calls for all levels of government (federal, state, and municipal) to implement the National PFAS Control Policy to: map, monitor, and control sources of PFAS emissions; set maximum and progressively stricter PFAS concentrations limits in water, air, soil, and food; regulate use, production, and disposal of PFAS; and promote health surveillance of exposed populations, among other activities. Companies and industries that use PFAS would be required to submit annual reports on use and disposal and adopt measures to reduce use and phase out their presence in products and processes — including monitoring and protecting from occupational exposures. The first substitute text included a requirement that companies label all products containing PFAS. That article disappeared from the second substitute text presented in 2025 despite the rapporteur's reference to it in her report to the Committee. It will be important to monitor the evolution of the proposal to determine whether the labeling requirement returns to the text of the bill.

Until now, PFAS have not dominated headlines in Brazil as they have in the United States or EU. If Brazil adopts this proposal, it will serve as an important precedent in the region and a harbinger of greater focus on this group of chemicals.

6. 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 implemented GHS (Rev. 7) and established a national inventory of hazardous chemicals. The GHS provisions of Decree No. 57 were phased in over six years following its adoption: industrial substances in 2022, non-industrial substances in 2023, industrial mixtures in 2025, and finally, non-industrial mixtures in **2027**.

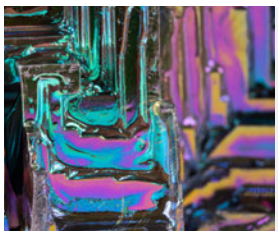
Likewise, the national inventory portion of Decree No. 57 is also being implemented in stages. Chile requires notification of chemicals that present a hazard per the GHS imported or manufactured at or above one metric ton per year. The first notification requirement for hazardous industrial substances was September 30, 2024. The first national inventory of those substances was approved in Resolution 07595/2024. For hazardous substances for non-industrial use, the first notifications were due August 30, 2025, and a first national inventory of those substances was expected by the end of 2025. Notifications for industrial substances contained in mixtures are due **August 30, 2027**. Notifications for non-industrial substances contained in mixtures are due by **August 30, 2029**.

The online system originally planned for notification malfunctioned in 2024, and officials revised the plan to require notification through use of a downloadable Excel file submitted via e-mail. That system continues to be the standard operating procedure for notification for the foreseeable future. Although Decree No. 57 does not envision a role for foreign manufacturers in the notification process, in practice, the use of the downloadable Excel files has allowed foreign companies to assist with completion of the forms to support local customers.

In 2026, companies that registered their hazardous industrial substances by the first notification deadline (*i.e.*, 2024) will need to re-notify those substances by **August 30, 2026**, with information on the products manufactured and/or imported in the preceding two calendar years (*i.e.*, 2024 and 2025). Notification is due every two years.

7. Colombia

On November 30, 2021, the Ministry of the Environment and Sustainable Development published Decree 1630/2021 regarding the comprehensive management of hazardous chemicals for industrial use, including risk management.



In 2026, expect Mexico to continue addressing industrial chemicals through its unique system of import and export controls based on the Regulation on Registration, Import and Export Authorizations, and Export Certificates for Pesticides, Plant Nutrients, and Toxic or Hazardous Substances and Materials.

The Decree established the National Registry of Industrial Chemical Substances (Registro Nacional de Sustancias Químicas de Uso Industrial). 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 had until May 30, 2025, to report the required information. The Colombian government created the National Inventory of Industrial Chemical Substances (Inventario Nacional de Sustancias Químicas de Uso Industrial (INSQUI)) based on chemicals registered, publishing it in November 2025.

On May 31, 2022, the Ministry of Commerce (MINCIT) issued Circular 18, announcing the launch of the online system to register chemicals, which has come to be known as the "INSQUI." Colombia has updated the official instruction guide to the INSQUI various times to provide new guidance on confidentiality claims, substance identity, and clarification on obligations for information being provided in the system.

In 2026, Colombia plans to prepare in final the draft regulation on prioritization of substances for future risk assessments. The risk assessment regulation would be a separate instrument with a projected completion date of **2027**. Also in 2026, government officials will begin to develop enforcement provisions and mechanisms to address noncompliance with the new chemical registration requirements.

8. Mexico

Mexico has made no significant progress in implementing a comprehensive chemical law. Despite embracing a National Integrated Policy for the Management of Chemical Substances (La Política Nacional Integral para la Gestión de Sustancias Químicas) in 2019, the country has not taken any steps toward the plan laid out in that document. In the Sectoral Programme for Environment and Natural Resources 2025-**2030** (PROMARNAT), the federal government set out its environmental agenda for the next five years. Nowhere did the program mention addressing the need for a national chemical management law or even chemical management more generally.

Instead, in 2026, expect Mexico to continue addressing industrial chemicals through its unique system of import and export controls based on the Regulation on Registration, Import and Export Authorizations, and Export Certificates for Pesticides, Plant Nutrients, and Toxic or Hazardous Substances and Materials (known as the "PLAFEST Regulation" — a shorthand/acronym derived from "Plaguicidas, Nutrientes Vegetales, Sustancias o Materiales Tóxicos" (pesticides, plant nutrients, toxic or hazardous substances/materials)). A series of agreements sets out the lists of substances that are subject to permits from various federal agencies with oversight over regulated substances (*i.e.*, SEMARNAT (Secretaría de Medio Ambiente y Recursos Naturales or Secretary of the Environment and Natural Resources), COFEPRIS (Comisión Federal para la Protección contra Riesgos Sanitarios or Federal Commission for Protection Against Sanitary Risks), and SENASICA (Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria or National Service for Agrifood Health, Safety, and Quality)).

9. 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 safety data sheets (SDS); 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. Since 2024, Peru has been working on a lengthy draft regulation to implement this Decree. The draft went through a public comment period in 2024. Since then, the draft has evolved significantly based on input from industry received during that process.

The draft regulation will include: a classification list 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 Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Manufacturers and importers will be responsible for registering substances with the Ministry of Environment (MINAM). Registration deadlines will vary based on classification.

Expect 2026 to be a busy time. Publication of the implementing regulation is expected in **early 2026**. Once published, the government will commence work on the new online registration system, and the deadlines for compliance will finally be known. Until then, the ability for foreign manufacturers to participate remains unclear. Guidance is expected as the online systems are deployed.

CONTRIBUTORS

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E. GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS

1. Overview

In 2025, the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) advanced with the release of its 11th revised edition (Rev 11) by the United Nations (UN). This revision introduced significant changes, including clarified classification criteria for aerosols and chemicals under pressure, new guidance for skin sensitization using non-animal test methods, and the addition of a global warming hazard class addressing substances with high global warming potential. The UN also added new provisions for identifying simple asphyxiants and refined precautionary statements to improve label and Safety Data Sheet (SDS) consistency. The UN published the electronic text in September 2025, marking a key milestone for global harmonization through implementation, depending on national adoption. Regionally, South Africa implemented Rev 10 in July 2025, Jordan mandated GHS labeling in June 2025, the European Union (EU) is expected to begin aligning its Classification, Labelling and Packaging (CLP) Regulation with Revs 8 through 11, and the United States continued phasing in its 2024 update aligning with Rev 7 and parts of Rev 8. 2025 changes emphasized greater global consistency, movement toward non-animal testing, and expanded environmental hazard recognition within the GHS framework.

2. United Nations

The 46th session of the UN Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals convened on 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 to the two preceding sessions. Documents of note include the consolidated list of draft amendments adopted at the 44th, 45th, and 46th sessions.

The 48th session was held July 7-9, 2025. Key topics for discussion included updates to the precautionary statements, bridging principles for health hazard classifications, and progress on non-animal testing methods. The Sub-Committee also reviewed proposals on digital labeling, simple asphyxiants, and endocrine disruptors.

The 49th session was expected to be held on December 3-5, 2025. According to the United Nations Economic Commission for Europe's (UNECE) website, this has been postponed to **July 8-10, 2026**, due to the staff shortage resulting from the UN liquidity crisis.

The UN published an electronic version of Rev 11 on September 12, 2025. The UN states that Rev 11 takes into account the amendments to Rev 10 (adopted by the Sub-Committee in December 2024), including: provisions further clarifying the classification criteria for aerosols and chemicals under pressure (Rev 11, Chapter 2.3); new guidance for classification for skin sensitization using non-animal methods (Rev 11, Chapter 3.4); classification for substances and mixtures that are hazardous by contributing to global warming (Rev 11, Chapter 4.2); further rationalization of precautionary statements to improve users' comprehensibility while taking into account usability for labeling practitioners; and a new section in Annex 11 with guidance addressing identification of simple asphyxiants.

3. U.S. OSHA, HCS 2024

On May 25, 2012, the U.S. Occupational Safety and Health Administration (OSHA) revised and updated the U.S. Hazard Communication Standard (HCS). On February 5, 2021, OSHA issued a notice of proposed rulemaking (NPRM) to amend the 2012 HCS to align with Rev 7. The NPRM included many other elements and also incorporated some aspects of Rev 8.

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, Appendices A - D, and the Trade Secret provisions. Most of these changes are to align with Rev 7 and elements of Rev 8. OSHA spent most of late 2024 updating supporting documents and providing guidance for the final rule. On October 9, 2024, OSHA issued a correction of several inadvertent errors to the final rule.

OSHA proposed to stagger implementation dates, similar to its approach with the HCS in 2012. To adhere to the 2024 final rule, 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 2026, with updates to guidance documents and further clarification on regulatory elements that are not part of the UN GHS approach. 2026 is set to be a major operational year for HCS 2024. Specifically for substances, manufacturers/importers should complete evaluations by **January 2026**, and employers should ensure updated training, labeling, and SDSs are in place by **July 2026**. While mixture-related obligations extend beyond 2026, preparations should ramp up this year to ensure timely compliance. Employers and supply chain partners should treat 2026 as a "go-live and transition" phase rather than merely a planning phase.

4. Canada, Health Canada HPR

On December 9, 2020, Health Canada (HC), Canada's federal agency responsible for health policy, published a proposal in the *Canada Gazette I* to update the Hazardous Products Regulation (HPR) from its current approach to align with Revs 5-7. 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. On January 4, 2023, HC published in the *Canada Gazette II* the revisions to the HPR. The changes include updates to the HPR to align with Rev 7, as expected, but also include elements from Rev 8 to align with the U.S. NPRM. The three-year transition period ended on December 14, 2025, after which all hazardous products must comply fully with the amended HPR. From December 15, 2025, onward, labels, SDSs, and classifications must meet the amended HPR requirements. 2026 will be the first full "post-transition" year and is expected to see a surge in compliance activity, increased scrutiny from suppliers/importers of hazardous materials, more stakeholder queries, and a potential influx of supply chain changes as companies catch up.

5. Brazil

Brazil first implemented the GHS in 2009 based on Rev 4. The Brazilian Association of Technical Standards (Associação Brasileira de Normas Técnicas, or ABNT) contained the specific implementation 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: changing the SDS name to "*Ficha com Dados de Segurança* (FDS)," allowing a Quick Response (QR) code on the label to access FDS content, and requiring Section 1 of the FDS to 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 and ended on July 3, 2025. The "new" NBR 14725:2023 became mandatory as of July 4, 2025. In 2026, many companies likely will be updating SDSs, labels, classification systems, training, and supply chain documents to reflect the new standard. 2026 is likely to be the year of uptake, enforcement, and refinement.

6. Chile

The Ministry of Health (MoH) and the Ministry of Environment (MoE) published on February 9, 2021, Decree 57, that approved the Regulation on the Classification, Labelling, and Notification of Chemical Substances and Mixtures. The Regulation aligns with Rev 7 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 was three years later on 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. 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 the newly enacted notification requirements.

7. China

Set forth under China's overarching goal of safely managing hazardous chemicals, as specified in the Regulations on the Safety Management of Hazardous Chemicals (State Council Order No. 591), and to align with Rev 8, China's Ministry of Industry and Information Technology (MIIT) released the revised mandatory standard GB 30000.1-2024 on July 24, 2024. The revised standard became effective 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). Adoption of GB 30000.1-2024 is a significant step toward enhancing chemical safety and regulatory compliance in China and facilitating global safety standard alignment for chemical safety management.

On June 30, 2025, China's State Administration for Market Regulation (SAMR) published GB 30000.30-2025, Specifications for Classification and Labeling of Chemicals – part 30: Desensitized Explosives. This standard specifies the classification, identification, and labeling of desensitized explosives, and is aligned to GHS Rev 10. GB 3000.30-2025 will become effective on **July 1, 2026**.

On August 1, 2025, SAMR issued its new mandatory national standard for Restriction of Hazardous Substances (RoHS), GB 26572-2025, establishing concentration limits for hazardous substances, labeling requirements, and classification management for electrical and electronic products sold, produced, or imported in China. This new standard will become effective on **August 1, 2027**, and will require companies to audit existing products for hazardous substances, update labeling systems to meet new requirements, and invest in eco-friendly materials and processes to ensure compliance with the tightened limits on hazardous substances.

To standardize and enhance dangerous-goods management, on March 28, 2025, SAMR and the Standardization Administration published updates for two national standards, GB 12268-2025 (List of Dangerous Goods) and GB 6944-2025 (Classification and Code of Dangerous Goods). Both standards were initially published in 1990, underwent revisions in 2005 and 2012, and their updates became effective on October 1, 2025. The 2025 updated standards align with the 23rd UN Model Regulations on the transport of dangerous goods and provide standardized information on classifying, packaging, labeling, and transporting dangerous goods.

Regarding food safety standards, on March 27, 2025, the National Health Commission (NHC) and SAMR jointly issued GB 7718-2025 (General Standard for the Labeling of Prepackaged Foods) and GB 28050-2025 (General Standard for Nutrition Labeling of Prepackaged Foods), two mandatory national food safety standards that will become effective on **March 16, 2027**. These updated standards introduce mandatory labeling of major allergic substances and details regarding ingredient and other labeling requirements.

8. 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 the CLP Regulation, which entered into force on 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 the CLP Regulation. Most entries are from adopted opinions in 2021 and include both updates and new entries. The enforcement of the 21st ATP began 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 in 2022. The most relevant entries are 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 was published on June 20, 2025, and includes 22 new entries with ten existing index numbers replaced. The enforcement date for these updates and revisions is **February 1, 2027**.

The European Commission (EC) amended the CLP Regulation to include new hazard classes currently not addressed within the Regulation or as part of the 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 2026. As stated in the changes, for new substances on the market, companies need to comply with the new rules from May 1, 2025, whereas substances that have already been on the EU market, companies have until **November 1, 2026**, to comply. Separate transition times apply for mixtures. New hazard classes apply from **May 1, 2026**, to new mixtures, whereas companies have until **May 1, 2028**, to update the C&L for existing mixtures.

The European Chemicals Agency (ECHA) Guidance documents web page, 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 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 the CLP Regulation entered into force. Regulation (EU) 2024/2865 of October 23, 2024, includes many changes to enhance chemical safety and information transparency. In positive news, expect a more transparent process for reconciliation of the C&L notification inventory and new approaches to harmonizing 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, ECHA will now require 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. ECHA intends to flag notifier entries that it believes are incomplete, incorrect, or obsolete. These changes may help harmonize the process.

Table 3 of Annex VI to the CLP Regulation 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, European Union Hazard (EUH) statements indicated in Annex VI will apply to all mixtures if relevant, regardless of classification.

The CLP revisions also 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 ten milliliters (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 in the revisions as well.

The concept of digital labeling, which includes QR codes, is also addressed in the CLP revisions. A QR code must now be accompanied by the phrase "More hazard information available online," or something similar. The digital label must be accessible online within two clicks, without using a login, and accessible for a period of ten years or longer. 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 with the requirements by **July 1, 2026**, with the exception of label formatting. Label formats are applicable starting **January 1, 2027**. Substances and mixtures placed on the market within these dates will have until **July 1, 2028**, and **January 1, 2029**, respectively, to comply.

Since the main obligations of the revised CLP go into effect on **July 1, 2026**, 2026 will be a major "go-live" year for many. Suppliers and downstream users should expect heightened compliance pressure with updating SDSs, labels, packaging, and digital/online hazard communication. In 2026, expect more substances to be subject to CLH under CLP Annex VI.

9. United Kingdom

January 1, 2021, marked the official end of the transition period for the United Kingdom's (UK) exit from the EU. The Health and Safety Executive (HSE) continues to be responsible for the UK equivalent to the EU CLP and for

In 2026, the UK implementation of the GHS is expected to focus on consolidation and selective reform rather than major structural changes.

certain aspects of the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) that impact the 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 includes all existing EU CLH in force on December 31, 2020, the day before the UK's exit from the EU took effect.

2025 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-23rd). 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, known as the "GB mandatory classification and labelling list" (GB MCL list), that is updated frequently on its website. These changes continue to require considerable diligence for those navigating trade within the region.

In October 2023, the GB MCL list was amended to adopt 98 substances with a compliance date of April 20, 2025. In March 2024, the list was amended again to adopt 25 substance classifications, some appearing to be portions of the 21st ATP. The transition period ended September 2, 2025. The list was amended twice in 2025. In February 2025, 46 substances were adopted, with a compliance date of **August 15, 2026**. In September 2025, another 32 substances were adopted, with a compliance date of **March 23, 2027**. Expect further updates to the GB MCL list throughout 2026.

In 2026, the UK implementation of the GHS is expected to focus on consolidation and selective reform rather than major structural changes. The HSE will likely continue expanding the GB MCL list, incorporating additional substances aligned with international and former EU ATP updates. While the UK will monitor emerging hazard classes, such as endocrine disruptors and persistent/mobile chemicals, it is unlikely to adopt them automatically without further consultation.

10. 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. 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. 2026 will be the year to implement supporting infrastructure.

11. 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 ended January 16, 2025. The final MSDS deadline for submission for existing substances less than one metric ton per year is **January 16, 2026**. Compliance checks will result in increased importer scrutiny in **early 2026**.

12. Peru

A draft bill was circulated in 2020 proposing a regulation that would follow GHS for C&L of all substances. The draft bill includes provisions for a national registry within one year of the regulation's approval. 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.

The Peruvian SDS must comply with GHS Annex 4 and include the chemical hazard classification. The SDS must be in Spanish, but manufacturers and importers are able to include additional languages, if required. Publication of the implementing regulation is expected in **early 2026**.

13. 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 align with Rev 2 and one in 2014 to align with Rev 4. On June 6, 2022, consultation on a draft update to align with many of the requirements outlined in 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 ended February 6, 2025. No further changes are expected in 2026. SSs are for purchase only and updated from time to time.

14. Taiwan

Following the progress made in 2024, Taiwan fully implemented Rev 8, which included new hazard classes for desensitized explosives and updates to hazard communication rules, effective February 24, 2025. After issuing revisions to 12 Chinese National Standards (CNS) in the 15030 standard series and addition of CNS 15030-29:2025, on April 25, 2025, Taiwan's OSHA officially announced the revised Classification and Labeling of Chemicals – General Rules (CNS 15030:2025), replacing the previous CNS 15030:2015 version. These updates brought the content and classification decision logic in alignment with Rev 8 and implemented significant changes, including testing guidelines and criteria for classification items such as flammable gases, aerosols, pressurized chemicals, and explosive chemicals.

On February 13, 2025, Taiwan OSHA announced that companies handling certain Priority Management Chemicals must submit additional operational data by March 31, 2025. This requirement is in line with Article 12 of the Regulations on the Designation and Operation Management of Priority Management Chemicals, which allows authorities to request additional data, such as updated SDSs, to assess chemical exposure risks. Twenty specific chemicals, including boric acid and cobalt compounds, are subject to these additional reporting requirements to help better assess exposure risks.

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.

CONTRIBUTORS

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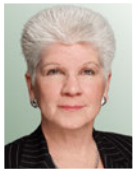


F. TURKEY

1. Overview

Turkey's efforts to align its chemicals legislative framework with the European Union's (EU) chemicals regulations underwent a pivotal transition in 2025 as the Turkish Ministry of Environment, Urbanization and Climate Change (MoEUCC) published on August 12, 2025, its updated Principles and Procedures Framework (PPF) for implementing the KKDIK (Kimyasalların Kaydı, Değerlendirilmesi, İzni ve Kısıtlanması) regulation, providing operational clarity and new binding steps for industry. Key milestones included a pre-registration deadline of October 31, 2025, for substances already on the Turkish market, a 30-day registration window for new substances to be placed on the market, designation of Lead Registrants (LR) by December 31, 2025, for existing substances, a six-month window for designation of LRs for new substances, and a framework for transitional registrations. With the Kimyasal Kayıt Sistemi (KKS) Information Technology (IT) system unavailable for most of 2025, registrants or their Only Representatives (OR) found it challenging to enter the information required to register a substance into the KKS IT system. The system re-opened during the third quarter of 2025 for entry of information but remained closed for submission of registrations until November 19, 2025. Implementation of KKDIK continued to drive major chemical regulatory activities in 2025. In 2026, expect the regulatory pace to accelerate as the "transitional/provisional registration" window closes and full registration deadlines come into force. An extension of the December 31, 2025, submission deadlines for pre-registration and for selection of LRs into early 2026 is possible to ensure continuity of access to the Turkish market as registrants work diligently to complete registration activities by a deadline that was impracticable, given the previous lack of guidance from MoEUCC and the prolonged inaccessibility of KKS IT.

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.

In 2026, Turkey's KKDIK regulation will enter its most intensive phase of implementation, making it a decisive year for industry compliance and regulatory enforcement. Following the August 2025 adoption of the PPF, many will face multiple critical deadlines. LRs who cannot submit full dossiers must submit transitional registrations by **March 31, 2026**, using a limited data set, and non-lead member companies must follow with their transitional submissions by **September 30, 2026**, to ensure continuity of market access while preparing full dossiers.

The first major full registration deadline, **December 31, 2026**, is expected to remain unchanged and as specified in the Revision of KKDİK Regulation Regarding the Extension of Registration Deadlines published in the *Official Gazette* No. 32408 on December 23, 2023.

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.

As these deadlines approach, a surge of dossier submissions is expected, prompting the MoEUCC to intensify its scrutiny of data completeness, justification for waivers, data sharing, and safety data sheet (SDS) consistency within the KKS system.

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 the lack of necessary clarifications and guidance from the MoEUCC until mid-August 2025, made the end of 2025 chaotic in terms of implementing KKDIK. Expect movement in 2026, with at least KKS IT being open again for submissions to allow co-registrants and LRs opportunities to meet the 2026 deadlines efficiently and effectively. Overall, 2026 will be a pivotal year defined by high compliance pressure, operational learning, and strategic positioning for continued access to the Turkish chemical market.

3. Biocidal Products

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

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

On January 6, 2025, the Turkish Ministry of Health, General Directorate of Public Health (HSGM) published the "2025 Biocidal Products Registration Fee Guidance." The guidance includes fees to be charged for the authorization of biocidal products.

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G. ASIA/PACIFIC RIM

1. Australia

a. Industrial Chemicals

The Australian Industrial Chemicals Introduction Scheme (AICIS) is expected to issue an updated version of the Industrial Chemicals Categorisation Guidelines in **September 2026** to coincide with the beginning of the next AICIS registration cycle (**September 1, 2026, through August 31, 2027**). During 2026, AICIS is expected to propose changes to the Categorisation Guidelines, and stakeholders will have an opportunity to submit comments. AICIS will consider the comments before making final revisions.

Beginning September 1, 2025, chemical importers and manufacturers were required to comply with the September 2025 Industrial Chemicals Categorisation Guidelines. The revisions include an updated list of chemicals with high hazards for categorization. These 118 chemicals were added based on updates to external sources, plus four AICIS-assessed chemicals. AICIS did not add any chemicals to Part 6 of the Guidelines, meaning that introducers do not need to check any additional esters and salts of chemicals on the list. Minor edits to the Guidelines include:

- Skin corrosion (Part 6.12.2) — Minor clarification about information required to demonstrate absence of this hazard characteristic;
- Skin sensitization (Part 6.14.2) — Minor clarification about information required to demonstrate absence of this hazard characteristic;
- List of chemicals with high hazards for categorization (Part 8.1) — Improved clarity in descriptions of information sources;
- Acceptable test guidelines for human health hazard characteristics (Part 8.4.1) — Table amended because it incorrectly implied that the July 2010 Organisation for Economic Co-operation and Development (OECD) Guidance Document on Using Cytotoxicity Tests to Estimate Starting Doses for Acute Oral Systemic Toxicity Tests is an OECD test guideline;
- Improved formatting for accessibility and consistency with other AICIS publications;
- Renaming of the document to avoid confusion with the Guide to Categorising Your Chemical Importation and Manufacture; and
- Reorganized footnotes to eliminate repetition.

b. Packaging

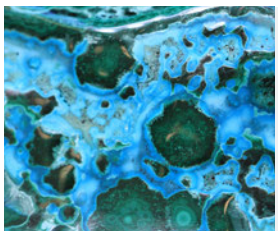
Australia continues to reform its packaging regulations to minimize packaging waste and build a circular economy for packaging. Under the National Environment Protection (Used Packaging Materials) Measure 2011 (NEPM), businesses with an annual turnover of $5 million or more that produce or sell packaging or packaged products in Australia can meet their obligations in one of two ways:

- Becoming a Signatory to the Australian Packaging Covenant and becoming a member of the Australian Packaging Covenant Organization (APCO); or
- Reporting to their state or territory government agency under the NEPM.

Following the Department of Climate Change, Energy, the Environment and Water's (DCCEEW) 2024 release of a consultation paper seeking comment on options for reforming the packaging regulations, DCCEEW has summarized comments provided by stakeholders. While the government reforms its packaging regulations, DCCEEW encourages businesses to make their packaging more recyclable by using the following resources to support adoption of sustainable packaging design:

- APCO's QuickStart Guides; and
- World Packaging Organisation's Packaging Design for Recycling.

In September 2025, the Australian Council of Recycling (ACOR) and APCO launched the Advancing Plastics Recycling in Australia (APRA) Project, aiming to "inform Australia's governments how to support and strengthen domestic recycling and manufacturing capability, create resilient markets, reduce reliance on virgin and cheap imported plastics, and support national efforts to manage plastic waste responsibly." Strategic consultancy firm Rennie Advisory was commissioned to undertake the APRA Project and scheduled to deliver findings by the end of 2025. The Project will support government and industry decision-making, including upcoming national packaging reform processes.



We anticipate that the Ecological and Environmental Code will come into force in 2026, replacing at least ten existing environmental laws and creating a unified legal framework for environmental protection.

c. Per- and Polyfluoroalkyl Substances

On October 14, 2025, AICIS announced that it has initiated an evaluation on the introduction and use of per- and polyfluoroalkyl substances (PFAS) in Australia under Section 74 of the Industrial Chemicals Act 2019 (IC Act). According to AICIS, the evaluation will review the 522 PFAS listed on the Australian Inventory of Industrial Chemicals. The evaluation will confirm whether the listed PFAS have been introduced in Australia, and if so, in what volumes and for what purpose. AICIS will use this information to consider which PFAS should be the subject of further evaluation. During the week of October 13, 2025, AICIS sent written notices to AICIS introducers registered between September 1, 2023, and August 31, 2025. Responses were due 40 working days after the date of the notice. AICIS has added the 522 PFAS to its Rolling Action Plan. More information is available in our October 24, 2025, memorandum.

d. Work Health and Safety

Safe Work Australia (SWA) announced on September 4, 2025, that it is reviewing the model Work Health and Safety (WHS) Act and model WHS Regulations to strengthen and maintain harmonization. SWA will consider jurisdictional differences from the model WHS framework and recommendations from recent reviews and inquiries. SWA has published a discussion paper on which SWA seeks comment on how it can maintain best practice WHS laws within the context of strengthening and maintaining harmonization. The formal consultation process, including written submissions, closed November 3, 2025. The review team will continue to meet with interested parties and feedback can be left via bestpracticereview@swa.gov.au until the **end of March 2026**. SWA will provide a final report of its findings with recommendations from the Best Practice Review to WHS ministers in **mid-2026**.

2. China

a. Chemical Substances

On August 5, 2025, China released an action plan for the 2025-**2030** period aimed at improving environmental conditions to safeguard public health. The plan outlines 16 measures for greener, safer, and more livable environments. Many of these efforts are part of the larger 15th Five-Year Plan, which guides China's economic and social development from 2026 to **2030**. Specifically for the next five years, China plans to strengthen the "full lifecycle management of chemical substances" to balance industrial innovation with ecological safety, phase out specific substances to control ozone-depleting and high-global warming potentials, and continue using a "dual control" system for carbon emissions control.

Aligned with the Plan, one of the most impactful pieces of legislation unveiled in 2025 was the release of the first draft of the Ecological and Environmental Code (Draft Code) for public comment by the National People's Congress (NPC) Standing Committee (NPCSC) on April 30, 2025, following the first reading by the NPCSC on April 27, 2025. The Draft Code is designed to integrate existing environmental regulation, incorporate emerging environmental issues, and strengthen legal framework and enforcement actions. The Draft Code is composed of five chapters, 59 sections, and 1,188 articles, covering general provisions, pollution prevention and control, ecological protection, green and low-carbon development, legal liability, and supplementary provisions. After public comment closed on June 13, 2025, and the NPCSC completed its second reading in September 2025, the Draft Code underwent further rolling reviews, and potential revisions by the end of 2025 and will be presented for final approval in the **beginning of 2026**. We anticipate that the Code will come into force in 2026, replacing at least ten existing environmental laws and creating a unified legal framework for environmental protection, addressing emerging issues like climate change, establishing mechanisms for green finance and industry, and strengthening enforcement and penalties for environmental violations. Once adopted, it will become China's second formal statutory code, after the Civil Code adopted in 2020.

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 (LSHC) continues to progress toward

final form. The draft LSHC underwent a first reading in December 2024 by the NPCSC and was submitted on September 8, 2025, for a second reading by the NPCSC. The updated draft LSHC was released on September 16, 2025, for public comments, with the comment period closing on October 11, 2025. The updated draft focuses on national security and enhanced hazard reporting, improved management systems, lifecycle management, stricter supervision, and stricter penalties. Following the public consultation, the draft will be reviewed by the NPCSC and be advanced for final review in a future NPC session, anticipated by the end of 2025 or **early 2026**. Once final, 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.

As a crucial part of new chemical substance regulation in China, MEE continued to update the Inventory of Existing Chemical Substances in China (IECSC) in 2025. As of August 11, 2025, MEE had released 28 supplemental notices, with a total of 1,513 substances added to the IECSC. We anticipate that MEE will continue reviewing new chemical substance applications and adding those with demonstrated safety records to the IECSC in 2026 and beyond.

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 the National Hazardous Waste List (2025 Edition) on November 26, 2024, and it became effective on January 1, 2025. The List is an important foundation and key reference for hazardous waste environmental management in China. Since its initial release in 1998, the List has been revised three times (in 2008, 2016, and 2021), and has helped establish a standardized system for hazardous waste identification, preventing environmental risks associated with hazardous waste, and supporting overall hazardous water management in China.

We expect that many of these ongoing regulatory activities regarding chemical substance management will be further streamlined by the adoption of the Ecological and Environmental Code, expected in 2026.

b. Cosmetics and Cosmetic Ingredients

China's National Medical Products Administration (NMPA) made significant progress in 2025 on Cosmetics Supervision and Administration Regulation (CSAR) subsidiary regulations. To strengthen the supervision and management of cosmetics, and to standardize the monitoring and evaluation of cosmetic safety risks, NMPA issued on April 9, 2025, the Measures for the Management of Cosmetic Safety Risk Monitoring and Evaluation in accordance with the Regulations on the Supervision and Administration of Cosmetics and other relevant laws and regulations. The Measures, effective as of August 1, 2025, introduce mandatory lifecycle-wide safety risk monitoring for cosmetics and outline standardized protocols for risk assessment and control.

To enhance the implementation of the CSAR subsidiary regulations, on August 21, 2025, NMPA issued the 2025 Cosmetics Standard Development Plan (2025 Plan), notifying the secretariat of the Cosmetics Standardization Technical Committee to carry out standard drafting and revision work, enhancing the tracking and management system, and providing technical guidance to ensure the quality and standard of the work. A total of 34 cosmetic standards are included in the 2025 Plan, of which 29 are new standards and five are revised standards.

Even before the publication of the 2025 Plan, continuing its progress made in 2024, NMPA's Cosmetics Standardization Technical Committee held chairpersons meetings on March 27 and July 28, 2025. The 2025 Plan and 12 further cosmetic standards were approved during these meetings. The core technical standards for cosmetics in China, Technical Specifications for Cosmetic Safety, 2015 edition (Specifications), covers general safety requirements for cosmetics, prohibits or restricts ingredients, and permits ingredients (preservatives, sunscreens, colorants, hair dyes), physicochemical and microbiological testing methods, toxicology testing methods, and human safety and efficacy evaluation methods. The standards apply to cosmetics produced and marketed within China (excluding products intended solely for export). Since its adoption on December 1, 2016, the Specifications have undergone multiple revisions and additions. 2025 updates include, for example, the addition of analytical methods for toothpaste, revisions for detection methods for 43 elements, including lithium in toothpaste and cosmetic products, and the addition of new testing methods, including *in vitro* skin absorption test methods and immunotoxicity test methods.

At the same time, NMPA continues updating the Inventory of Existing Cosmetic Ingredients in China (IECIC), according to its Notice on the Management of Cosmetic Ingredients. As of June 24, 2025, the IECIC will be managed in two separate dynamic categories as List I

and List II. List I is the cosmetic ingredients that have historically been used in China and are considered to pose relatively low risks. NMPA created List I based on the IECIC published by NMPA in 2021. Revisions made to the 2021 IECIC to create List I include removing the historical maximum use limits and standardizing certain ingredient names based on current NMPA standards. List II comprises new cosmetic ingredients that have recently been registered or notified for cosmetic uses and have completed a three-year safety monitoring period after registration or notification in China. List II ingredients are considered relatively high risk and require higher quality standards and risk management due to lack of historical information. Revisions were also made to these Lists to align with the updated Technical Specification for the Safety of Cosmetics.

To enhance cosmetic product quality improvement and new development, on January 26, 2025, NMPA issued Several Provisions Supporting Innovation in Cosmetic Ingredients. The Provisions provide nine directional supports, including, for example, optimizing the technical requirements and taking into consideration existing information for new cosmetic ingredients, promoting the simultaneous declaration of new ingredients and related cosmetic products, establishing dedicated review channels and prioritization mechanism to strengthen innovation, research, and launch of new ingredients, expediting the development of technical guidelines for new cosmetic ingredient research and standardization, and improving the management of the safety monitoring period. We expect that this trend will continue in 2026 and beyond.

c. Food Contact Materials

China made significant updates to its food contact materials (FCM) regulations in 2025. On March 27, 2025, the National Health Commission of China (NHC), along with the State Administration for Market Regulation (SAMR), released 50 new and nine updated national food safety standards. Six of the standards directly impact FCM regulation in China, including an amendment to the standards for the use of additives in FCMs. Effective March 16, 2025, GB 9685-2016 Amendment No. 1 expands the permitted additives for rubber to include those only allowed for silicone rubber. Standard references for certain clauses are also clarified in this update. Amendment No. 1 also includes updates to Appendix A (Positive List of Additives) and Appendix B (Specific Migration Limits (SML)), adjustments to the maximum usage limit for oxidized starch (FCA 1221), calculation methods for new SMLs, and revisions of the Chinese nomenclature for some additives to align with the most updated standards. NHC and SAMR also issued five revised FCM testing method standards (GB 31604 series) that became effective on September 16, 2025. The five new GB 31604 standards cover:

- The determination of migration for phthalate compounds (GB 31604.30-2025);
- Residual and migration amounts of vinyl chloride, 1,1-dichloroethylene, and 1,1-dichloroethane (GB 31604.31-2025);
- The determination of migration for 2,2,4,4-tetramethyl-1,3-cyclobutanediol (GB 31604.61-2025);
- The determination of migration and release of N-nitrosamine compounds (GB 31604.62-2025); and
- The determination of migration for 4,4′-biphenylene glycol and 1,1′-sulfonylbis(4-chlorobenzene) (GB 31604.63-2025).

These updates aim to enhance FCM safety management and protect consumer health.

In addition, NHC and SAMR also issued in final the General Principles for the Labeling of Prepackaged Foods (GB 7718-2025) on March 27, 2025. This standard sets basic labeling requirements for both domestic and imported prepackaged foods and will be enforced after a two-year transition period, starting **March 16, 2027**. To refine further the requirements for digital labeling, NHC and SAMR announced additional details on September 8, 2025, specifying the scope, content, and format for the digital label, process and documentation for digital label amendment, accuracy and consistency of the information included in the digital label, and responsibilities of the manufacturer regarding digital labeling.

National Food Safety Standard: General Rules for Nutritional Labeling of Prepackaged Foods (GB 28050-2025) and an updated standard for testing *Listeria monocytogenes* in food (GB 4789.30-2025) were also published on March 27, 2025. GB 28050-2025 became effective immediately, while GB 4789.30-2025 replaced the previous standard on September 16, 2025.

On July 25, 2025, NHC published the official version of the 2025 National Food Safety Standard Development Plan, outlining China's plan for the formulation and revision of 44 priority GB food standards to enhance risk prevention and to ensure industry compliance. The FCM-related plan includes updates for ceramic materials and products as FCMs, revisions for 11 food additive standards, and establishment of food claim standards.

On September 25, 2025, NHC and SAMR issued 32 national food standards, including National Standard for Food Safety — Limits for Contaminants in Food (GB 2762-2025), and two amendments to existing standards. Two FCM standards and two SML standards, Coatings and Layers for Food Contact Materials and Products (GB 4806.10-2025) and Silicone Rubber Materials and Products for Food Contact Applications (GB 4806.16-2025), and Determination of Migration Levels of Benzoic Acid, Phthalic Acid, and Trimellitic Acid in Food Contact Materials and Articles (GB 31604.21-2025) and Determination of Migration Levels of Citrate Esters and Sebacate Compounds in Food Contact Materials and Articles (GB 31604.64-2025), respectively, are included in this batch of updates.

3. New Zealand

In June 2025, the New Zealand Environmental Protection Authority (New Zealand EPA) announced that following recently approved updates to the Hazardous Substances and New Organisms Act 1996 (HSNO Act) intended to make the application process simpler while maintaining strong safety standards, further key improvements were already underway, including:

- Streamlining processes: New legislative changes will provide more transparent pathways for applicants, including temporary product use under specific safety criteria for novel substances while they are undergoing assessment. New Zealand EPA is also investigating streamlined processes for lower-risk substances;
- Reducing application wait times: Since July 1, 2024, New Zealand EPA has reduced the queue of release applications by 19 percent and approved 58 hazardous substances, putting it on track for its highest number of assessments in five years;
- Strengthening its assessment team: New Zealand EPA added 11 new frontline staff and expanded its technical specialist team, doubling the number of tox/ecotoxicologists since 2020; and
- Updating its ecotoxicological models: With the budget funding announced in May 2025, New Zealand EPA began working to create reliable, transparent tools that align with international standards while incorporating its unique environmental needs.

New Zealand EPA intends to continue to build on these improvements, consulting on a prioritization framework for hazardous substance applications that will be implemented in 2026.

Under the Hazardous Substances (Importers and Manufacturers) Notice 2015, importers and manufacturers of hazardous substances must provide New Zealand EPA with their business contact information. In 2024, New Zealand EPA amended the reporting requirements. Beginning 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 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

By the end of 2025, the Ministry of Environment (MOE) was expected to implement an amendment to the Act on the Registration and Evaluation of Chemicals (K-REACH) that is intended to improve the accuracy of data, streamline the exemption process, and clarify how to change an Only Representative (OR). Under the draft amendment, the National Institute of Chemical Safety (NICS) would verify the annual

import and manufacturing volumes reported in registration and exemption applications. Comments on the draft amendment were due September 25, 2025.

b. K-BPR

Under the Consumer Chemical Products and Biocides Safety Act (K-BPR), beginning January 1, 2026, disinfectants, algicides, and insect repellent products are now classified as "products subject to approval" instead of "products subject to safety checks." This means that the products must be reviewed by NICS before being placed on the market. Products manufactured or imported before January 1, 2026, may be sold until **June 30, 2026**, without approval. Products that were approved before January 1, 2026, may be sold using the previous safety-confirmed labeling until the **end of 2026**.

On July 30, 2025, MOE notified the World Trade Organization (WTO) of a regulation that would amend the labeling rules for biocidal products. According to MOE, the regulation is intended to strengthen and improve the labeling standards, improving readability. The notification does not include proposed dates of adoption or entry into force.

5. Taiwan

Following its efforts in 2024 to align with international chemical safety standards, Taiwan's Ministry of Environment (MOENV) announced a draft regulation on August 5, 2025, proposing to designate 269 PFAS as "concerned chemical substances" under the Toxic and Concerned Chemical Substances Control Act. Some PFAS, such as perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA), perfluorohexane sulfonic acid (PFHxS), and their salts and related compounds have already been regulated under Taiwan's Categories and Management of Handling for Toxic Chemical Substances due to their confirmed environmental and health hazards. MOENV plans to draft the List of Per- and Polyfluoroalkyl Substances and Related Management Measures for the purpose of preventive management of the other previously unregulated PFAS given their broad applications. The regulation will introduce tiered management measures for PFAS, including requiring approval, recordkeeping, and quarterly reports for perfluoroalkyl acids (PFAA) and related compounds, while polymers and gases will have different requirements based on their concentrations. We expect the regulation to be issued by January 1, 2026.

Taiwan also updated its cosmetic products regulation in 2025 to align with international cosmetics regulatory standards. Specifically, the Taiwan Food and Drug Administration (Taiwan FDA) announced that the amended List of Ingredients Prohibited in Cosmetic Products became effective on January 1, 2025. Revisions were made to the lists of prohibited and restricted ingredients in cosmetic products, including adding new substances and updating usage restrictions for existing ingredients like Kojic Acid and Arbutin. Further, Taiwan FDA released a draft amendment on April 7, 2025, proposing a full ban on boric acid in cosmetic products, for a 60-day public comment. The boric acid ban, along with other changes to the restricted ingredient list, is expected to become effective on **July 1, 2026**.

On July 1, 2025, Taiwan FDA's Product Information File (PIF) requirements became mandatory for baby products, lip and eye cosmetic products, and general toothpaste/mouthwash products. The comprehensive PIF requires product details, formulation, manufacturing processes, toxicological data, safety assessments, and other safety-related information be included to allow for scientific evaluation and to ensure product safety. For all other cosmetic products, except for certain handmade soaps, the PIF requirements will be effective on **July 1, 2026**. Companies must provide complete PIFs for all products seeking authorization to sell in Taiwan. As specified in Taiwan FDA's May 30, 2019, regulation, Cosmetic Categories Required to Establish the Product Information File and Effective Dates, the first wave of cosmetic products requiring PIF submission was for specific cosmetic products, such as sunscreen, hair dyes, and perms, and became effective on July 1, 2024.

On January 21, 2025, Taiwan FDA released two draft regulations, Labeling Requirements for Outer Packaging, Containers, Labels, or Package Inserts of Cosmetics and Specific Fragrance or Flavor Ingredients Required to Be Labeled in Cosmetics, for a 60-day public consultation. Taiwan FDA proposed amendment to Article 7 of the Labeling Requirements in accordance with Paragraph 4, Article 7 of the Cosmetic Hygiene and Safety Act. As specified in the second draft regulation, 24 fragrance or flavor ingredients must be explicitly listed on the product label if they are present in a cosmetic product at concentrations exceeding the specified limits. These ingredients cannot be generically labeled as "Fragrance," "Flavor," "Perfume," or "Aroma." Their specific names must be disclosed according to the regulation. The draft regulations are expected to become effective one year after their official promulgations.

On August 26, 2025, Prime Minister Phạm Minh Chính issued the Implementation Plan for the New Law on Chemicals. The Plan specifies tasks, deadlines, and responsibilities for agencies and organizations to ensure the law's timely, unified, and effective implementation.

6. Vietnam

In 2025, the Ministry of Industry and Trade (MOIT) continued its effort to revise Vietnam's overarching chemical law, the Law on Chemicals (No. 06/2007/QH12). On June 14, 2025, the National Assembly of Vietnam passed the new Law on Chemicals (No. 69/2025/QH15), replacing the old law from 2007. This comprehensive revision introduces significant changes, including a revised chemical classification system, tighter regulations for chemical licensing and import/export, and greater emphasis on Globally Harmonized System of Classification and Labelling of Chemicals (GHS)-compliant labeling and hazard classification for chemicals and products. The Law introduces a new system, including categories like "conditional chemicals" and "specially controlled chemicals," aligning with global best practices and replacing older categories. The new Law also promotes digital transformation through a centralized national chemical database, enhancing chemical safety and management. Businesses handling hazardous chemicals must now appoint certified safety personnel, develop emergency plans, and upgrade infrastructure to meet safety standards.

On August 26, 2025, Prime Minister Phạm Minh Chính issued the Implementation Plan for the New Law on Chemicals. The Plan specifies tasks, deadlines, and responsibilities for agencies and organizations to ensure the law's timely, unified, and effective implementation. The Plan focuses on enhancement of hazardous chemical control, digital transformation of data management, improvement of chemical traceability, specification on new licensing requirements for conditional chemicals, tightened restrictions on chemical use in sensitive products, and promotion of green chemistry and sustainable development in Vietnam.

Following these efforts, on October 2, 2025, MOIT notified WTO of the following draft decrees implementing the Law on Chemicals:

- Draft decree to organize and guide the implementation of provisions concerning the development of the chemical industry and chemical safety and security. The draft provides a comprehensive regulatory framework covering development of chemical industry, project management, specialized consultancy, chemical safety-security management, chemical safety training, and incident response.

- Draft decree establishing a comprehensive regulatory framework for the management of chemical activities and hazardous chemicals contained in products and goods. This draft decree aims to operationalize and strengthen the legal framework established under the Law on Chemicals. It introduces mechanisms for classifying, listing, and managing chemical substances, including licensing, declaration, specialized database, inspection procedures, and response capacity to minimize risks; protect public health, the environment, and national security; prevent loss and misuse (including use in criminal activity, production of chemical weapons, or manufacture of narcotics); and address regulatory gaps arising from the transition from previous regulations to the new Law in the context of increasingly complex chemical production and trade.

- Draft decree promulgating the lists of chemicals subject to management under the Law on Chemicals. These lists are provided in five Annexes: Annex I — list of basic chemicals in prioritized chemical industry sectors; Annex II — list of chemicals subject to conditional production and trading; Annex III — list of chemicals subject to special control in production and trading; Annex IV — list of chemicals required to prepare a Chemical Accident Prevention and Response Plan; and Annex V — list of training disciplines eligible to conduct chemical safety activities. This draft decree applies to domestic agencies, organizations, and individuals and foreign organizations and individuals conducting activities related to chemicals in the territory of Vietnam.

MOIT intended to adopt the decrees on December 1, 2025, to enter into force on **July 1, 2026**.

On September 4, 2025, the Ministry of Health notified WTO of a draft decree on the management of cosmetics. The notification states that the draft decree establishes a comprehensive regulatory framework for the management of cosmetics. It provides provisions on the export and import of cosmetic products, the issuance of certificates of free sale, and requirements for product information files, labeling, and advertising in line with the Association of Southeast Asian Nations' (ASEAN) guidelines and the Law on Advertising. The decree also introduces online procedures for product notification and dossier archiving; regulates the inspection and supervision of cosmetic safety and quality, including dossier reviews, product sampling, and testing; and stipulates the circumstances under which cosmetics may be suspended, recalled, or destroyed. Finally, the draft decree assigns responsibilities to ministries, agencies, organizations, and individuals involved in its implementation, while also setting forth transitional provisions, the effective date, and enforcement mechanisms. According to the notification, Vietnam intended to adopt the decree on November 4, 2025, to enter into force on **July 1, 2026**.

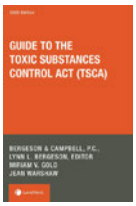
Acta is active and knowledgeable in assisting its clients in dealing with the complexities of chemical management regulations in Asia and the Pacific Rim, with boots on the ground resources in China and South Korea. Acta's services include notification of new chemical substances, as well as hazardous chemicals management, and troubleshooting complex issues that require significant insights and experience dealing with local regulatory authorities. Acta's team includes bilingual professionals fluent in English and Mandarin. Visit our website for a full description of our services. Contact Lynn L. Bergeson, lbergeson@actagroup.com, if you would like to discuss your needs in the region.

CONTRIBUTORS

CARLA N. HUTTON, MEIBAO ZHUANG, PH.D., EMMA L. JACKSON, CHRISTINE M. PALERMO, PH.D., DABT

APPENDIX A: SPEECHES AND WRITINGS

BOOKS



Lynn L. Bergeson, Heather J. Blankinship, Lisa R. Burchi, Richard E. Engler, Ph.D., Kelly N. Garson, Lara A. Hall, MS, RQAP-GLP, Carla N. Hutton, co-authors, "*Guide to the Toxic Substances Control Act (TSCA),*" LexisNexis (2025).

Lynn L. Bergeson, Lisa R. Burchi, Richard E. Engler, Ph.D., Kelly N. Garson, Carla N. Hutton, and Todd J. Stedeford, Ph.D., DABT, ERT, ATS, co-authors, "*Chemical Product Law and Supply Chain Stewardship: A Guide to New TSCA*," ABA Book Publishing (2025).

Lynn L. Bergeson, Lisa R. Burchi, Heather F. Collins, MS, Richard E. Engler, Ph.D., and Carla N. Hutton, co-authors, "Pesticides, Chemical Regulation, and Right-to-Know 2024 Annual Report," in *The Year in Review 2024: Environment, Energy, and Resources Law*, American Bar Association (2025).

ARTICLES

Recent articles on critical issues:

Lynn L. Bergeson, "Hallelujah, EPA Proposes to Narrow Scope of TSCA Section 8(a)(7) PFAS Reporting Rule," *Chemical Processing*, December 10, 2025.

Lynn L. Bergeson, "Microplastics Regulation Revs Up in 2025, More Action Expected in 2026," *Chemical Processing*, November 10, 2025.

Lynn L. Bergeson, "Defining Risk: EPA Seeks Major TSCA Chemical Evaluation Reforms," *Chemical Processing*, October 13, 2025.

Lynn L. Bergeson, "Compliance: Microplastics Regulation Surges," *Chemical Processing*, September 16, 2025.

Lynn L. Bergeson, "What Does a Much Smaller Office of Research and Development Mean?," *Chemical Processing*, August 18, 2025.

Lynn L. Bergeson, "Leveraging Chemical Data More Efficiently," *PCB007 Magazine*, July 2025.

Lynn L. Bergeson, "Good News: PFAS Reporting Deadline Postponed," *Chemical Processing*, July 14, 2025.

Lynn L. Bergeson, "Chemical Policy Crossroads: What Are the Make America Healthy Again Report's Implications?," *Chemical Processing*, June 17, 2025.

Lynn L. Bergeson, "EPA Outlines Actions to Address PFAS," *Chemical Processing*, May 14, 2025.

Lynn L. Bergeson, "Rethinking Environmental Governance: The Age of Deregulation?," *Chemical Processing*, April 16, 2025.

Lynn L. Bergeson, "EPA, OSHA Sign Ambiguous Memorandum of Understanding," *Chemical Processing*, March 12, 2025.

Lynn L. Bergeson, "Chemical Compliance: Is TSCA Reform in Our Future?," *Chemical Processing*, February 18, 2025.

Lynn L. Bergeson, Kelly N. Garson, and Lara A. Hall, MS, RQAP-GLP, "Testing, Testing," *Environmental Forum*, March/April 2025.

Lynn L. Bergeson, "The "Undoing" Season," *American College of Environmental Lawyers (ACOEL) Blog*, January 29, 2025.

Lynn L. Bergeson, "Chemical Regulations: 2025's Fuzzy Forecast," *Chemical Processing*, January 28, 2025.

Lynn L. Bergeson, "The Cost of Cleanup: Preparing for PFAS Remediation Battles," *Corporate Disputes*, January – March 2025.

Lynn L. Bergeson, "Compliance Advisor: What to Expect from EPA in 2025," *Chemical Processing*, January 10, 2025.

PRESENTATIONS

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

"TSCA Regulatory Update," Richard E. Engler, Ph.D., 2025 Annual Meeting, Household & Commercial Products Association (HCPA) (December 9, 2025).

"TSCA Fundamentals," Richard E. Engler, Ph.D., Chemical Watch (October 28-29, 2025).

"Transactional Toolkit: How to Uncover Environmental Risks Through Due Diligence, Cover Them Through Insurance, and Talk About It at Parties," Lynn L. Bergeson, Section of Environment, Energy, and Resources 33rd Fall Conference, American Bar Association (ABA) (October 23, 2025).

"FIFRA Fundamentals," Lisa R. Burchi, Heather F. Collins, MS, Dana S. Lateulere, Meibao Zhuang, Ph.D., Chemical Watch (September 24-25, 2025).

"PFAS policy, regulatory, and stewardship developments in the U.S.," Lynn L. Bergeson, Regulatory Summit North America: PFAS Updates, Chemical Watch (September 18, 2025).

"Current status of the new chemicals procedural rule," Richard E. Engler, Ph.D., Regulatory Summit North America: Chemicals Control, Chemical Watch (September 15, 2025).

"Plastic Pollution, Waste and Recycling," Lynn L. Bergeson, Environmental Regulation in Practice 2025, Practising Law Institute (PLI) (September 3, 2025).

"TSCA as a driver and barrier for us chemical manufacturing," Richard E. Engler, Ph.D., Fall 2025, American Chemical Society (ACS) (August 18, 2025).

"Incorporating TSCA Considerations into Sustainable Product Design and Commercialization Plans," Richard E. Engler, Ph.D., Green Chemistry & Engineering Conference, ACS (June 25, 2025).

"Proposition 65 Short-Form Warning Requirements and Compliance Strategies," Lisa R. Burchi, Alliance for Chemical Distribution (ACD) (June 24, 2025).

"TSCA Policy and Congressional Developments," Richard E. Engler, Ph.D., Mid-Year Meeting, HCPA (June 24, 2025).

"Adapting to a Rapidly Changing Regulatory Environment," Richard E. Engler, Ph.D., Mid-Year Meeting, HCPA (June 23, 2025).

"A Sponsor's Role in Regulatory Testing under EPA GLP," Lara A. Hall, MS, RQAP-GLP, and Michelle C. Mims, MS, RQAP-GLP, Annual Meeting, Society of Quality Assurance (SQA) (April 8, 2025).

"The PFAS Playbook: Strategies to Minimize Regulatory and Commercial Risk," Lynn L. Bergeson, American Law Institute Continuing Legal Education (ALI CLE) (March 11, 2025).

"Navigating early policy shifts and associated challenges," Lynn L. Bergeson, TSCA Developments, Chemical Watch (February 27, 2025).

"New Chemicals," Richard E. Engler, Ph.D., TSCA Developments, Chemical Watch (February 27, 2025).

"Evolving Developments in the Regulation of PFAS," Lynn L. Bergeson, Environmental Law 2025: Tackling the Issues in a Pivotal Year, ALI CLE (February 20, 2025).

APPENDIX B: WEBINARS AND PODCASTS

2026 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 in Chemicals Policy and Regulation and on Capitol Hill in 2026 *Register now*	January 27, 2026 11:00 a.m. - 12:00 p.m. (EST)
EPR and Microplastics: Regulatory Trends and Updates *Register now*	March 17, 2026 11:00 a.m. - 12:00 p.m. (EDT)
Lexology Masterclass: PFAS in Consumer Products: Navigating Multi-State Compliance and Regulatory Strategy *Register now*	April 14, 2026 11:00 a.m. - 12:00 p.m. (EDT)
TSCA Hot Topics	May 19, 2026 11:00 a.m. - 12:00 p.m. (EDT)
FIFRA Hot Topics	July 21, 2026 11:00 a.m. - 12:00 p.m. (EDT)
An Update on European REACH	September 15, 2026 11:00 a.m. - 12:00 p.m. (EDT)

WEBINARS AVAILABLE ON DEMAND

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

31st Annual Green Chemistry Challenge Awards: New Categories and Expanded Opportunities

In this webinar, Richard E. Engler, Ph.D.; Adelina Voutchkova, Ph.D., Director of Sustainable Development at the American Chemical Society (ACS) and leader of the ACS Green Chemistry Institute®; and Edmond Lam, Ph.D., Assistant Director of the ACS Green Chemistry Institute, discuss the new opportunities available in this year's Green Chemistry Challenge Awards and provide guidance and tips on preparing a strong awards entry package.

Phthalate Risk Evaluation under TSCA and the Potential Impacts to the Plastics Industry

In this webinar, Heather J. Blankinship, Lara A. Hall, MS, RQAP-GLP, Lindsay A. Holden, Ph.D., DABT, and Lynn L. Bergeson discuss the changing priorities of EPA OPPT, industrial stakeholder expectations, key scientific aspects of the TSCA risk evaluations, paths to address claimed data gaps, and how these issues influence domestic plastic production and global efforts to regulate plastics.

Regulation Without Borders: The EUDR and the New Era of Global Due Diligence

In this webinar, Diana Borcea, Senior Account Manager, EPPA; Jennifer Mleczko, Senior Manager, Sustainability Advisory, North America, PBN; and L. Claire Hansen, discuss the current state of EUDR implementation in the United States and EU, as well as the real world consequences to businesses that are not compliant, and case studies demonstrating how to determine if you fall within the scope of this regulation.

***Loper Bright*: Has the Demise of *Chevron* Deference Mattered?**

In this webinar, Kelly N. Garson and James V. Aidala discuss the basis for the U.S. Supreme Court's decision in *Loper Bright*, the impacts on administrative law, and observations on how *Loper Bright* may shape current and future chemical safety or TSCA and FIFRA policy development and litigation.

TSCA Reform — Nine Years Later
The Environmental Law Institute (ELI), the George Washington University Milken Institute School of Public Health, and B&C hosted the ninth annual TSCA Reform conference, providing updates and insights regarding the current state of TSCA implementation, ongoing and emerging issues, and related developments. Speakers covered a variety of topics, including risk management rules; the risk evaluation framework; new chemical review; key TSCA considerations in the production, use, and recycling of plastics; the role chemicals play in chronic disease; and the prospects for TSCA reform.

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.

PFAS Updates: What's Happening in the U.S. and EU
In this webinar, Meglena Mihova, Managing Partner, EPPA, and Richard E. Engler, Ph.D., discuss regulatory developments in the United States and EU, including TSCA and FIFRA developments, actions being taken by the states, and proposed PFAS restriction in the EU.

What's New with New Approach Methodologies
In this webinar, Adam Bettmann, MS, DABT, a Toxicology Specialist representing PETA Science Consortium International e.V.; Katie Paul Friedman, Ph.D., Acting Director for the Biomolecular and Computational Toxicology Division in the Center for CCTE in EPA's ORD; and Richard E. Engler, Ph.D., discuss the current state of NAMs and their use for TSCA submissions.

What to Expect When You Don't Know What to Expect in Chemicals Policy and Regulation and on Capitol Hill in 2025
In this webinar, Lynn L. Bergeson, James V. Aidala, Richard E. Engler, Ph.D., and Mark J. Washko unpack the likely impacts of the new Administration on the regulated community, provide their seasoned outlook on how similar or different the Trump II Administration might be from the first term, and discuss what companies can do to respond to the opportunities and challenges presented.

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.

Inside ACS's Green Chemistry Challenge — A Conversation with Adelina Voutchkova, Ph.D. and Richard E. Engler, Ph.D.
Lynn L. Bergeson, Richard E. Engler, Ph.D., and Adelina Voutchkova, Ph.D., Director of Sustainable Development at the American Chemical Society (ACS) discuss ACS' much-coveted Green Chemistry Challenge Awards, ACS' Green Chemistry Institute's (GCI) mission and some new opportunities for competing for the Green Chemistry Challenge Awards.

Behind the Scenes of Chemical Safety Reform — A Conversation with Ryan Schmit
Lynn L. Bergeson and Ryan N. Schmit discuss Ryan's illustrious career at EPA and experience at the forefront of TSCA policy development, new chemical determinations under TSCA, and OCSPP's evolving approach to PFAS strategy, among many other responsibilities.

The Future of Chemical Data Intelligence — A Conversation with Greg Gartland, Chief Executive Officer of 3E
Lynn L. Bergeson and Greg Gartland, Chief Executive Officer of 3E discuss the very competitive world of chemical information management, the role artificial intelligence has in this space, and trends Greg sees driving growth in chemicals, product stewardship, and sustainability.

EUDR Issues — A Conversation with Claire Hansen — *transcript available*
Lynn L. Bergeson and L. Claire Hansen discuss the basic requirements of EUDR, who is in scope, the costs of non-compliance, and how best to prepare for the effective date.

Sessions from TSCA Reform — Nine Years Later
On June 25, 2025, B&C, along with ELI and the George Washington University Milken Institute of Public Health, sponsored the all-day virtual conference, TSCA Reform —

Nine 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.

- Plastics Production, Use, and Recycling – Key TSCA Considerations
- New Chemicals Review
- Risk Evaluation
- Risk Management

Prop 65 "Short Form" Warning Requirements — A Conversation with Lisa R. Burchi — *transcript available*
Lynn L. Bergeson and Lisa R. Burchi discuss why companies doing business in California need to know about the latest version of the so-called "short form" warning requirements that will be fully phased in by **2028**.

***Loper Bright* and the End of *Chevron* Deference? — A Conversation with Kelly N. Garson** — *transcript available*
Lynn L. Bergeson and Kelly N. Garson explain what *Chevron* deference is, other types of deference that are still very much a part of judicial review, and how *Chevron's* elimination could impact the implementation of the 2016 amendments to TSCA given the many issues in dispute now pending before many federal circuit courts.

First Six Months of the Trump Administration — A Conversation with James V. Aidala — *transcript available*
Lynn L. Bergeson and James V. Aidala discuss the first six months of the Trump Administration including Presidential actions, their impact on the EPA workforce, EPA actions to date, and a bit about the MAHA Report's "Make Our Children Healthy Again" Assessment and its impact on the pesticide community.

Chemical and Material Risk Management Program TSCA Market Analysis — A Conversation with Patricia Underwood, Ph.D., DABT, MBA and Richard E. Engler, Ph.D. — *transcript available*
Lynn L. Bergeson, Patricia Underwood, Ph.D., DABT, MBA, Chief Toxicologist, Principal Director – Chemical and Material Risk Management, Office of the Assistant Secretary of Defense, Department of Defense, and Richard E. Engler, Ph.D., discuss the U.S. DOD's recent RFI on chemicals undergoing EPA review as part of TSCA's Section 6 risk evaluation process.

U.S. State PFAS Initiatives — A Conversation with Richard E. Engler, Ph.D. and Carla N. Hutton — *transcript available*
Lynn L. Bergeson, Carla N. Hutton, and Richard E. Engler, Ph.D., address the TSCA PFAS reporting obligation and the diverse constellation of state-specific reporting and product restrictions that are mushrooming around the country.

Chemical Law and Policy — A Conversation with Karyn Schmidt — *transcript available*
Lynn L. Bergeson and Karyn Schmidt, now a principal at Squire Patton Boggs in its Public Policy practice, after spending 25 years at ACC, discuss Karyn's transition to private practice, her work at ACC, and Karyn's thoughts on what is in store for chemical stakeholders now and in the foreseeable future.

REACH and GHS in Latin America — A Conversation with Melissa Owen — *transcript available*
Lynn L. Bergeson and Melissa Owen, attorney/owner of Ambiente Legal, discuss the significant regulatory developments regarding chemical registration in Latin America, including Latin American REACH initiatives and GHS.

CLP Changes And What They Mean For Commercial Operations — A Conversation with Karin Baron and Lioba Oerter — *transcript available*
Lynn L. Bergeson, Lioba Oerter, Director of Expert Services, 3E Expert Service Processing Centre (ESPC), and Karin F. Baron discuss the significant changes to CLP in the EU. These forthcoming CLP changes will have a profound commercial impact on product classification, labeling, and packaging globally.

Chemical Product Law and Supply Chain Stewardship: A Guide to New TSCA — A Conversation with Richard E. Engler, Ph.D. and Kelly N. Garson — *transcript available*
Lynn L. Bergeson, Richard E. Engler, Ph.D., and Kelly N. Garson, discuss *Chemical Product Law and Supply Chain Stewardship: A Guide to New TSCA*, written by B&C and Acta professionals and published by the American Bar Association. This conversation focuses on several chapters in the book and explores writing a book about a law from the perspective of the business community.

TSCA Developments — A Conversation with Richard E. Engler, Ph.D. — *transcript available*
Lynn L. Bergeson and Richard E. Engler, Ph.D. discuss TSCA developments including the new Administration, the

lack of clarity regarding what the new leaders at OCSPP will do to address new chemical review concerns, risk evaluation under TSCA Section 6, and risk management actions resulting from those evaluations.

The New Administration and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Developments — A Conversation with Jim Aidala — *transcript available*
Lynn L. Bergeson and James V. Aidala discuss the early days of the new Administration, what changes we can expect at EPA generally, and key issues OPP can be expected to tackle.

What to Expect from The 119th Congress — A Conversation with Mark Washko — *transcript available*
Lynn L. Bergeson and Mark J. Washko discuss the 119th Congress and what might be key legislative actions our listeners should look for. The new Congress reflects many new members, new staffs, and a new Republican majority in both chambers.

APPENDIX C: TRAINING COURSES ON DEMAND

B&C is pleased to present our complete 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
T107: Articles and the Articles Exemption

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
T205: Chemical Testing (Regulatory)/Animal Welfare — TSCA Section 4
T206: Prioritization and Risk Evaluation — TSCA Section 6
T207: Understanding TSCA Significant New Use Rules (SNUR)

T100-series bundle (six modules)
T200-series bundle (seven modules)
Complete TSCA Tutor course (13 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
F209: FIFRA Inspections and Enforcement

F100-series bundle (ten modules)
F200-series bundle (nine modules)
All currently available FIFRA Tutor modules (19 modules)

APPENDIX D: GLOSSARY

1-BP — 1-Bromopropane
1,1-DCE — 1,1-Dichloroethane
1,2-DCE — 1,2-Dichloroethane (also known as ethylene dichloride, EDC)
6:2 FTAc — 6:2 Fluorotelomer Acrylate
6:2 FTSB — 6:2 Fluorotelomer Sulfonamide Betaine
6PPD — N-(1,3-Dimethylbutyl)-N′-phenyl-p-phenylenediamine
ABNT — Brazilian Association of Technical Standards
ACC — American Chemistry Council
ACD2 — Accelerated Cell Death 2
ACOR — Australian Council of Recycling
Acta® — The Acta Group
ADA — Azodicarbonamide
ADAO — Asbestos Disease Awareness Organization
AICIS — Australian Industrial Chemicals Introduction Scheme
ALJ — Administrative Law Judge
AMS — Agricultural Marketing Service
ANPRM — Advance Notice of Proposed Rulemaking
APCO — Australian Packaging Covenant Organization
APHIS — Animal and Plant Health Inspection Service
APRA — Advancing Plastics Recycling in Australia
ASEAN — Association of Southeast Asian Nations
ATE — Acute Toxicity Estimates
ATP — Adaptation to Technical Progress
ATRm — Alternative Transitional Registration Model
B&C® — Bergeson & Campbell, P.C.
B2B — Business-to-Business
BBP — Butyl Benzyl Phthalate
BCCM — B&C® Consortia Management, L.L.C.
BHA — Butylated Hydroxyanisole
BHT — Butylated Hydroxytoluene
BLT — Bulletins Live! Two
BPA — Bisphenol A
BPR — Biocidal Products Regulation
BRS — Biotechnology Regulatory Services
C&L — Classification and Labelling
CAA — Circular Action Alliance
CAC — Clean Air Council (TSCA)
CAC — County Agricultural Commissioners (FIFRA)
CAS RN® — Chemical Abstracts Service Registry Number®
CBE — Communities for a Better Environment
CBI — Confidential Business Information
CCCR — Consumer Chemicals and Containers Regulations, 2001
CCPSA — Canada Consumer Product Safety Act
CDR — Chemical Data Reporting
CDX — Central Data Exchange
CEA — Center for Environmental Accountability
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
CGMP — Current Good Manufacturing Practices
CLH — Harmonized Classification and Labeling
CLP — Classification, Labelling and Packaging
CMR — Carcinogenic, Mutagenic, or Toxic to Reproduction
CNS — Chinese National Standard
COFEPRIS —Comisión Federal para la Protección contra Riesgos Sanitarios
CONASQ — Comissão Nacional de Segurança Química
CoRAP — Community Rolling Action Plan
COU — Condition of Use
CPR — Cosmetics Products Regulation
CRO — Contract Research Organization
CRS — Congressional Research Service
CSAR — Cosmetics Supervision and Administration Regulation
CSF — Confidential Statement of Formula
CSS — Chemicals Strategy for Sustainability
CUU — Currently Unavoidable Use
CVM — Center for Veterinary Medicine
CWA — Clean Water Act
D4 — Octamethylcyclotetra-siloxane
DBP — Dibutyl Phthalate
DCCEEW — Department of Climate Change, Energy, the Environment and Water
DCHP — Dicyclohexyl Phthalate
DCI — Data Call-In
DCNA — Dicloran
decaBDE — Decabromodiphenyl Ether

DEFRA — Department for Environment, Food and Rural Affairs
DEHP — Di-ethylhexyl Phthalate
DEI — Diversity, Equity, and Inclusion
DEQ — Department of Environmental Quality
DIBP — Di-isobutyl Phthalate
DIDP — Di-isodecyl Phthalate
DINP — Di-isononyl Phthalate
DnOP — Di-n-octyl phthalate
DOD — U.S. Department of Defense
DOGE — Department of Government Efficiency
DPR — California Department of Pesticide Regulation
dsRNA — Double-stranded RNA
EA — Environmental Assessment
EC — European Commission
ECCC — Environmental and Climate Change Canada
ECEL — Existing Chemical Exposure Limit
ECGT — Directive on Empowering Consumers for the Green Transition
ECHA — European Chemicals Agency
ECRAD — Existing Chemicals Risk Assessment Division
EDC — Ethylene Dichloride (also known as 1,2-dichloroethane)
EDF — Environmental Defense Fund
EDSP — Endocrine Disruptor Screening Program
EHS — Environmental, Health, and Safety
EIB — New Mexico's Environmental Improvement Board
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
EPR — Extended Producer Responsibility
ESA — Endangered Species Act
ESPR - Ecodesign for Sustainable Products Regulation
EU — European Union
EUDR — European Union Deforestation Regulation
EUH — European Union Hazard
EWG — Environmental Working Group
f/cc — Fibers per Cubic Centimeter
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
FOIA — Freedom of Information Act
FQPA — Food Quality Protection Act
FSIS — Food Safety and Inspection Service
FTE — Full-Time Equivalent
FWS — U.S. Fish and Wildlife Service
FY — Fiscal Year
GB — Great Britain
GCD — Green Claims Directive
GE — Genetically Engineered
GFI — Guidance for Industry
GHS — Globally Harmonized System of Classification and Labelling of Chemicals
GLP — Good Laboratory Practices
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
HCS — Hazard Communication Standard
HDPE — High-Density Polyethylene
HFP — Human Foods Program
HFPO — 2,3,3,3-Tetrafluoro-2-heptafluoropropoxy) propanoyl fluoride
HHCB — 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[γ]-2-benzopyran
HHHOC — Human Health Hazard of Concern
HHS — U.S. Department of Health and Human Services
HPA — Hazardous Products Act
HPR — Hazardous Products Regulation
HSE — Health and Safety Executive
HSGM — Turkish Ministry of Health, General Directorate of Public Health
HSNO — Hazardous Substances and New Organisms
HSRB — Human Studies Review Board

ICR — Information Collection Request
IECIC — Inventory of Existing Cosmetic Ingredients in China
IECSC — Inventory of Existing Chemical Substances in China
IEPA — Illinois Environmental Protection Agency
IGA — Intentional Genomic Alteration
Inhance — Inhance Technologies, L.L.C.
INSQUI — Inventario Nacional de Sustancias Químicas de Uso Industrial
IRIS — Integrated Risk Information System
IT — Information Technology
IUCLID — International Uniform ChemicaL Information Database
IUR — Inhalation Unit Risk
K-BPR — Consumer Chemical Products and Biocides Safety Act
K-OSHA — South Korean Occupational Safety and Health Act
K-REACH — Act on the Registration and Evaluation of Chemicals
kg — Kilogram
KKDIK — Kimyasalların Kaydı, Değerlendirilmesi, İzni ve Kısıtlanması
KKS — Kimyasal Kayıt Sistemi
Lautenberg — Frank R. Lautenberg Chemical Safety for the 21st Century Act
LCPFAC — Long-chain Perfluoroalkyl Carboxylate
Lls1 — Lethal Leaf Spot 1
LoREX — Low Release and Low Exposure Exemption
LR — Lead Registrant
LSHC — Law on Safety of Hazardous Chemicals
LVE — Low Volume Exemption
MADL — Maximum Allowable Dose Level
MAHA — Make America Healthy Again
MBOCA — 4,4′-Methylenebis(2-chloroaniline)
MC — Methylene Chloride
MCAN — Microbial Commercial Activity Notice
MCDA — Multi-Criteria Decision Analysis
MCL — Maximum Contaminant Level
MCLG — Maximum Contaminant Level Goals
MCL List — Mandatory Classification and Labeling List
MEE — Ministry of Ecology and Environment
mg/m³ — Milligram per Cubic Meter
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 — Margin of Exposure (TSCA)
MoE — Ministry of Environment
MoEL — Ministry of Employment and Labor
MOENV — Ministry of Environment
MoEUCC — Ministry of Environment, Urbanization and Climate Change
MoH — Ministry of Health
MOIT — Ministry of Industry and Trade
MPCA — Minnesota Pollution Control Agency
MRL — Maximum Residue Limit
MRRE — Manufacturer-Requested Risk Evaluation
MS — Member State
MSA — Microplastics Safety Act
MSDS — Material Safety Data Sheet
NAM — New Approach Methodologies (TSCA)
NAM — New Approach Methods (FDA)
NAP — National Action Plan (UK)
NASA — National Aeronautics and Space Administration
NAW — National Association of Wholesaler-Distributers
NCD — New Chemicals Division
NDAA — National Defense Authorization Act
NEHI — Nanotechnology Environmental and Health Implications
NEPA — National Environmental Policy Act
NEPM — National Environment Protection (Used Packaging Materials) Measure
NESHAP — National Emission Standards for Hazardous Air Pollutants
New Zealand EPA — New Zealand Environmental Protection Authority
NGO — Non-governmental Organization
NHC — National Health Commission
NICS — National Institute of Chemical Safety
NIH — National Institutes of Health
NMED — New Mexico Environment Department
NMeFOSE — 2-(N-Methylperfluoro-1-octanesulfonamido) ethanol

NMP — N-Methylpyrrolidone
NMPA — National Medical Products Administration
NNCO — National Nanotechnology Coordination Office
NNI — National Nanotechnology Initiative
NOAA — National Oceanic and Atmospheric Administration
NPC — National People's Congress
NPCSC — National People's Congress Standing Committee
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
NRDC — Natural Resources Defense Council
NSCEB — National Security Commission on Emerging Biotechnology
NSRL — No Significant Risk Level
NZBN — New Zealand Business Number
OCSPP — Office of Chemical Safety and Pollution Prevention
OEC — Oregon Environmental Commission
OECA — Office of Enforcement and Compliance Assurance
OECD — Organisation for Economic Co-operation and Development
OEHHA — Office of Environmental Health Hazard Assessment
OMB — Office of Management and Budget
OP — Organophospate
OPMP — Office of Pest Management Policy
OPP — Office of Pesticide Programs
OPPT — Office of Pollution Prevention and Toxics
OR — Only Representative
ORD — Office of Research and Development
OSHA — U.S. Occupational Safety and Health Administration
OTNE — Octahydro-Tetramethyl-Naphthalenyl-Ethanone
OTT — Over The Top
PAG — Photo Acid Generator
PANNA — Pesticide Action and Agroecology Network North America
PBT — Persistent, Bioaccumulative, and Toxic
PCE — Perchloroethylene, also known as PERC
PCPC — Personal Care Products Council
PEER — Public Employees for Environmental Responsibility
PEL — Permissible Exposure Limit
PERC — Perchloroethylene, also known as PCE
PFAA — Perfluoroalkyl Acids
PFAS — Per- and Polyfluoroalkyl Substances
PFBA — Perfluorobutanoic Acid
PFBS — Perfluorobutanesulfonic Acid
PFDA — Perfluorodecanoic Acid
PFHxA — Perfluorohexanoic Acid
PFHxS — Perfluorohexanesulfonic Acid
PFHxS-Na — Sodium Perfluorohexanesulfonate
PFNA — Perfluorononanoic Acid
PFOA — Perfluorooctanoic Acid
PFOS — Perfluorooctanesulfonic Acid
PHRA — Plastic Health Research Act
PIF — Product Information File
PIP — Plant-Incorporated Protectant
PLCP — Papain-Like Cysteine Protease
PM — Project Management
PMN — Premanufacture Notice
PMRA — Pest Management Regulatory Agency
PMT — Persistent, Mobile, and Toxic
POD — Point of Departure
POP — Persistent Organic Pollutant
PPA — Plant Protection Act
PPDC — Pesticide Program Dialog Committee
PPE — Personal Protective Equipment
PPF — Principles and Procedures Framework
PPG — PPG Industries, Inc.
ppm — Part Per Million
PPP — Plant Protection Product
PPPR — Plant Protection Product Regulation
PRIA — Pesticide Registration Improvement Act
PRIA 5 — Pesticide Registration Improvement Act of 2022
PRN — Pesticide Registration Notice
PRO — Producer Responsibility Organization
Prop 65 — Proposition 65
PRRS — Porcine Reproductive and Respiratory Syndrome
PULA – Pesticide Use Limitation Area
PV29 — Colour Index Pigment Violet 29
QR Code — Quick Response Code
R&D — Research and Development

RAC — Risk Assessment Committee
RAP — Rolling Action Plan
RCRA — Resource Conservation and Recovery Act
REACH — Registration, Evaluation, Authorisation and Restriction of Chemicals
Rev — Revised Edition
RFC — Request for Correction
RFCU — Reasonably Foreseeable Condition of Use
RFI — Request for Information
RFR — Request for Reconsideration
RIF — Reduction in Force
RMOA — Risk Management Option Analysis
RO1 — Restriction Option 1
RO2 — Restriction Option 2
RO3 — Restriction Option 3
RoHS — Restriction of Hazardous Substances
RQ — Reportable Quantity
RSR — Regulatory Status Review
RUP — Restricted Use Pesticide
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
SAP — Scientific Advisory Panel
SDS — Safety Data Sheet
SEAC — Committee for Socio-Economic Analysis
SECURE — Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient
SEMARNAT —Secretaría de Medio Ambiente y Recursos Naturales
SENASICA — Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria
SME — Small and Medium Enterprises
SML — Specific Migration Limits
SNAP — Supplemental Nutrition Assistance Program
SNUN — Significant New Use Notice
SNUR — Significant New Use Rule
SS — Singapore Standard
SVHC — Substances of Very High Concern
SWA — Safe Work Australia
T-BPR — Turkey Biocidal Products Regulation
Taiwan FDA — Taiwan Food and Drug 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
TCE — Trichloroethylene
TCEP — *tris*(2-Chloroethyl) Phosphate
TDCE — *trans*-1,2-Dichloroethylene
TDR — Tiered Data Reporting
TERA — TSCA Environmental Release Application
TES — Threatened and Endangered Species
TPP — Phosphoric Acid, Triphenyl Ester
TRI — Toxics Release Inventory
TSCA — Toxic Substances Control Act
TWA — Time Weighted Average
UCC — Union Carbide Corporation
UID — Unique Identifier
UK — United Kingdom
UN — United Nations
UNECE — United Nations Economic Commission for Europe
USDA — U.S. Department of Agriculture
vPvB — Very Persistent and Very Bioaccumulative
vPvM — Very Persistent and Very Mobile
WCPP — Workplace Chemical Protection Program
WHS — Work Health and Safety
WTO — World Trade Organization

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Updated on December 11, 2025

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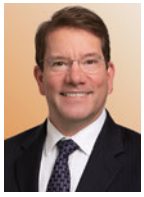

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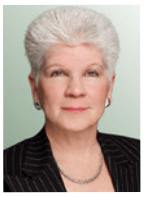

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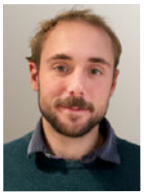

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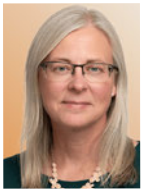

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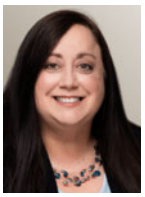

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