



BERGESON & CAMPBELL, P.C.

Forecast for U.S. Federal and International Chemical Regulatory Policy 2019



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FORECAST 2019

Bergeson & Campbell, P.C. (B&C[®]) and its consulting affiliate The Acta Group (Acta[®]) are pleased to offer you our Forecast 2019. In this richly detailed document, the legal, scientific, and regulatory professionals of B&C and Acta distill key trends in U.S. and global chemical law and provide our best informed judgment as to the shape of key developments we are likely to see in the New Year.

Our unique business platform and growing global team of highly skilled professionals are perfectly suited to offer this detailed forecast for 2019. Our core business, about which each of us feels passionately, is the law, science, regulation, and policy of chemicals of all varieties -- industrial, agricultural, intermediate, specialty, biocidal, manufactured at the bulk or nano scale, or using conventional or innovative technologies including biotechnology, synthetic biology, or biobased. Our highly acclaimed team of scientists (seven Ph.D.s) including toxicologists, exposure experts, and geneticists; regulatory and policy experts; and lawyers is deeply versed in chemical law, science, and policy and our specialized business platform seamlessly leverages and ensures the integration of law and science to achieve success at every level, and in all parts of the globe.

We offer you our very best wishes for good health and happiness in the New Year, and continued commercial success in your business endeavors.

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I. UNITED STATES: CHEMICAL FORECAST

A. Introduction

Once again, we get to exclaim: What a difference a year makes! Another election has redefined the political winds in Washington, or at least, agitated them. And now, believe or not, the **2020** Presidential election race begins in earnest. What these new currents will mean for the U.S. Environmental Protection Agency (EPA) in general and the Office of Chemical Safety and Pollution Prevention (OCSPP) in particular is subject to much speculation: will aggressive oversight by the new Democratic House majority stymie Administration initiatives? Will the Administration continue to move forward on numerous initiatives to “reform” Washington or, as we suggested a year ago, will much of the anticipated agenda of the Trump Administration remain unfulfilled, prospective, and fluid at best? And, finally, will there be any bipartisan cooperation on any legislation of substance -- or simply a cacophony of political insult and tumult while the wheels of government grind on in spite of what some refer to as “the circus?”

Behind the more visible political activities and rhetoric of both parties, there remains serious business that Executive Agencies like EPA must attend to: implementation of the laws designed to protect the air and water; clean up and regulation of hazardous waste; regulation of toxic chemicals; and ensuring that pesticides used on crops are both safe to use and avoid unreasonable impacts on the environment. For OCSPP, the agenda remains busy as the not-so-new (but immensely important) TSCA amendments, now 30 months after enactment, reach critical decision points about definitions of key terms and appropriate approaches to assessing chemical risks. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) issues remain controversial with regard to both individual pesticides causing controversies (example: chlorpyrifos) as well as continued debates about policies used to comply with the Endangered Species Act (ESA), which necessarily involves interagency coordination -- always a tenuous endeavor.

And all of this, party control of Congress, controversies about EPA, Presidential ambition of more than a dozen U.S. Senators, is a subset of the global issues surrounding the regulation of pesticides and toxic chemicals on the world stage. Our predictions presented here attempt to cover that even broader waterfront.

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1. Elections Have Consequences

The 2018 elections will bring a change in the party control of the House of Representatives. With Democrats in charge, EPA and other agencies will face intense scrutiny and probing inquiries as part of Congressional oversight of Executive Branch agencies. Effective oversight is no small task. Developing penetrating and effective oversight will take some time as the new Congress organizes committee leadership positions and jurisdictions (both formal and informal) between committee responsibilities. The committees must hire new staff that will then have to become familiar with both the subject matter and how to conduct oversight. Compared to when the Democrats last had control, some important veterans are now retired. Specifically, Rep. Henry Waxman (D-CA) and Rep. John Dingell (D-MI) are now retired, and the absence of their oversight experience over EPA programs will be noticeable. For OCSPP, the major committees of jurisdiction in the House are the House Agriculture Committee for FIFRA and the House Energy and Commerce Committee for both TSCA and the Federal Food, Drug, and Cosmetic Act (FFDCA) (which dictates the requirements EPA is to follow to ensure the safety of residues of pesticides used on food).

In the Senate, there are at least four Senators widely presumed to be Presidential candidates on the Environment and Public Works Committee, which has jurisdiction over TSCA implementation. This will allow Sens. Cory Booker (D-NJ), Kirsten Gillibrand (D-NY), Jeff Merkley (D-OR), and Bernie Sanders (D-VT) to have a platform to emphasize environmental protection issues on a regular basis. The Senate Agriculture Committee, with jurisdiction over FIFRA, will have three members seen as Presidential candidates: Sens. Klobuchar, Gillibrand, and Brown.

Of most concern will be environmental issues of broad interest and media coverage -- examples include climate change, EPA budget and enforcement activities, lead poisoning, and contaminated drinking water. At the same time, as the many candidates vie for visibility, pesticide regulation or controls on toxic chemicals could emerge as an identifying issue for a candidate (example: presence of legacy perfluorinated chemicals in drinking water in some parts of the country -- perhaps including Iowa or New Hampshire).

2. EPA Leadership

Two years into the Trump Administration, EPA finds itself still missing a number of senior appointees who typically would have significant experience in their respective offices. Most obvious is the lack of an EPA Administrator, due to the resignation of Scott Pruitt under a cloud of controversies. Effective July 6, 2018, Mr. Pruitt resigned his office; this elevated Andrew Wheeler to Acting Administrator -- who had only recently been himself confirmed to the position of Deputy Administrator in April 2018. Mr. Wheeler faced questions about his past experience as an energy lobbyist and in particular his representation of coal company interests. To date, however, Mr. Wheeler has not engendered the kind of bitter and withering concerns about his policy decisions and general actions as Acting Administrator that Mr. Pruitt did when in office (which is subject to change, of course). Some of the reasons behind his "gentler" approach and reputation may be due to his background as a member of the Washington "establishment" -- or perhaps more interestingly as a former federal employee. In fact, earlier in his career Mr. Wheeler worked in what is now OCSPP -- as part of OPPT -- which then, as now, was responsible for implementing TSCA (in his case, the "old" TSCA). President Donald Trump announced on November 16, 2018, that he intends to nominate Wheeler to be Administrator permanently.

For OCSPP, the leadership situation is still in flux. Two years into the new Administration, OCSPP still awaits the arrival of a new Assistant Administrator (AA). The first nominee for the position was announced in July 2017: Michael L. Dourson, Ph.D., a toxicologist with an extensive background in the risk assessment of chemicals and pesticides, who was at one time a career employee at EPA. Despite what would seem to be strong qualifications for the position, controversy over Dr. Dourson's past work, sponsored by industry, on various controversial chemicals undergoing review by EPA, led at least three Republican Senators to declare that they would not support Dr. Dourson; Dr. Dourson asked that his nomination be withdrawn in December 2017.

Finally, in August 2018, a second nominee was announced: Ms. Alexandra Dapolito Dunn who currently serves as the Regional Administrator (RA) of EPA's Region 1. This region covers EPA program activities in New England including the states of Connecticut, Massachusetts, Rhode Island, Vermont, New Hampshire, and Maine. Ms. Dunn has also served as the Executive Director of the Environmental Council of the



The “science rule” was published as a proposed rule, but has faced intense criticism on almost every aspect of it including how it might work, the meaning of various new terms used in the proposal, what kinds of “science” new requirements would apply to, and fundamentally the authority upon which any new regulation would be based.

States (ECOS), an organization of state environmental regulatory agencies. The AA positions are subject to Senate confirmation (the RA positions are not), so Ms. Dunn could not simply be transferred into the OCSPP position. Ms. Dunn had to undergo the process of consideration by the Senate Environment and Public Works Committee and will undergo a vote by the Senate. On November 29, 2018, the Senate Environment and Public Works Committee convened a confirmation hearing on the nomination of Ms. Dunn, and the full Senate approved the confirmation on January 2, 2019.

3. Administration Initiatives

Notwithstanding any turmoil about appointments, the Administration generally continued high-profile priorities initiated earlier. Along with the arrival of President Trump came a flurry of Executive Orders (EO) and other directives designed to foster business investment and lessen the requirements imposed on regulated entities. Across the government, including EPA, there has been a continued emphasis on “regulatory reform” initiatives, budget cuts, and reforming the civil service personnel system. For EPA, this meant continuation of efforts to, among other things, review and revise controversial regulations in the air and water and all EPA media programs, along with a new initiative to “improve” EPA science.

The reviews of individual regulations and any proposals for changing previously established regulations must follow the rulemaking process, which is inherently cumbersome and time-consuming. Those efforts are ongoing across the various EPA media programs.

The stated purpose of the science proposal is to ensure that the “science” EPA relies on is sound through meeting certain guidelines about the quality and availability of “pivotal”

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science studies and review policies. Essentially, it is an attempt to propagate the legislation that advanced in the House but was not supported in the Senate: H.R. 1430, the “Honest and Open New EPA Science Treatment Act of 2017” or “HONEST Act.” The purpose of this legislation was to address criticism that EPA in the past has been selective in its emphasis on what science can justify a regulatory proposal and downplay the expected costs. Others see the proposal for new procedures and requirements as an agenda to slow down the development of, and reduce the protections offered by, regulatory options available under environmental laws.

The “science rule” was published as a proposed rule, but has faced intense criticism on almost every aspect of it including how it might work, the meaning of various new terms used in the proposal, what kinds of “science” new requirements would apply to, and fundamentally the authority upon which any new regulation would be based. In short, it is not clear how or when the Administration might proceed to refine further and eventually promulgate a final “rule” in this context. Acting Administrator Wheeler has stated publicly, however, that he plans to move the rule forward to completion as it is important for EPA to be more transparent and to increase confidence in EPA decisions.

Concerning the budget, proposals for reducing the budgets of EPA and other agencies have not been supported by Congress; instead of budget cuts of 15-25 percent, as proposed by the President’s budget, EPA has remained capable of absorbing any reductions without drastic action to personnel or program activities. Budgets and personnel numbers continue to shrink, however, and when combined with proposals for reductions in pension funding, “streamlined” procedures for firing employees, and lengthening the time for automatic increases in staff pay grades, the federal workforce at EPA and across the government will face eroding morale and less incentive to remain in or join federal service. With a projected 41 percent of the federal workforce eligible to retire in the next five years, and with restrictions on hiring new staff, a steady drip of budget cuts, and changes to the pension scheme, the government altogether may face a serious personnel crisis in the coming years.

4. Operating Environment

4.1 Congress

The biggest change in the operating environment for any Executive Branch agency is the change in party control in the House of Representatives. An analysis by EPA's office that addresses Congressional affairs counted 30 Committees and Subcommittees in the House of Representatives with some jurisdiction over EPA program activities (they counted 21 in the Senate). These include Committees relating to appropriations, environmental laws, oversight of government program implementation, and general agency operations. Congressional offices will also ask the General Accountability Office (GAO) and even the Congressional Research Service (CRS) to evaluate program initiatives and behavior. Altogether, there will be a significant amount of distraction for senior program officials, but in addition, the rank-and-file staff (non-political) will be engaged supporting the responses and testimony of the senior political officials. And, each of the 30 Committees and Subcommittees of the House has a press operation, looking to ensure favorable media coverage for the leadership of the Committee -- for some, that will mean the more provocative the headline, the better.

Some speculate that the divided control between the House and Senate will mean little substantive legislating will be successful. Besides any expected partisan grandstanding, the Committees across both the House and Senate will have to agree on budgets and spending for government programs. Amendments to these "must pass" bills then become a target for pushing forward by one or both sides on key priorities (immigration and health care, to name two). In recent years, raising the debt ceiling and funding government operations have led to threats of a shutdown and consumed significant legislative capital while the debates continue. It is widely assumed that the prospects for any breakthrough towards compromise or serious cooperation among the constituencies appear to be remote.

4.2 Media Coverage

As we noted last year, media coverage of EPA actions under the Trump Administration has been intense and mostly critical. News in the current era is described as "tribal" -- consumers can pick from many sources and receive a constant stream of information tuned to their

personal biases without necessarily receiving many contrary views. One problem with media coverage of media coverage is that it is covered by the media. One person's "fake news" is another person's important stand of telling truth to power.

Major national news outlets spent significant time on where former Administrator Pruitt shopped for a mattress, whether he had the siren on when he was in a vehicle, and to who and how much he paid rent to while in Washington, D.C. This coverage raised important questions of whether laws about conflict of interest were violated and possible violations of spending rules. It also meant that less reporting time and energy was spent on how best to address air or water pollution issues, actions states were taking to protect the environment in their jurisdiction, or what was going on behind the scenes at EPA in the media programs.

Ad hominem attacks are not new in politics, but the present rancor in Washington has raised the intensity and focus of such attacks to an unprecedented level. Advocates of all views have taken to attacking the messenger as well as the message to support a position. Given the expected "oversight" and "investigations" into the Administration, there is likely to be more intense scrutiny of not only actions, but also the personal behavior, of those in question.

4.3 Litigation

Litigation is a time-tested tool of advocacy, either to support or to prevent change to a desired policy position. As soon as the new Administration arrived, environmental advocacy groups planned on using litigation as a key strategy since advocacy through both the Executive and Legislative branches of government was considered to be ineffective. Two years later, that plan has been executed, and it has been effective in both delaying some changes in rules and policies sought by the Administration and in ensuring that proper tools and procedures are followed in making changes to established regulations. For example, using Executive Orders to "make it happen" and other means simply to impose changes have been slowed or reversed due to procedural defects. Similarly, even when the appropriate procedures were followed to propose changes, challenges to the development process or judicial challenges to the final decision have been filed to delay or reverse the outcome.

Litigation is also not a new tool, but here again the frequency and intensity of using the tool has been emphasized.

B. TOXIC SUBSTANCES CONTROL ACT (TSCA)

1. Predictions and Outlook for the U.S. Environmental Protection Agency's Office of Chemical Safety and Pollution Prevention 2019

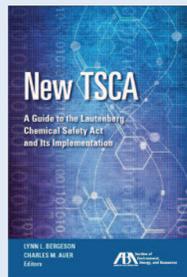
The U.S. Environmental Protection Agency's (EPA) Office of Chemical Safety and Pollution Prevention (OCSPP) has been drinking from the proverbial firehose all year, working hard to comply with the many deadlines embedded in the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg) in addition to fulfilling its regularly scheduled programming. Bergeson & Campbell, P.C.'s (B&C®) Toxic Substances Control Act (TSCA) [TSCAblog™](#) has closely tracked and reported on all implementation measures, which OCSPP has done a good job in addressing timely and well. The summary below reflects our thoughts on key issues.

1.1 Section 4 -- Testing

(a) Regulatory Actions

Two years post implementation of Lautenberg, and EPA has not yet issued a Section 4 testing action. Given issues that have been raised as part of Section 5 reviews about toxicological concerns with certain categories of chemicals, it is somewhat surprising that EPA has not yet used its new order authority under Section 4. EPA has focused instead on issuing Section 5(e) testing requirements on individual new chemical submitters. The inability of EPA to require testing under old TSCA was one of the primary issues of concern in amending the law. While industry may not relish being subject to such testing, EPA needs to utilize the tools afforded to it by Congress to help address data gaps more equitably and improve the knowledge of hazard and exposure to chemicals.

EPA might use the Section 4 tools (particularly the new order authority) to fill critical data needs as part of the ongoing risk evaluations under Section 6. At the same time, the short deadline for completing risk evaluations will affect EPA's ability to obtain completed studies that can be timely reviewed and incorporated in risk evaluations. EPA has indicated that it may not proceed with prioritization



For a comprehensive and, to date, one-of its kind guide to the substantial revisions to TSCA occasioned by enactment of Lautenberg, look no further than our book [New TSCA: A Guide to the Lautenberg Chemical Safety Act and Its Implementation](#), American Bar Association Section of Environment, Energy, and Resources (2017).

for chemicals that do not have sufficient data. Section 4 is the tool available to address that issue, although to use order authority in such cases (rather than a rule or an enforceable consent agreement (ECA)), EPA would need to support a “may present” conclusion. Another complication in requiring prioritization testing is that EPA must make a prioritization designation within 90 days after receiving the Section 4 information.

B&C believes it is likely, given the completion in 2018 of the “framework” rules required under new TSCA, that Section 4 testing actions will be taken in 2019.

(b) Alternative Test Methods

As required under TSCA Section 4(h)(2)(A), EPA released its [Strategic Plan to Promote the Development and Implementation of Alternative Test Methods Within the TSCA Program](#) (Strategic Plan) in June 2018. The goal of the Strategic Plan is to reduce the level of testing in vertebrates and the strategy relies on a range of applications and testing approaches to characterize human health and environmental endpoints. EPA coined a new term “new approach methodologies” (NAM) as encompassing any “alternative test methods and strategies to reduce, refine or replace vertebrate animal testing.” The Strategic Plan identified current and near term (under three years), intermediate (five years), and longer (unspecified) term activities. More information is available in our June 22, 2018, [memorandum](#) and in our [podcast](#) on “Animal Testing and New TSCA.” In 2019, EPA is expected to continue to apply existing NAMs to evaluate hazard, exposure, and environmental fate for new and existing chemicals, extend the application of NAMs to identify candidates for prioritizing chemicals for risk evaluation, and develop information technology platforms to disseminate and increase access to these tools.

1.2 Section 5 -- New Chemicals

Return to equilibrium on new chemicals.

Table 2. Section 5(a) Case Statistics under New TSCA from June 22, 2016 - November 27, 2018¹

	All Valid Cases	Completed PMN Cases
Total valid cases²	1,410	
Determinations completed	1,774 (76%)	
Determinations under review	563 (24%)	
Completed 5(a) cases³	847 (36%)	847 (100%)
§5(g) “not likely” determination	169 (7%)	169 (20%)
§5(g) “not likely” with SNUR	13 (0.6%)	13 (1.6%)
§5(e) order allowing commercialization with restriction	438 (19%)	438 (52.5%)
§5(e) order with testing required before commercialization	6 (0.3%)	6 (0.7%)
Cases withdrawn by notifier	221 (10%)	221 (26.5%)
Uncompleted cases⁴	563 (24%)	

¹ Based on EPA’s Statistics for the *New Chemicals Review Program under TSCA*, available at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsc/statistics-new-chemicals-review#stats>. It includes premanufacture notices (PMN), Microbial Commercial Activity Notices (MCAN), and Significant New Use Notices (SNUN), but excludes exemption notices, that were within the 90-day review period as of June 22, 2016 -- cases in which EPA restarted the 90-day clock and re-reviewed regardless of the outcome of its initial review.

² Total Section 5(a) notices (PMN, SNUN, MCAN) received minus invalid or incomplete cases (N = 106).

³ TSCA Section 5(a)(3) determination (PMN, SNUN, MCAN) and final Section 5(e) or Section 5(g) action, as appropriate, completed; the right-hand column provides the breakdown as a percentage of the completed cases.

⁴ Valid PMN cases that await final determinations (Total valid cases, less withdrawn PMNs, and both completed and withdrawn Low Volume Exemptions (LVE)).

At the end of 2018, EPA no longer proposed consent orders or Significant New Use Rules (SNUR) on chemicals for which it has identified a hazard other than low hazard for health and ecotoxicity endpoints (so-called low/low cases). B&C has written and commented extensively on the lack of legal and policy support for such a broad interpretation of “not likely to present unreasonable risk under the reasonably foreseen conditions of use.” See Lynn L. Bergeson, Richard E. Engler, Charles M. Auer, and Kathleen M. Roberts, “[New Chemicals Under New TSCA -- Stalled Commercialization](#),” *Bloomberg Environment Insights*, September 11-13, 2018; Charles M. Auer, Lynn L. Bergeson, “[Role of ‘Conditions of Use’ Under Sections 5 and 6 of Amended Toxics Law](#),” *BNA Daily Environment Report*, October 14, 2016. Thus, EPA is moving away from its initial view under amended TSCA that any identifiable hazard required it to propose a regulation. EPA held this view because “reasonably foreseen” was interpreted as synonymous with “any conceivable” and “not likely” was synonymous with “reasonable certainty.” Neither of these interpretations is supported in the language of the statute, nor in the legislative record. B&C applauds this careful reconsideration of the new law’s requirements.

Another notable change is that EPA is now relying on the U.S. Occupational Safety and Health Administration (OSHA) for routine worker protection, especially dermal and eye protection. In the first two years after enactment of Lautenberg, EPA was foreseeing that workers would not use personal protective equipment (PPE) absent the issuance of a consent order or SNUR requiring this result. The B&C-led TSCA New Chemicals Coalition (NCC) demonstrated that, based on OSHA’s database of violations that covers four decades and more than 12 million violations, only a tiny fraction of OSHA violations related to workers not using appropriate gloves, goggles, or general dermal protection. After receiving this information, EPA shifted its view of what is reasonably foreseen regarding use of worker protection.

(a) Backlog of “5e SNURs” Getting Cleared

EPA has proposed many SNURs derivative of Section 5(e) consent orders. EPA is required, under new TSCA, to do so or to explain why the companion SNUR is not necessary. B&C expects that EPA will continue its work to publish 5(e) SNURs and clear this backlog at some point in 2019.



EPA stated that, since it issued the Framework Document for comment in November 2017, it has made 150 determinations on PMNs under TSCA Section 5(a)(3), but “has not yet followed the SNUR approach described in the Framework.”

(b) Non-order SNURs Proposed

EPA took the novel step of proposing a SNUR in October 2018 to make certain conditions of use subject to SNUR notification once the SNUR is in place, such that these conditions of use would not be reasonably foreseeable for purposes of the associated PMNs. With the limitation on foreseeable conditions of use, EPA could then make “not likely” determinations on these cases. Although this construction is not specified in Lautenberg, neither is it prohibited. New TSCA requires that EPA enter into a consent order if EPA makes a “may present” or other Section 5(a)(3)(B) determination. If, on the other hand, there are enforceable SNUR limits on what would otherwise be reasonably foreseen conditions of use that might lead to concerns, EPA can determine that these conditions of use are no longer reasonably foreseeable (because they are prohibited by the SNUR) and, as such, EPA can make a “not likely” finding.

If, following consideration of comments on the first proposed non-order SNUR, EPA proceeds to issue the SNUR in final as proposed, B&C believes that additional such SNURs will be proposed in 2019, thus clearing out additional backlog cases. The interpretation that underlies the non-order SNUR approach, however, relates to issues raised in the New Chemicals Decision-Making Framework litigation discussed below. For this reason, we believe that the final SNUR seems likely to be the target of future litigation.

(c) New Chemicals Litigation

In January 2018, the Natural Resources Defense Council (NRDC) petitioned the U.S. Court of Appeals for the Second Circuit for review of EPA’s [“New Chemicals Decision-Making Framework: Working Approach to Making Determinations under Section 5 of TSCA”](#) (Framework Document). *NRDC v. EPA*, No. 18-25. In its petition for review, NRDC described the Framework Document as a final rule, and argued in its May 1, 2018, opening brief that, based on the Framework Document, EPA “limits its review of a new chemical substance to the manufacturer’s intended conditions of

use and disregards Congress’s instruction to address risk concerns through enforceable orders and regulations.” EPA’s July 31, 2018, opening brief included a declaration from Office of Pollution Prevention and Toxics (OPPT) Director Jeffery Morris, Ph.D. According to Morris, EPA considers the “conditions of use” of the PMN when making determinations under TSCA Section 5(a)(3).

EPA stated that, since it issued the Framework Document for comment in November 2017, it has made 150 determinations on PMNs under TSCA Section 5(a)(3), but “has not yet followed the SNUR approach described in the Framework.” For 19 PMNs, EPA determined that the new chemical substance was not likely to present an unreasonable risk. According to EPA, “[f]or none of these determinations did EPA consider whether a significant new use rule had been issued in concluding that unreasonable risk was unlikely.” Additionally, for 131 determinations, EPA made a determination under TSCA Section 5(a)(3)(B) related to the sufficiency of information regarding the substance, and then issued orders under TSCA Section 5(e). The basis for a significant number of these determinations was related to the reasonably foreseen conditions of use of the new chemical substance at issue. In light of EPA’s representations, NRDC filed a motion on August 27, 2018, for voluntary dismissal of its petition for review.

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Several weeks after the court dismissed the suit, EPA proposed non-order SNURs for new chemicals with pending PMNs. The preamble to the proposed rule contains novel language to address the new circumstances and legal issues encountered in the rule and, as noted, B&C expects that there will be a legal challenge to this interpretation of Section 5 if the SNURs are promulgated as proposed.

1.3 Section 6 -- Existing Chemicals

(a) Prioritization

TSCA Section 6(b)(2)(B) requires that, as of three and a half years after enactment (by **December 22, 2019**), at least 20 high-priority chemicals to be undergoing risk evaluations (these appear to be in addition to the “first ten” risk evaluations currently underway as discussed below) and at least 20 low-priority chemicals to be designated by EPA. Accordingly, between now and **December 2019**, EPA must identify at least 20 high- and 20 low-priority candidates and then complete the prioritization designation process within the allowed nine to 12 months. The process will be conducted consistent with the prioritization procedural rule (40 C.F.R. Section 702.5) which, as discussed below, has been legally challenged. EPA also released the document [A Working Approach for Identifying Potential Candidates for Prioritization](#) (Working Approach) that it plans to apply in this process.

Under the near-term Working Approach, EPA plans to identify high-priority candidate chemicals by using information from other EPA program offices, state and federal agencies, and including assessments or evaluations from various U.S. and international organizations. For low priority chemicals, EPA may identify substances from multiple sources, including one or more of the following: EPA’s Safer Chemical Ingredients List (SCIL); EPA’s Chemical Assessment Management Program (ChAMP); and the Organization for Economic Cooperation and Development (OECD) Screening Information Data Set (SIDS) initial assessment documents.

Once candidate chemicals have been identified, EPA will initiate the prioritization process, as outlined in the procedural rule, including two 90-day comment periods, and complete the final prioritization designations in nine to 12 months, but no later than **December 22, 2019**.

Thus, 2019 will be an important year for stakeholders to participate in and consider EPA’s efforts throughout the prioritization process and in its designations.

(b) Risk Evaluations

EPA is in the process of developing risk evaluations for the [first ten chemicals](#) selected from the 2014 update to the TSCA Work Plan. Under new TSCA, EPA has three years to complete a risk evaluation, extendable for six months. EPA released its first draft risk evaluation in November 2018 concerning the chemical Colour Index (C.I.) Pigment Violet 29. EPA’s draft concluded that the chemical does not present an unreasonable risk. As discussed below, the Science Advisory Committee on Chemicals (SACC) will hold its first public meeting in January 2019, when it will take public comment and conduct a peer review of this draft risk evaluation.

During 2019, EPA will be releasing additional draft risk evaluations for peer review and public comment prior to preparing the final risk evaluations by the **December 16, 2019**, deadline (extendable to **June 16, 2020**). Presumably, for most of these cases, EPA will be working behind closed doors during 2019 on the evaluations, which means there may not be heightened media coverage or public discourse on the ongoing EPA work. Nonetheless, release of the draft and possibly final risk evaluations will be one of the more important developments expected to occur in 2019.

We expect the upcoming peer review of C.I. Pigment Violet 29 to receive close attention from stakeholders and the media. It will be an important milestone that could serve to outline the nature and depth of the scientific and analytic work required to meet the new law’s requirements, and the peer review may foretell the breadth and depth of the attention that will be expected for other such reviews. Given that EPA’s perceived inability to act under Section 6 was one of the hallmark criticisms of old TSCA, EPA’s ability to stay on schedule and complete scientifically and legally sound risk evaluations represents a critical test for the Agency’s existing chemicals work.

New TSCA also requires that, by the **end of calendar year 2019**, EPA must have at least 20 chemical risk evaluations ongoing at any given time on high-priority



The delay in pursuing regulatory actions on NMP and TCE may indicate that EPA intends to rely on the risk evaluations of these chemicals that are currently underway, rather than the existing OPPT risk assessments.

substances. In addition, as allowed under Section 6(h)(5), EPA has initiated manufacturer-requested risk evaluations on two persistent, bioaccumulative, and toxic (PBT) chemicals.

(c) Risk Management, including of Certain PBT Chemicals

During the late stages of the Obama Administration, EPA issued proposed Section 6(a) rules to regulate methylene chloride, N-methylpyrrolidone (NMP), and trichloroethylene (TCE). EPA also proposed SNURs relating to several of these substances. The [Fall 2018 Regulatory Agenda](#) states that EPA was scheduled to issue the final rule prohibiting consumer and commercial paint stripping uses for methylene chloride by December 2018. The Regulatory Agenda characterizes EPA’s two co-proposed Section 6(a) rules on NMP, as well as its proposed SNUR on several alkylpyrrolidones, as long-term actions for which the final rule date is “To Be Determined.” The Regulatory Agenda also includes three long-term actions on TCE. These include issuance in final of two proposed Section 6(a) rules for which the dates are “To Be Determined” and a proposed Section 5(a)(2) SNUR with a date of **July 2020**. The delay in pursuing regulatory actions on NMP and TCE may indicate that EPA intends to rely on the risk evaluations of these chemicals that are currently underway, rather than the existing OPPT risk assessments.

There is, in addition, a 2019 statutory deadline for regulatory action on certain PBT chemicals. TSCA Section 6(h) requires EPA to propose Section 6(a) regulatory action by **June 22, 2019**, on chemicals from the 2014 update of the TSCA Work Plan that meet the PBT requirements laid out in Section 6(h). The proposed Section 6(a) rules must, pursuant to Section 6(h)(4), “address the risks” presented by the chemicals and reduce exposure “to the extent practicable.” EPA identified [five PBT chemicals](#) that meet the statutory criteria (decabromodiphenyl ethers (DecaBDE); hexachlorobutadiene (HCBd); pentachlorothiophenol (PCTP); phenol, isopropylated, phosphate (3:1); and

2,4,6-tris(tert-butyl) phenol). The proposed rules that must be issued by **June 2019** will represent another of the important developments in 2019, as they will be the first use by the Trump Administration of the new regulatory authority and requirements under Sections 6(a) and (c) of the amended law.

(d) Prioritization and Risk Evaluation Litigation

Several environmental, health, and labor organizations challenged in two different federal appellate courts EPA’s final prioritization and risk evaluation rules. The cases were consolidated in the U.S. Court of Appeals for the Ninth Circuit (Ninth Circuit) with Safer Chemicals, Healthy Families as the lead petitioner. *Safer Chemicals, Healthy Families v. EPA*, No. 17-72260. The petitioners argue that EPA’s claim of authority to exclude conditions of use and their resulting exposures from risk evaluations “violates TSCA’s plain text, structure, and purpose.” According to the petitioners, the directive to “determine whether a chemical substance presents an unreasonable risk” requires an evaluation of the chemical’s total risk. The phrase “‘under the conditions of use’ unambiguously means all of the chemical’s conditions of use.” Petitioners claim that EPA’s use-by-use approach cannot be reconciled with TSCA’s requirement that EPA “make a single, holistic risk determination on ‘a chemical substance.’” The petitioners argue that EPA unlawfully rewrote the definition of “conditions of use” to omit a chemical’s current and future use and disposal if the chemical’s manufacture, processing, and distribution for that specific use are not ongoing, but petitioners believe that Congress’ inclusion of “use” and “disposal” as “conditions of use” foreclose this construction. According to the petitioners, EPA’s rules are inconsistent with its duty to “take into consideration” all “reasonably available” information when prioritizing chemicals and conducting risk evaluations.

On August 6, 2018, EPA filed a motion for partial voluntary remand of three provisions at issue in the consolidated petitions. The motion concerns three provisions of the final risk

evaluation rule -- the penalty provision, the relevancy provision, and the consistency provision. According to EPA, in light of petitioners' arguments and upon further consideration and review, "EPA intends to reconsider these provisions and take appropriate agency action. Because EPA intends to revisit the challenged provisions, remand would best serve the interests of judicial economy." Petitioners asked the court to grant in part and deny in part EPA's request. The petitioners supported EPA's request to remand 40 C.F.R. Section 702.31(d) with vacatur, which currently penalizes submission to EPA of incomplete or misleading information pursuant to a risk evaluation. EPA also asked the court to remand 40 C.F.R. Sections 702.37(b)(4) and (b)(6) (the "manufacturer-discretion provisions"), but without vacatur. The petitioners urged the court to deny this part of EPA's motion. According to the petitioners, EPA's request, if granted, will effectively deny the petitioners any opportunity to seek judicial review of the manufacturer-discretion provisions, while leaving the provisions in place indefinitely. The petitioners want a court, rather than EPA, to review these provisions that they maintain create loopholes that will prevent EPA from obtaining and developing the "reasonably available information" it needs to conduct "sound, comprehensive risk evaluations" under TSCA. On December 12, 2018, the court granted in part and denied in part EPA's motion. The court granted EPA's request to remand 40 C.F.R. Section 702.31(d) (the penalty provision). The court denied EPA's motion to remand Sections 702.37(b)(4) and (b)(6) (the manufacturer-discretion provisions), referring them to the merits panel.

EPA argued in its August 6, 2018, brief that it reasonably exercised its discretion to determine that legacy activities that EPA has limited tools to regulate should not form the basis for findings of unreasonable risk. According to EPA, the risk evaluation rule's provision on iterative risk evaluations is consistent with TSCA, and the information-gathering and consideration provisions still at issue should be upheld.

Petitioners argued in their November 9, 2018, reply brief that new TSCA requires EPA to consider "so-called" legacy

activities in its risk evaluations. According to the petitioners, EPA's justifications for eliminating legacy use, associated disposal, and legacy disposal from the "conditions of use" definition are "divorced from the statutory text" and must be rejected. The petitioners maintain that EPA fails to show how excluding conditions of use from risk evaluations comports with new TSCA's "text, structure, and purposes." In addition, petitioners assert that EPA fails to show how use-by-use "no unreasonable risk" determinations "can be squared with the text or health-protective purpose of TSCA." The petitioners claimed that EPA will fail to ensure that it has adequate information for risk evaluation by failing to obtain "often-vital information that can be generated only through longer-term testing." The petitioners stated that such information may be "reasonably available" because EPA "can reasonably generate" it "considering the deadlines" for both prioritization and risk evaluation.

(e) Proposed SNURs on Existing Chemicals

EPA previously proposed SNURs on several groups of existing chemicals including nonylphenols and nonylphenol ethoxylates (NP/NPE), long-chain perfluoroalkyl carboxylates (LCPFAC) and sulfonates (LCPFAS), and toluene diisocyanates (TDI). Because of the significant burden of the required framework rules, the risk evaluations and risk management actions related to the "first ten" existing chemicals, and the PBTs, EPA has not had the bandwidth to move these SNUR actions forward. Although the Fall 2018 Regulatory Agenda identified 2018 and 2019 dates for issuance of these rules in final, it is not surprising that nothing has been issued yet, and B&C would not be surprised if the dates slip further. The [Regulatory Agenda](#) also states that EPA is developing a supplemental proposal for part of the SNUR on LCPFACs to make inapplicable the exemption for importation of articles containing a subset of LCPFAC chemicals. This change flows from the new requirement in Section 5(a)(5) that EPA must make a finding that the reasonable potential for exposure to the chemical from the article "justifies notification."

In addition, the Trump Administration issued a proposed SNUR on June 11, 2018 ([83 Fed. Reg. 26922](#)), on certain non-ongoing uses of asbestos and the [Fall 2018 Regulatory Agenda](#) states that the rule is scheduled to be issued in final by January 2019. This SNUR received a fair amount of attention in the popular press, although it was interpreted as permitting, rather than regulating, that is, requiring a

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Because most substances added to the Inventory through the PMN process were added with CBI identities (62.7 percent), we interpret this statistic as supporting B&C's contention, that, as a general matter, new chemicals do not necessarily remain long term in the market, thus fewer are active over time.

SNUN prior to initiating these legacy uses. Given all the issues and attention focused on asbestos under TSCA, we expect that this rule will be promulgated during the **first quarter of 2019**.

1.4 Sections 8 and 14

(a) Active-Inactive Status for TSCA Inventory Goes into Effect (Reset Inventory)

In April 2018, EPA issued an updated TSCA Inventory that included a field designating substances that are “active” in U.S. commerce based on the following:

- Reporting from the 2012 and 2016 Chemical Data Reporting (CDR) cycles;
- Notices of Commencement (NOC) received by EPA since June 21, 2006; and
- Notice of Activity (NOA) Form As received by EPA through the February 7, 2018, deadline, submitted under the TSCA Inventory Notification (Active-Inactive) rule.

As of April 2018, the Inventory lists approximately 38,303 total active substances, or about 44.5 percent of the substances listed on the Inventory. It is somewhat surprising that a greater percentage of the non-confidential substances were notified as active (45.6 percent of non-confidential business information (CBI) substances compared to 40.5 percent of confidential substances). Because most substances added to the Inventory through the PMN process were added with CBI identities (62.7 percent), we interpret this statistic as supporting B&C's contention, as articulated in articles and in communications to EPA from the TSCA NCC, that, as a general matter, new chemicals do not necessarily remain long term in the market, thus fewer are active over time. This may be because they are overtaken by even newer chemicals, or because they fail to gain sufficient hold on the market.

The deadline for voluntary submission of a NOA Form A by processors was October 5, 2018. Presumably, processors should only find substances in their supply chain that were notified as active by a manufacturer or importer. It is important, however, that suppliers verify that all non-exempt chemicals in their supply chains are listed on the Inventory as active.

EPA expected to publish the updated Inventory with active and inactive status by the end of the year or in **early 2019**. Ninety days from that date, it will be impermissible to manufacture, import, or process a substance that is inactive without first submitting a NOA Form B. The ninety-day period is an opportunity for notification by submitters who have commenced activity on a substance that was not identified as active on one of the interim lists (*e.g.*, if activity started after June 22, 2016).

With the notification process nearly complete, stakeholders will have a much clearer concept as to what chemicals are being manufactured and used in commerce. We note, however, that there are still hundreds if not thousands more substances in commerce that are exempt from listing on the Inventory, such as exempt polymers and substances granted LVEs.

(b) CBI Inventory Review Rule

The CBI Inventory review rule requires that within one year of publishing the final active/inactive Inventory, EPA must promulgate a rule describing its plan to require submitters to substantiate CBI claims made on active notice submissions and to review claims for confidential substance identities and the associated substantiations. We note that the lawsuit on the Inventory notification rule (discussed below) may presage a challenge to the CBI review rule.

(c) Inventory Notification Rule Litigation

On October 12, 2018, the U.S. Court of Appeals for the District of Columbia Circuit heard oral argument in the Environmental Defense Fund's (EDF) challenge to the

final rule. *EDF v. EPA*, No. 17-1201. According to EDF, in promulgating the final rule, EPA “repeatedly violated the statutory text and erred in favor of concealment instead of disclosure.” TSCA Section 8(b)(f)(B)(ii) states that the Inventory rule must require manufacturers or processors that “seek[] to maintain an existing claim for protection against disclosure of the specific chemical identity” to submit a request to maintain that claim. EPA allowed a manufacturer or processor to assert confidentiality claims even if that manufacturer or processor had never asserted such a claim in the past, as long as someone had. EDF maintains that confidentiality claims are person-specific and a person cannot “maintain an existing claim” if the person has never asserted the claim before. New TSCA Section 14 now requires that confidentiality claims meet numerous substantive and procedural requirements beyond those required by Exemption 4 of the Freedom of Information Act (FOIA). According to EDF, the final rule fails to incorporate several of Section 14’s requirements and instead directs EPA to follow its general FOIA regulations. EPA will therefore process confidentiality claims without complying with all of the requirements in new TSCA Section 14.

EPA argued that its decision was required by new TSCA, which mandates EPA to “require any manufacturer or processor of a chemical substance on the confidential portion of the [TSCA Inventory] that seeks to maintain an existing claim for protection against disclosure of the specific chemical identity” to submit such request when submitting their NOA. According to EPA, “[e]ven if the statute were ambiguous on this point, EPA’s interpretation is reasonable and entitled to deference.” EPA noted that EDF is merely speculating that EPA’s compliance with the Inventory rule will “somehow” lead to noncompliance with the procedural requirements relating to EPA’s review of confidentiality claims.

During the oral argument, the three-judge panel focused on the Trump Administration’s revisions to the proposed rule released in the final days of the Obama Administration. The judges noted that new TSCA specifies criteria for substantiating CBI claims, including whether the information is readily attainable through reverse engineering. While this was part of the proposed rule, the Trump Administration removed this criterion from its final rule. EPA responded that while the final rule does not specifically require consideration of whether data are readily attainable through reverse engineering, the final rule’s remaining criteria for substantiating claims capture that

concern. EPA argued that if the judges find in favor of EDF, the proper remedy would be to remand the final rule to EPA without vacatur to allow it to explain better why certain criteria were dropped from the rule’s provisions for substantiating CBI claims. EDF requested partial vacatur and remand. According to EDF, a complete vacatur would postpone the release of some of the “very information” sought by EDF, allowing EPA to postpone the published TSCA Inventory based on the information that it has already collected. EPA could still explicitly include a consideration of “reverse engineering” in the upcoming review plan that EPA must promulgate under Section 8(b)(4)(C) that must include the provisions for substantiating a CBI claim.

(d) Unique ID Implementation

TSCA Section 14(g)(4) requires that EPA develop a system to assign a unique identifier (UID) to each substance identity for which EPA approves a CBI claim. On June 27, 2018, EPA published its [UID plan](#). Under it, EPA will assign a numeric identifier (in the format of UID-YYYY-NNNNN, where YYYY is the year in which the CBI claim was asserted). That UID would then be applied to documents that relate to the confidential substance. EPA plans not to apply that UID to documents that would disclose the substance identity. For example, EPA receives a submission with a valid CBI claim for identity and assigns a UID to that substance, tagging toxicity studies related to that substance with the UID. EPA later receives a Section 8(e) submission from another entity for the same substance, but that submitter does not claim the substance identity as CBI. EPA would not associate the UID with the non-confidential document because doing so would disclose the identity of the confidential substance. EPA anticipated applying UIDs starting in late 2018. We speculate that if the UID system is ready in time, EPA might include UIDs for all substances on the confidential portion of the Inventory for which EPA has reviewed and approved the CBI claim.

(e) Mercury Rule

On June 27, 2018, EPA promulgated a final rule regarding reporting requirements for applicable persons to provide information to assist in the preparation of an “inventory of mercury supply, use, and trade in the United States,” where “mercury” is defined as “elemental mercury” and “a mercury compound.” [83 Fed. Reg. 30054](#). The final rule applies to any person who manufactures (including imports) mercury or mercury-added products, or otherwise



Although they may have been developed as potential substitutes for existing chemicals, some new biobased chemicals are not listed on the TSCA Inventory by virtue of the fact that the substance identity specifies the source of the substance.

intentionally uses mercury in a manufacturing process (including uses traditionally not subject to TSCA, such as for the manufacture of pharmaceuticals and pesticides). EPA will use data from the 2018 reporting year for the **2020** mercury inventory. The 2018 reporting year is from January 1, 2018, to December 31, 2018, and the submission deadline for the 2018 reporting year is **July 1, 2019**.

The reporting requirements include activities that are well-established under TSCA, including manufacture, import, and distribution in commerce, storage, and export. EPA notes that the reporting requirements also apply to the otherwise intentional use of mercury in a manufacturing process. Persons who manufacture (including import) mercury or mercury-added products, or otherwise intentionally use mercury in a manufacturing process regardless of the end use (*e.g.*, if the end use is as a drug regulated by the U.S. Food and Drug Administration (FDA) that would normally be excluded from TSCA jurisdiction according to Section 3(2)(B), are required to report amounts of mercury used in such activities during a designated reporting year. Reporters must also identify specific mercury compounds, mercury-added products, manufacturing processes, and how mercury is used in manufacturing processes, as applicable, from preselected lists. For certain activities, reporters must provide additional, contextual data. More detail is provided in B&C's June 25, 2018, memorandum, "[EPA Publishes Final Reporting Requirements for TSCA Mercury Inventory](#)."

(f) Mercury Rule Litigation

On July 19, 2018, NRDC petitioned the U.S. Court of Appeals for the Second Circuit to review and set aside the final mercury rule. NRDC v. EPA, No. 18-2121. On October 15, 2018, the court granted a joint motion filed by NRDC, EPA, and Vermont to consolidate NRDC's case with *Vermont v. EPA*, No. 18-2670. NRDC and Vermont filed separate opening briefs on December 7, 2018. NRDC's statement of issues includes: (1) whether the reporting rule is unlawful because it

exempts manufacturers and importers of products with mercury-added component parts, despite TSCA's instruction that EPA require reporting from "any person who manufactures [or imports] mercury or mercury-added products"; and (2) whether the reporting rule is unlawful because it exempts manufacturers and importers of mercury in amounts (i) greater than or equal to 2,500 pounds per year for elemental mercury, or (ii) greater than or equal to 25,000 pounds per year for mercury compounds despite TSCA's requirement that EPA require reporting from "any person" who manufactures or imports mercury and that EPA prepare an accurate and comprehensive "inventory" of mercury supply and trade. Vermont's statement of issues includes these issues, as well as whether EPA's decision to exempt certain entities from the reporting requirements is contrary to Congress' intent to create a detailed and complete inventory of the relevant mercury activities involving mercury supply, use, and trade under TSCA. On December 14, 2018, 11 states -- Oregon, Connecticut, Hawaii, Massachusetts, Maine, Maryland, Minnesota, New Jersey, Pennsylvania, Rhode Island, and Washington -- filed an *amici* brief in support of NRDC and Vermont. EPA's brief is due **March 8, 2019**.

(g) Nomenclature

Although they may have been developed as potential substitutes for existing chemicals, some new biobased chemicals are not listed on the TSCA Inventory by virtue of the fact that the substance identity specifies the source of the substance. Because the novel source leads to a new identity, the substances are subject to "new chemical" review and evaluation processes by EPA scientists even if the constituents are indistinguishable. These reviews can and do result in EPA applying risk management conditions on the production and distribution in commerce of renewable chemicals, restrictions that may not apply to older chemistries (whether from petroleum or traditional bio sources, such as vegetable oils) even though they may be functionally identical and have a nearly indistinguishable composition.

Ironically, the new chemical may offer a more benign environmental footprint but nonetheless be subject to stricter EPA regulation. The new policies adopted by EPA for amended TSCA have resulted in some cases in even more obstacles and longer timelines for commercialization of innovative new chemicals. B&C staff, in coordination with the Biobased and Renewable Products Advocacy Group (BRAG®), have been advocating for equivalency determinations for biobased chemicals. See [“Proposal for a Toxic Substances Control Act \(TSCA\) Inventory Representation and Equivalency Determinations for Renewable and Sustainable Bio-based Chemicals.”](#)

(h) CDR Rule Changes

In the Fall 2018 Regulatory Agenda, EPA indicated that it would be issuing a [proposed rule with revisions to the CDR rule](#). EPA is expected to incorporate updates to the small manufacturer definition for purposes of CDR. In addition, EPA may be proposing additional reporting elements related to required reporting of chemicals that are recycled or processed. EPA had initially identified potential changes as part of its participation in the 2017 Negotiated Rulemaking Committee (Committee) for CDR requirements for inorganic byproducts. The proposed reporting changes would help clarify whether chemicals reported as recycled or reprocessed are considered byproducts or are derived from byproducts.

While these proposed changes may be helpful to the reporting community, it is imperative that EPA move quickly with its proposals so stakeholders are fully educated well before the next reporting cycle in **2020**. EPA has made changes in the last four cycles of CDR (or its predecessor, the Inventory Update Reporting (IUR) rule). We hope that this upcoming adjustment will be the last for a while, so companies can set their internal processes with the confidence that no further changes are forthcoming.

1.5 Section 21

(a) Litigation

EPA is still wrestling with a complaint filed on April 18, 2017, to compel it to initiate a rulemaking under TSCA Section 6 to prohibit the addition of fluoridation chemicals to drinking water supplies (*Food & Water Watch, Inc. v. EPA*, Case No. 3:17-cv-02162-EMC (N.D. Cal.)). This complaint was filed as an appeal following [EPA’s denial of a TSCA Section 21 petition requesting it to exercise its Sec-](#)

[tion 6 authority](#) to prohibit the purposeful addition of fluoridation chemicals to U.S. water supplies filed by several organizations and individuals. On February 7, 2018, the court denied EPA’s motion for a protective order to limit review to the administrative record, stating that the “text of the TSCA, its structure, its purpose, and the legislative history make clear that Congress did not intend to impose such a limitation in judicial review of Section 21 citizen petitions,” and, therefore, allowed for the plaintiffs’ case to be heard *de novo* – a decision that will allow plaintiffs to introduce evidence above and beyond what was included in the administrative record when EPA responded to plaintiffs’ petition. The case is scheduled for an eight court day Bench Trial beginning **August 5, 2019**, and ending **August 16, 2019**, per the court’s April 14, 2018, order and discovery is currently ongoing.

The court’s October 4, 2018, order reiterated its edict to review the case *de novo* and granted plaintiffs’ request for an order to compel EPA: (1) to produce documents beyond the administrative record that EPA disputed, including specifically defined studies, papers, and meetings such as documents related to the first-ever National Institutes of Health (NIH)-funded study of fluoride and IQ published in September 2017; and (2) to produce a witness, specifically an EPA staff person, that plaintiffs can depose regarding whether EPA considered the neurotoxic risk of fluoride when establishing its safety standards. Close of fact discovery was due November 21, 2018. Opening Expert Reports are due **January 24, 2019**; Rebuttal Expert Reports are due **February 21, 2019**; and the close of expert discovery is scheduled for **March 14, 2019**.

Given the many significant issues at play, the legal and policy problems [we foresaw in EPA’s denial decision](#), the evident commitment and determination of the plaintiffs to see this through, and the novel and potentially wide-ranging nature of the *de novo* proceeding, this case promises to produce important developments during 2019. The decision, when rendered, is likely to be portentous and result in more litigation from the losing side.

1.6 Section 26

(a) Fee Rule Implemented/Next Steps in 2019 for Section 6-related Fees

EPA issued the final Section 26(b) fees rule on October 18, 2018. [83 Fed. Reg. 52694](#). The final rule calls for EPA to



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collect fees for Section 6 risk evaluation work in conjunction with the publication of the risk evaluation scope. EPA is soon expected to issue its list of chemicals subject to prioritization under Section 6, and then has nine to twelve months to determine if those chemicals are high or low priority. If a chemical is deemed high priority, EPA must initiate a risk evaluation, including publication of the scope, within six months. Thus, by **mid-2020**, EPA will likely be assessing fees for these chemicals and, per the final rule, the entire risk evaluation fee of \$1,350,000 for TSCA Work Plan chemicals will be required sixty days after the scope is published.

This timeline requires that industry stakeholders be prepared to organize into consortia quickly in 2019 if they are not already organized. For those groups already organized, there will likely be time and effort spent in ensuring that the consortium memberships include all applicable parties. More importantly, it means that companies will need to find their share of the \$1,350,000 price tag in their 2019 budget to have the funds ready to submit to EPA in **2020**.

(b) SACC

New TSCA Section 26(o) required EPA to establish within one year of enactment a committee "to provide independent advice and expert consultation, at the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this title." Just before the end of the Obama Administration, EPA appointed 18 expert members to the SACC and in March 2018, the Trump Administration selected eight additional SACC members. This brought the current membership to 26 experts in toxicology, environmental risk assessment, exposure assessment, and related sciences. In September 2018, EPA requested public nominations of scientific experts for *ad hoc* participation in peer reviews of EPA's risk evaluations for the first ten chemicals addressed under TSCA and possible membership on the SACC.

EPA announced in November that it will convene the first public meeting of the SACC in January 2019, to review the draft risk evaluation of C.I. Pigment Violet 29. We expect a number of additional meetings of the SACC to review risk evaluations as they are released by EPA over the course of the year.

1.7 Other Topics

(a) OPPT Staffing and Reorganization

The final fees rule, issued in October 2018, opened the door for OPPT to obtain the much needed resources to meet its new obligations under amended TSCA. [83 Fed. Reg. 52694 \(Oct. 17, 2018\)](#). The new fees apply to Section 5 notices received after October 1, 2018, and to future Section 4 testing actions and Section 6 risk evaluations. We expect that during 2019, OPPT will work to use the new resources to increase its staff and contractor capabilities as the fees begin to flow into EPA's budget.

Another consideration is the pending reorganization of OPPT. EPA took steps during Spring 2018 to delay its pending reorganization to consider a six division structure that has separate new and existing chemical risk management divisions complemented by separate new and existing chemical risk assessment divisions. Under this scheme, OPPT's other functions were to be distributed into a mission operations division and a division that sweeps together chemical right-to-know, economics, information reporting, and the Safer Choice/Design for the Environment (DfE) program. While we like the concept of parallel risk assessment divisions, critical questions and issues concern us regarding OPPT's ability to obtain both adequate hiring authority to meet its scientific needs and then being able to locate and hire the needed technical experts. While the first may be satisfactorily resolved, based on our experience, the second will be challenging, as expertise is in short supply in areas such as toxicology, environmental fate, exposure assessment, biotechnology, and nanotechnology. A related and critical reorganization issue that could be joined in earnest in 2019 is the process to select the four Division Directors

needed to manage and lead the separate new and existing chemical risk assessment and risk management divisions. These selections will be critical in determining the near-term path forward and potentially affecting the long-term direction and implementation of TSCA Sections 4, 5, 6, and 8.

(b) International

(i) OECD Chemicals

Among the highlights of work done in 2018 by the OECD chemicals program are the following:

The OECD Council adopted a Decision-Recommendation that revises and replaces a 1991 Decision-Recommendation that resulted in the OECD’s SIDS program. This program produced basic data sets and initial international assessments on hundreds of high volume chemicals. The first part of the new action focuses, among others, on cooperative development of harmonized hazard and exposure assessment methodologies, collaborative assessment, and sharing the burden of information generation. The second part focuses on risk prevention and reduction including implementation of the United Nation’s Globally Harmonized System of Classification and Labeling of Chemicals (GHS). Perhaps the most significant advance is that it is now mandatory for OECD members to implement the GHS.

OECD [updated its guidance document on standardized test guidelines for endocrine disruption](#).

OECD started a new program in 2018 to look into the interface between chemicals and waste management policies. A first step was the organization of a Global Forum on Environment on “Plastics in a Circular Economy: Design of Sustainable Plastics from a Chemicals Perspective.”

Potential deliverables in 2019 include the following:

- In 2010, OECD first published a report estimating how the OECD’s Environment, Health and Safety Program (which includes both chemicals- and pesticides-related work) saved governments and industry more than 150 million euros/year (~\$170 million U.S.). It is believed that this figure underestimates actual savings generated by the program and an update is expected to be published in **early 2019**.

- On the scientific front, OECD is developing a “defined approach” to combine different *in vitro* methods for skin sensitization that collectively could replace animal tests. At present, while more and more *in vitro* methods are developed for this endpoint (including many OECD Test Guidelines), there is no harmonized way to apply them to decide on the skin sensitization potential of chemicals. The defined approach aims to develop a harmonized way forward under the OECD system for Mutual Acceptance of Data (MAD) and thereby avoid development of national strategies and interpretation schemes that would result in added costs and duplication for industry and government.

(ii) SAICM

The Strategic Approach to International Chemicals Management (SAICM) is a voluntary policy framework to promote chemical safety around the world that was agreed to internationally in 2006. Its main objective is achieving sound management of chemicals throughout their life cycle by the year **2020**. During 2019, SAICM’s existing policy framework will be revisited and possible changes considered through an international process under the auspices of UN Environment and the World Health Organization (WHO). In **2020**, the effort will culminate with an international decision on SAICM’s future arrangements beyond **2020**.

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C. NANOTECHNOLOGY

1. Reporting Rule for Existing Chemical Nanoscale Materials

Under EPA's January 12, 2017, TSCA Section 8(a) reporting rule for certain chemical substances already in commerce as nanoscale materials, persons who manufactured or processed a reportable chemical substance during the three years prior to the final effective date of the final rule had until August 14, 2018, to submit information to EPA. There is also a standing one-time reporting requirement for persons who intend to manufacture or process a discrete form of a reportable chemical substance on or after the effective date of the rule. These persons must report to EPA at least 135 days before manufacturing or processing of that discrete form. EPA has stated that it will use the data to decide if further action under TSCA, including additional information collection, is needed. More information regarding the final rule is available in our January 12, 2017, memorandum, "[EPA Promulgates Final TSCA Reporting and Recordkeeping Rule for Nanoscale Materials](#)." Our August 14, 2017, blog item "[EPA Publishes Final Guidance as Final TSCA Section 8\(a\) Rule Takes Effect](#)" provides information on EPA's final guidance.

2. Draft Current Intelligence Bulletin (CIB) for Silver Nanomaterials

In September 2018, the National Institute for Occupational Safety and Health (NIOSH) issued a revised draft *Current Intelligence Bulletin: Health Effects of Occupational Exposure to Silver Nanomaterials*. NIOSH first released a draft CIB on silver nanomaterials in January 2016. Unlike the 2016 draft, the 2018 draft includes a recommended exposure limit (REL) for silver nanoparticles (<100 nanometers (nm) primary particle size) of 0.9 micrograms per cubic meter (µg/m³) as an airborne respirable eight-hour time-weighted average (TWA) concentration. The REL would

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apply to processes that produce or use silver nanomaterials. In 2019, NIOSH will be reviewing peer reviewer and stakeholder comments on the revised draft CIB and making any necessary changes as it prepares the final CIB. In addition, NIOSH will be completing peer and stakeholder review of a draft CIB concerning approaches to developing occupational exposure limits or bands for engineered nanomaterials.

D. BIOTECHNOLOGY

Even without urging from the White House Office of Science and Technology Policy, EPA, the FDA, and the U.S. Department of Agriculture (USDA) have all taken steps to modernize the biotechnology regulatory system, embracing the spirit of the 2017 National Academies of Sciences, Engineering, and Medicine report, "[Preparing for Future Products of Biotechnology](#)." This progress is expected to continue in 2019.

In October 2017, the EPA Office of Pesticide Programs' (OPP) Biopesticide and Pollution Prevention Division (BPPD) reorganized to create the new Emerging Technologies Branch (ETB). ETB's scope of responsibility includes the registration of pesticides that are the product of biotechnology. The growing ETB portfolio includes pesticides that are plant-incorporated protectants (PIP), genetically-engineered (GE) microbes, and GE mosquitoes. In 2019, ETB will continue to expand as it navigates the data requirements, risk assessment approaches, and regulatory issues applicable to the novel technologies that it encounters in submitted experimental use permit and product registration applications. BPPD recently projected that its future biotechnology registration activities may include products of synthetic biology, genome-edited PIPs, RNA interference products, and possibly eventually gene drives.

In 2019, FDA will continue to implement its [Plant and Animal Biotechnology Innovation Action Plan](#). The Action Plan advances policy priorities that FDA will pursue to clarify its science-and-risk-based approach for product developers;



USDA is working on several fronts to address biotechnology issues in 2019. On December 21, 2018, USDA promulgated a final rule establishing the National Bioengineered Food Disclosure Standard.

avoid unnecessary barriers to future innovation in plant and animal biotechnology; and advance safety and FDA’s public health mission. As a first step, FDA will adopt a comprehensive policy framework for the development and regulatory oversight of animal biotechnology products, including for intentionally genetically altered animals and the food and drug products derived from them. According to FDA, this flexible framework will advance its commitment to safety while promoting innovation. As part of this effort, FDA intends to publish two guidance documents in 2019 that will provide more clarity on how FDA is applying its regulatory oversight to evaluate new animal biotechnology products based on the risk profile of various products.

In October 2018, FDA and USDA jointly hosted a meeting, [“The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry.”](#) Both FDA and USDA had claimed oversight of cell-cultured meat (also referred to as lab-grown meat, clean meat, in vitro meat, imitation meat, synthetic meat, and fake meat), which is grown in laboratories from animal cell-cultures. In a [November 16, 2018, statement](#), the agencies announced that they concluded that “both the USDA and the FDA should jointly oversee the production of cell-cultured food products derived from livestock and poultry.” The agencies announced an agreement on a joint regulatory framework wherein FDA oversees cell collection, cell banks, and cell growth and differentiation. A transition from FDA to USDA oversight will occur during the cell harvest stage. USDA will then oversee the production and labeling of food products derived from the cells of livestock and poultry. FDA and USDA “are actively refining the technical details of the framework, including robust collaboration and information sharing between the agencies to allow each to carry out our respective roles.”

USDA is working on several fronts to address biotechnology issues in 2019. On December 21, 2018, USDA promulgated a [final rule establishing the National Bioengineered Food Disclosure Standard \(Standard\)](#). The new Standard

requires food manufacturers, importers, and other entities that label foods for retail sale to disclose information about bioengineered (BE) food and BE food ingredient content. The Standard is intended to provide a mandatory uniform national standard for disclosure of information to consumers about the BE status of foods. Following publication of the Standard, USDA will provide outreach and education to inform regulated entities and the public about the new disclosure terms. The Standard includes the following initial compliance dates: (1) except for small food manufacturers, entities responsible for BE food disclosure must comply with the requirements of this part by **January 1, 2020**; and (2) small food manufacturers must comply with the requirements of this part by **January 1, 2021**.

USDA’s Animal and Plant Health Inspection Service (APHIS) [signaled on June 29, 2018](#), its intent to prepare a “programmatic environmental impact statement (EIS) in connection with potential changes to the regulations regarding the importation, interstate movement, and environmental release of certain genetically engineered organisms.” When published, the EIS will have a significant impact on how APHIS chooses to amend its regulation of GE organisms. APHIS requested comment on issues to be considered in preparing the EIS, as well as how to define the scope of the alternatives and environmental impacts. [According to an item in APHIS’s Fall 2018 Regulatory Agenda](#), APHIS intends to publish in **April 2019** a proposed rule to update the regulations in response to advances in genetic engineering and APHIS’s understanding

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BRAG's Biobased Products News and Policy Report is an excellent source of information on regulatory, legal, policy, and business developments in renewable chemicals, biofuels, and other biobased products. The weekly newsletter is published by B&C for BRAG, managed by B&C® Consortia Management, L.L.C (BCCM). Subscribe to the BRAG report online at <http://www.braginfo.org/subscribe>, or visit the BRAG Biobased Products Blog at blog.braginfo.org.

of the plant health risk posed by GE organisms, thereby reducing the burden for regulated entities whose organisms pose no plant health risks. More information is available in our July 24, 2018, memorandum, "[APHIS/USDA Prepare to Revise Regulations Pertinent to Genetically Engineered Organisms](#)."

E. BIOBASED AND RENEWABLE PRODUCTS ADVOCACY GROUP (BRAG®)

The trajectory for development of new biobased and renewable chemical products is promising in 2019 given the growing sustainability objectives for many companies and their stockholders. As these new sustainable chemistries are developed and become available for commercialization, the Biobased and Renewable Products Advocacy Group (BRAG®) is ready to be part of the solution to facilitate their availability on the market. A key objective of BRAG in 2019 is to address the regulatory challenges related to naming conventions as outlined in its April 2018 white paper, "[Proposal for a Toxic Substances Control Act \(TSCA\) Inventory Representation and Equivalency Determinations for Renewable and Sustainable Bio-based Chemicals](#)." BRAG intends to coordinate with EPA staff and leaders within the biobased chemical industry to outline a process that allows for Class 2 chemical equivalency determinations for chemistries derived from different sources.

Biobased industry stakeholders are encouraged to express support for the initiative and the allocation of resources to address the recommendations outlined in the white paper. The next generation of biotechnology products may be on the line if a modernized and more efficient regulatory system is not developed.

Although it remains unclear whether and how far the Trump Administration will carry on with these demands, global and national policy reforms are increasingly focusing on renewable chemistry as a critical part of addressing climate change. The U.S. Department of Energy (DOE)

Bioenergy Technologies Office (BETO), for example, has announced a request for information (RFI) on algae, biomass, and waste feedstocks that can be used in the production of biofuels, bioproducts, and biopower. Additionally, DOE funding opportunities in 2019 will concentrate on incentivizing biotechnology and energy efficiency through renewable and sustainable sources. This shift in focus is also expected throughout the globe as the United Kingdom (UK), Canada, and Finland, among other nations, emphasize the need for collaboration and transformations necessary to encourage growth of the bioeconomy.

It is expected that agencies involved in regulation of future biotechnology products, such as EPA, FDA, DOE, and USDA, will increase scientific capabilities, tools, expertise, and horizon scanning in key areas of expected growth of biotechnology, including natural, regulatory, and social sciences. We can also foresee such agencies further increasing their use of pilot projects to advance the understanding and use of ecological risk assessments and benefit analyses for future biotechnology products. The biobased industry should plan to remain engaged in all aspects of TSCA implementation to ensure regulatory parity with traditionally-sourced chemicals and to avoid additional obstacles to commercialization.

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**F. FEDERAL INSECTICIDE, FUNGICIDE, AND
RODENTICIDE ACT (FIFRA)**

1. Pesticide Registration Improvement Act (PRIA)

The Pesticide Registration Improvement Act of 2003 (PRIA), administered by the Office of Pesticide Programs (OPP), established a fee schedule for pesticide registration and amendment applications, and specified decision time periods in which EPA must make a regulatory decision. PRIA has been reauthorized twice and was scheduled to expire at the end of the 2017 federal fiscal year, on September 30, 2017. Despite prior coalitions of registrants, labor, and environmental advocates working with Congress to pass what would be PRIA 4, concerns about possible regulatory changes and delays on the Worker Protection Standard (WPS) regulations and Certification and Training (C&T) programs, and the Administration’s March 2017 decision effectively allowing the continued use of chlorpyrifos, fractured the PRIA coalition.

Suddenly PRIA, expected to be routinely reauthorized as it had been in the past, became a political football, kept alive not by passage of PRIA 4 but through stopgap funding bills. Now, almost 18 months after PRIA 3 was set to expire, PRIA 3 authority continues to limp along with no clear outcome in sight.

There was some movement to pass PRIA 4 when the Senate Committee on Agriculture, Nutrition and Forestry passed the PRIA bill on June 28, 2018. That version includes a compromise amendment from Senator Tom Udall (D-NM) that would maintain certain provisions related to the WPS farmworker and pesticide applicator rules that have been subject to controversy since their promulgation in 2015. The Senate version of PRIA 4 was also included in the Senate-approved Farm Bill but, in the final Farm Bill of December 2018, PRIA 4 reauthorization was not accepted by the House conferees, so PRIA 4 is still not approved.

As funding for many government agencies, including EPA, ran out in December 2018, so did authorization for PRIA 3. Although the budget fight will continue into January 2019 when the new Congress convenes, any resolution which reopens the federal government is expected to continue the PRIA fee program.

Most likely any kind of authorization for funding government operations, such as a Continuing Resolution (CR) for a limited time period or for Fiscal Year 2019, is likely to include at least a simple reauthorization of the PRIA 3 provisions for the duration of the CR. This would also mean the new Congress will have to act sometime in the next session to reauthorize PRIA either to continue PRIA 3 beyond a new CR time period or approve amendments such as those considered as PRIA 4 during the 115th Congress. Given the difficulty of Congress in reaching agreement on appropriations legislation, it is possible that PRIA reauthorizations will continue to be included as part of CRs for an indefinite time period.

Unfortunately, this uncertainty about the status of PRIA may also impact generally the program’s ability to plan and schedule review of registration applications.

The positive news is that many members of both the House and Senate appear to remain committed to legislative reauthorization of PRIA. At the same time, with the change in party control in the House of Representatives, reauthorization may continue to be delayed as the new Congress, with new Committee leadership, devotes time and energy to competing priorities.

In addition, as PRIA amends FIFRA, it could provide an opportunity for amendments to FIFRA outside of the funding context to be offered by members interested in other pesticide-relevant issues. Debate on additional pesticide issues would only likely lead to further delay and uncertainty about the long-term reauthorization of PRIA.

Should, for whatever reasons, PRIA not be reauthorized then the existing PRIA provisions of FIFRA require a phase-down of the current process for processing registration submissions that include reduced PRIA fees and different decision deadlines. The larger issue would be the potential for the elimination of approximately 200 positions from the pesticide program workforce, or approximately one-third of the current staff (this is in line with the share of program costs supported by fees). This is because PRIA has also included the authorization for the “maintenance fee” provisions first included in the 1988 amendments to FIFRA, designed as general support for the EPA pesticide program budget. Taken together, PRIA reauthorization has become a major contributor to the program budget.



The analytical approach and conclusions that EPA is using in the chlorpyrifos case are expected to have important implications for other organophosphate insecticides, even to the extent that some fear (and others advocate) a complete elimination of all organophosphate product registrations.

2. Chlorpyrifos

Chlorpyrifos is a widely used organophosphate insecticide and has been the target of activist group attention and controversy over many years. Pesticide Action Network North America (PANNA) and NRDC filed a petition to revoke the tolerances and cancel the registrations for chlorpyrifos in 2007. After many rounds of legal wrangling through the last years of the Obama Administration, the Court stated unequivocally that it would not grant any further extension beyond March 31, 2017, for final action on the petition.

At the time that PANNA and NRDC began the court case, EPA had issued a preliminary decision indicating that it intended to deny the petition, but EPA later reversed course and, in the process, issued several controversial documents upon which it relied in support of the 2015 proposal to revoke the food use tolerances for the pesticide. [80 Fed. Reg. 69080 \(Nov. 6, 2015\)](#). This action is described in more detail on [B&C's Pesticide Law and Policy Blog under key word chlorpyrifos](#). See also March 30, 2017, blog item "[EPA Denies Petition to Ban Chlorpyrifos](#)."

EPA determinations supporting the 2015 chlorpyrifos proposal sparked significant controversy, and not just among chlorpyrifos stakeholders. Some of the assumptions and analytical approaches used in EPA documents regarding its chlorpyrifos assessment had a significant potential to reach far beyond chlorpyrifos in their potential impact. For example, EPA relied upon a new determination regarding the interpretation of epidemiological data and how such data are used in making Food Quality Protection Act (FQPA) safety factor decisions. EPA utilized epidemiological data for chlorpyrifos to select risk endpoints for chlorpyrifos and to determine that the 10X FQPA safety factor must be retained for all organophosphate pesticides. The FQPA safety factor determination has been the subject of much concern and comment, with industry suggesting numerous scientific, legal, and procedural flaws in the scientific predicate for the determination and the procedure by which it was adopted.

Further, the analytical approach and conclusions that EPA is using in the chlorpyrifos case are expected to have important implications for other organophosphate insecticides, even to the extent that some fear (and others advocate) a complete elimination of all organophosphate product registrations.

The Trump Administration arrived long after the beginning of this controversy and only a few months before the court-ordered March 31, 2017, deadline for a final EPA response to the chlorpyrifos petition. As many expected, in meeting the deadline for a decision on the petition, the Trump EPA denied the petition and stated that it would continue to review the safety of chlorpyrifos, noting that the deadline for a conclusive decision would be part of the registration review of the pesticide, due in **2022**.

In response to what was described as EPA inaction, Senator Udall and others introduced legislation to eliminate chlorpyrifos uses (S. 1624). The legislation was not acted upon during this session of Congress, but concern about EPA regulation of organophosphates has remained controversial and has affected the movement of legislation to renew PRIA fee provisions. Even as the fee provisions are resolved, S. 1624 marked the first chemical specific pesticide legislation calling for a ban in years. This signals Congressional concern about a specific pesticide case. In light of Democratic control of the House in 2019, it is likely that this and other pesticides may become specific targets of Congressional action.

On August 9, 2018, [the majority of a three-judge panel of the U.S. Court of Appeals for the Ninth Circuit \(Ninth Circuit\) issued an opinion in the latest chlorpyrifos case \(League of United Latin American Citizens \(LULAC\) v. Wheeler, No. 17-71636\)](#) granting the petition for review of a 2017 EPA order that denied an administrative petition to revoke the tolerances for chlorpyrifos; vacating the 2017 order; and remanding the matter back to EPA with explicit directions to EPA to "revoke all tolerances and cancel all registrations for chlorpyrifos within 60 days." A separate dissent stated that the court should have dismissed the case

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

for lack of jurisdiction. On September 24, 2018, EPA petitioned the Ninth Circuit for an *en banc* and panel rehearing concerning the Ninth Circuit's August 9, 2018, decision. Petitioners responded to EPA's request for rehearing on October 16, 2018, stating that they agreed that the remedy "should be modified to exclude nonfood uses and cohere with statutory timelines for cancelling pesticide registrations, the remainder of the rehearing petition lacks merit and should be denied." On November 13, 2018, the Ninth Circuit denied EPA's request to file a reply brief in support of their request for rehearing.

Although parties to appellate litigation often seek rehearing or rehearing *en banc*, federal agencies represented by the U.S. Department of Justice (DOJ) are considerably more selective about the circumstances in which they will file a petition for rehearing. There are some compelling arguments supported by precedent that judicial review is not available under the FFDCFA for the type of initial order concerning which the petitioners in this case sought review. Moreover, EPA has identified some practical factors that make it literally impossible for EPA both to adhere to mandatory statutory procedures under FIFRA and to comply with the terms of the court's order. For this reason, even if a broader rehearing is not granted concerning the jurisdictional question or the authority of the court to order EPA to take specific actions, a narrower rehearing before the appellate panel may be ordered, which would allow the parties an opportunity for further briefing on the remedy and permit the court to modify its order.

3. Endangered Species Act (ESA)

This issue of how EPA should interact with the U.S. Fish and Wildlife Service (USFWS) and the National Marine

Fisheries Service (NMFS) (collectively the Services) to implement ESA provisions has dogged the program for many years, since continued litigation challenges were first initiated during the Administration of George W. Bush. A pivotal question is how extensive EPA's assessment is to determine compliance with ESA, an assessment that is to be done in coordination with the Services (the federal agencies that have responsibility for implementing ESA). The problem of "how much is enough" when conducting an assessment, and the degree of coordination of assessments between EPA and the Services (including "who decides" various issues such as the need for consultation between EPA and the Services), have been debated for more than ten years and are the subject of extensive litigation.

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

Efforts have been made to coordinate more closely information and review procedures and policies between EPA and the Services, but delays and litigation continue unabated. With the arrival of the Republican Administration and with Republican majorities in both the House and Senate, there was initially hope that some more practical, or at least predictable, process for ESA compliance could be put into place. Some observers have explored whether legislative action would be possible to tailor how ESA review of pesticide registrations could better fit the goals of the law that originated with a call for review of projects such as building dams or highways. Given the controversies about ESA outside of the pesticide arena, prospects for legislation have always seemed daunting. Nevertheless, some believe that there may be no alternative but to seek amendments



Like others before them, the Trump Administration is embarking on a journey to address the problem of how to integrate ESA assessment and consultation requirements with the FIFRA registration process.

depending on the outcome of various legal challenges (for example, if new registration actions were vacated or otherwise indefinitely suspended).

To be sure, the ESA issues remain far from resolved, but two significant events initiated in 2018 will drive the development of the issue throughout 2019, described below.

3.1 Interagency Working Group

On January 31, 2018, the Administration announced a [Memorandum of Agreement](#) (MOA) between the agencies involved (the U.S. Department of the Interior (DOI), the U.S. Department of Commerce (DOC), and EPA) to evaluate and coordinate in fashioning revisions to the current ESA review process; in the words of Administrator Pruitt: “to harmonize interagency efforts, and create regulatory certainty for America’s farmers and ranchers.” To undertake this ambitious goal, the Administration created an interagency working group consisting of EPA and the Services, USDA, the Office of Management and Budget (OMB), and the Council on Environmental Quality (CEQ) acting as chair; with White House staff chairing the effort, the agencies could face more pressure to achieve a consensus about how to utilize the extensive work EPA does when registering a pesticide, along with the need for ESA requirements to protect threatened and endangered species.

Like others before them, the Trump Administration is embarking on a journey to address the problem of how to integrate ESA assessment and consultation requirements with the FIFRA registration process. The directive will help organize a senior level effort to coordinate activities of EPA and the Services and, like past efforts, at the senior management level there will likely be at least a recognition that something needs to be done to fashion a more efficient and predictable process. Currently, ESA reviews add months and years to the registration review process, and to date, that process is then followed by seemingly inevitable litigation challenging EPA’s decision as not

sufficient to meet ESA requirements. Both the George W. Bush Administration and the Obama Administration tried similar efforts with very limited success in getting the bureaucracies to understand better the work and mission of the individual agencies, and perhaps this latest effort (with White House prodding) may result in an improved (and legally defensible) process.

3.2 Congressional Attention -- The Farm Bill

The second pivotal event of 2018 was the release on April 12, 2018, of a draft House Farm Bill reauthorization, circulated by House Agriculture Committee Chairman Michael Conaway (R-TX). This draft included, among other things, significant amendments to FIFRA to incorporate the ESA requirements for registration of a pesticide. The House legislation gave authority to EPA to register a pesticide -- if doing so was compliant with the ESA goals -- because the registration incorporated the central ESA requirements to protect threatened and endangered species as part of EPA’s decision that the pesticide product at issue met the FIFRA requirements to not presenting unreasonable adverse effects when used as a pesticide. Most notably, the amended language would incorporate the ESA requirement to prevent harm to threatened or endangered species as part of the definition of what is an “unreasonable adverse effect” -- strong language that would be added to FIFRA to protect species, and is designed to break the gridlock between EPA and the Services (“who decides,” or more precisely, “who is allowed to decide,” is the fundamental disagreement between EPA and the Services). Nonetheless, the reception by environmental advocates was forceful and unequivocal -- that they would strongly oppose any amendments giving EPA decision authority in this arena.

Even though these provisions were included in the legislation approved by the full House as part of the Farm Bill on June 21, 2018, environmental group opposition led Democrats in the Senate to oppose consideration of the issue in any legislative compromise. The ranking Democrat on the Senate

Agriculture Committee, Senator Debbie Stabenow (D-MI), made it clear that the House language was unacceptable, and the Senate Farm Bill as approved contained a much different approach to the issue of pesticides and ESA. The Senate bill was approved on June 28, 2018, as a broad bipartisan vote in the Senate approved a compromise Farm Bill that did not include the House ESA language and did not contain any provisions concerning ESA whatsoever. The Senate provision was accepted in the Conference Committee on the different House and Senate bills, and the [Farm Bill legislation](#) was approved and signed by the President on December 20, 2018.

The language approved in the final legislation essentially codifies the January MOA -- to require the agencies across the government to better coordinate and utilize the expertise of the respective agencies. It further specifies steps and timelines that the agencies must take to implement these goals over the next two to five years with reports back to the Agriculture Committees every six months. The biannual reports are designed to help keep the process on a "short leash" to prod the respective bureaucracies into finding a solution to the problem.

What is less certain is the impact these provisions will have on the continued litigation EPA has faced over registration decisions -- will this language support the argument that this process to improve coordination and revise procedures is sufficient for the courts to allow EPA and the Services more time to devise and implement the new review schemes? If so, how might this affect the schedule of past litigated registration decisions or the FIFRA requirements to complete registration review for pesticides by **2020**?

4. Worker Protection Standard (WPS)

EPA's 2018 Fall Regulatory Agenda includes two items related to potential changes to the WPS:

- Pesticides; Certification of Pesticide Applicators Rule; Reconsideration of the Minimum Age Requirements ([RIN 2070-AK37](#)): In spring 2017, EPA solicited comments on regulations that may be appropriate for repeal, replacement, or modification. EPA states that it received comments specific to the January 4, 2017, certification rule and has decided to reconsider one requirement of the final rule regarding the minimum age requirements for applicators

certified to use restricted use pesticides (RUP) and for persons who use RUPs under the supervision of a certified applicator. Specifically, EPA is proposing to defer lowering the minimum age requirements for commercial applicators, private applicators, and non-certified applicators who use RUPs under the supervision of a certified applicator and to defer establishing a federal minimum age of 16 years (that is currently 18 years) for all three types of applicators if states or tribes do not establish enforceable minimum age requirements. Although the Fall 2018 Regulatory Agenda states that EPA intends to publish a proposed rule in January 2019, this item has been included on the Regulatory Agenda for several years now -- it is unclear if this is the year when a proposed rule would actually be issued.

- Pesticides; Agricultural Worker Protection Standard; Reconsideration of Several Requirements ([RIN 2070-AK43](#)): As reported above, in spring 2017, EPA solicited comments on regulations that may be appropriate for repeal, replacement, or modification. EPA received comments suggesting specific changes to the 2015 revised WPS requirements related to lowering minimum age requirements, a provision that would allow farmworkers to choose a "designated representative" to obtain pesticide use information on their behalf, provisions that defined application exclusions zones, and entry restrictions for enclosed space production. Based on comments raised, EPA stated in the Fall 2018 Regulatory Agenda that it intends to publish a proposed rule in January 2019, but again any timeframe remains far from certain.

5. Pollinators

To some degree, there was relatively little movement on the subject of pollinators during 2018. Technically EPA continues its work under initiatives announced in 2014 when the Obama White House issued a ["Presidential Memorandum - Creating a Federal Strategy to Promote the Health of Honey Bees and Other Pollinators,"](#) eventually followed in 2015 by ["EPA's Proposal to Mitigate Exposure to Bees from Acutely Toxic Pesticide Products."](#)

The 2015 plan targeted pesticide use by those who use contracted pollinator services and included a list of pesticides



Despite somewhat stalled activities in the U.S., pollinators will remain an issue to monitor in 2019 based on regulatory actions in other countries, notably Canada and the European Union (EU), that have severely curtailed or altogether prohibited the use of neonicotinoid insecticides.

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

EPA has not officially changed its guidance about pollinator issues since the 2017 policy was announced (it was announced during the last days of the Obama Administration). The 2017 policy clarified that certain thresholds that may indicate risk concerns and stated that new labeling would be imposed on products with certain characteristics, but registrants report they have received relatively few significant disagreements over label requirements in regards to the 2017 guidance.

There continues to be concern among pesticide registrants about how broadly EPA might attempt to require certain studies of possible risks to bees without clear decision rules for which pesticides appropriately need higher tier studies and what questions additional studies might answer, especially if the requirements are cast too broadly or without clear decision criteria. As part of the Administration review of general regulatory requirements and whether they are appropriate, there may be further changes to label policies and blanket testing requirements. Further, evaluation of state

managed pollinator protection plans is due to be part of the general approach to EPA’s pollinator protection strategy. EPA released on August 16, 2018, a [“Frequently Asked Questions” document](#) to provide EPA’s responses to inquiries it received about protocols used to generate honeybee toxicity data submitted in support of pesticide registrations.

Despite somewhat stalled activities in the U.S., pollinators will remain an issue to monitor in 2019 based on regulatory actions in other countries, notably Canada and the European Union (EU), that have severely curtailed or altogether prohibited the use of neonicotinoid insecticides. EPA evaluations of similar, if not identical, data about neonicotinoid use have not led to similar prohibitions. Moving forward, given existing protocols for shared data evaluations and coordinated protocols, over time it may be helpful to registrants if the EPA conclusions about the (lack of) risk from neonicotinoid uses was shared with their Canadian counterparts. Behind the scenes, the difference in regulatory conclusions may represent more politics than science, but these international agreements have been promoted to more closely align the regulation of identical products (while respecting member rights to be different). If the risks are considered low on this side of the border, EPA may want to ask why bans, in effect, are needed a few miles north in Ontario production areas.

6. Dicamba

An issue of increasing notice throughout 2018 was the pending decision EPA needed to make about the continued use of new formulations of the dicamba herbicide designed to be used on cotton and soybean crops genetically engineered to resist dicamba exposure. The new formulations are specifically created to reduce the possibility of off-site movement of the herbicide after application. The “old” formulations of dicamba, still in wide use for various applications, historically are considered to have greater potential for application drift causing possible injury to nearby, non-target crops. Many growers were eager for the arrival of the new formulations and genetically modified organism (GMO) seeds to control

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Notwithstanding any high-profile pesticide or policy pronouncements, the bulk of OPP's work continues, as it has for many years, to focus on the thousands of pesticide label amendments, label extensions, me-too evaluations, and routine data reviews.

problematic weeds causing significant yield loss due to glyphosate resistance.

These products were first used in the 2017 growing season, but sale of the GMO seeds came before the approval of the new, lower volatility dicamba formulations. Many drift incidents were reported during the 2017 season. It was unclear whether the far larger number of incidents were caused by either misuse (using the older, already registered products), difficulty in following new application and stewardship requirements (e.g., buffer zones and wind speeds), or unanticipated effects of the new formulations. In addition, the first approvals were time-limited and, to continue use, needed to be renewed by the end of 2018. EPA declared that a decision would be made by September 1, 2018, in time for growers to know about the availability of the new products for the 2019 season.

EPA did not, however, announce until October 31, 2018, that it was extending the registration of the new dicamba products for an additional two years. EPA added further requirements designed to reduce the likelihood of any drift problems. These requirements include additional training, timing, record-keeping, and stewardship when using the new formulations designed to reduce or eliminate injury reports. Some of the new requirements are of note since they are not typically imposed as a condition of use, especially the requirements for increased training and stewardship by the registrants, the requirement that all applicators be certified applicators (not allowing use by applicators “under the supervision” of a certified applicator), and the requirement imposing a time-limit (two years) to the registration.

This will allow EPA more time to assess whether injury reports are mostly due to misuse (applicators who do not use the new formulations designed to reduce volatility, which is a label violation since the “old dicamba” product is considered more prone to cause drift injury), or, are due to characteristics of the new formulations which are not yet fully understood and

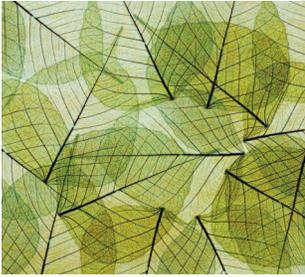
which lead to unexpected volatility and other drift problems. Some have argued that problems are also due to the difficulty (or reluctance) in following the more prescriptive requirements for the new formulations. During the two-year renewal period, EPA will closely monitor injury and misuse reports, as well as continued academic and registrant research into the likely cause of any reported problems.

EPA will rely on state officials to report and evaluate the experience of users in their states, especially concerning whether the additional training and stewardship requirements significantly reduce local injury reports.

EPA's decision could have repercussions on the outcome of the lawsuit filed by farm and environmental groups in 2017 in the Ninth Circuit arguing that EPA's 2016 registration of dicamba violated FIFRA and ESA. A motion to dismiss this lawsuit was filed quickly after EPA's 2018 registration, arguing that the petition to review EPA's 2016 dicamba registration is now moot and should be dismissed for lack of jurisdiction. EPA responded to this motion on November 13, 2018, stating its agreement that the case is moot, to which petitioners filed a response opposing EPA's motion.

7. Clock Ticking on Registration Reviews; OPP Staffing and Budget

Notwithstanding any high-profile pesticide or policy pronouncements, the bulk of OPP's work continues, as it has for many years, to focus on the thousands of pesticide label amendments, label extensions, me-too evaluations, and routine data reviews. To get this large amount of work completed continues to raise issues about EPA's staffing and budget. PRIA and maintenance fees provide a substantial contribution to support the pesticide review workload. At the same time, Agency- or government-wide policies about hiring and spending have hindered fully utilizing even the industry-contributed funds. EPA has now had a substantial



With WOTUS likely to be under a microscope and the subject of Congressional oversight, any legislation seen as removing CWA protections may meet Democratic opposition in the House.

surplus of fees over the past few years, but the program reports that hiring has been affected by hiring freezes and decisions to not spend the available funds. Partly this may be due to the uncertainty surrounding the reauthorization of PRIA; OPP, however, has more recently been allowed to fill available positions. Budget uncertainty and threats to pension and promotion practices, as mentioned earlier, nonetheless have a negative impact on morale. Also having an impact is the recruitment of OPP staff to bulk up the toxics program in OCSPP as implementation of the 2016 TSCA amendments gets more robustly underway.

Meanwhile, the clock continues to click towards the registration review deadline of **2022** for the bulk of the program registrations. Real progress has been made but many, if not most, of the registration reviews of the more controversial or widely used active ingredients remain to be completed; once EPA has issued its conclusion, by definition, the more controversial pesticides are likely to face litigation challenges over touchstone disagreements about several issues (e.g., ESA assessments and pollinator risks) that have characterized the public debate about numerous active ingredients in recent years.

On top of the challenges within the OCSPP world, the aging work force of EPA and the federal government generally presents a serious workforce issue. As mentioned earlier, estimates are that approximately 41 percent of the federal workforce is eligible for retirement now or within the next five years -- and many critics question whether government personnel policies for recruitment, hiring, and training will be adequate to meet the challenge this demographic wave represents.

8. Legislative Effort to Fix Duplicative Permitting under FIFRA and CWA

Since a 2009 U.S. Court of Appeals for the Sixth Circuit decision, EPA has required the Clean Water Act's (CWA) National Pollutant Discharge Elimination System (NPDES) permitting for aerial spraying of pesticides into, over, or near CWA jurisdictional waters. Agriculture producers, mosquito control officials, and other stakeholders have argued that CWA permitting is

duplicative, burdensome, and unnecessary for FIFRA-compliant pesticide applications. Indeed many of the NPDES pesticide permit requirements are directly tied to adherence to pesticide label requirements and other FIFRA best practices. In successive Congresses since the 2009 decision, companion legislation has been introduced in both the House and Senate that would amend both the CWA and FIFRA to exempt FIFRA-compliant pesticide applications from NPDES permitting. Each time, the NPDES legislative "fix" has managed to pass the House with some support from House Democrats, but has not made it to a vote in the Senate. With the Democratic House majority in the 116th, it is unclear if the NPDES legislation will have enough Democratic support to pass a House vote, should it be reintroduced. EPA and the U.S. Army Corps of Engineers' (USACE) very recent joint proposal to revise and replace the "Waters of the U.S." (WOTUS) definition, which describes which waters and wetlands are under CWA jurisdiction, has immediately come under fire as leaving too many waters "unprotected." With WOTUS likely to be under a microscope and the subject of Congressional oversight, any legislation seen as removing CWA protections may meet Democratic opposition in the House.

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G. HAZARDOUS MATERIALS TRANSPORTATION

1. Predictions and Outlook for the U.S. Department of Transportation’s Pipeline and Hazardous Materials Safety Administration for 2019

The U.S. Department of Transportation's (DOT) Pipeline and Hazardous Materials Safety Administration (PHMSA) is charged with a vital, if often taken for granted, task: protecting the public from the hazards associated with the transportation in commerce of hazardous materials. While its operations may lack the high profile of some of its federal sister agencies, its mission is, literally, one of life and death. Lethal train derailments and explosions, fires aboard aircraft, and spills of toxic materials are all potential -- and real -- consequences if PHMSA fails to exercise its duty effectively.

PHMSA operates in a dynamic and challenging environment. In 2019, the scope and complexity of its mission will continue to grow, requiring it fundamentally to rethink how it will use data, information, and technology to achieve its safety goals.

PHMSA’s mission is to protect people and the environment by advancing the safe transportation of energy and other hazardous materials that are essential to our daily lives. To do this, it establishes national policy, sets and enforces standards, educates, and conducts research to prevent incidents. It also prepares the public and first responders to reduce consequences if an incident does occur. In this context, PHMSA has updated its strategic framework to focus on risk reduction, and much of what it is anticipated to do in 2019 reflects this revamped strategy.

PHMSA oversees the safe movement of hazardous materials and energy-related products. The consistently safe delivery of these commodities supports the growth of American industry -- ensuring that packagers, shippers, and transporters can move these products to the consumers, homes and businesses that rely on them. PHMSA’s safety programs advance industry safety systems, promote safety standards, encourage innovation and research, provide comprehensive safety inspections and, when necessary, initiate enforcement actions.

PHMSA is responsible for promoting the safe and reliable transportation of dangerous goods by air, water,

highway, rail, and pipeline. The expansive U.S. pipeline network extends more than 2.7 million miles and moves more than 16 billion barrels of hazardous liquids and gases safely and without incident 99.9997 percent of the time; and, PHMSA’s safety operations add less than one cent per barrel to achieve this unmatched safe delivery rate.

Surface, air, and vessel transportation of hazardous materials accounts for more than 2.7 billion tons of regulated hazardous products annually with a value of 3.1 trillion dollars. Despite the amount of activity and risk posed by hazardous materials, safe delivery occurs 99.9994 percent of the time. PHMSA’s safety operations add about three cents per ton of material shipped to maintain this significant rate.

PHMSA works to improve the safety systems of the more than 40,000 companies involved in the commercial manufacture, packaging, and transportation of DOT-regulated hazardous commodities as well as the operators responsible for the nation’s expansive 2.7 million mile network of liquid and gas pipelines.

(PHMSA’s authorities extend to transportation of hazardous materials by pipeline, rail, air, and highway. This forecast does not address pipeline hazardous materials issues.)

New information and research will drive much of what PHMSA undertakes in 2019. Advances in technology, enhanced commerce, and a rapidly evolving global trade in hazardous materials must be matched by PHMSA if it is to satisfy its mandates. At this point, PHMSA appears to recognize these new challenges and is poised to maintain its highly honed edge on hazardous materials transportation.

1.1 FAST Act Implementation -- High Hazard Flammable Trains

In 2019, PHMSA is expected to continue to carry out the legislative requirements in the Fixing America's Surface Transportation (FAST) Act of 2015 (Pub. L. No. 114-94) that call for PHMSA to improve the safe movement of liquefied natural gas and crude oil transported by rail. On December 4, 2015, President Obama signed the FAST Act into law. The new law requires PHMSA to undertake a number of regulatory and other actions to safeguard the transportation of flammable crude oil by rail and highway. Passage of



The Pipeline and Hazardous Materials Safety Administration (PHMSA) is developing a rule amending the Hazardous Materials Regulations applicable to the transport of lithium cells and batteries by aircraft.

the act was catalyzed by a number of incidents involving so-called “high hazard flammable trains.”

PHMSA is slated to [promulgate a final rule](#) pursuant to the FAST Act that will expand the applicability of comprehensive oil spill response plans based on thresholds of liquid petroleum that apply to an entire train. The rulemaking would also require railroads to share information about high-hazard flammable train operations with state and tribal emergency response commissions. The rule also will include a reference to an initial boiling point test for flammable liquids for better consistency with the American National Standards Institute and the American Petroleum Institute Recommended Practice 3000, “Classifying and Loading of Crude Oil into Rail Tank Cars.”

PHMSA is [considering revising](#) the Hazardous Materials Regulations (HMR) to establish vapor pressure limits for unrefined petroleum-based products and potentially all Class 3 flammable liquid hazardous materials that would apply during the transportation of the products or materials by any mode. PHMSA was prompted to do this via a petition for rulemaking submitted by the Attorney General of the State of New York regarding vapor pressure standards for the transportation of crude oil. The petition requests that PHMSA implement a Reid Vapor Pressure (RVP) limit less than 9.0 pounds per square inch (psi) for crude oil transported by rail. On January 18, 2017, PHMSA issued an [Advanced Notice of Proposed Rulemaking](#) (ANPRM) in response to the petition; after several extensions, comments were due by May 19, 2017. 82 Fed. Reg. 5499. PHMSA will use the comments submitted in response to this ANPRM to help assess and respond to the petition and to evaluate any other potential regulatory actions related to sampling and testing of crude oil and other Class 3 hazardous materials. PHMSA will also evaluate the potential safety benefits and costs of utilizing vapor pressure thresholds within the hazardous materials classification process for unrefined petroleum-based products and Class 3 hazardous materials.

1.2 Transportation of Lithium Batteries by Air

Lithium batteries are found in virtually every commercial aircraft that flies in the U.S. airspace. They are found in everything from laptops, cellphones, iPods, wheelchairs, and other devices. If not properly packaged and transported, they can -- and have -- caused fires on board commercial aircraft. PHMSA is thus [developing a rule](#) amending the HMRs applicable to the transport of lithium cells and batteries by aircraft. The rule is likely to contain three amendments:

- A ban on the transport of lithium ion cells and batteries as cargo on passenger aircraft;
- A requirement that lithium ion cells and batteries be shipped at not more than a 30 percent state of charge aboard cargo-only aircraft; and
- Limits on the use of alternative provisions for small lithium cell or battery shipments to one package per consignment or overpack.

PHMSA believes the rule is necessary to address an immediate safety hazard and harmonize the HMRs with emergency amendments to the 2015-2016 edition of the International Civil Aviation Organization's Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions).

1.3 Conversion of Special Permits

PHMSA will continue to convert special permits into the text of the HMRs. Specifically, as mandated by Sections 33012(c) and (d) of the Moving Ahead for Progress in the 21st Century Act (MAP-21), PHMSA will amend the HMRs to adopt provisions contained in certain widely-used or long-standing special permits that have an established safety record. This rulemaking action is intended to provide wider access to the regulatory flexibility offered in special permits and eliminate



PHMSA is required by law to ensure that, to the extent practicable, regulations governing the transportation of hazardous materials in commerce are consistent with standards adopted by international authorities.

the need for numerous renewal requests. The rulemaking action will also reduce paperwork burdens and facilitate commerce while maintaining an appropriate level of safety. PHMSA conducted an extensive analysis of active special permits, approvals, and related petitions, and those deemed suitable will be adopted into the HMR.

1.4 International Standards Harmonization

PHMSA is required by law to ensure that, to the extent practicable, regulations governing the transportation of hazardous materials in commerce are consistent with standards adopted by international authorities. Harmonization yields many benefits: it enhances safety, facilitates compliance, and improves the efficiency of the global transportation system by minimizing the regulatory burden on the public, thus promoting trade. After a thorough review of the provisions recently adopted by various international regulatory bodies, PHMSA has identified areas in the HMR in which harmonization with international regulations will provide an enhanced level of safety, an economic benefit, or in many instances both increased safety and economic benefits. As a result, PHMSA has proposed a rule (issued November 27, 2018) that amends the HMR, where appropriate, to maintain alignment with international standards and consequently facilitate the safe global trade of hazardous materials. [83 Fed. Reg. 60970](#). Proposals in this rulemaking action include, but are not limited to: non-testing alternative methods for classifying corrosive materials, a classification scheme and transport provisions for articles containing hazardous materials that do not already have a proper shipping name, provisions to recognize one-time movement approvals issued by Transport Canada, and the incorporation by reference of various international standards including the latest editions of the UN Model Regulations on the Transport of Dangerous Goods, the International Maritime Dangerous Goods Organization (IMDG) Code, the ICAO Technical Instructions, and the International Organization for Standardization (ISO) technical standards applicable to cylinders. Comments are due by **January 28, 2019**.

1.5 Research Gaps and Priorities

To its credit, PHMSA has given significant attention to identifying perceived research gaps and prioritizing projects for research, with an emphasis on risk identification and mitigation. Gaps identified by PHMSA include:

- Risk Analysis and Perception:
 - > Hazards, Risks and Mitigation;
 - > Data Development;
 - > Modeling Techniques;
 - > Systems Approaches;
 - > Risk Communication and Perception; and
 - > Hazmat Release Consequences.
- Emerging Materials and Technologies:
 - > Batteries and Emerging Energy Products;
 - > Automated and Connected Vehicles; and
 - > Technologies for Safety and Decision Maker.
- Emergency Planning and Response:
 - > Guidance Development;
 - > Education and Training; and
 - > Communication, Tracking and Detection.
- Materials and Equipment Testing:
 - > Hazardous Material Characterization and Testing;
 - > Package Lining and Corrosion Resistance; and
 - > Monitoring and Inspection.

Consistent with its identification of these research gaps, PHMSA has identified over 30 prioritized research projects. These include:

- Development of an Overarching Structure for Assessing and Managing Risks through the Hazmat Transportation Supply Chain;
- Understanding Failure Rates of New and Reconditioned Hazmat Drums in Transportation;



Our clients have a substantial interest in anticipating and responding to the destabilizing developments on international trade that have taken the spotlight over the past year, and that loom large for 2019.

- Understanding the Impact of Recycled Material Content on Failure Rates of Hazmat Containers;
- Understanding and Preparing for Changes in Lithium Battery Uses, Characteristics, and Commercial and Non-Commercial Transportation; and
- Testing Methods and Criteria for the Classification of a Material as a Corrosive Solid.

1.6 Conclusion and Summary

PHMSA can be expected to continue to promulgate rules in compliance with its statutory mandates but it also recognizes the need to shore up gaps and to keep pace with an accelerating array of products that are transported in commerce. New information and research will drive much of what PHMSA undertakes in 2019. Advances in technology, enhanced commerce, and a rapidly evolving global trade in hazardous materials must be matched by PHMSA if it is to satisfy its mandates. At this point, PHMSA appears to recognize these new challenges and is poised to maintain its highly honed edge on hazardous materials transportation.

H. TRADE

1. Introduction

B&C’s and Acta’s clients manufacture innovative and essential products that span all sectors of the economy and that are distributed across the globe. But the efficacy of these products means little if barriers to trade -- such as prohibitive tariffs, intellectual property (IP) theft, lack of a trade agreement and unfair or illegal trade practices -- block or restrict them from entering other nations and getting into the hands of those who need them. Our clients consequently have a substantial interest in anticipating and responding to the destabilizing developments on international trade that have taken the spotlight over the past year, and that loom large for 2019.

A bedrock platform of Donald Trump’s Presidential campaign was his promise to take actions on trade that he believes will disclose unfair practices; he also promised to promote free, fair, and reciprocal trade and strongly enforce U.S. trade laws. When Mr. Trump accepted the Republican nomination for President in Cleveland in July 2016, he avowed that “[n]o longer will we enter into these massive deals, with many countries, that are thousands of pages long -- and which no one from our country even reads or understands. We are going to enforce all trade violations, including through the use of taxes and tariffs, against any country that cheats.”

Mr. Trump promised to take several unilateral actions. He stated he would punish China and other “cheaters” with crippling tariffs. Calling the North American Free Trade Agreement (NAFTA) “the worst deal ever,” he vowed to dismantle it. Decrying multi-lateral trade agreements, Mr. Trump claimed that he would withdraw from the Trans-Pacific Partnership (TPP), cease negotiations on the Transatlantic Trade and Investment Partnership (T-TIP), and focus instead on securing bilateral agreements.

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President Trump threatened to take actions on specific products to protect American workers and industry, even if that meant imposing restrictions on our closest trading partners; and he promptly did so. On March 8, 2018, he issued two proclamations that imposed a 25 percent tariff on imported steel and a ten percent tariff on imported aluminum. The President claimed the tariffs were necessary for national security justifications, citing Section 232 of the Trade Act of 1974 (Trade Act) (Pub. L. No. 93-618). The tariffs impacted Canada, Mexico, the EU, and other close trading partners. The President eventually suspended the duties against Canada and Mexico, citing on-going NAFTA discussions. And DOC subsequently promulgated procedures for excluding products from the tariffs. But these exclusions only apply to individuals or organizations using steel or aluminum articles identified in the proclamations. Nonetheless, the bell in the ring had been clanged. It was clear that President Trump intended to follow through on his promises regarding trade.

Mr. Trump has made good on his promises, and more. Since taking office, the President has taken scores of actions on trade issues -- often unprecedented actions that at times unsettled global financial markets -- and 2019 promises to be equally as turbulent. The President will no doubt continue to advance his "America First" trade agenda, and that is a recipe for more uncertainty and angst for any company that trades outside the U.S.

Prognosticating on what specifically may occur in the next year is made even more difficult by the fact that the President and his staff often telegraph conflicting messages on trade. At the G20 Summit in December, however, President Trump and Chinese President Xi Jinping did reach an agreement of sorts on trade issues and agreed to begin 90 days of negotiations on trade issues. B&C will soon be releasing a podcast on trade issues as part of its "All Things Chemical™" series available on [iTunes](#), [Spotify](#), [Stitcher](#), and [Google Play Music](#). Please stay tuned!

2. Pillars of U.S. Trade Policy

President Trump has launched a new era in American trade policy. His agenda is driven by a determination to use the leverage available to the world's largest economy to obtain fairer treatment for American workers. This policy rests on the following five major pillars:

1. Trade Policy that Supports National Security Policy;
2. Strengthening the American Economy;
3. Negotiating Trade Deals that Work for All Americans;
4. Enforcing and Defending U.S. Trade Laws; and
5. Strengthening the Multilateral Trading System.

2.1 Trade Policy that Supports National Security Policy

Consistent with the National Security Strategy President Trump announced in December 2017, the President's trade policy recognizes that economic prosperity at home is necessary for American power and influence abroad. Free, fair, and reciprocal trade relations are a key component of the President's strategy to promote American prosperity. Therefore, the Trump Administration is working and will continue to work aggressively to address trade imbalances, promote fair and reciprocal trade relationships, enforce U.S. rights under existing trade agreements, and work with like-minded countries to defend our common prosperity and security against economic aggression. The President's Trade Policy Agenda states "[c]ountries that are committed to market-based outcomes and that are willing to provide the United States with reciprocal opportunities in their home markets will find a true friend and ally in the Trump Administration." In 2019, the U.S. will continue to take steps to protect its national interests against hostile policies imposed by China, Russia, or any other countries. The United States will respond to unfair economic competitors by using all available tools to discourage any country from undermining true fair market competition.

2.2 Strengthening the American Economy

The President's trade agenda seeks to build on the economic momentum provided by the Tax Cuts and Jobs Act passed in December 2017 and the Administration's efforts to reduce regulatory burdens. The Trump Administration believes that its focus on fair and reciprocal trade, combined with the President's tax cuts and regulatory relief, will lead to more efficient markets and make it easier for American workers and companies to succeed.

2.3 Negotiating Trade Deals that Work for All Americans

The Trump Administration will seek an extension of Trade Promotion Authority until **2021** and aggressively use that



The Trump Administration has successfully litigated a number of World Trade Organization (WTO) disputes, helping force countries to abandon unfair practices and preserving the U.S. right to enact fair laws.

authority to negotiate or revise trade agreements so they are fair and balanced and support American prosperity. The Trump Administration intends to reach other agreements designed to promote fair, balanced trade and support American prosperity. As part of this effort, the U.S. and the UK established a Trade and Investment Working Group to lay the groundwork for commercial continuity and prepare for a potential future trade agreement once the UK leaves the EU. The Administration will continue preparing for other potential bilateral agreements, including in the Indo-Pacific and African regions.

2.4 Enforcing and Defending U.S. Trade Laws

The Trump Administration is committed to using all tools available under U.S. law to combat unfair trade. For example, in January 2018, President Trump exercised his authority under Section 201 of the Trade Act to provide safeguard relief to U.S. manufacturers injured by imports of washing machines and solar panels. This was the first time Section 201 had been used to impose tariffs in 16 years. In 2017, the Trump Administration launched a self-initiated Section 301 investigation with an in-depth probe into Chinese practices related to forced technology transfer, unfair licensing, and IP policies and practices. More discussion on this investigation is below. The Trump Administration has successfully litigated a number of World Trade Organization (WTO) disputes, helping force countries to abandon unfair practices and preserving the U.S. right to enact fair laws.

2.5 Strengthening the Multilateral Trading System

President Trump is no fan of the WTO. He claims that the WTO is not operating as the contracting parties envisioned and, as a result, is undermining America's ability to act in its national interest. The Trump Administration will work with like-minded countries to address these concerns.

3. U.S. - China Trade Dispute: "The Entire World Is Worried."

Deem it a war, battle, skirmish, or whatever military confrontation moniker you choose, there is little doubt that President Trump is pursuing an aggressive and retaliatory assault on China for what the administration believes are unfair trade practices and an indefensible trade deficit with the second largest economy on the planet -- and China is punching back.

The President's ire towards China's trade practices are not likely to abate. He has stated that China is one of the chief violators of unfair trade practices. The U.S. and China are, and in 2019 likely will continue to be, engaged in a tit-for-tat trade and tariff confrontation as the two countries battle for superiority in Asia.

Although President Trump has stated that he is confident he can reach an agreement with China at the G20 Summit, consider this: for the first time in 29 years, the Asia-Pacific Economic Cooperation Summit concluded on November 18, 2018, with officials failing to issue a joint closing statement. The 21 countries at the summit represent 60 percent of the world economy. The day before the summit closed, Vice President Mike Pence and Chinese President Jinping criticized each other in speeches, adding to the tension and uncertainty over whether the U.S. and China can resolve their trade disputes. Press accounts paint the meeting in Papua New Guinea as acrimonious, highlighting widening divisions between China and the U.S. The holdup was that the U.S. and China could not reach common ground on language over trade. Draft versions of the communique showed the U.S. wanted strong language against unfair trade practices that it claims China practices. China wanted a reaffirmation of opposition to protectionism and unilateralism that it says are hallmarks of the U.S. trade strategy. The spat seems to have boiled down to one sentence in the draft joint closing statement: "[w]e agreed to fight protectionism including all unfair



Taken in sum, the U.S. Trade Representative (USTR) and an interagency team of subject matter experts and economists estimated that China's policies result in harm to the U.S. economy of at least \$50 billion per year.

trade practices.” China reportedly objected to that sentence, as it is accused by the U.S. as the main culprit of “protectionism” and “unfair trade practices.” That disagreement is a small slice of the growing rivalry between the world’s two biggest economies. Perhaps Papua New Guinea Prime Minister Peter O’Neill, who hosted the summit, summed it up best when at the end of the summit he told reporters: “[t]he entire world is worried.”

President Trump’s actions towards China began soon after he took office. In August 2017, he issued a [memorandum](#) directing the U.S. Trade Representative (USTR) to determine if China’s policies regarding IP theft and forced technology requirements “may be harming American [IP] rights, innovation, or technology development,” and thus warrant USTR action under Section 301 of the Trade Act. Following the memorandum, on August 18, 2017, the USTR initiated an investigation under Section 301 of the Trade Act into China’s acts, policies, and practices related to technology transfer, IP, and innovation. [82 Fed. Reg. 40213 \(Aug. 24, 2017\)](#). Then, in January 2018, the USTR submitted to Congress its [annual report on China’s WTO compliance](#). The report states that “it seems clear that the United States erred in supporting China’s entry into the WTO on terms that have proven to be ineffective in securing China’s embrace of an open, market-orientated trade regime.”

It was not until March 2018, however, that things really started heating up. On March 22, 2018, the [USTR released its report](#). Among other things, it found that China: uses joint venture requirements, foreign investment restrictions, and administrative review and licensing processes to force or pressure technology transfers from American companies; uses discriminatory licensing processes to transfer technologies from U.S. companies to Chinese companies; directs and facilitates investments and acquisitions that generate large-scale technology transfer; and conducts and supports cyber intrusions into U.S. computer networks to gain access to valuable business information. Taken in sum, the USTR and an interagency team of subject matter experts and economists

estimated that China’s policies result in harm to the U.S. economy of at least \$50 billion per year.

President Trump swiftly took action. In April, he proposed to impose a tariff of 25 percent on \$50 billion worth of imported Chinese goods. He eventually culled this list in June down to \$34 billion worth of goods. In July, however, Trump struck China again, imposing a 25 percent tariff on some \$16 billion worth of Chinese imports; and in July he dropped the hammer -- setting a ten percent tariff on \$200 billion worth of imported Chinese products. That tariff is slated to increase to 25 percent in January 2019, unless the U.S. and China can reach an agreement. In short, at this time virtually every item imported from China is subject to additional tariffs. China, of course, has retaliated and imposed its own tariffs on goods from the U.S.

Adding to the tensions, on November 20, 2018, the USTR [updated its Section 301 report on China](#). The USTR found that the tariffs and other actions imposed by the U.S. have not deterred China’s practices, and that China denies its practices are unfair or illegal. The USTR’s findings are likely to inspire further action by the Trump Administration.

At the G20 summit, President Trump and President Jinping called a 90-day truce on raising tariffs and agreed to begin negotiations on trade. USTR Robert Lighthizer -- considered a trade hawk -- is leading the negotiations. The deadline for the negotiations is **March 1, 2019**, and Mr. Lighthizer has stated that is a “hard” deadline. He has also stated that the President wants China to implement trade practices that protect U.S. technology and IP and increase market access for American companies. “If that can be done, the President wants us to do it. If not, we’ll have tariffs,” he stated, specifying how the U.S. will increase tariffs on \$200 billion worth of Chinese goods from ten percent to 25 percent if a deal hasn’t been struck by **March 1, 2019**. Trump could also impose tariffs on \$267 billion in additional Chinese goods.

It remains to be seen whether President Trump, author of “The Art of the Deal,” can strike an accord with China on trade issues. Tensions between the two nations are high. What is certain is that the continued trade spat will upset global financial markets and supply chains and breed festering uncertainty for U.S. companies that trade with China.

4. Renegotiating NAFTA

Candidate Trump loved to rail against NAFTA and vowed that he would dismantle and renegotiate it in a manner that yields better returns for the U.S. against its North American neighbors. He did exactly that.

After he was sworn in in May 2017 as the USTR, Mr. Lighthizer said that the U.S. was going to renegotiate NAFTA. Three days after taking office, Mr. Lighthizer [formally notified Congress](#), as required under the Trade Act, that the U.S. intended to renegotiate NAFTA. The purpose of the renegotiation would be to support higher-paying jobs in the U.S. and to grow the U.S. economy by improving U.S. opportunities to trade with Canada and Mexico. The notification stated that the renegotiation will address chapters in NAFTA that are “outdated and do not reflect modern standards.” Specific trade agendas that the negotiation may address include digital trade, IP rights protection, regulatory practices, state-owned enterprises, services, customs procedures, sanitary and phytosanitary (SPS) measures, small and medium-sized enterprises as well as labor and environmental standards.

Canada, however, was, at least in the eyes of the White House, slow to get on board with the negotiations. President Trump, thus, decided to move ahead and negotiate with Mexico. In August 2018, the U.S. and Mexico announced that they had reached “a preliminary agreement in principle” to update NAFTA. The swiftness with which the U.S. and Mexico were reaching agreement forced Canada to participate more directly in the negotiations.

The negotiations ended on September 30, 2018, when the U.S., Mexico, and Canada reached agreement on the revamped accord. Now dubbed the United States-Mexico-Canada Agreement (USMCA), the agreement is more of a modification to NAFTA than a complete rewrite of it. According to Administration officials, USMCA will include new provisions on textiles that incentivize greater North American production in textiles and apparel trade, strengthen customs enforcement, and facilitate broader consultation and cooperation among the parties. More specifically, USMCA

will promote greater use of Made-in-the-USA fibers, yarns, and fabrics.

Reviews from industry and others on the renegotiated trade pact garnered positive initial reviews. It is believed that the USMCA will include increased labor protections for workers, increased standards for duty-free auto shipments, increased access to the Canadian dairy market for U.S. farmers, and improvements to the dispute-resolution system. Stocks surged after the trade deal was announced.

Implementation of the USMCA is underway. The devil is in the details, however. Whether the revised agreement lives up to its promises is yet to be seen, but it appears to be a positive step in leveling the playing field for North American trade.

5. Abandoning Multi-Lateral Trade Agreements

President Trump wasted little time in following up on his vow to scuttle multi-lateral trade agreements. Just three days after taking office, on January 23, 2017, President Trump [announced the withdrawal](#) of the U.S. from the TPP Negotiations and Agreement. In making the announcement, he stated that it “is the policy of my Administration to represent the American people and their financial well-being in all negotiations [SIC], particularly the American worker, and to create fair and economically beneficial trade deals that serve their interests.” He further added that it is his intention to abandon multilateral trade deals and instead deal directly with individual countries on a one-on-one basis in negotiating future trade deals. Similarly, the U.S. abandoned the multi-year negotiations with the EU on the T-TIP accord.

In place of these multilateral agreements, the President has forged ahead with his intent to ink bilateral agreements. On October 16, 2018, Trump [formally notified Congress](#) that the U.S. has launched negotiations with the UK on a trade accord. His announcement has received immediate and high praise from many in Congress and the business community. The USTR has also begun trade negotiations with several other nations.

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I. PROPOSITION 65 (PROP 65)

Two years after the California Office of Environmental Health Hazard Assessment (OEHHA) issued final revisions to its Proposition 65 (Prop 65) Article 6 “clear and reasonable warnings” regulations, those regulations were implemented in 2018. Since August 30, 2018, companies are now required to comply with the revised regulations for consumer product, occupational, and environmental exposures.

The most significant changes are those related to the required warning language. Below is a comparison of the warning requirement for consumer products before the 2016 amendments and after:

BEFORE	AFTER
<p>WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.</p>	<p> WARNING: This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer, and [name of one or more chemicals], and [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.</p>

Cal. Code Regs. tit. 27, § 25603. These changes include:

- Adding a new warning symbol, consisting of a black exclamation point in a yellow equilateral triangle with a bold black outline:



OEHHA’s [website provides links](#) to download several sizes of the warning symbols required to be included on most safe harbor warnings for exposures to listed chemicals under the new regulations.

Companies should note that the symbol can be printed in black and white if the sign, label, or shelf tag for the product is not printed using the color yellow, even if other colors are used.

- Changing the warning language to state that the product “can expose you” to the Prop 65 chemical.
- Referencing OEHHA’s new website, www.P65Warnings.ca.gov/product.
- Identifying the name of one or more of the listed chemicals for which the warning is being provided. When the warning is being provided for more than one endpoint (cancer and reproductive toxicity), the warning must include the name of one or more chemicals for each endpoint, unless the named chemical is listed as known to cause both cancer and reproductive toxicity and has been so identified in the warning.
- Although OEHHA’s prior Prop 65 regulations contained no requirements with regard to providing warnings in languages other than English, the new regulations (Section 25602(d)) state the following with regard to consumer product exposure warnings: “Where a sign or label used to provide a warning includes consumer information about a product in a language other than English, the warning must also be provided in that language in addition to English.” “Consumer information” is defined (Section 25600.1(c)) to include warnings, directions for use, ingredient lists, and nutritional information and to exclude the brand name, product name, company name, location of manufacture, or product advertising.

Section 25603(b) now provides a “short-form” on-product label as an acceptable alternative to the revised requirements for consumer product exposure warnings. This option requires the hazard symbol, the word “warning” in capital letters and bold print -- **WARNING**, and a reference to OEHHA’s website, but importantly does not require a company to name a listed chemical within the text of the warning. Under this option, the entire warning must be in a type size no smaller than the largest type size used for other consumer information on the product. In no case shall the warning appear in a type size smaller than six-point type.

While the revised regulations expand the list of acceptable methods for providing a warning via electronic means, the revised regulations also make clear that the warning must be provided to the purchaser “prior to or during the purchase of the consumer product, without requiring the purchaser to seek out the warning.” For Internet purchases, the warning



Under California Health and Safety Code Section 25249.7, penalties for violating Prop 65 warning requirements may be assessed in the amount of \$2,500 per day, per violation.

must be provided to the purchaser prior to completing the purchase, which entails a warning separate from the warning that is provided on the consumer product.

It is too soon to assess the consequences of the 2018 changes. 2019 should continue to see companies reviewing their products and practices for potential exposures and determining how they will meet these new regulatory requirements, including whether the short-form warning language is a desirable option for some or all consumer products and how to satisfy online warning requirements. Considering the potentially complicated supply chain configurations that can raise issues regarding who is responsible for providing what warning, when, and how, companies also will continue to define those relationships and perhaps transfer warning requirements to “retail sellers” by complying with warning and written requirements to its retail sellers set forth at Section 25600.2. [Amendments](#) to the retail seller regulations were proposed on November 16, 2018, a hearing was held on January 3, 2019, and written comments are due by **January 11, 2019**.

Failure to comply with these new regulations may see an increase in alleged violations. Under California Health and Safety Code Section 25249.7, penalties for violating Prop 65 warning requirements may be assessed in the amount of \$2,500 per day, per violation. Enforcement of these new regulations through California’s Attorney General Office, or more likely private plaintiffs “acting in the public interest” (i.e., bounty hunters), is expected to be immediate and potentially widespread. The focus by private parties on Prop 65 compliance is evidenced by the total amount of settlement payments that have risen in recent years. Between 2007 and 2017, total settlement payments, which include civil penalties and attorney fees, increased from \$11.8 to \$25.8 million. Interestingly, the average percentage of settlements that are paid as attorney fees has risen between 2007 and 2017 from 57 percent to 76 percent.

Another Prop 65 issue that will be of continuing focus in 2019 is the applicability of these new warning requirements for pesticide products registered under FIFRA. Despite significant criticism and concerns regarding the conflict between the amended Prop 65 regulations and FIFRA labeling requirements, OEHHA on December 6, 2018, released its [final amendments](#) modifying its consumer product exposure warning requirements applicable to pesticide products regulated by EPA under FIFRA without any changes from its proposed language. The modifications provide a very narrow exception to the requirement to include the word “WARNING” in the warning language, permitting the word “ATTENTION” or “NOTICE” in cases where there is a conflict using the word “WARNING” with a pesticide product’s Toxicity Category assigned to the product by EPA (i.e., “Danger” (Toxicity Category I), “Warning” (Toxicity Category II), and “Caution” (Toxicity Categories III and IV)).

OEHHA’s decision not to modify its regulations beyond the scope of its original proposal was based on several factors, including its understanding that EPA has historically permitted Prop 65 warnings on FIFRA labels, and further that “[o]ther warning options are available in the event US EPA does not approve a given label application.” It is not as clear to those in industry that EPA is prepared to accept label amendments to include the new Prop 65 warnings, and even less clear what will transpire if EPA rejects the addition of Prop 65 language -- as OEHHA acknowledges is a possibility -- and registrants are forced to consider other warning options (e.g., shelf tags) that may be difficult to implement.

Another issue putting FIFRA-regulated pesticide labels and Prop 65 warning requirements on a collision course is the ongoing lawsuit challenging OEHHA’s listing of glyphosate as a chemical known to cause cancer. In February 2018, in *National Association of Wheat Growers v. Becerra*, the U.S. District Court for the Eastern District Court of California issued a [memorandum and order on the plaintiffs’ motion for preliminary injunction](#) (Order) to enjoin OEHHA from

enforcing the Prop 65 “requirement that any person in the course of doing business provide a clear and reasonable warning before exposing any individual to glyphosate.” As a result of that Order, although glyphosate continues to be listed under Prop 65, products containing glyphosate will not be required to comply with the warning requirement.

The substantive case will address the plaintiffs’ following claims: (1) Claim I: Violation of the First Amendment to the United States Constitution; (2) Claim II: Violation of the Supremacy Clause of the United States Constitution; and (3) Claim III: Violation of the Due Process Clause of the Fourteenth Amendment to the United States Constitution. In support of granting the request for a preliminary injunction enjoining the application of the attendant warning requirement, the court stated: “[o]n the evidence before the court, the required warning for glyphosate does not appear to be factually accurate and uncontroversial because it conveys the message that glyphosate’s carcinogenicity is an undisputed fact, when almost all other regulators have concluded that there is insufficient evidence that glyphosate causes cancer.” This determination, while preliminary, has potentially significant consequences for glyphosate products and for other FIFRA-regulated pesticides generally. If final resolution of this case addresses conflicts between Prop 65 warning requirements and conclusions supported by the data and reached by EPA or other agencies, this case could set precedent for other challenges related to pesticides listed under Prop 65.

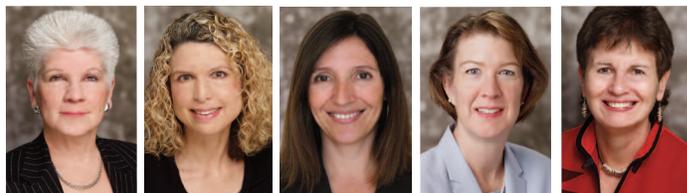
Pursuant to a September 6, 2018, order, this District Court case is now in abeyance pending decisions to be reached in two related cases: (1) the pending *en banc* Ninth Circuit case in *American Beverage Ass’n v. City and County of San Francisco*, No. 16-16072 (9th Cir. 2018); and (2) the pending Ninth Circuit case in *CTIA-The Wireless Ass’n v. City of Berkeley, CA*, No. 16-15141 (9th Cir. 2018). These cases are not related to Prop 65 warnings but do relate to the First Amendment to the United States Constitution and compelled government speech, and in particular the interpretation and application of the “purely factual and uncontroversial” requirements, upon which the claims in plaintiffs’ *National Association of Wheat Growers* case are in part based. The court agreed with OEHHA that the rulings in these cases could provide useful guidance to the parties and the court on the interpretation of the First

Amendment in compelled commercial speech cases involving issues of health and safety. While the *CTIA-The Wireless Ass’n* case is still in its briefing stage, oral arguments were heard in the *American Beverage Ass’n* case on September 26, 2018. If these cases are resolved in 2019, the parties in *National Association of Wheat Growers* will place this case back on schedule.

Moving forward, there also could be increased activity in requests that OEHHA issue Safe Use Determinations (SUD). While the SUD process has always been an option, requests for this determination are on the rise. Under this option, applicants seek OEHHA’s determination that an exposure of a particular listed substance to a particular consumer product does not require warning under Prop 65 (*i.e.*, that an exposure is at or below the safe harbor level). There have, however, been extremely few SUDs approved by OEHHA over the years, attributable either to companies disinclined to engage in a public process that can be lengthy and costly or OEHHA’s early determinations that applications are incomplete, thus ending the process unless additional information is generated and/or submitted. With the new regulations focusing attention on Prop 65 warnings, as well as several recent high profile Prop 65 listings of chemicals (*e.g.*, styrene, perfluorooctanoic acid (PFOA)/perfluoroalkyl substances (PFAS), and nickel (soluble compounds)) that are prompting potentially ubiquitous warning requirements, the appeal of OEHHA’s issuance of SUDs is increasing as a means to ensure OEHHA’s agreement as to the limitations of Prop 65 warning requirements and thereby thwart potential enforcement actions.

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Despite the fact that California and New York's intent seems similar -- to require manufacturers of certain consumer cleaning products to disclose information regarding the ingredients in those products -- the requirements to be implemented have significant differences that may complicate compliance by affected industries.

J. INGREDIENT DISCLOSURE

1. Consumer Cleaning Product Ingredient Disclosure Requirements

Companies in 2019 will be addressing new requirements established under New York's [Household Cleansing Product Information Disclosure Program](#) (Disclosure Program) and California's [Cleaning Product Right to Know Act of 2017](#) (S.B. 258). California's disclosure requirements were signed into law in October 2017 with implementation required, in part, by **January 1, 2020**, while New York's Disclosure Program was issued, somewhat surprisingly, on June 6, 2018, with implementation required, in part, by **July 1, 2019**. Despite the fact that California and New York's intent seems similar -- to require manufacturers of certain consumer cleaning products to disclose information regarding the ingredients in those products -- the requirements to be implemented have significant differences that may complicate compliance by affected industries.

S.B. 258 requires a manufacturer of a "designated product" sold in California to disclose certain intentionally added ingredients contained in a covered product that are included on a "designated list" (*i.e.*, one of more than 20 state, federal, and international lists (the so-called "list of lists")); thirty-four "nonfunctional constituents" identified in the regulations, and fragrance allergens included on Annex III of the EU Cosmetics Regulation No. 1223/2009 as required to be labeled by the EU Detergents Regulation No. 648/2004 on January 1, 2018 (Annex III). S.B. 258 sets forth the concentration levels above which certain ingredients must be disclosed (*e.g.*, when present in the product at a concentration at or above 0.01 percent (100 parts per million (ppm)) and the order in which the ingredients must be disclosed.

The ingredient information to be communicated has two components: one for labels and another for online. The online disclosure requirements will apply to designated

products sold in California on or after **January 1, 2020**. The product label disclosure requirements will apply to designated products sold in California on or after **January 1, 2021**. A designated product manufactured before these dates will be deemed compliant if the designated product displays either the date of manufacture or a code indicating the date of manufacture. Manufacturers may, at their discretion, label designated products manufactured before **January 1, 2021**, in accordance with the requirements.

The New York Disclosure Program has a similar purpose to S.B. 258, but differs in several significant respects. These include, but are not limited to, the following:

- The scope of covered products may be more expansive under S.B. 258, particularly as applicable to disinfectant products regulated under FIFRA.
- The designated lists of "chemicals of concern" to be reviewed for substances that trigger particular disclosure requirements are not the same lists under S.B. 258 and the New York Disclosure Program.
- New York's definition of "nonfunctional ingredients" are divided into two subcategories: "nonfunctional byproducts" and "nonfunctional contaminants." The scope of such ingredients is significantly broader than the 34 substances identified as nonfunctional ingredients under S.B. 258.
- S.B. 258's requirements for online disclosure of nonfunctional constituents is relatively straightforward, namely, disclosure would be required at concentrations at or above 0.01 percent (100 ppm), with limited exceptions (*i.e.*, list Prop 65 substances when constituent "triggers a product warning," and list 1,4 dioxane at concentration at or above 0.001 percent (ten ppm)). The New York Disclosure Program, by contrast, has varying concentrations above which disclo-

sure would be required, requiring companies to determine if they “know” the presence of substances at or below “trace quantities,” “practical quantification limits,” and/or “applicable thresholds for disclosure.”

- The extent of disclosure is quite detailed under the New York Disclosure Program, requiring companies to indicate the “Level” of non-fragrance and fragrance information being communicated based on whether certain information is claimed as CBI, as well as other information on effects on human health and the environment not claimed as CBI (*e.g.*, certain TSCA defined “health and safety” studies and any investigation or research performed by or for the manufacture and submitted to the European Chemicals Agency (ECHA) pursuant to the EU’s Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation.
- New York does not require any disclosures on labels but instead requires manufacturers to submit a “Disclosure Certification Form” providing, in part, the covered products for which ingredient information is being disclosed.
- The New York Disclosure Program has specific requirements applicable to nanoscale materials. Specifically, for each ingredient that is a nanoscale material, a term describing the nanoscale material should be disclosed (*e.g.*, if the nanoscale material is carbon, the disclosure should use the term “nanoscale” carbon). A nanoscale material is defined in the Disclosure Program by referencing EPA’s definition under the TSCA Section 8(a) nano reporting rule, namely: “a chemical substance that meets the TSCA definition of a reportable chemical substance manufactured or processed at the nanoscale.”

Particular focus for affected companies will likely be determining what information may be claimed as CBI. Under S.B. 258, CBI claims may be asserted with respect to any intentionally added ingredient or combination of ingredients for which a claim has been approved by EPA for inclusion on the TSCA Confidential Inventory, or for which the manufacturer or its supplier claim protection under the Uniform Trade Secrets Act. CBI cannot be claimed for an intentionally added ingredient or combination of ingredients that is on a designated list; a nonfunctional constituent; or a fragrance allergen included on Annex III, or subsequent updates to those

regulations, when present in the product at a concentration at or above 0.01 percent. For purposes of the New York Disclosure Program, CBI is any record(s) that would be exempt from disclosure as either a trade secret or confidential commercial information pursuant to New York law, which may not necessarily harmonize with the criteria under S.B. 258.

On December 19, 2018, the New York Department of Environmental Conservation (NYDEC) announced it was delaying the effective date of its Disclosure Program to **October 1, 2019**.

The Disclosure Program will now require most manufacturers of cleaning products sold in New York to disclose on their websites, by **October 1, 2019**, intentionally added ingredients other than fragrance ingredients and nonfunctional ingredients present above trace levels. Other effective dates set forth in the Disclosure Program have not changed. Manufacturers that are independently owned and operated and employ 100 or less people are not required to post such information until **July 1, 2020**. Manufacturers must post all required information for the following ingredients by **July 1, 2020**: fragrance ingredients; nonfunctional byproducts listed in Appendix D present at or above 100 parts per million (ppm), except for 1,4 dioxane, which should be reported at or above 350 parts per trillion (ppt); and PFOA and perfluorooctanesulfonic acid (PFOS), which should be reported at a combined level of at or above 70 ppt. There are rolling effective dates from **January 1, 2020**, through **January 1, 2023**, before all the requirements set forth in the Disclosure Program are fully effective.

NYDEC’s delay of the effective date is a result of a lawsuit filed in the Supreme Court of the State of New York. The lack of alignment between New York and California, and the fact that the New York Disclosure Program, unlike the California law, was not extensively vetted among cleaning product

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manufacturers before its issuance, forced two trade associations, the Household Cleaning Products Association (HCPA) and the American Cleaning Institute (ACI), to challenge the New York Disclosure Program in court. According to a Joint Statement issued by HCPA and ACI, the suit alleges NYDEC violated important administrative procedure and that its refusal to work with industry has created an "unworkable and impractical" policy that should be retracted so that a consistent national model for ingredient communication can be implemented instead. The case will likely also address whether NYDEC exceeded its regulatory authority by issuing the Disclosure Program under the authority of the Environmental Conservation Law, a law enacted in the early 1970s. NYDEC agreed to delay the effective date of the Disclosure Program while it prepares its response to the complaint.

This is definitely an area to watch. It remains to be seen if enhanced ingredient disclosure promotes more discriminating purchasing decisions, increases costs, or otherwise improves the world as we know it. Considering the time involved to determine the ingredients in each covered cleaning product, the concentrations of each ingredient, and CBI protection applicability, affected entities should be working now to identify potentially covered products and those in their supply chain that may need to supply information for compliance purposes.

K. FDA FOOD SAFETY MODERNIZATION ACT (FSMA)

1. Food Defense Plan Deadline -- July 2019

FDA's Food Safety Modernization Act (FSMA) has had many significant impacts on industry and on the evolution of policy and procedures for safe food handling, contact, and distribution. In terms of what is to come in the New Year, FSMA's final rule on [Mitigation Strategies to Protect Food Against Intentional Adulteration](#), issued in May 2016, may be most impactful in the coming months, as the deadline stipulated in the final rule for major industrial manufacturers to submit a food defense plan (FDP) is **July 2019**. This is the first time companies are required to submit a FDP. Food defense is described as "the effort to protect food from intentional acts of adulteration where there is an intent to cause wide scale public health harm."

1.1 Who is subject to this requirement?

Covered facilities include domestic and foreign food facilities that are required to register under FFDCa to address hazards

that may be introduced with the intention to cause wide scale public health harm. Businesses employing fewer than 500 persons must comply four years after the publication of the final rule.

1.2 Who is exempt?

The full requirements of the rule do not apply to "very small businesses." Compliance with modified requirements, specifically providing documentation upon request for official review that is sufficient to demonstrate that the business meets the definition of a very small business, will be required by **July 26, 2021**. A very small business is defined as one that, including any subsidiaries or affiliates, averages less than \$10,000,000, adjusted for inflation, per year, during the three-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale. Further exemptions, applicable to domestic and foreign facilities, are detailed in the regulations at [21 C.F.R. Section 121.5](#).

1.3 Regulatory Requirements

Under the final rule and implementing regulations codified at [21 C.F.R. Section 121.126](#), a FDP must include:

1. A written vulnerability assessment (VA), including required explanations, to identify significant vulnerabilities and actionable process steps for each type of food manufactured, processed, packed, or held at its facility using appropriate methods to evaluate each point, step, or procedure in its food operation. Appropriate methods are detailed in the regulations at [21 C.F.R. Section 121.30](#).
2. Written mitigation strategies, including required explanations, identified and implemented at each actionable process step to provide assurances that the significant vulnerability at each step will be significantly minimized or prevented and the food manufactured, processed, packed, or held by its facility will not be adulterated under FFDCa Section 402. Further details are included in the regulations at [21 C.F.R. Section 121.135](#).
3. Written procedures, including the frequency with which they are to be performed, for monitoring the mitigation strategies. Further details are included in the regulations at [21 C.F.R. Section 121.140](#).



In the May 2016 final rule, FDA stated caveats to the Food Defense Plan requirements as a concession to comments submitted by interested stakeholders.

4. Written procedures for corrective actions that must be taken if mitigation strategies are not properly implemented. Further details are included in the regulations at [21 C.F.R. Section 121.145](#).
5. Written procedures for verification: (1) that food defense monitoring is being conducted as required; (2) that appropriate decisions about food defense corrective actions are being made; (3) that mitigation strategies are properly implemented and are significantly minimizing or preventing the significant vulnerabilities; and (4) of reanalysis. Further details are included in the regulations at [21 C.F.R. Section 121.150](#).
5. The rule requires a reanalysis of the FDP as a whole or to the applicable portion of the plan when any of the following circumstances occur: (1) a significant change made in the activities conducted at the facility creates a reasonable potential for a new vulnerability or a significant increase in a previously identified vulnerability; (2) a facility becomes aware of new information about potential vulnerabilities; (3) a mitigation strategy, a combination of mitigation strategies, or the FDP as a whole is not properly implemented; or (4) whenever FDA requires reanalysis to respond to new vulnerabilities, credible threats to the food supply, or developments in scientific understanding.

In the May 2016 final rule, FDA stated the following caveats to the FDP requirements, as a concession to comments submitted by interested stakeholders:

1. There needs to be flexibility within the requirements for a facility to develop a FDP that meets its needs and unique characteristics; in the final rule, FDA states it has added flexibility for management components.
2. FDPs should change over time based on emerging threats and identification of new mitigation strategies.
3. FDA recognizes that some facilities have already voluntarily developed and implemented FDPs; in terms of existing records, FDA states that they do not need to be duplicated if they contain all of the required information and satisfy the requirements.
4. All foreign facilities do not have to prepare and implement a FDP. For example, foreign facilities that are not required to register are not subject to this rule; this includes a foreign facility, if food from such a facility undergoes further manufacturing/processing (including packaging) by another facility outside the U.S.

2. Foreign Supplier Verification Program

The deadline for very small businesses to comply with the Foreign Supplier Verification Program (FSVP) is **March 18, 2019**. This is the last group impacted by this FSMA rule, as the first compliance dates began on May 30, 2017. The rule, first proposed in 2013, requires importers to “perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards.” Additional aspects and details on the requirements can be found on the [FDA website](#).

3. FDA Regulatory Agenda Items

The following items were listed on the Fall 2018 Regulatory Agenda. Each could have substantial impacts on businesses in the New Year.

3.1 Proposed Rule Stage Items

- Sunscreen Drug Products For Over-The-Counter-Human Use; Tentative Final Monograph, [RIN 0910-AF43](#). FDA is developing a proposed rule that will address the general recognition of safety and effectiveness (GRASE) status of the 16 sunscreen monograph ingredients and describe data gaps that FDA believes

need to be filled for FDA to permit the continued marketing of these ingredients without submitting new drug applications for premarket review. Consistent with the Sunscreen Innovation Act, FDA also expects to address sunscreen dosage forms and maximum sun protection factor (SPF) values. The proposed rule was scheduled to be issued by November 2018.

On a related note, on August 22, 2018, FDA announced ([83 Fed. Reg. 42509](#)) an opportunity for public comment on the proposed collection of certain information, specifically comments on SPF labeling and testing requirements for over-the-counter (OTC) sunscreen products containing specified ingredients and marketed without approved applications, and comments on compliance with Drug Facts labeling requirements for all OTC sunscreen products.

- Food Standards: General Principles and Food Standards Modernization (Reopening of Comment Period), [0910-AC54](#). FDA is reopening the comment period on a proposed rule, issued jointly with USDA/Food Safety and Inspection Service (FSIS) in 2005 that proposed to establish general principles that would be the first step in modernizing and updating the framework for food standards (also known as standards of identity). [70 Fed. Reg. 29214 \(May 20, 2005\)](#). FDA states it is reopening the comment period because of the time that has elapsed since the publication of the proposed rule during which time there have been additional technological advances and other changes in the food industry that could help inform the development of a modernized food standards framework. FDA is proposing to reopen the comment period until **June 2019**.
- Investigational New Drug Applications Requirements for Conventional Foods, Dietary Supplements, and Cosmetics, [0910-AH07](#). FDA is developing a proposed rule intended to broaden the regulatory criteria for studies exempt from FDA’s Investigational New Drug (IND) requirements and provide clarity and consistency regarding when studies evaluating drug uses of products that are lawfully marketed as conventional foods, dietary supplements, or cosmetics are subject to IND review. FDA is scheduled to issue a proposed rule by **April 2019**.

- Streamlining Provisions Requiring Disclosure to Commercial Customers and Receipt of Written Assurances From Commercial Customer is in Current Good Manufacturing Practice and Preventative Control; Human, [0910-AH77](#). FDA is developing a proposed rule that would remove certain requirements that currently apply when a manufacturer/processor of human food has identified a hazard that requires a preventive control, but does not control that hazard. Although that manufacturer/processor would still be required to provide documentation that the food has not been processed to control the identified hazard, that manufacturer/processor would no longer be required to obtain written assurance from the commercial customer that the identified hazard will be controlled. The proposed rule was scheduled to be issued by December 2018, or **early 2019**.
- Amendments to Registration of Food Facilities, [0910-AH82](#). FDA is developing a proposed rule that would make clarifying changes to general provisions related to the registration of food facilities rule, including edits to the definition of “farm.” FDA is scheduled to issue the proposed rule by **April 2019**.
- Food Additives: Food Contact Substance Notification That Is No Longer Effective, [0910-AI01](#). FDA is proposing to amend its food additive regulations to allow a Food Contact Notification (FCN) to become no longer effective for reasons other than safety. In addition, under the proposed rule, FDA would provide manufacturers or suppliers an opportunity to address any safety concerns earlier in the determination process. FDA is scheduled to issue the proposed rule by **March 2019**.

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The thirty-sixth session of the UN Sub-Committee of Experts on GHS was held on December 5-7, 2018. The agenda included several of the items from the thirty-fifth meeting, including draft amendments to Rev 7.

L. OSHA WHMIS AND UN GHS

1. GHS Update for OSHA, WHMIS, and UN GHS

2019 is expected to bring significant changes to the U.S. as OSHA is expected to issue a proposed rule in **March 2019** amending the Hazard Communication Standard (HCS). Summaries of the current state of GHS are provided in more detail below.

1.1 UN GHS

In 2017, the seventh revised edition ([Rev 7](#)) of the GHS was published. The thirty-fifth session of the UN Sub-Committee of Experts on GHS was held in July 2018. The agenda included discussions on classification of aerosols and chemicals under pressure, revised OECD Test Guideline 431 allowing sub-categorization for skin corrosion, desensitized explosives, classification of physical hazards, Chapters 2.1 and 2.3, use of non-animal testing methods for classification of health hazards, labeling of small packaging, improvements of Annexes 1 to 3, further rationalization of precautionary statements, and possible development of a list of chemicals classified in accordance with GHS.

The thirty-sixth session of the UN Sub-Committee of Experts on GHS was held on December 5-7, 2018. The agenda included several of the items from the thirty-fifth meeting, including draft amendments to Rev 7. The expectation is that these amendments would become the eighth revised edition and be published in 2019. The eighth revised edition is expected to include an entirely new annex (Annex 11) that addresses dust explosions. This topic has long been discussed at the UN level and was viewed as extremely relevant to U.S. stakeholders. The new Annex contains substantial details that could be beneficial to those seeking clarification on how to address dust explosion hazards.

The UN model is adopted by countries in several different ways. Some countries chose to adopt all the building blocks

(physical, health, and environmental hazard classes and categories) “as is” into their legislation. The revised edition adopted will determine the details implemented into the legislative framework. Some countries will adopt the criteria-based approach of the UN model, but exclude certain building blocks (excluding either an entire hazard class or just certain categories within the hazard class). The most common hazard class categories excluded are flammable liquid category 4, acute toxicity category 5, skin corrosion/irritation category 3, and various blocks within the environmental hazard classes. A criteria-based approach allows the ability to self-evaluate the hazards, based on the criteria, to determine the classification. Other countries have chosen to adopt the basic UN model, but will modify it to fit within their existing legislation or regulatory framework. This often results in a merging of regulations where the country may choose to retain existing schemes (*e.g.*, required substance classifications or lists of classifications for specific substances) and elements of self-classification based somewhat on the UN criteria. There are currently 72 countries listed on the UN GHS site that are in the process of adopting or have adopted the GHS standards.

1.2 OSHA

On May 25, 2012, OSHA revised and updated the [HCS](#). Currently, all substances and mixtures are required to comply with HCS 2012, as the transition period ended on June 1, 2015, for manufacturers and December 1, 2015, for distributors. OSHA extended the deadline under very specific circumstances on May 29, 2015. Those circumstances are considered to be limited and must be documented to demonstrate compliance. OSHA continues to issue guidance to employers on how to address specific aspects of HCS 2012, but no new substantial changes or updates to the regulation have occurred. The Trump Administration’s Fall 2018 Regulatory Agenda stated that OSHA intends to publish a [proposed rule](#) to update the HCS “to the latest edition of the GHS and to codify a number of enforcement policies that have been issued since the 2012 standard” by **March 2019**. More information

on this proposed analysis is available in our memorandum [“A Glimpse of Things to Come: OSHA’s Soon to Be Updated Hazard Communication Standard.”](#) B&C will be releasing our related podcast, “Dis-harmonization’ of GHS,” on **January 10, 2019**, as part of its “All Things Chemical™” series available on [iTunes](#), [Spotify](#), [Stitcher](#), and [Google Play Music](#).

1.3 WHMIS

On February 11, 2015, Health Canada published the [Hazardous Products Regulation](#) (HPR). The HPR revised and updated the Workplace Hazardous Materials Information System (WHMIS). WHMIS 2015 significantly altered the previous system (WHMIS 1988) and is a modified criteria-based approach following Rev 5 of the UN model. Health Canada worked with the U.S. to align, as much as possible, each country’s GHS implementation. WHMIS 2015 retains elements from WHMIS 1988 that are unique to Health Canada’s program (*i.e.*, Biohazardous Infectious Materials). The WHMIS 2015 transition period was to end June 1, 2017, but was extended from May 31, 2017, to June 1, 2018, to address additional complexities with the updated system. There are no significant changes expected in 2019.

Health Canada and OSHA continue to work through variances in their implementations through the Regulatory Cooperation Council (RCC). The [Memorandum of Understanding](#) (MOU) for the RCC was reaffirmed on June 4, 2018. The variances between the two approaches are present, but are not as substantial as other country approaches to GHS.

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II. KEY GLOBAL CHEMICAL MANAGEMENT PREDICTIONS

A. EUROPEAN UNION (EU)

1. Chemical Substance Management in the EU

1.1 Introduction

Chemical substance management in the EU in 2019 will be a mix of new and ongoing activities. The EU faces unprecedented challenges in the form of the UK’s decision to leave the EU (Brexit), possibly without an agreement between the UK and EU. The UK’s transition to its own chemical substance management system is expected to be a major development in 2019. Ongoing compliance and enforcement challenges are expected to continue under REACH and the Biocidal Products Regulation (BPR). Updates to the EU’s Classification, Labeling and Packaging (CLP) regulation, evaluation of EU food contact materials (FCM) legislation, and implementation of the criteria for identification of endocrine disruptors recently adopted by the European Commission (EC) will impact the management of chemical substances in 2019 and beyond.

B. BREXIT

On June 23, 2016, more than 30 million people voted in a referendum to decide whether the UK should remain in, or depart from, the EU. The “Leave Campaign” won the referendum by 52 percent to 48 percent, and since then [“Brexit”](#) has become an important matter globally with a wide range of stakeholders. Since the referendum in 2016, there have been numerous Brexit-related political and legal developments, including issuance of a [Draft Withdrawal Agreement \(DWA\)](#) and [Political Declaration Outline](#). These documents, issued on November 14, 2018, can be regarded as the only substantive result of UK-EU negotiations to date -- and quite possibly represent the only basis for a Brexit outcome other than a “hard,” “no deal,” or “disorganized” exit. Critically, for the DWA to hold legal relevance, it requires approval from UK and EU Parliaments.

UK Prime Minister Theresa May delayed a House of Commons vote on the DWA scheduled for December 11, 2018, amidst concerns regarding being unable to obtain required support from Members of Parliament (MP). Mrs. May survived a Conservative party “no-confidence vote” in her leadership, and is in discussions with EU representatives to



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amend the DWA to achieve support from UK MPs. Among the key issues for discussion is the Irish “backstop.” Mrs. May has indicated, to the Labor Party’s frustration, that the UK’s House of Commons will vote on the DWA during the week of **January 14, 2019**. The Labor party contends this is an unnecessary delay, and other UK political parties are urging Jeremy Corbyn to push for a no-confidence vote against Mrs. May’s government as a whole, in contrast to the no-confidence vote mentioned above, which focused on Mrs. May. The upcoming “meaningful vote” will play a critical role in determining the UK’s next Brexit steps. Meanwhile, the European Court of Justice has ruled that the UK can cancel Brexit without permission of the EU-27.

For many interested parties, the DWA represents a favorable practical Brexit process due to its transition period until **December 31, 2020**, and related EU-UK cooperation. If the DWA receives approval in the UK, it will be considered by the European Parliament (EP). It is far from certain that UK MPs will support Mrs. May’s proposed DWA. If the DWA does not obtain required support in the House of Commons, the default position would be for a “no-deal Brexit” to occur on **March 29, 2019**, which would raise a range of political and legal issues including an extension of the two-year time-frame under Article 50 of the Lisbon Treaty, changes in UK leadership, and further EU-UK negotiations. Much to “Brexiters” disbelief, an additional UK referendum on Brexit has also been suggested.

The Commons vote scheduled to occur in January 2019 is a critical Brexit moment. European approval and a full transition period are considered highly likely if the House of Commons votes in favor of the DWA, but the chances of this occurring are uncertain and a no-deal Brexit in **March 2019** is entirely possible. If the House of Commons does not support the DWA, the UK and entities globally face further Brexit-related uncertainty, as well as ongoing and significant political tensions in the UK. The good news is that we are quickly approaching **March 2019**, and it is expected that industry will understand better the Brexit process by this time, including its mechanics and timing.

Brexit has numerous potential consequences for chemical regulatory compliance and product stewardship in the EU and UK. Personnel addressing compliance or marketing products are well advised to review regularly information made available by ECHA and the UK’s Health and Safety Executive (HSE). It is anticipated that **early to mid-2019** will provide much meaningful information for the chemicals industry.

As expected, the UK has already signaled that it will oversee a robust regulatory framework for the management of chemicals post-Brexit. Chemical companies with interests in the UK market should follow developments in 2019 regarding the UK’s potential future chemical regulatory frameworks. Based on their corporate interests, companies may also wish to engage in advocacy or stakeholder discussions regarding potential future UK legislation (*e.g.*, UK REACH Regulation).

The DWA does not include measures that mitigate the regulatory impact of the UK becoming a “non-Community” or “third” country in the context of EU regulations, including REACH. Therefore, it appears, that the following Brexit-driven practical changes will occur, among many others, either on **March 29, 2019**, or at the end of the applicable transition period:

- UK chemical manufacturers become non-Community manufacturers, and are required to appoint EU-27 based Only Representatives (OR) if they wish to address REACH compliance for their EU-27 based customers;
- Exclusively UK-based ORs are considered outside the scope of REACH, and can no longer provide OR services from the UK; and
- UK-based Downstream Users under REACH are no longer required to inform UK- or EU-27-based suppliers of their uses.

In addition to REACH, Brexit has a range of potential consequences under many regulations including the BPR, the CLP Regulation, and the Prior Informed Consent (PIC) Regulation.

UK chemical manufacturers selling to the EU-27 market, EU-27 chemical manufacturers selling to the UK market, and chemical manufacturers established outside the UK and the EU-27 and engaged in either market must understand the impacts of the DWA for their businesses, and prepare to adapt accordingly and for a no-deal exit in **March 2019**. Preparing for both scenarios appears essential to support ongoing market access and business prosperity. A no-deal scenario, in particular, could raise significant challenges and have negative consequences for unprepared supply chains.

Chemical companies can benefit from monitoring diligently Brexit-related developments in 2019, and performing the following tasks to prepare their businesses for Brexit:

- Determine if legal entities addressing compliance are established in the UK or EU-27, and transfer operations to an EU-27 entity if required;
- Evaluate and re-negotiate contracts affected by Brexit; and
- Request confirmations from supply chain actors to document that Brexit-related measures are in place.

Brexit has attracted unparalleled levels of attention globally due to its significance and potential for worldwide impact on supply chains and financial markets. Good planning and sound regulatory and legal support are essential to managing the potential implications of Brexit and chemical companies addressing EU and UK compliance that have a busy year ahead. The chemicals industry can benefit significantly from proactive and strategic planning to protect businesses from the potentially damaging consequences of Brexit on important issues such as market access and legality of sales.

1. Biocides

The EU's BPR, which repealed and replaced the Biocidal Products Directive (BPD) on September 1, 2013, covers the "placing on the market" and use of biocidal products for the protection of humans, animals, materials, or articles against harmful organisms (*e.g.*, pests). BPR is intended to improve

the functioning of the biocidal products market in the EU, while ensuring a high level of protection for humans and the environment. BPR promotes the reduction of animal testing by providing mandatory data sharing obligations and encouraging the use of alternative testing methods.

In the recent past, there have been several important developments in the European biocides space. These include approvals for biocidal products, determinations of ECHA's Biocidal Products Committee (BPC), activities of the Enforcement Forum's BPR Subgroup (BPRS), implementation under BPR of the scientific criteria for the determination of endocrine-disrupting properties, and of course, numerous Brexit-related matters. It is expected these recent matters will influence decision-making and drive many activities under BPR in 2019.

From a legal standpoint, perhaps the most interesting of these developments is the implementation of the criteria for endocrine-disrupting properties under BPR. As such criteria have not yet been applied in other important chemical regulatory sectors, many regard BPR as the proving ground for such criteria. [Commission Delegated Regulation \(EU\) 2017/2100](#) provides the legal text for the endocrine disruptor criteria, and Member State Competent Authorities have issued agreed upon notes on how to apply the criteria.

Among the legal issues raised by the criteria, guidance, and notes is whether the criteria can be applied to biocidal product components other than the active substance. BPR indicates that the criteria on endocrine-disrupting properties are relevant in the context of exclusion of biocidal active substances. Supporting documents for the legal criteria paint a different picture, suggesting that non-active co-formulants within a biocidal product may lead to a conclusion that a biocidal product has endocrine-disrupting properties. It can be reasonably expected that, in due course, there will be challenges and clarification in this regard.

Further concerns raised by the endocrine disruptor criteria and supporting documents include application of the criteria to active substances that are still under review. To such substances, the complete criteria apply with immediate effect. Industry has already seen ECHA's BPC to support approval of an active substance, but sent the dossier back to the evaluating Member State to assess whether the substance meets the criteria. New data may need to be developed and submitted for purposes of the criteria, and companies need to



Based on the wide array of ongoing issues in the biocides arena, it is clear that companies' technical, scientific, regulatory, and legal personnel have vital roles to play this year.

prepare for these circumstances. The criteria represent an important measure in terms of biocidal product safety, but raise a number of questions at this late stage in the BPR timeline. Application of the criteria at this stage evidently threatens the goal of completing examinations by **2024**.

It is clear that the biocides sector has an interesting and challenging year ahead. As companies seek to bring biocidal products to market, it is expected the endocrine disruptor criteria will attract substantial attention and cause significant delays. As the criteria are progressively applied to cases, it can be expected there will be questions on, and additional supporting documentation regarding, the criteria. The BPR data sharing and compensation rules, which are similar to yet distinct from the REACH rules, are expected to continue to attract attention in 2019. Data sharing is typically contentious under chemical regulatory regimes, and BPR is no exception. The longstanding and much discussed requirements of fairness, transparency, and non-discrimination are expected to keep regulatory personnel busy this year as companies engage in mandatory data sharing. Many data sharing agreements will likely be exchanged, and it is expected that binding arbitrations and referrals of data sharing disputes to ECHA will also continue in 2019.

There are many deadlines in 2019 under BPR. These include deadlines for notification to ECHA to include substances in the Review Program, and deadlines for Union Authorization applications. Substances with deadlines in 2019 for Union Authorization applications include margosa extract, propan-1-ol, and imiprothrin. The BPC has a busy Work Program in 2019, and many companies globally with relevant product portfolios will likely follow closely regulatory consideration of their active substances.

Although enforcement of BPR is in the sole competence of Member States, BPRS plays an important role in coordinating strategies and joint inspections. The main priority of BPRS is to coordinate enforcement projects on BPR issues in Member States. In 2019, BPRS will launch a coordinated enforcement project dedicated solely to BPR requirements

regarding treated articles (BEF-1). BEF-1 aims at covering the full supply chain making treated articles available on the market. BEF-1 will be executed in 2019, and a report will be published in **2020**. BEF-1 will include broad participation from Member States, and is an important project because, to date, there is limited experience on specific enforcement of duties related to treated articles. Companies engaged in European commerce for treated articles are well advised to review and improve their compliance strategies to avoid unpleasant surprises this year under BEF-1.

Companies placing biocidal products on UK and EU-27 markets should follow closely Brexit-related developments and update compliance strategies as needed. As of the date of this writing, a DWA has been agreed between the UK and EU. To hold legal relevance, the document requires approval from the UK and EP. It is not certain that the DWA will receive required approvals, and this means a “no-deal” or “disorderly” Brexit is possible. Companies with interests in EU-27 and UK markets face the challenge of preparing appropriately for multiple potential Brexit outcomes and implementing plans timely. As reported extensively, among other changes, upon Brexit:

- UK-based biocidal product authorization holders will be considered outside the scope of EU BPR;
- EU-27 Member States will no longer be able to issue a national BPR authorization based on recognition of a UK authorization; and
- The UK will no longer act as an evaluating Competent Authority under BPR.

Based on the wide array of ongoing issues in the biocides arena, it is clear that companies' technical, scientific, regulatory, and legal personnel have vital roles to play this year. Coordinated and well-informed regulatory approaches, and assistance from external specialists as required, can assist entities in the biocides sector to achieve their compliance and business goals in 2019.

2. Classification and Labeling Initiatives

In January of 2009, [Regulation \(EC\) No 1272/2008 of the Classification, Labelling and Packaging](#) (CLP) of Substances and Mixtures came into force. CLP aims to harmonize several elements of hazard communication, and to ensure consistent communication of those hazards to the workers and consumers within the EU Member States. CLP repealed Directives 67/548/EEC and 1999/45/EC and amended Regulation (EC) 1907/2006. CLP is originally based on a combination of Revision 3 and Revision 4 of GHS. The eighth adaptation to technical progress (ATP) notes that CLP was reviewed against Revision 5 of the UN model and updated accordingly. In 2019, it is likely that the twelfth ATP will be published and adopted. It will align CLP to Revision 6 and Revision 7 of the GHS.

CLP contains, in Annex VI, substance-specific required classification and labeling. These substance level classifications can include specific concentration limits triggering the required classification when used in mixtures. CLP also includes supplemental hazards (*i.e.*, EU Specific Hazard (EUH) statements) and specific notes for consideration for classification of substances. CLP updates and amendments occur about once or twice annually. The thirteenth ATP was adopted on October 4, 2018, published in the *EU Official Journal*, entered into force on November 9, 2018, and shall apply beginning **May 1, 2020**. It amends CLP by adding the ECHA Risk Assessment Committee's (RAC) 2017 opinions on harmonized classification of several substances to Annex VI. The ATP includes 18 updates to existing entries and 16 new entries. In 2019, manufacturers and importers will need to review these changes to determine if any of the new or revised entries are present, and if the changes result in amended classifications. If a change in the classification is noted, safety data sheets (SDS) and labels will require updates as specified in the regulation.

3. Food Contact Materials

FCMs in the EU must comply with the Framework Regulation EC No. 1935/2004 and Good Manufacturing Practice EC No. 2023/2006. The general requirements are that the FCM must not release constituents into food at levels that are harmful to human health or change the organoleptic properties of food. There is no requirement for FCMs to be reviewed, monitored, or approved at the EC level at this time. The Framework Regulation includes, in Annex I,

specific measures on materials. Currently, there is legislation that relates to specific materials (*i.e.*, plastics, recycled plastics, regenerated cellulose, ceramics, and active and intelligent materials). There is no material-specific legislation at the EU level for inks, coatings, paper and paperboard, rubber, and adhesives. There are substance-specific measures for vinyl chloride monomer, specific bisphenol-A based epoxy resins, nitrosamines, and n-nitrosables.

On September 24, 2018, DG SANTÉ of the EC organized an introductory workshop to commence the official start of the evaluation of EU FCM legislation. The EC, with the support of an external contractor, will collect data, analyze the findings, and issue a report by **September 2019**.

The consultation involves targeted interviews with stakeholders, focus group discussions, and an open public consultation. On the basis of the findings and analysis of the consultation, the EC will determine how it will revise the regulatory framework for the European FCM sector.

Those interested in commenting on the Framework's effectiveness and perhaps shaping the legislative process should look for opportunities during the open public consultation periods expected from December of 2018 until **February of 2019**. B&C will soon be releasing a podcast on EU FCM Legislation as part of its "All Things Chemical™" series available on [iTunes](#), [Spotify](#), [Stitcher](#), and [Google Play Music](#). Stay tuned!

4. SVHC/Restrictions/Authorizations

Substances of Very High Concern (SVHC) are those that fulfill one or more of the criteria defined in Article 57 of the REACH Regulation. Substances meeting the definition of a SVHC are those:

- Meeting the criteria for classification as carcinogenic, mutagenic, or reprotoxic (CMR), category 1 or 2;
- Considered PBT or very persistent and very bioaccumulative (vPvB); or
- For which there is an equivalent level of concern, for example endocrine disruptors and sensitizers.

The candidate list for authorization, or SVHC list, was first published in October 2008, but is updated regularly. The



The ECHA SVHC Roadmap to 2020 gives an EU-wide commitment for having all relevant known SVHC included in the Authorization list by 2020 and outlines how ECHA intends to achieve this objective.

most recent update occurred in June 2018 when ten new substances were added, taking the total number of substances on the SVHC list to 191. In 2018, a total of 17 substances were added to the SVHC list. A list of the substances included on the SVHC list can be found at <https://echa.europa.eu/candidate-list-table>.

ECHA regularly assesses the SVHC list to decide which substances should be added to REACH Annex XIV, or the Authorization list, as a priority. This is primarily based upon information within the registration dossier, for example on uses and volumes. There are currently 43 substances listed on the Authorization list, no new substances were added in 2018. A list of the substances included on the Authorization list can be found at <https://echa.europa.eu/authorisation-list>. Four of the substances listed on the Authorization list, Dichromium tris(chromate (EC Number 246-356-2), Strontium chromate (EC Number 232-142-6), Potassium hydroxyoctaoxidizincatedichromate (EC Number 234-329-8), and Pentazinc chromate octahydroxide (EC Number 256-418-0), have their sunset date on **January 22, 2019**.

The ECHA SVHC Roadmap to **2020** gives an EU-wide commitment for having all relevant known SVHC included in the Authorization list by **2020** and outlines how ECHA intends to achieve this objective. The following groups of substances are to be covered by the implementation plan:

- CMRs (Categories 1A/1B);
- Sensitizers;
- PBTs or vPvBs;
- Endocrine disruptors; and
- Petroleum/coal stream substances that are CMRs or PBTs.

Each year, ECHA publishes a report on the progress of implementing the SVHC Roadmap. These reports summarize

the achievements and activities carried out the previous year and set out the activities planned for the following year. The 2018 report is not yet available.

ECHA released on December 14, 2018, its [Strategic Plan for 2019-2023](#), in which it lays out its strategic outlook for managing chemicals in the years ahead.

Although there is no direct link between the Community Rolling Action Plan (CoRAP) and the authorization and restriction process, inclusion in the CoRAP means that a substance's potential risk is going to be evaluated by a Member State. Hence, a follow up may be that the Member State wishes to begin the authorization process. The draft CoRAP for 2019 - **2021** currently contains 100 substances, four of which were added late in 2018. These will be evaluated by Member States in **2019**, **2020**, and **2021**. It is planned that 31 of these will be evaluated in 2019, but the final plan will not be released until **March 2019**.

5. Post-2018 REACH

May 31, 2018, closed the last registration window for phase-in substances subject to registration in accordance with REACH. On June 1, 2018, ECHA issued a press release entitled "[21,551 chemicals on EU market now registered](#)." In its press release, ECHA states "[t]he 10-year registration period for existing chemicals is now complete following the last REACH registration deadline on 31 May 2018. 13 620 European companies have submitted information to ECHA in nearly 90 000 registrations for chemicals manufactured in or imported to the EU and [European Economic Area (EEA)] at above one tonne a year."

ECHA indicates that more is known today about chemicals used in Europe than ever before. This knowledge, generated by industry, is stored and published by ECHA in the world's largest public regulatory database on chemicals and forms the basis for protecting citizens and the environment from the risks posed by chemicals. ECHA provides that over the first ten years of REACH, the EU has established a fair and

transparent internal market for chemicals with strict safety rules, thereby promoting innovation towards safer substances and strengthening EU competitiveness.

ECHA's [REACH Registration Results](#) indicate that registrations for 21,551 substances were submitted to ECHA, and 20,608 of these registrations were completed. The total number of completed registrations, including co-registrations of the same substance and Notification of New Substance (NONS) notifications, is 82,874. The highest number of REACH registrations was submitted by Germany and the UK. The registrations are distributed among REACH tonnage bands as follows:

- 1-10 tonnes per year = 14,865 completed registrations;
- 10-100 tonnes per year = 11,080 completed registrations;
- 100-1,000 tonnes per year = 12,489 completed registrations; and
- 1,000 tonnes per year and more = 20,113 completed registrations.

The registration process is expected to slow down in 2019, but existing dossiers will require revisions and updates continually. In September, ECHA [alerted](#) member registrants that “[a]s of 1 January 2019, ECHA will start checking the compliance of all relevant dossiers for a given substance and will address its decisions to all registrants with non-compliant dossiers.” This is a change from the previous approach that included primarily notifying the lead registrant. To this point, ECHA [reminded](#) companies in November that there is an expectation that completed registrations are to be kept up to date. ECHA noted that “[y]our registration has to reflect the **most up-to-date knowledge** on how a substance can be used safely at production sites and through the supply chain all the way down to the end user.”

6. Endocrine Disruptors

The EC [adopted on November 7, 2018](#), a [Communication](#) on the criteria for identification of endocrine disruptors as applied to biocides and pesticides. The Communication was developed in response to concerns expressed by the EP and Council in 2017 about keeping the EC strategy on endocrine disruptors “the most modern and fit-for-purpose in the world,” and provides follow up on the 7th Environment

Action Programme. The Communication follows the publication and subsequent application of endocrine disruptor criteria for biocidal products from June 7, 2018, and for plant protection products from November 10, 2018.

The European Food Safety Authority (EFSA) and ECHA were asked by the EC to develop guidance for applicants and Competent Authority assessors to apply in the context of the BPR (EU) No 528/2012 and the Plant Protection Products Regulation (EC) No 1107/2009 for identifying endocrine disruptors in accordance with the criteria in Commission Delegated Regulation (EU) No 2017/21003 (for biocidal products) and Commission Regulation (EU) No 2018/6054 (for plant protection products).

The document describes the process for compiling and evaluating all information relevant to an endocrine disruptor assessment and determination of whether the endocrine disruptor criteria, according to the WHO/International Program on Chemical Safety (IPCS) definition of an endocrine disruptor (WHO/IPCS, 2002) are fulfilled, including the use of mode of action analysis and a weight of evidence approach.

The EC is being pressed by non-governmental organizations (NGO) to step up efforts in 2019 to provide guidance for application in other regulatory contexts, including chemicals regulated under REACH, cosmetics, and FCMs. We can expect additional advocacy in this area in 2019.

7. Turkey REACH

As reported in Acta's [2018 Forecast](#) and [earlier memorandum](#), Turkey has implemented a REACH-like chemical regulatory program, KKDIK. KKDIK was published by Turkey's Ministry of Environment and Urbanization (MoEU) on June 23, 2017, and the regulation entered into force on December 23, 2017. Among other goals, KKDIK seeks to align rules for chemicals in Turkey with EU laws. KKDIK replaces the following Turkish chemical laws:

- Regulation on the Inventory and Control of Chemicals (CICR);
- Regulation on the Preparation and Distribution of SDS for Hazardous Materials and Products; and
- Regulation on Restrictions for the Manufacture, Marketing, and Use of Certain Dangerous Substances and Preparations.



Similar to the EU's REACH regulation, Turkey REACH (KKDIK) is an ambitious law that covers a wide range of matters pertaining to chemical safety.

Similar to the EU's REACH regulation, KKDIK is an ambitious law that covers a wide range of matters pertaining to chemical safety. The principles, rules, and requirements of KKDIK are very similar to EU REACH, and only few substantive differences exist between EU REACH and KKDIK. Similar to EU REACH, KKDIK is a hazard-based chemical regulatory program that requires registration for chemicals manufactured or imported in quantities of one metric ton per annum or more. KKDIK contains the same annual tonnage bands as EU REACH (i.e., 1-10 metric tons, 10-100 metric tons, 100-1,000 metric tons, 1,000+ metric tons). Similar to EU REACH, KKDIK contains pre-registration and registration deadlines for chemicals. In contrast to EU REACH, the registration deadline under KKDIK does not vary depending on the applicable tonnage band or differentiate "new" substances from "existing" substances. The pre-registration deadline under KKDIK is **December 31, 2020**, and the registration deadline is **December 31, 2023**, for all chemical substances or mixtures manufactured in or imported into Turkey in quantities of one metric ton or more annually.

KKDIK rules relating to OR, Restrictions, Authorizations, polymers, and "articles" are also very similar to those under EU REACH. Somewhat unsurprisingly, KKDIK submissions are required to be made in Turkish. While in most respects KKDIK resembles a Turkish translation of EU REACH, certain material differences exist between these two laws.

KKDIK Annex 18 provisions are unique to the Turkish legislation, and allow Turkish regulators to manage and oversee personnel who may engage in certain regulatory activities. Annex 18 contains qualification requirements for technical experts, as certain registration, notification, and SDS activities under KKDIK can only be performed by Chemical Assessment Experts certified by an institution that has been accredited by the Turkish Accreditation Institution. In addition to qualification requirements for the Experts, Annex 18 includes criteria for trainers and requirements for the institutions providing training.

Based on ongoing developments and the current state of play under KKDIK, 2019 promises to be a busy year under this important law, with the swiftly approaching pre-registration deadline driving increased demand for expert KKDIK services. Many companies with business interests in Turkey will likely seek, in 2019, to address pre-registration either via an OR or through their corporate entities established in Turkey. Global chemical companies addressing in-house regulatory compliance for industrial chemicals in Turkey will likely consider having appropriate personnel trained as Chemical Assessment Experts.

Although pre-registration activities focus on substance identity and a company's role in supply chains, entities globally are well aware of the potential challenges related to legitimate data citation for full registration under KKDIK. EU REACH data use is permissible under KKDIK, and many companies placing similar products on EU and Turkish markets will likely seek to secure legitimate use rights to EU REACH data for KKDIK reliance. For many entities, this may represent a significant challenge due to the nature of EU REACH contracts and joint data ownership.

Numerous EU REACH registration agreements specify that rights obtained by co-registrants are limited to EU REACH citation, and that additional data use requires a separate agreement with the data owner. Under these circumstances, entities interested in using EU REACH data for KKDIK would need to negotiate new data usage rights with data owners, and provide compensation as appropriate. If relevant study data are jointly owned, this presents a further hurdle for KKDIK usage because each of the owners would need to agree on terms for KKDIK data citation.

Based on experience gained under chemical regulatory programs similar to KKDIK, Acta believes that many global entities will likely be keen to sublicense data for KKDIK purposes, but some limited instances may exist where companies decline to provide data access for Turkish compliance.

Due to these issues and potential challenges in obtaining rights for legitimate KKDIK data citation, numerous chemical companies will likely commence review, in 2019, of pertinent executed data sharing agreements.

Acta expects that additional information will be made available in 2019 regarding specific KKDIK processes, the operation of the regulation, and future plans. To date, limited KKDIK guidance documents are available in English. English translations of Turkish KKDIK guidance documents are important for industry globally to comply with the law, and stakeholders are well-advised to request from regulators official translations or develop such reliable translations themselves.

Acta also expects that 2019 may provide important information regarding the principles and operation of KKDIK Substance Information Exchange Forums (SIEF). Acta believes that SIEF operation in Turkey will be structured similarly to EU REACH SIEF operations. As implementation of KKDIK progresses, Acta expects that additional practical information on dossier development and submission will be made available. The Turkish Chemicals Registration System (KKS) is currently available for submission of KKDIK pre-registrations. It is anticipated that KKS, which can be regarded as a hybrid of International Uniform Chemical Information Database (IUCLID) and REACH-IT, will be updated progressively for harmonization with current versions of these EU REACH platforms. Based on experience gained under EU REACH, it would appear critical for a bulk submission utility to be incorporated into KKS sooner rather than later.

Acta foresees an interesting year ahead for chemical regulatory compliance in Turkey, anticipates that KKDIK will attract substantial attention globally from a range of interested

parties, and that noteworthy efforts will be made to comply in 2019. As activities increase under KKDIK, Acta believes that many aspects of the regulation, including its interpretation and enforcement, will be clarified to a much greater degree. Such information, which could be made available via official MoEU communications or industry discussions, would be useful as chemical companies refine their compliance approaches. Companies engaged in, or wishing to engage in, commerce for chemical products in Turkey should follow closely KKDIK developments and jurisprudence to achieve their business and regulatory compliance goals.

C. ASIA

1. Chemical Substance Management in Asia

2018 saw the continued development primarily in China, S. Korea, Taiwan, and Vietnam of a wide range of chemical substance and product management statutes. 2019 is expected to bring changes to chemical control legislation in S. Korea, Taiwan, and Vietnam.

1.1 China

China is expected to continue its legislative changes and regulatory development as mandated in 2016 in its [13th Five Year Plan for Economic and Social Development](#). It is certain that more regulations and national/industrial standards will be released and more enforcement campaigns will be carried out in 2019. Enterprises should pay close attention to the upcoming regulations for their activities, such as substance notification and transport/storage of hazardous products, which may be affected.

Chinese government agencies went through major reorganization through mergers and setting up new offices in 2018. The Ministry of Environmental Protection (MEP) was rebranded and expanded to the Ministry of Ecology and Environment (MEE), while also assuming some responsibilities previously assigned to the National Development and Reform Commission (NDRC), Ministry of Water Resources, Ministry of Agriculture, and Ministry of Land and Resources. The Ministry of Agriculture was rebranded and expanded to the Ministry of Agriculture and Rural Affairs (MARA) to oversee agriculture, rural development, and land uses, including registration and supervision of pesticides, fertilizers, and veterinary medicine. The Ministry of Emergency Management (MEM) was established to be responsible for work safety issues and natural disasters, assuming the responsibilities

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The List of Toxic Chemicals Strictly Restricted for Import and Export (2014), which contains 162 categories of chemicals, was replaced by the List of Toxic Chemicals Strictly Restricted (2018).

of the State Administration of Work Safety (SAWS), including registration, licensing, and management of hazardous chemicals. The National Health and Family Planning Commission (NHFPC) and State Council Leading Office on Reform of the Medical and Health System were merged into the National Health Commission (NHC) to oversee healthcare, including registration and management of drinking water-related products, and food-related products such as food additives, and FCMs and articles. The China Food and Drug Administration (CFDA), the State Administration for Industry and Commerce (SAIC), and the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) were merged into the State Administration for Market Regulation (SAMR), a new competition law enforcement agency that takes over the anti-monopoly enforcement functions previously spread among the NDRC, Ministry of Commerce (MOFCOM), and SAIC. The SAMR is also responsible for food safety and the National Medical Products Administration (NMPA) under the SAMR is responsible for registration and supervision of medicines, medical devices, and cosmetics.

(a) Industrial Chemicals

The China State Council published on September 28, 2018, a Plan to Optimize Environmental Protection Regulations with an intention to improve environmental quality. The optimization plan includes repeal, consolidation, and optimization of current regulations, national/industrial standards, and normative documents regarding environmental protection to decrease inconsistencies and contradictions and ensure consistent alignment of local, provincial, and central legal stipulations. The regulations on chemicals will certainly continue evolving based upon the commitment to a greener future that was laid out in the 13th Five Year Plan and the Belt and Road Ecological and Environmental Cooperation Plan in 2017.

The 13th Five Year Plan requires the MEE to develop strategies and regulatory measures for greener environment and protection of the ecosystem by **2020**, which includes establishing a hazardous chemical database, capacity and capability for hazard identification and risk assessment,

management of hazardous chemicals and wastes, and improving control of toxic chemicals. Several new regulations have already been released or updated in 2018, including the [List of Priority Control Chemicals \(First Batch\)](#), the [List of Toxic Chemicals Strictly Restricted \(2018\)](#), and GB 36700.1-.8-2018 Guidance on Hazard Classification to the Aquatic Environment.

The implementation of the List of Priority Control Chemicals (First Batch) will gradually phase out products contained in the list. The first batch of priority chemicals contains 22 categories of chemicals that are mainly intrinsically hazardous and highly bioaccumulative, and have the potential to pose great risk to the environment and human health; many of these chemicals are also listed in Annex XIV of REACH. The list will be updated periodically, and the “Guideline for Screening Priority Chemicals” is expected to be released by **2020**. It has been suggested that some of the priority chemicals may be incorporated into product-specific regulations in the future.

The List of Toxic Chemicals Strictly Restricted for Import and Export (2014), which contains 162 categories of chemicals, was replaced by the List of Toxic Chemicals Strictly Restricted (2018). The 2018 revision is mainly based on the Stockholm and Rotterdam Conventions and contains ten categories of toxic chemicals. The uses of these toxic chemicals are prohibited, except for some special permitted uses, due to their serious adverse effects to human health or the environment.

The national standards, GB 36700.1-.8-2018 Guidance on Hazard Classification to the Aquatic Environment, provide supplementary classification guidance on aquatic environmental hazards. GB 36700.1-.7-2018 is based on Annex 9 of Revision 4 of the UN GHS and will become effective on **April 1, 2019**; GB 36700.8-2018 relates to Annex 10 of UN GHS Revision 4 and became effective on January 1, 2019. The GB 36700.1-.8 plus already implemented GB 30000.28-2013 enable China to align fully with the UN GHS Revision 4 with respect to aquatic environmental hazard classification.

Strengthening the enforcement of regulations was one of the key governmental efforts for improvement of environmental quality in 2018. MEE has conducted several enforcement campaigns against water and air pollution in 2018, which have resulted in the shutdown of thousands of factories and global shortages of many raw material supplies, including some pesticides and preservatives such as benzisothiazolinone (BIT). (Reisch MS, Shortage of BIT, A Key Preservative, Looms. C&EN. Volume 96(36) (Sept. 10, 2018), available at <https://cen.acs.org/business/consumer-products/Shortage-BIT-key-preservative-looms/96/i36>.) The Jiangsu provincial government announced on September 4, 2018, the closing of 1,000 chemical factories over the next three years. A new chemicals inspection campaign was also initiated in Shanghai to enforce registration and annual reporting of new chemicals.

The Environmental Management of New Chemical Substances (MEP Order No. 7), that has been in force since 2010 and is a revision of the 2003 regulations of new chemical substances, is currently under revision. The revised draft version has been under internal review since fall 2017 and is expected to be released in the **first half of 2019**.

SAWS drafted a new law called the Law on the Safety of Hazardous Chemicals for internal review in 2017. It was expected that the law might replace the current State Council Decree 591 Regulations on Safe Management of Hazardous Chemicals, which provides a legal framework for hazardous chemicals, including general provision for production, uses, licensing, and registrations of hazardous chemicals, GHS promulgation, and transport of dangerous goods. SAWS was, however, dissolved and its responsibilities were assigned to the newly established MEM in the overhaul of the executive branch of the Chinese government in early 2018, which will likely delay the progress of the proposed Law on the Safety of Hazardous Chemicals.

The Rules on Restriction of the Use of Hazardous Substances in Electrical Appliances and Electronic Products (China RoHS2) became effective on July 1, 2016. Its implementation requires the Ministry of Industry and Information Technology (MIIT) to develop a standard achieving management catalogue and a list of its exemptions. The [Standard Achieving Management Catalogue for the Restriction of the Use of Hazardous Substances in Electrical Appliances and Electronic Products \(First Batch\)](#) and the [Exemption List for the Restriction of the Use of Hazardous Substances of the](#)

[Standard Achieving Management Catalogue](#) have been released and will be implemented on **March 12, 2019**.

The Standard Achieving Management Catalogue (First Batch) includes refrigerators, air conditioners and filters, washing machines, electric water heaters, printers, copy machines, fax machines, television sets, monitors, personal computers, handsets for wireless communication, and telephones, totaling 12 types of products that must comply with the hazardous substance restriction limits, set out in national standard GB/T 26572-2011. The Exemption List contains details on 39 products or component parts that are exempt from the hazardous substance restrictions of China RoHS2, and their limits, if applicable; for example: mercury in certain lamps, lead in certain glass, alloys, or lamps, cadmium in certain electronic products, and hexavalent chromium as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators.

China is gradually phasing out ozone-depleting substances (ODS). The uses of hydrochlorofluorocarbons (HCFC) will also be phased out as were uses of chlorofluorocarbons (CFC), halons, carbon tetrachloride, methyl chloroform, and methyl bromide. MEE announced that the uses of dichlorofluoroethane (HCFC-141b) as a foaming agent for the production of refrigerators, freezers, refrigerated containers, and electric water heaters will be banned as of January 1, 2019.

New legislation addressing soil contamination, the Soil Pollution Prevention and Control Law, became effective on January 1, 2019, and sets out general principles for soil pollution prevention, risk management and control, pollution liability, public participation, supervision, and enforcement. The law introduces a series of soil pollution prevention and control management systems, including a soil environment database and information sharing platform, a management system for cropland, controls for pesticides and fertilizers, an inventory of construction land subject to risk control and remediation, and a directory of entities subject to key supervision for soil contamination.

(b) Agricultural Chemicals

China revised its pesticide regulations in 2017, which significantly changed the pesticide registration requirements and process in China. The revisions significantly impact foreign/multinational entities. Two requirements in particular



Foreign entities cannot directly distribute or sell pesticides in China, but must distribute or sell pesticides through either their own distribution entity in China or engage pesticide distribution agents in China.

are noteworthy: the requirement that chemistry and toxicology tests completed in countries without a MAD agreement with China must be repeated in China, and that foreign entities cannot directly distribute or sell pesticides in China, but must distribute or sell pesticides through either their own distribution entity in China or engage pesticide distribution agents in China.

Chinese MARA will gradually phase out highly toxic pesticides and complete the first 15-year registration review and reevaluation cycle by **2022**. There are 40 banned and 32 restricted pesticides in China currently; four additional pesticides will be banned, including the production and use of sulfluramid on **March 25, 2019**, the marketing and use of phorate, aldicarb, and acesulfame on **October 1, 2020**, and of their production on **October 1, 2023**. Five of the restricted pesticides will have additional restrictions, including prohibition of agricultural use of bromomethane and endosulfan starting on January 1, 2019, and **March 26, 2019**, respectively, and banned uses of acephate, carbosulfan, and dimethoate on vegetables, fruits, tea leaves, fungus, and Chinese medicine herbs starting on **August 1, 2019**. It is expected that methylisophosphorus, phosphine, omethoate, and aluminum phosphide will be phased out by **2020** and carbofuran, methomyl, and chloropicrin will be phased out by **2022**. The initial ten pesticides for the first 15-year registration review and reevaluation cycle are glyphosate, carben-dazim, triazophos, atrazine, imidacloprid, alachlor, butachlor, dimethacarb, metolcarb, and quintozone.

Eighty-nine agricultural standards, including NY/T 3283-2018 Criteria for Technically Equivalency of Chemical Pesticide Technical Material and Technical Concentrate and NY/T 788-2018 Guideline on Pesticide Residue Trials on Crops, were published in [MARA Proclamation No. 50](#) and became effective on December 1, 2018. Several new draft agricultural standards for environmental risk assessment of pesticides, ecotoxicology testing of pesticides in earthworm, fish, daphnia, avian, and amphibian, and pesticide metabolism and residue testing in livestock were released for public comments in the [ICAMA Notice No. \[2018\]145](#) on

September 25, 2018, and the [ICAMA Notice No. \[2018\]152](#) on October 22, 2018.

(c) Food Contact Regulations

The Chinese regulatory system for FCMs and articles is comprised of a series of national food safety standards (NFSS) for FCMs, including GB 4806.1-2016 on general requirements, GB 9685-2016 on the use of 1,294 approved additives for FCMs, GB 5009.156-2016 general principles of pre-treatment methods for migration test, GB 31604.1-2015 general principles of migration tests, GB 31603-2015 general hygienic practice for FCM production, material standards, and test guidelines for individual substances under the Food Safety Law. GB/T 14251-2017 General Technical Standard for Metal Container of Canned Food became effective on October 1, 2018.

China's NHC [announced](#) on May 9, 2018, that the draft NFSS on Food-contact Starch-based Plastic Materials and Articles and the draft NFSS on Food-contact Composite Materials and Articles were available for public comment. The draft standards define the FCMs and impose manufacturing and migration testing requirements. The China National Center for Food Safety Risk Assessment (CFSA) is drafting several new FCM NFSSs, including standards for adhesives and printing ink, and migration tests for several substances, which are expected to be released in 2019. Several existing FCM standards are also under revision, including GB 31604.1-2015, GB 4806.6-2016 on plastic resins, GB 4806.7-2016 on plastic materials and articles, GB 4806.8-2016 on paper and cardboard, GB 4806.9-2016 on metal and alloy, GB 4806.10-2016 on paints and coatings, GB 4806.11-2016 on rubbers, and GB 31604.7-2016 on decolonization test.

GB 2763 NFSS -- Maximum Residue Limits (MRL) of Pesticides in Food has been updated every two years since 2012. The latest version (GB 2763-2016) was implemented on June 18, 2017. The NHC [published](#) GB 2763.1-2018 NFSS -- MRLs of 43 Pesticides in Food on June 21, 2018, with the implementation date of December 21, 2018. Draft MRLs for

105 pesticides were notified to the WTO on Technical Barriers to Trade on February 19, 2018, with no implementation date provided. China's MARA also released for public comment in 2018 several NFSSs on MRLs; these limits will be integrated into the next revision of GB 2763 and are expected to be implemented in 2019.

1.2 New Zealand

The New Zealand Environmental Protection Authority (New Zealand EPA) [announced](#) in October 2018 that it would be "ramping up" its chemical reassessments program and taking action on a [priority chemicals list](#) to ensure that risks to people and the environment continue to be managed effectively. When New Zealand EPA approves a chemical for use in New Zealand, the approval does not expire, and can be amended or revoked only through formal action. New Zealand EPA states that it has already established the grounds for reassessment and completed a call for information for the herbicide paraquat. On October 29, 2018, New Zealand EPA [announced](#) that it is investigating products containing synthetic pyrethroids as part of the reassessments program. The call for information on such products will close **February 1, 2019**.

A sub-group of the Hazardous Substances and New Organisms (HSNO) Decision-Making Committee will consider further grounds for other chemicals on the priority list "in the near future." If the sub-group decides that grounds exist to reassess a chemical, and an application is made for the reassessment to progress, then New Zealand EPA will consider issues such as manufacture and import volumes; use and application information; environmental exposure mitigation measures; scientific and technical information; cultural impacts; and the existence of alternatives. The sub-group will make a decision about the reassessment, and could make no change to the existing approval; increase or change the controls, or rules, around the chemical's use, or revoke the existing approval and ban its use.

1.3 South Korea

2019 is expected to be a busy time in S. Korea resulting from substantial revisions of the chemical control legislation in the country that imposes new requirements on stakeholders. The amended Act on the Registration and Evaluation of Chemicals (K-REACH) is expected to come into force on January 1, 2019. After the implementation date, any person who intends to manufacture or import a new substance, or an

existing chemical substance in quantities of one metric ton or greater per year must register under K-REACH. New substances must be registered before manufacture or importation. To ease the registration process, all new chemical substances manufactured or imported in quantities less than 100 kilograms per year will require only a notification, which includes administrative information but not a hazard evaluation of the substance.

All existing chemical substances manufactured or imported at greater than or equal to one metric ton per year shall be registered within given grace periods. There are different deadlines for each tonnage tier. The first deadline of **December 31, 2021**, is for existing chemical substances greater than or equal to 1,000 metric tons per year and for existing chemical substances at greater than or equal to one metric ton per year that are CMR. The next deadline, **December 31, 2024**, is for existing chemical substances within the 100-1,000 metric tons per year band. By **December 31, 2030**, existing substances from 1-100 metric tons per year shall be completed.

Before registration, existing substances must be notified to the Ministry of Environment (MoE) in advance to benefit from the grace periods. The pre-notification period will start on January 1, 2019, and end on **June 30, 2019**. This pre-notification will require the company's information, substance name, volume, classification, and end uses. During this time of pre-notification, one can manufacture or import the pre-notified substances without full registrations. A S. Korean-based OR shall be appointed for foreign manufacturers who import chemical substances that require pre-notification or registration.

1.4 Taiwan

In Taiwan, the full legislature passed on December 21, 2018, a bill amending the Toxic Chemical Substance Control Act (TCSCA). As reported in our 2018 Forecast, in 2017, the Taiwan Environmental Protection Administration (Taiwan EPA) proposed and approved revisions to the TCSCA. The changes were sent to the national legislature for review in 2017 and expected to be adopted in 2018, but instead were forwarded to the Social Welfare, Health, and Environmental Protection Affairs Committee (Committee) for review. In 2018, during the Committee's review, the Committee revised the bill to include the creation of a National Chemical Substances Control Board. Under the legislation, the Board will be tasked with policy related to chemical substances;

decision-making; and cross-ministerial policy coordination. The Committee also revised the legislation to strengthen the toxic chemical disaster response and reporting systems, and improve the insurance and liability provisions. Under the bill, the TCSCA will be renamed the Toxic and Chemical Substances of Concern Control Act. A rider to the legislation calls for Taiwan EPA to draft a bill within one year to regulate the existing chemicals manufactured, imported, and used in Taiwan. Once the legislation is signed into law, Taiwan EPA is expected to review over 30 subordinate laws and proposed updates as necessary.

As reported in Acta's May 11, 2018, [Global Regulatory Update](#), Taiwan EPA notified the WTO of proposed amendments to the regulations regarding the registration of new and existing chemical substances on March 31, 2018. The major amendments include designating the first 106 priority existing chemicals (PEC) that will be subject to the registration of existing chemical substances. The proposed amendments were expected to be promulgated by the end of 2018. Taiwan EPA planned to adopt the amendments almost a year earlier, with registration for the PECs beginning January 1, 2019, and annual reports on the volumes of PECs sold due in 2019. The delay means that registration will begin **July 1, 2019**, and the annual reports will be due in **2020** instead of 2019. The list of PECs is available in the English translation submitted to WTO.

1.5 Vietnam

Vietnam has spent several years developing a National Chemicals Inventory that will list existing chemicals in commerce in Vietnam. The first draft Inventory, released by the Ministry of Industry and Trade (MOIT) in 2016, contained approximately 3,000 chemical substances, while the most recent [draft National Chemical Inventory](#), released in September 2018, contains over 31,000 chemical substances. Once MOIT issues a final National Chemicals Inventory, chemicals not included on the list will be considered new, and companies will be required to conduct an assessment and register the new chemical before import or manufacture.

In 2017, Vietnam replaced a number of regulations under the Law on Chemicals with Decree No. 113/2017/ND-CP specifying and providing guidelines for implementation of certain articles of the Law on Chemicals and Circular No. 32/2017/TT-BCT clarifying the Law on Chemicals and

ACTA PROFESSIONALS have many years of experience with the manufacture, import, and export of chemicals in Asia, with resources including offices in Asia and bi- and tri-lingual professionals. [Visit our website](#) for a full description of our services. Contact lbergeson@actagroup.com if you would like to discuss your needs in the region.

Decree No. 113/2017/ND-CP. Decree No. 113/2017/ND-CP, which took effect November 25, 2017, lists chemicals that are:

- Subject to conditional production or import (Appendix I);
- Restricted from production or trade (Appendix II);
- Prohibited (Appendix III);
- Required to have incident prevention and response plans (Appendix IV); and
- Subject to mandatory declaration (Appendix V).

Circular No. 32/2017/TT-BCT, which took effect December 28, 2017, includes information on the classification and labeling of chemicals and guidance on compiling SDSs, as well as declaring imported chemicals. In 2019, Vietnam intends to continue with administrative reforms and improve the permit system for chemicals. Vietnam will also review the implementation status of the Law on Chemicals since its adoption in 2007.

2. GHS Initiatives

2019 is not expected to bring significant changes to GHS within the region. Summaries of some specific changes to GHS in the region are provided below.

2.1 Japan

In Japan, the government launched the GHS Inter-ministerial Committee. This committee began to exchange information to establish GHS-related domestic laws, promote the classification of substances in Japan, and implement the GHS classification of substances requiring a SDS under the



Philippines Joint Administrative Order No. 1 of 2009 (JAO) established the coordinated effort to implement GHS. Eight governmental agencies that are part of the JAO are required to implement GHS.

Pollutant Release and Transfer Register (PRTR) Law, the Industrial Safety and Health Law (ISHL), and the Poisonous and Deleterious Substances Control Law (PDSCL). The National Institute of Technology and Evaluation (NITE) also provides GHS classifications performed by relevant Japanese Ministries in accordance with GHS Classification Guidance for the Japanese Government. The NITE list was last updated in May of 2018. 2019 is not expected to bring any significant changes to Japan's approach to GHS.

2.2 The Philippines

2019 will see the completion of GHS implementation in the Philippines. Philippines Joint Administrative Order No. 1 of 2009 (JAO) established the coordinated effort to implement GHS. Eight governmental agencies that are part of the JAO are required to implement GHS. The Department of Environment and Natural Resources (DENR) issued a draft order in 2009 with expected transitions in various stages for industrial chemicals. The [DENR Administrative Order No. 2015-09](#) was issued in May of 2015. Implementation is phased, with mixtures to be completed by 2019. The implementation is criteria-based according to Revision 3 of the UN model. No hazard classes or categories appear to have been excluded.

2.3 Vietnam

Vietnam's Law on Chemical (Law 06/2007/HQH12) was implemented in 2007. Subsequent Decrees and Circulars have been issued in support of the GHS framework. In late December of 2017, [Decree 113/2017/TT-BCT](#), Decree 34/2017/ND-CP, and Circular 32/2017/ND-CP were issued by MOIT. The Decrees and Circular allow the use of classification in accordance with any version of the UN model from Revision 2 to current. Vietnam is allowing companies tremendous flexibility. Appendix 7 of Circular 32/2017/ND-CP includes exact guidance for those that do not wish to choose which revision of GHS to follow, and appears to be in

alignment with Revision 6 of the UN model. On July 31, 2018, the [Vietnam National Chemical Database](#) (CDAI) became available. The implementation of this database provides non-mandatory classifications mostly based on compiled lists from Japan, the United States, Europe, and other foreign companies operating in Vietnam. It also provides support and administrative procedures for the management of chemicals, sharing information between various departments in the chemical field, evaluating statistical data on chemical assessment, and providing information in response to chemical incidents.

D. AUSTRALIA

1. Timing of Australia's New Regulatory Scheme for Introducing Industrial Chemicals Is Uncertain

As of this writing, the Australian Industrial Chemicals Introduction Scheme (AICIS) is still scheduled to begin **July 1, 2019**. The Australian government began work in 2015 to reform the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). As reported in our November 9, 2015, memorandum, "[Australia Implementing Reforms to the National Industrial Chemicals Notification and Assessment Scheme \(NICNAS\)](#)," the aim of the reforms is to rebalance post- and pre-market requirements to reflect the risk of a new chemical, to streamline the current risk assessment process for new and existing chemicals, to use better international assessment materials, and to create a more appropriate compliance tool. In 2017, the Australian government submitted to Parliament a package of six bills that will establish the new regulatory scheme. The [Industrial Chemicals Bill 2017](#) describes the legislative framework for AICIS, a reformed, risk-based regulatory scheme for Australia to continue to regulate the introduction of industrial chemicals. In 2018, NICNAS held public consultations on the following draft documents that, together with the Industrial Chemicals Bill 2017, will form the scheme for the introduction of industrial chemicals in Australia:

- [Industrial Chemicals \(General\) Rules 2018](#): The General Rules contain details on how the introduction of industrial chemicals will be regulated under the new framework;
- [Industrial Chemicals Categorization Guidelines](#): The Categorization Guidelines contain the technical details and requirements that industrial chemical importers and manufacturers will need to categorize their chemical introductions under the new scheme; and
- [Industrial Chemicals \(Consequential Amendments and Transitional Provisions\) Rules 2018](#): The Transitional Rules describe how processes under the previous laws will transition to the new scheme.

The House of Representatives passed the legislation without amendment on October 17, 2017, and the legislation is awaiting debate in the Senate in 2019. As a result, the bills may not be accepted until **mid-2019**. The General Rules, Categorization Guidelines, and Transitional Rules have not been issued in final.

In 2019, Safe Work Australia (SWA) will continue its review of workplace exposure standards (WES). According to SWA, the review will result in recommendations for WES values, notations, and the list of chemicals. After reviewing comments received in 2018 on the consultation regulation impact statement for the WES framework, SWA plans to release the decision regulation impact statement in **early 2019**. SWA began its evaluations of individual chemicals in 2018 and intends to complete its evaluations, as well as an independent peer review process, in **May 2019**. By the **end of 2019**, SWA intends to have completed its review and issue final, revised WES for airborne contaminants.

The Department of Agriculture and Water Resources began a [public consultation](#) in December 2018 on proposed changes

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to regulations for agricultural and veterinary chemicals regulated by the Australian Pesticides and Veterinary Medicines Authority (APVMA). The proposed amendments are intended to balance better regulatory effort with risk, improve the flexibility and responsiveness of the regulatory framework, and remove unnecessary restrictions. Draft measures include extending the range of applications that can be assessed as timeshift applications and broadening the range of application types that allow an active constituent to be approved with a product registration. The proposed changes would amend the Agricultural and Veterinary Chemicals (Administration) Regulations 1995, Agricultural and Veterinary Chemicals Code Regulations 1995, and Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995. The Department anticipates that further regulatory amendments, including those related to other measures in the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018 (such as extending data protection as an incentive to register priority uses), will follow.

MEXICO, CENTRAL AND SOUTH AMERICA

1. Chemical Substance Management in Mexico, Central America, and South America

In 2018, we witnessed the continued development throughout the region of a wide range of chemical substance and product management statutes, at both the national and regional (*e.g.*, state, municipality) levels. This is expected to continue in 2019.

1.1 Central and South America

In 2019, we anticipate continued focus on waste minimization and waste management policies and related legislation in the region. For the last several years, this topic has garnered significant media attention in the region, most notably with the visual broadcast worldwide of polluted waterways used to host sailing, rowing, and related sports for the 2016 Olympics in Rio de Janeiro, Brazil. This attention has focused the deliberative bodies of countries in the region to offer several legislative approaches to minimize and remediate these types of situations.

Argentina is expected to vote on a series of bills in both the lower (*Cámara de Diputados*; Chamber of Deputies) and upper (*Senado*; Senate) houses of its Congress in 2019 to



With respect to industrial chemicals, Brazil has the most legislation on the cusp of implementation. Arguably the most anticipated regulation to be implemented in 2019 will be Brazil's Regulamento Químico Industrial (Industrial Chemicals Regulation; Regulamento).

accomplish this strategy. *Senado* Bill 2965/18 would create a National Strategy for the Reduction, Reuse and Recycling of Household Waste, while *Câmara de Deputados* bills 5390-D-2018 and 5563-D-2018 would prohibit the “pre-programmed obsolescence” of electrical and electronic products, as well as legal requirements to manage waste electrical and electronic equipment (WEEE), respectively. At the city level, Buenos Aires plans to vote on Bill 2711-2018 addressing the disposal of household medications that are past their established shelf life.

With respect to industrial chemicals, Brazil has the most legislation on the cusp of implementation. Arguably the most anticipated regulation to be implemented in 2019 will be Brazil's *Regulamento Químico Industrial* (Industrial Chemicals Regulation; *Regulamento*), the bill expected to serve as a national chemical substance inventory and notification process in the country. The final text of the *Regulamento* was agreed upon in September 2018. The *Regulamento* is presently undergoing a judicial review of the text. Once completed, it is expected to receive signatures from the relevant Ministries (Environment, Health, Labor and Industry) before being sent to the *Ministro-Chefe*. The *Ministro-Chefe* will analyze the text again and, once it is validated, will send it to the Congress. Then the legislative voting process will start. We expect the text to be sent **early in 2019**, when President-Elect Jair Bolsonaro's new government will be in place, although expected governmental changes may well delay this.

Additionally, Brazil's draft resolution regulating governing the use of hazardous substances used in electrical and electronic equipment (EEE) is expected to be released in its final form sometime in 2019. The draft is based on Directive 2011/65/EU, the “Restrictions on the use of Certain Hazardous Substances,” and as such is colloquially known as “Brazilian RoHS.” The draft sets forth proposed restrictions on the use of lead, cadmium, mercury, hexavalent chromium, bifenyl polybromate (PBB), diphenyl polybromate ether (PBDE), and four types of phthalates.

2019 is expected also to bring a consolidation of sorts in the Brazilian government, with respect to chemical substance

management. The *Ministério do Meio Ambiente* (Ministry of Environment) of Brazil will merge with the *Ministro da Agricultura* (Ministry of Agriculture). This merger is anticipated to delay the legislative review process for the *Regulamento*. The two Ministries are of immense national relevance, and have their own agendas, which overlap only a small fraction of their competencies. As such, the integration time and efforts are expected to be considerable.

(a) Product Stewardship Initiatives

In early October 2018, Chile became the first country in the region to ban plastic shopping bags. In 2019, Brazil's *Senado* is scheduled to debate Bill 382/2018, a measure that would place an outright ban on the production, sale, and import/export of plastic bags in the city limits. A similar bill in the Peruvian Congress (No. 03278/2018-CR) would ban commercial-use plastic bags, but would replace them with biodegradable ones. Additionally, a bill before the Colombian *Câmara de Deputados* (Bill 123/18) aims to place a prohibition on the manufacturing, sale, and use of single-use plastic containers in the food and beverage industry, while Costa Rican Bill 20.958 would set requirements for the reduction and prevention of all types of plastic pollution. Finally, Peru is expected to further develop a decree that bans the purchase and use of single-use plastic bags, straws, or containers made of polystyrene.

Finally, the countries of Argentina, Barbados, Brazil, Chile, Colombia, Costa Rica, the Dominican Republic, Ecuador, Granada, Guatemala, Honduras, Panama, Peru, St. Lucia, and Uruguay have each [signed](#) on to the UN's “[Clean Seas](#)” program. The program aims to reduce the “production and consumption of non-recoverable and single-use plastic.”

(b) GHS Initiatives

Latin America has been slow to adopt the GHS. The lack of infrastructure and in-country support has resulted in few countries in the regions adopting GHS. Those that have adopted tend to follow the UN model with little to no deriva-

tions. This is primarily because many of the countries lacked a robust regulatory framework for classification previously. 2019 is not expected to bring significant changes to GHS within the region. Summaries of the current state of GHS are provided in more detail below.

Chile has not officially adopted GHS. In 2017, the Health Ministry finished and published the draft version of the GHS regulation, *Draft Reglamento de Clasificación, Etiquetado y Notificación de Sustancias Químicas y Mezclas* (Regulations on the classification, labelling and notification of chemical substances and mixtures). The draft regulation was approved on October 26, 2018. The regulation, once it is approved, will implement the UN GHS and will provide a transition period for the updating of the SDSs and labels.

Chile will accept GHS classifications in accordance with Chilean Standard NCh2245:2015. NCh2245:2015 indicates GHS classification, including the appropriate pictograms, signal words, hazard statements, and precautionary statements, is allowed in Section 2 of the SDS and on labels, but additional standards should be consulted to determine if additional information specific to Chile is required. In 2019, Chile could finalize the proposed regulation, publish it in the country's Official Gazette, and provide the transition period for updating the SDSs and labels.

Colombia recently entered into the OECD in 2018. Becoming a member of OECD required Colombia to implement GHS. The Colombian *Ministerio de Trabajo* (Ministry of Labor) has issued final legislation adopting the Sixth Edition of GHS. Decree 1496 was published on August 6, 2018. The responsible Ministries -- Labor, Agriculture, Transportation, and Health -- will establish the transition period(s) and date(s) for implementation.

Mexico's Ministry of Labor and Social Welfare published the Harmonized System for the Identification and Communications of Hazards and Risks from Hazardous Chemicals in the Workplace ([NOM-018-STPS-2015](#)) on October 9, 2015. NOM-018-STPS-2015 is a UN GHS Rev 5 implementation. All hazard classes and categories were included in the NOM with the exception of the environmental hazard classes. No additional hazards were added. The transition period for mandatory compliance ended October 9, 2018. With the transition period ending in 2018, 2019 should be a relatively quiet one for Mexico.

F. MIDDLE EAST

1. Chemical Substance Management in the Middle East

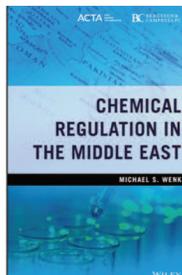
The Middle East historically has been considered to be at a relatively nascent stage with regard to the development and implementation of chemical substance regulations. There may be a variety of reasons for this perception, ranging from a lack of fluency in Arabic, Hebrew, or Urdu, to a somewhat insular culture within the region, and to the tendency to focus on geographic regions with more robust commercial and business operations. There are, however, chemical regulations in force, many of which have been in place for several decades. There is little legislative development on the horizon for 2019 except in three key areas -- the development of a GHS-type regulation, the implementation of a cosmetic substance directive, and the potential enactment of a ban on non-degradable plastic products.

1.1 GHS

On May 24, 2018, OECD adopted the "[Decision-Recommendation of the Council on the Co-operative Investigation and Risk Reduction of Chemicals](#)" (Decision-Recommendation). As noted in our October 25, 2018, "[Clients and Friends Memorandum](#)," Article IX mandated "that Adherents shall implement the GHS in order to further hazard communication in the supply chain." As such, Israel, the only Middle Eastern OECD Member State, has elected to begin the implementation process in 2019.

Israel has submitted two drafts of legislation that would implement GHS in the country to the WTO. The two drafts encompass aspects relating to substances and mixtures, and to transportation.

"[SI 2302 Part 1 - Dangerous Substances and Mixtures: Classification, Labelling, Marking and Packaging](#)" replaces the December 3, 2013, draft that was predominantly based on EU Regulation 1272/2008, colloquially known as the CLP regulation. There is, however, some uncertainty about the GHS version Part 1 is based upon; for example, Part 1 identifies "flammable aerosols" and not "aerosols" as an endpoint, which would appear to make it based on the Third Revision. Additionally, hazard classifications H229, H230, and H231, which were first introduced in the Fourth Revision, are



Acta is active and knowledgeable in assisting its clients in dealing with the complexities of chemical management regulations in the Middle East, having literally ‘written the book’ on the region: “[Chemical Regulation in the Middle East](#),” 2018, John Wiley & Sons Ltd. [Visit our website](#) for a full description of our services. Contact lbergeson@actagroup.com if you would like to discuss how Acta can help commercialize your products in the Middle East.

included in Part 1. “[SI 2302 Part 2 - Dangerous Substances and Mixtures: Transportation -- Classification, Labelling, Marking and Packaging](#)” remains largely unchanged.

The Gulf Cooperation Council (GCC) has begun developing plans to implement GHS among its Member States (Saudi Arabia, Kuwait, the United Arab Emirates (UAE), Qatar, Bahrain, and Oman), with work potentially beginning in **mid-2019**. This follows efforts by the Gulf Standardization Organization made in 2018, in partnership with the Gulf Petrochemical and Chemicals Association’s Responsible Care Committee, to implement a [Code of Practice](#) relating to chemical hazard communication. The Code of Practice proposed data and rules used to classify such substances, as well as directed the format of SDSs and product labels. The Committee largely based its classification criteria on the CLP regulation, as it is an extremely robust source of information. The GCC views adoption of this Code of Practice by its Member States as the first step to implementing GHS.

1.2 Product Stewardship

Somewhat similar to countries in Central and South America, the Middle East is beginning to make legislative inroads into waste reduction. In 2019, the Kingdom of Bahrain is expected to promulgate a National Technical Regulation (TR) to phase out the import, sale, or distribution of non-degradable plastic products. The proposed TR sets out the requirements with respect to specifications, licenses, labeling, and other requirements for such products.

1.3 Chemical Substances

While a comprehensive chemical substance regulation at the national level continues to be a distant goal, the countries of Bahrain, Oman, Saudi Arabia, and the UAE have each announced that they plan to incorporate the GCC’s draft regulation for cosmetic products into their respective national laws, sometime in 2019. This regulation, “Cosmetic Products - Safety Requirements of Cosmetics and Personal Care Products,” addresses the general safety requirements and parameters, as well as labeling and packaging requirements, for all cosmetics and personal care products. The regulation specifies six functions, or purposes, of use for cosmetic and personal care products: to clean, to perfume, to change the appearance, to protect, to keep in good condition, and to correct body odors.

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APPENDIX A: GLOSSARY

- AA** -- Assistant Administrator
- Acta**[®] -- The Acta Group
- AICIS** -- Australian Industrial Chemicals Introduction Scheme
- ANPRM** -- Advanced Notice of Proposed Rulemaking
- APHIS** -- Animal and Plant Health Inspection Service
- APVMA** -- Australian Pesticides and Veterinary Medicines Authority
- AQSIQ** -- Administration of Quality Supervision, Inspection and Quarantine
- ATP** -- Adaptation to Technical Progress
- B&C**[®] -- Bergeson & Campbell, P.C.
- BCCM** -- B&C[®] Consortia Management, L.L.C.
- BE** -- Bioengineered
- BETO** -- Bioenergy Technologies Office
- BIO** -- Biotechnology Innovation Organization
- BIT** -- Benzisothiazolinone
- BPC** -- Biocidal Products Committee
- BPD** -- Biocidal Products Directive
- BPPD** -- Biopesticide and Pollution Prevention Division
- BPR** -- Biocidal Products Regulation
- BPRS** -- BPR Subgroup
- BRAG**[®] -- Biobased and Renewable Products Advocacy Group
- C&T** -- Certification and Training
- CBI** -- Confidential Business Information
- CDAI** -- Vietnam National Chemical Database
- CDR** -- Chemical Data Reporting
- CEQ** -- Council on Environmental Quality
- CFC** -- Chlorofluorocarbon
- CFDA** -- China Food and Drug Administration
- CFSA** -- China National Center for Food Safety Risk Assessment
- ChAMP** -- Chemical Assessment Management Program
- China RoHS2** -- Rules on Restriction of the Use of Hazardous Substances in Electrical Appliances and Electronic Products
- CIB** -- Current Intelligence Bulletin
- CICR** -- Regulation on the Inventory and Control of Chemicals
- CLP** -- Classification, Labeling and Packaging
- CMR** -- Carcinogenic, Mutagenic, or Reprotoxicant
- CoRAP** -- Community Rolling Action Plan
- CR** -- Continuing Resolution
- CRS** -- Congressional Research Service
- CWA** -- Clean Water Act
- DENR** -- Philippines Department of Environment and Natural Resources
- DfE** -- Design for the Environment
- DOC** -- U.S. Department of Commerce
- DOE** -- U.S. Department of Energy
- DOI** -- Department of the Interior
- DOJ** -- U.S. Department of Justice
- DOT** -- U.S. Department of Transportation
- DWA** -- Draft Withdrawal Agreement
- EC** -- European Commission
- ECA** -- Enforceable Consent Agreement
- ECHA** -- European Chemicals Agency
- ECOS** -- Environmental Council of the States
- EDF** -- Environmental Defense Fund
- EEA** -- European Economic Area
- EEE** -- Electrical and Electronic Equipment
- EFSA** -- European Food Safety Authority
- EIS** -- Environmental Impact Statement
- EO** -- Executive Order
- EP** -- European Parliament
- EPA** -- U.S. Environmental Protection Agency
- ESA** -- Endangered Species Act
- ETB** -- Emerging Technologies Branch
- EU** -- European Union
- EUH** -- EU Specific Hazard statement
- FAST Act** -- Fixing America's Surface Transportation Act of 2015
- FCM** -- Food Contact Material
- FCN** -- Food Contact Notification
- FDA** -- U.S. Food and Drug Administration
- FDP** -- Food Defense Plan
- FFDCA** -- Federal Food, Drug, and Cosmetic Act
- FIFRA** -- Federal Insecticide, Fungicide, and Rodenticide Act
- FOIA** -- Freedom of Information Act
- FQPA** -- Food Quality Protection Act
- FSIS** -- Food Safety and Inspection Service
- FSMA** -- Food Safety Modernization Act
- FSVP** -- Foreign Supplier Verification Program
- GAO** -- Government Accountability Office
- GCC** -- Gulf Cooperation Council
- GE** -- Genetically-engineered
- GHS** -- Globally Harmonized System of Classification and Labeling of Chemicals
- GMO** -- Genetically Modified Organism
- GRASE** -- General Recognition of Safety and Effectiveness
- HCFC** -- Hydrochlorofluorocarbon
- HCFC-141b** -- Dichlorofluoroethane
- HCS** -- Hazard Communication Standard
- HMR** -- Hazardous Materials Regulations

HPR -- Hazardous Products Regulation	NDRC -- National Development and Reform Commission
HSE -- Health and Safety Executive	New Zealand EPA -- New Zealand Environmental Protection Authority
HSNO -- Hazardous Substances and New Organisms	NFSS -- National Food Safety Standard
ICAO Technical Instructions -- International Civil Aviation Organization's Technical Instructions for the Safe Transport of Dangerous Goods by Air	NGO -- Non-governmental Organization
IMDG Code -- International Maritime Dangerous Goods Code	NHC -- National Health Commission
IND -- Investigational New Drug	NHFPC -- National Health and Family Planning Commission
IP -- Intellectual Property	NICNAS -- National Industrial Chemicals Notification and Assessment Scheme
IPCS -- International Program on Chemical Safety	NIH -- National Institutes of Health
ISHL -- Industrial Safety and Health Law	NIOSH -- National Institute for Occupational Safety and Health
ISO -- International Organization for Standardization	NMFS -- National Marine Fisheries Service
IUCLID -- International Uniform Chemical Information Database	NMP -- N-methylpyrrolidone
IUR -- Inventory Update Reporting	NMPA -- National Medical Products Administration
JAO -- Philippines Joint Administrative Order No. 1 of 2009	NOA -- Notice of Activity
KKDIK -- Turkey REACH	NOC -- Notice of Commencement
KKS -- Turkish Chemicals Registration System	NONS -- Notification of New Substance
K-REACH -- Act on the Registration and Evaluation of Chemicals	NPDES -- National Pollutant Discharge Elimination System
Lautenberg -- Frank R. Lautenberg Chemical Safety for the 21st Century Act	NP/NPE -- Nonylphenols and Nonylphenol Ethoxylates
LCPFAC -- Long-chain Perfluoroalkyl Carboxylates	NRDC -- Natural Resources Defense Council
LCPFAS -- Long-chain Perfluoroalkyl Sulfonates	NYDEC -- New York Department of Environmental Conservation
LVE -- Low Volume Exemption	OCSP -- Office of Chemical Safety and Pollution Prevention
MAD -- Mutual Acceptance of Data	ODS -- Ozone-depleting Substances
MAP-21 -- Moving Ahead for Progress in the 21st Century Act	OECD -- Organization for Economic Cooperation and Development
MARA -- Ministry of Agriculture and Rural Affairs	OEHHA -- Office of Environmental Health Hazard Assessment
MCAN -- Microbial Commercial Activity Notice	OMB -- Office of Management and Budget
MEE -- Ministry of Ecology and Environment	OPP -- Office of Pesticide Programs
MEM -- Ministry of Emergency Management	OPPT -- Office of Pollution Prevention and Toxics
MEP -- Ministry of Environmental Protection	OR -- Only Representative
MEP Order No. 7 -- Environmental Management of New Chemical Substances	OSHA -- U.S. Occupational Safety and Health Administration
MIIT -- Ministry of Industry and Information Technology	OTC -- Over-the-Counter
MOA -- Memorandum of Agreement	PANNA -- Pesticide Action Network North America
MoE -- South Korea Ministry of Environment	PBB -- Binefil Polybromate
MoEU -- Ministry of Environment and Urbanization	PBDE -- Diphenyl Polybromate Ether
MOFCOM -- Ministry of Commerce	PBT -- Persistent, Bioaccumulative, and Toxic
MOIT -- Ministry of Industry and Trade	PDSCL -- Poisonous and Deleterious Substances Control Law
MOA -- Memorandum of Agreement	PEC -- Priority Existing Chemical
MOU -- Memorandum of Understanding	PFAS -- Perfluoroalkyl Substances
MP -- Member of Parliament	PFOA -- Perfluorooctanoic Acid
MRL -- Maximum Residue Limit	PFOS -- Perfluorooctanesulfonic Acid
NAFTA -- North American Free Trade Agreement	
NAM -- New Approach Methodologies	

PHMSA -- Pipeline and Hazardous Materials Safety Administration
PIC -- Prior Informed Consent
PIP -- Plant-Incorporated Protectant
PMN -- Premanufacture Notice
PPE -- Personal Protective Equipment
PPT -- Parts Per Trillion
PRIA -- Pesticide Registration Improvement Act
Prop 65 -- Proposition 65
PRTR -- Pollutant Release and Transfer Register
PSI -- Per Square Inch
RA -- Regional Administrator
RAC -- Risk Assessment Committee
RCC -- Regulatory Cooperation Council
REACH -- Registration, Evaluation, Authorization and Restriction of Chemicals
REL -- Recommended Exposure Limit
RFI -- Request for Information
RUP -- Restricted Use Pesticide
RVP -- Reid Vapor Pressure
SACC -- Science Advisory Committee on Chemicals
SAIC -- State Administration for Industry and Commerce
SAICM -- Strategic Approach to International Chemicals Management
SAMR -- State Administration for Market Regulation
SAWS -- State Administration of Work Safety
SCIL -- Safer Chemical Ingredients List
SDS -- Safety Data Sheet
Services -- USFWS and NMFS
SIDS -- Screening Information Data Set
SIEF -- Substance Information Exchange Forum
SNUN -- Significant New Use Notice
SNUR -- Significant New Use Rule
SPF -- Sun Protection Factor
SPS -- Sanitary and Phytosanitary
SUD -- Safe Use Determination
SVHC -- Substance of Very High Concern
SWA -- Safe Work Australia
Taiwan EPA -- Taiwan Environmental Protection Administration
TCE -- Trichloroethylene
TCSCA -- Taiwan Toxic Chemical Substance Control Act
TDI -- Toluene Diisocyanates
TPP -- Trans-Pacific Partnership
TR -- Technical Regulation
TSCA -- Toxic Substances Control Act
TSCA NCC -- TSCA New Chemicals Coalition
T-TIP -- Transatlantic Trade and Investment Partnership
TPP -- Trans-Pacific Partnership
Trade Act -- The Trade Act of 1974
UAE -- United Arab Emirates
UID -- Unique Identifier
UK -- United Kingdom
UN -- United Nations
U.S. -- United States
USACE -- U.S. Army Corps of Engineers
USDA -- U.S. Department of Agriculture
USFWS -- U.S. Fish and Wildlife Services
USMCA -- United States-Mexico-Canada Agreement
USTR -- U.S. Trade Representative
VA -- Vulnerability Assessment
vPvB -- Very Persistent and Very Bioaccumulative
WEEE -- Waste Electrical and Electronic Equipment
WES -- Workplace Exposure Standards
WHMIS -- Workplace Hazardous Materials Information System
WHO -- World Health Organization
WOTUS -- Waters of the U.S.
WPS -- Worker Protection Standard
WTO -- World Trade Organization

APPENDIX B: 2019 COMPLIMENTARY WEBINAR SCHEDULE

B&C’s complimentary webinars feature leading figures from government, industry, and private practice analyzing and advising on pressing chemical policy issues to equip regulatory professionals to succeed in an ever-changing regulatory environment. More information and registration details are available at www.lawbc.com/seminars-webinars.

[Visit our website](#) to view these recent webinar recordings, available on demand:

[Proposition 65 Warning Requirements and Compliance Strategies](#), [Lynn L. Bergeson](#), Managing Partner, B&C; and [Lisa R. Burchi](#), Of Counsel, B&C

[Keeping up with FSMA -- Rules, Obligations, and Key Compliance Dates](#), [Karin F. Baron, MSPH](#), Senior Regulatory Consultant; [Lynn L. Bergeson](#), Managing Partner; and [Scott J. Burya, Ph.D.](#), Regulatory Chemist, all with B&C

[TSCA Confidential Business Information and Generic Naming: Analyzing the New Rules](#), Tracy C. Williamson, Ph.D., Chief, Industrial Chemistry Branch, EPA; Scott M. Sherlock, Attorney Advisor, EPA; and [Richard E. Engler, Ph.D.](#), Director of Chemistry, B&C

[Chemical Regulation in the Middle East](#), [Michael S. Wenk, M.S.](#), Senior Regulatory Consultant, B&C

[TSCA at 2: An Update on Implementation and Hot Topics](#), Nancy B. Beck, Ph.D., D.A.B.T.®, Deputy Assistant Administrator, EPA OCSPP; [Lynn L. Bergeson](#), Managing Partner, B&C; Misty L. Bogle, Global Product Stewardship Manager, Vertellus Specialties Inc.; and Michael Gould, EH&S Committee Chairman, RadTech North America

[FIFRA Hot Topics](#), [Lisa M. Campbell](#), Partner, B&C; [James V. Aidala](#), Senior Government Affairs Consultant, B&C; Rick P. Keigwin, Jr., Director, OPP, OCSPP, EPA; Daniella Taveau, former International Trade Negotiator for EPA and now Regulatory and Global Trade Strategist, King & Spalding; and William L. Jordan, former senior toxics lawyer with EPA’s OPP and OGC

TOPIC	DATE
Chemical Regulation after the Mid-Terms: Who’s In, Who’s Out, and What’s Up	January 23, 2019 1:00 p.m. – 2:00 p.m. (EST) Register now
WOTUS: An Update and Analysis of the New State of Play	February 20, 2019
Prop 65: Exposure Monitoring and Compliance Implications	March 20, 2019
FIFRA Hot Topics in Pesticide and Biocides Regulation and Litigation	April 24, 2019
FDA Hot Topics: Cosmetics, Food Contact, and Other Topics	May 22, 2019
New TSCA at 3: Key Implementation Issues	June 26, 2019
FDA FSMA Food Defense Plan Requirements	July 24, 2019
RCRA Improvement Rules: An Update and Discussion	August 21, 2019
Implementation of RMP: A Discussion of Key Issues	September 25, 2019
Consumer Labeling and GHS: Avoiding the Pitfalls	October 23, 2019
TSCA Implementation: Chemical Identification for Active Chemicals	November 20, 2019
Final TSCA Risk Evaluations: A Review of Key Issues	December 18, 2019

APPENDIX C: SPEECHES AND WRITINGS

BOOKS AND REPORTS

Michael S. Wenk, M.S., [Chemical Regulation in the Middle East](#), John Wiley & Sons, Ltd. (2018).

Susan Kirsch, co-author, "[Water Quality and Wetlands 2017 Annual Report](#)," in [The Year in Review 2017: Environment, Energy, and Resources Law](#), American Bar Association (2018).

Lynn L. Bergeson, Richard E. Engler, Ph.D., co-authors, "[Pesticides, Chemical Regulation, and Right-To-Know 2017 Annual Report](#)," in [The Year in Review 2017: Environment, Energy, and Resources Law](#), American Bar Association (2018).

Lynn L. Bergeson, Charles M. Auer, Co-Editors; Timothy D. Backstrom, Lisa R. Burchi, Lisa M. Campbell, Sheryl L. Dolan, Richard E. Engler, Ph.D., Margaret R. Graham, Oscar Hernandez, Ph.D., Carla N. Hutton, Kathleen M. Roberts, Contributing Authors, [New TSCA: A Guide to the Lautenberg Chemical Safety Act and Its Implementation](#), American Bar Association Section of Environment, Energy, and Resources (2017).

ARTICLES

Recent articles on critical issues:

Lynn L. Bergeson, Richard E. Engler, Charles M. Auer, and Kathleen M. Roberts, "[New Chemicals Under New TSCA -- Stalled Commercialization](#)," *Bloomberg Environment Insights*, September 11-13, 2018.

Lynn L. Bergeson, "[The New Administration and International Chemical Issues](#)," *Environmental Quality Management*, Volume 27, Issue 4, Summer 2018.

Lynn L. Bergeson, "[U.S. Consumer Product Ingredient Disclosure Measures Pick Up Momentum](#)," *International Chemical Regulatory and Law Review*, Volume 1, Issue 2, 2018.

Richard E. Engler, Ph.D., "[EPA Includes Active-Inactive Designations on Updated TSCA Inventory](#)," *ABA Section of Environment, Energy, and Resources PCRRTK Newsletter*, Volume 19, Issue 3, July 2018.

All of our articles are available at www.lawbc.com/published-articles.

PRESENTATIONS

Materials from recent presentations are available by request.

"The Advantages and Legal Consequences of Ramped Up Supply Chain Communications," Richard E. Engler, Ph.D., Household and Consumer Products Association XPAND2018, Fort Lauderdale, Florida (December 4, 2018).

"Middle East -- Chemical Management and Product Regulation," Michael S. Wenk, ChemCon Europe, Budapest, Hungary (November 16, 2018).

"Life in the Trump Lane: Key U.S. Policy and Regulatory Initiatives under the Trump/Pruitt Administration," Lynn S. Bergeson, Electrical and Electronic Equipment and the Environment Conference, London, England (November 14, 2018).

"Pesticide Regulation in China," Brian Xu, M.D., Ph.D., DABT, Biocides USA, San Francisco, California (November 7, 2018).

"Sustainable Investment in Agriculture," Lynn L. Bergeson, moderator, International Bar Association 2018 Annual Conference, Rome, Italy (October 7, 2018).

Details regarding all [upcoming presentations](#) and [past presentations](#) are available on our website.



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