



BERGESON & CAMPBELL, P.C.

Forecast for U.S. Federal
and International Chemical
Regulatory Policy 2020



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FORECAST 2020

Bergeson & Campbell, P.C. (B&C®) and its consulting affiliate The Acta Group (Acta®) are pleased to offer you our Forecast 2020. In this detailed and comprehensive document, the legal, scientific, and regulatory professionals of B&C and Acta distill key trends in U.S. and global chemical law and policy, and provide our best informed judgment as to the shape of key developments we are likely to see in the New Year.

Our unique business platform and growing global team of highly skilled professionals are exceptionally well suited to offer this detailed 2020 forecast. Our core business, about which each of us feels passionately, is the law, science, regulation, and policy of chemicals of all varieties -- industrial, agricultural, intermediate, specialty, and biocidal, whether manufactured at the bulk or nano scale, or using conventional or innovative technologies, including biotechnology, synthetic biology, or biobased. Our highly acclaimed team of scientists (seven Ph.D.s), including toxicologists, chemists, exposure experts, and geneticists; regulatory and policy experts; and lawyers is deeply versed in chemical law, science, and policy and our unique business platform seamlessly leverages and ensures the integration of law and science to achieve success at every level, and in all parts of the globe.

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

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I. UNITED STATES: CHEMICAL FORECAST

A. Introduction

We quote Winnie the Pooh -- “Oh Bother!” -- to introduce what to expect in the New Year. After three years of increasing partisan rancor, 2020 is expected to be a doozie. No surprise that the U.S. Environmental Protection Agency (EPA) was affected in 2019 by budget debates, Congressional oversight, and specific policy differences over environmental issues. 2020 holds promise as one of the more tumultuous years that EPA will face. Climate change in particular seems to be a defining issue for some Presidential candidates, and that will add to debate about a mix of fleet mileage standards, states’ rights, energy production, and general environmental sustainability and how it might be regulated by a Green New Deal. Throw in a Presidential election and an Impeachment process throughout the year and 2020 ought to be “one for the books.”

2019 was not without controversy but compared to the first two years of the Trump Administration, some things seem to have settled down for EPA. In particular, EPA finally had Senate-confirmed appointees both for Administrator, Andrew Wheeler (confirmed February 28, 2019), and for the Office of Chemical Safety and Pollution Prevention (OCSPP) Assistant Administrator (AA), Alexandra Dunn (confirmed January 2, 2019). Of note is that there was significant bipartisan support voiced for AA Dunn at her confirmation hearings.

Dunn’s confirmation, however, was reported to be predicated on a letter from then Acting Administrator Wheeler to withdraw proposed changes to rules regarding some Toxic Substances Control Act (TSCA) implementation issues and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Worker Protection Standards (WPS), which critics feared would weaken requirements imposed during the Obama Administration. The changes that were withdrawn regarding the FIFRA WPS program involved changes to the designated representative and minimum age provisions, along with the Application Exclusion Zone (AEZ) provisions. The Pesticide Registration Improvement Extension Act of 2018 (PRIA 4), discussed below, included some explicit statutory provisions regarding what changes to the WPS program would be allowed. Accordingly, on November 1, 2019, EPA proposed “narrow updates” to the AEZ provisions that would clarify requirements designed to prevent unintended exposure to workers and bystanders during a pesticide application. [84 Fed. Reg. 58666](#). Comments on the proposal are due **January 30, 2020**. As a broader signal, perhaps, this indicated that Mr. Wheeler would take a slightly more accommodating approach to Senate Democrats than the policies of the previous Administrator, Mr. Scott Pruitt.

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This also meant that two years lapsed before OCSPP had the AA position filled since the Inauguration of President Trump. To this day, there remain important senior political positions that are still vacant (example: Office of Research and Development (ORD)).

2019 also saw the Democrats take control of the House, and with its new leadership, various House Committees began a promised agenda of EPA oversight to probe on a variety of issues, including implementation of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg) that amended TSCA in 2016 and a variety of FIFRA-related issues, including appropriate protections for farmworkers. As the 2020 Presidential race intensifies, EPA is expected to be scrutinized even more. At the same time, the Administration, like others before it, will articulate what it believes were the achievements of the President's first term, including more reasonable regulatory requirements, faster Superfund cleanups, improved scientific assessments, and lower budgets to achieve its goals. Of course, those claims will remain controversial, as environmental protection issues are woven into the party platforms as the election draws near.

For OCSPP, the agenda remains busy as the not-so-new TSCA amendments, now three and one half years after enactment, reach critical decision points about definitions of key terms and appropriate approaches to assess chemical risks. FIFRA remains controversial on issues involving both individual pesticides (example: glyphosate, chlorpyrifos), as well as continued debates and litigation about EPA's compliance with the Endangered Species Act (ESA) done in concert with interagency coordination.

The context of election year politics will color both initiatives and debate throughout 2020, and there remains a good chance that, at the end of the year, we may find a new Administration poised to take over. Alternatively, a re-elected Administration would likely take that victory as a sign of vindication for its current approaches, which could lead to a doubling-down of its priorities during a second term. As a result, as usual, we can expect to see significant debate about EPA actions in general and OCSPP issues in particular.

Our predictions presented here attempt to cover this broad waterfront.

1. Elections Have Consequences

The mid-term elections of 2018 brought a change in the party control of the House of Representatives. With Democrats in charge, EPA and other agencies faced intense questioning and inquiries as part of Congressional oversight of Executive Branch agencies. Although the transition meant some delays in staffing-up Committees and clarifying assignments, the new Congress rapidly began oversight hearings in the new year. For OCSPP, the major committees of jurisdiction in the House are the House Agriculture Committee for FIFRA and the House Energy and Commerce (E&C) 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, it is the Environment and Public Works (EPW) Committee that has jurisdiction over the implementation of TSCA, and the Senate Agriculture Committee that has jurisdiction over FIFRA. Although both Senate Committees have or had a number of 2020 Presidential candidates (Senators Cory Booker (D-NJ), Kamala Devi Harris (D-CA), Kirsten Gillibrand (D-NY), and Amy Klobuchar (D-MN)), there so far has been little mention of OCSPP-related issues on the campaign trail. To date, environmental issues most discussed on the campaign trail have been the issues of broad interest and media coverage -- for example, climate change, the Green New Deal, EPA budget and enforcement activities, and lead poisoning.

The House E&C Committee convened an oversight hearing that touched both the pesticides and toxics programs. Held on March 13, 2019, the Environment and Climate Change Subcommittee hearing addressed "[Mismanaging Chemical Risks: EPA's Failure to Protect Workers](#)." At that hearing, testimony included the topic of EPA's implementation of the amendments to TSCA as they relate to Section 5 new chemicals and EPA rules for protecting farmworkers under the FIFRA worker protection program. Other Congressional hearings included some discussion of water contamination by perfluorinated chemicals (PFAS) being found in many areas of the country.

2. Administration Initiatives

Notwithstanding the slow pace of political appointments, from its first days, the Administration issued a number of Executive Orders (EO) and other directives designed to foster



A leaked copy of the Administration's proposed "science rule" appears to be effectively a re-proposed rule that addresses many of the important criticisms made in response to the 2018 proposal, including clearer definitions of important terms and under what authority EPA would issue such requirements.

business investment and lessen regulatory requirements imposed on regulated entities. Across the government, including EPA, there was 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.

Under former EPA Administrator Pruitt, EPA issued a proposed rule to ensure that the "science" that EPA relies on is sound through meeting certain guidelines about the quality and availability of "pivotal" science studies and review policies. [83 Fed. Reg. 18768](#). When it was issued on April 30, 2018, the proposed rule was seen as an attempt to capture the purposes of the legislation proposed in past sessions of Congress by Congressional Republicans critical of past EPA decision-making. Opponents of some past EPA rules have been especially critical of some impactful regulations issued under the Clean Air Act (CAA) over the lack of "transparency" of the data upon which EPA relied. Such critics have claimed that access to the raw data of studies that form the basis of EPA's regulations is needed to review and understand the scientific justification supporting important EPA regulations.

The "science rule" was published as a proposed rule but has faced intense criticism about most every aspect, including how it might work, the meaning of various new terms used in the proposal, what kinds of "science" to which the new requirements would apply, and fundamentally the authority upon which any new regulation would be based. After the initial proposal, it was not clear how or when the Administration might proceed to further refine and eventually promulgate a final "rule" given the many issues raised in the comment period that seem to have not been well developed in the initial proposed rule.

Since that time, completion of this "science rule" has remained on EPA's stated regulatory agenda. Little mention of it, however, was heard for months since Administrator Wheeler was confirmed. In November 2019, however, the *New York Times* reported on a leaked update of the proposal

that was circulating at the Office of Management and Budget (OMB) for final review, a version that generally indicates the Administration is close to issuing the new proposal. The leaked copy of the next draft is, by definition, not official at this point and could change further before anything is released. The leaked document appears to be effectively a re-proposed rule that addresses many of the important criticisms made in response to the 2018 proposal, including clearer definitions of important terms and under what authority EPA would issue such requirements. Notably, the revised proposal would "clarify" that "the proposed rule would apply to all data and models underlying pivotal science used to support decision making."

Though the rule is at OMB in what appears to be near final form, it is not clear when any re-proposed requirements would be issued. The stated plan is to have any such policies completed and in force by the **end of 2020** -- an ambitious schedule for completion of a final rule in a routine proceeding, let alone in a controversial area. The leaked draft provides that there will only be a 30-day comment period, which would not likely be extended if the goal is to complete the rulemaking in 2020. It also may become a point of discussion in the Presidential election debate as 2020 unfolds, speaking to conflict between camps that support or oppose the way science is used, or for some, "manipulated," at EPA to support important regulatory decisions. See B&C's Pesticide Law and Policy Blog[®] entitled "[EPA Releases Strengthening Transparency in Regulatory Science Proposed Rule.](#)"

Concerning the budget, proposals for reducing the budget of EPA and other agencies have not been supported by Congress so, instead of budget cuts of 15-25 percent, as proposed by the President's budgets in the past, 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 few years, and with on-again, off-again, restrictions on hiring new staff, a steady drip of budget cuts, and proposed changes to the federal employee pension scheme, the government altogether may face a serious personnel crisis in the coming years.

3. Operating Environment

3.1 Congress

The biggest change in the operating environment for any Executive Branch agency in 2019 was the change in party control in the House of Representatives. An analysis by EPA's office that deals with Congressional affairs counted 30 Committees and Subcommittees in the House of Representatives with some jurisdiction over EPA program activities, and 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. In addition, any Inspector General reports or findings will have a different audience given the number of oversight Committees looking for "ripe" issues to review.

Not surprisingly, the divided control between the House and Senate meant that little substantive legislation on any environmental issue was completed. Besides any expected partisan grandstanding, the Committees across both the House and Senate will have to come to agreement on budgets and spending for government programs. After a prolonged government shutdown in early 2019, the prospect for another shutdown at the end of the year did not materialize, and now appears unlikely, and the debate on the debt ceiling appears to be at rest until after 2020. As it is an election year, for virtually all issues, the prospects for any breakthrough towards compromise or serious cooperation among the partisan constituencies appear to be remote.

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3.2 State and Local Jurisdictions

Generally, in recent years, there have been relatively few bills in Congress that direct EPA to take specific regulatory action on a specific pesticide and that appear to have a significant chance of seeing serious legislative debate. With the current Congress, including more rancorous partisan relations between the White House and Congress, there are more bills that threaten Executive Branch prerogatives about pesticide registrations. Specifically, legislation ([H.R. 230](#)) effectively banning the insecticide chlorpyrifos (discussed in more detail below) now has 114 co-sponsors in the House -- which represents a possibility of floor action sometime in this Congress. Legislation ([H.R. 1337](#)) about glyphosate similarly has 70 co-sponsors in the House. In addition, at the state and local government levels, there are over 70 pieces of legislation threatening bans or other restrictions on various classes of pesticides or individual products. As distrust of the federal government generally and EPA specifically grows due to partisanship or other reasons, such prescriptive legislation may increase the potential for registrants to have an even more unpredictable business environment in the coming years.

3.3 Litigation

Litigation is a time-tested tool of advocacy either to support or 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 were considered to be ineffective or hostile to environmental groups' interests. Three 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 EOs to "make it happen" and other means to impose simple 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.

For OCSPP, there has been continued litigation over EPA's compliance with ESA since at least 2001, and those

litigation battles continue. For toxic chemicals, almost all of EPA's initial policy determinations for defining important approaches or policies for chemical reviews and assessments under the 2016 TSCA amendments have been challenged in court. The outcome of these cases will continue to reverberate and have programmatic implications for some years to come.

B. TSCA

1. Predictions and Outlook for the EPA OCSPP Office of Pollution Prevention and Toxics (OPPT) 2020

EPA's OCSPP continues to be challenged by an extraordinary workload and its statutory deadlines. B&C tracks OCSPP on its [TSCAblog™](http://www.TSCAblog.com). OCSPP is working hard to keep up with new chemical notices while completing the "first 10" risk evaluations, and has consistently hit all of the statutory deadlines for action on existing chemicals. The summary below reflects our thoughts on key issues and a look forward.

1.1 Section 4 -- Testing

It has been over three years since enactment of Lautenberg and EPA still has not issued a Section 4 testing action. B&C suspects that between the requirements to complete the "first 10" risk evaluations and the requirement to designate the next 20 high-priority and 20 low-priority chemicals, among other statutory deadlines, EPA simply has not had time to evaluate its critical data needs and require testing.

EPA has been working with industry through the American Chemistry Council (ACC) to develop data that will help inform the new chemical categories related to worker and consumer inhalation concerns, a major step forward in providing greater certainty for new chemical submitters. This effort is voluntary, less labor intensive, and more efficient for industry and EPA to develop data as quickly as possible. On the other hand, EPA will soon be in a position to obligate testing to inform its future prioritization actions. With the "first 10" risk evaluations wrapping up, and the "next 20" designated at the end of 2019, EPA will soon have to select additional substances for prioritization. EPA will have to develop a forward-looking strategy and select substances for which EPA has a solid dataset for

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prioritization and possible risk evaluation, while planning ahead to obligate testing now on substances that EPA will nominate for prioritization one to three years in the future. In addition, as discussed below, the Science Advisory Committee on Chemicals (SACC), in its final peer review report on Pigment Violet 29's (PV29) risk evaluation, asked EPA to justify why additional testing was not necessary to confirm certain risk evaluation conclusions. We would not be surprised to see this point being made in other risk evaluation peer reviews, all of which will increase attention to this issue and pressure on this front.

For reasons such as these, B&C continues to believe that EPA will take the first Section 4 testing actions under amended TSCA in the coming year. Nonetheless, if the outcome of litigation forces EPA to re-review its framework policies and re-review risk evaluations and risk management actions, B&C speculates that testing actions will again take a back seat to required actions.

(a) Alternative Test Methods

News about EPA's work on alternative test method "new approach methodologies" (NAM) has quieted down since EPA's release of its strategic plan in 2018, until recently. In a more aggressive policy step, in September 2019, EPA's Administrator signed a [memo](#) directing EPA to prioritize efforts to reduce animal testing and to eliminate animal testing by **2035**. The memo directs EPA to reduce its requests for, and its funding of, mammalian studies by 30 percent by **2025** and to eliminate all mammalian study requests and funding by **2035**. Any mammalian studies requested or funded by EPA after **2035** will require Administrator approval on a case-by-case basis. The Administrator also announced the formation of an EPA expert group to formulate tangible steps for implementation and



PODCAST:
[Animal Testing and New TSCA](#)

monitoring compliance with the stated objectives. In addition, ORD and OCSPP were requested to hold a joint annual conference to serve as a resource on NAM developments for scientists and policy makers.

EPA has been implementing its approach in a number of ways. First, EPA continues to indicate *in vitro* methods as the first tier for several endpoints in response to premanufacture notices (PMN). EPA's new chemical categories for inhalation all start with particle or droplet size testing or other *in vitro* methods. Similarly, the first tier for sensitization testing is a suite of *in vitro* methods. EPA also requests that companies consult with EPA before performing testing on vertebrates so that EPA can weigh in on whether the *in vivo* tests are indicated or if *in vitro* (or *in silico*) methods or read-across data might suffice. EPA has also stopped being specific in indicating test methods in consent orders and Significant New Use Rules (SNUR) when the testing is not expected to begin right away. While this has raised some confusion and consternation among TSCA stakeholders, it allows EPA an opportunity to respond with specificity at a future date when testing will commence. At that point, EPA can evaluate current data and methods and determine if there is still a data need and, if so, if vertebrate testing is needed to fill that need. By deferring specifying testing until the future, EPA is deferring the decision to use vertebrates and, thereby, helping to meet its obligation under TSCA Section 4(h).

Developing and validating new NAMs will take some time. Utilization of NAMs in the assessment of new chemicals and in identification and designation of priority chemicals appear the most amenable and consequential to promote regulatory acceptance of these new methodologies. EPA continues to work cooperatively with government

and private research groups to advance the development of NAMs, in particular the understanding of mode of action and mechanisms of toxicity that would allow the development of frameworks (Adverse Outcome Pathways) for the integration of NAMs. As the science demonstrates that NAMs are appropriate in informing hazard endpoints, EPA will incorporate those NAMs into its hierarchy of testing, but we expect NAMs to be implemented at a fairly slow pace.

1.2 Section 5 -- New Chemicals

EPA made a difficult choice for Fiscal Year (FY) 2019. EPA decided to prioritize new submissions over old ones. While this tended to make the path for 2019 cases more predictable, the older "backlog" PMN cases have continued to languish. The past year amply demonstrated that OPPT simply does not have sufficient bandwidth to make determinations timely on all the cases currently under review, new and old. Exacerbating the problem is that EPA continues to make errors in some risk assessments and even in the text of proposed SNURs. This is consequential as each time an error is identified, the case must go back through the process to correct the error and reevaluate the outcome, further over-taxing an already overwhelmed system. EPA is hiring new staff, but it will be some time before staff is hired in sufficient numbers and has been sufficiently trained to make a significant difference in EPA's capacity. Meanwhile, senior staff continues to retire.

EPA has finally advanced its plan to issue "non-order SNURs" for cases in which EPA does not find unreasonable risk under the intended conditions of use as a mechanism to constrain the conditions of use that EPA views as reasonably foreseeable. The concept is simple: rather than allowing commercialization under a consent order, EPA delays its determination and (thereby) commercialization until the SNUR has been proposed. Once the SNUR has been proposed, EPA can confidently make a "not likely" determination allowing the substance to be commercialized with the SNUR protections in place. The non-order SNUR mechanism reduces the number of Section 5(e) orders that EPA must produce. For this reason, B&C views "non-order SNURs" as a useful tool for EPA to meet its statutory obligations in a more efficient manner - EPA would presumably have to promulgate the SNUR derivative of a 5(e) order anyway, so why not move straight to the SNUR?

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

In 2019, EPA released a helpful new tool that tracks the status of TSCA new chemical notifications. The new “[case tracker](#)” reflects EPA’s commitment to transparency and allows users to view and search active PMNs and Significant New Use Notifications (SNUN) submitted to EPA. As the tool matures, EPA expects to increase the frequency of updates to the tracker and otherwise enhance its utility.

Table 1. 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 PMNs, Microbial Commercial Activity Notices (MCAN), and SNUNs, 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)).

On January 2, 2020, EPA released an updated version of the “Working Approach” document that builds upon its November 2017 “New Chemicals Decision-Making Framework: Working Approach to Making Determinations under Section 5 of TSCA.” [85 Fed. Reg. 99](#). EPA states that the updated document, “[TSCA New Chemical Determinations: A Working Approach for Making Determinations under TSCA Section 5](#),” explains its approach for making one of the five affirmative determinations on new chemical notices under TSCA:

- The chemical or significant new use presents an unreasonable risk of injury to health or the environment;
- Available information is insufficient to allow EPA to make a reasoned evaluation of the health and environmental effects associated with the chemical or significant new use;
- In the absence of sufficient information, the chemical or significant new use may present an unreasonable risk of injury to health or the environment;
- The chemical is or will be produced in substantial quantities and either enters or may enter the environment in substantial quantities or there is or may be significant or substantial exposure to the chemical; or
- The chemical or significant new use is not likely to present an unreasonable risk of injury to health or the environment.

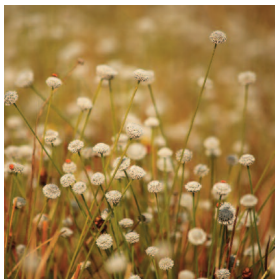
Comments are due **February 18, 2020**. More information is available in our December 20, 2019, memorandum, “[EPA Releases Updated Version of “Working Approach” Document for New Chemicals Review](#).”

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On December 20, 2019, EPA published the final list of high-priority chemicals. EPA stated that it plans to publish the final list of low-priority chemicals in early 2020.

(a) Pace of SNURs Increases

EPA continues to be a “SNUR machine,” as one senior OPPT manager put it. EPA has proposed SNURs covering 224 chemical substances in 12 batches during 2019 and promulgated SNURs covering 320 chemical substances in nine batches. This includes non-order SNURs and SNURs derivative of consent orders. It is critical that EPA keep up the pace of SNUR work. For non-order SNURs, the SNUR publication is on the critical path to commercialization. For order-based SNURs, the SNUR broadens the order’s obligations to others in the market (both leveling the commercial playing field and ensuring that others that might enter the market are sufficiently protective of health and the environment). Also, the distribution limitations in boilerplate consent orders are often so restrictive that manufacturers cannot commercialize until 75 days after the final SNUR is published.

(b) New Chemicals Litigation

As reported in our previous Forecast memorandum, on August 29, 2018, the U.S. Court of Appeals for the Second Circuit granted the Natural Resources Defense Council’s (NRDC) motion to dismiss its petition 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. EPA could soon see a new suit regarding its review of new chemicals, however. On September 3, 2019, Earthjustice filed with EPA a [notice of intent](#) (NOI) to sue EPA under TSCA Section 20(a)(2) for “EPA’s repeated and ongoing failures to comply with TSCA’s nondiscretionary mandates to disclose to the public information about new chemical substances reviewed by EPA.” According to Earthjustice, EPA “routinely fails to disclose” certain information regarding the submission and review of new chemical applications under the PMN and test marketing exemption (TME) provisions. Earthjustice states that these violations impede the ability of the listed parties “to be meaningfully informed of and able to participate in EPA’s review of new chemicals.”

Earthjustice asks that EPA immediately cease further violations of TSCA’s disclosure requirements for new chemicals and disclose the information to which the listed parties are legally entitled in the mandated time frames. More information is available in our September 17, 2019, memorandum, “[Earthjustice Notifies EPA of Intent to Sue for Failure to Disclose Information about New Chemical Substances.](#)”

1.3 Section 6 -- Existing Chemicals

(a) Prioritization

Pursuant to TSCA Section 6(b)(2)(B), EPA must have at least 20 high-priority chemicals undergoing risk evaluation and 20 low-priority chemicals designated by December 22, 2019 (three and one half years after enactment). In March 2019, EPA released a list of chemicals for which it initiated the prioritization process for risk evaluation. That list included initial designations of high-priority for 20 chemicals and low-priority for 20 chemicals. In two separate notices issued in August 2019, EPA formally proposed to designate those chemicals as high- or low-priority. On December 20, 2019, EPA published the final list of high-priority chemicals. EPA stated that it plans to publish the final list of low-priority chemicals in **early 2020**.

The proposed low-priority chemicals are:

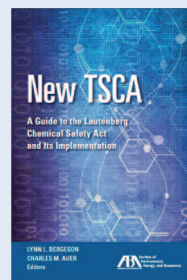
1. 1-Butanol, 3-methoxy-, 1-acetate
2. D-gluco-Heptonic acid, sodium salt (1:1), (2.xi.)-
3. D-Gluconic acid
4. D-Gluconic acid, calcium salt (2:1)
5. D-Gluconic acid, .delta.-lactone
6. D-Gluconic acid, potassium salt (1:1)
7. D-Gluconic acid, sodium salt (1:1)
8. Decanedioic acid, 1,10-dibutyl ester
9. 1-Docosanol
10. 1-Eicosanol
11. 1,2-Hexanediol
12. 1-Octadecanol

13. Propanol,
[2-(2-butoxymethylethoxy)methylethoxy]-
14. Propanedioic acid, 1,3-diethyl ester
15. Propanedioic acid, 1,3-dimethyl ester
16. Propanol, 1(or 2)-(2-methoxymethylethoxy)-, acetate
17. Propanol, [(1-methyl-1,2-ethanediyl)bis(oxy)]bis-
18. 2-Propanol, 1,1'-oxybis-
19. Propanol, oxybis-
20. Tetracosane, 2,6,10,15,19,23-hexamethyl-

The high-priority chemicals are:

1. p-Dichlorobenzene
2. 1,2-Dichloroethane
3. trans-1,2-Dichloroethylene
4. o-Dichlorobenzene
5. 1,1,2-Trichloroethane
6. 1,2-Dichloropropane
7. 1,1-Dichloroethane
8. Dibutyl phthalate (DBP) (1,2-Benzenedicarboxylic acid, 1,2- dibutyl ester)
9. Butyl benzyl phthalate (BBP) (1,2-Benzenedicarboxylic acid, 1-butyl 2-(phenylmethyl) ester)
10. Di-ethylhexyl phthalate (DEHP) (1,2-Benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl) ester)
11. Di-isobutyl phthalate (DIBP) (1,2-Benzenedicarboxylic acid, 1,2-bis-(2-methylpropyl) ester)
12. Dicyclohexyl phthalate
13. 4,4'-(1-Methylethylidene)bis[2,6-dibromophenol] (TBBPA)
14. Tris(2-chloroethyl) phosphate (TCEP)
15. Phosphoric acid, triphenyl ester (TPP)
16. Ethylene dibromide
17. 1,3-Butadiene
18. 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB)
19. Formaldehyde
20. Phthalic anhydride

EPA notes that a designation of a chemical substance as a high-priority substance is not a finding of unreasonable risk. Final designation of a high-priority substance initiates the three to three and a half year risk evaluation process, culminating in a finding of whether the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use.



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).

While EPA had a public review and comment period following the March 2019 initiation of the prioritization process, there were no changes in the initial chemical designations or final high-priority designations, calling into question whether the formally proposed designations were a foregone conclusion. More information is available in our December 20, 2019, memorandum, “[Final List of High-Priority Chemicals Will Be Next to Undergo Risk Evaluation under TSCA.](#)”

While further prioritization work is not expected in 2020, we are mindful of the unyielding timeline associated with the Section 6 prioritization-risk evaluation-risk management process. The high- and low-priority chemicals listed above are the first ones to be prioritized under the process described in the document, [A Working Approach for Identifying Potential Candidate Chemicals for Prioritization](#), which outlines near- and long-term approaches to prioritization. EPA describes several sources for considering additional low-priority chemicals, including EPA’s Safer Chemical Ingredients List (SCIL) and EPA’s Chemical Assessment Management Program (ChAMP). The near-term approach for additional high-priority chemicals that EPA generally intends to follow involves identification of relevant information on the 73 remaining chemicals listed under the 2014 update to the TSCA Work Plan.

(b) Risk Evaluations

EPA is completing risk evaluations for the “[first 10” 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. To date, EPA has released six draft risk evaluations that have been reviewed by the TSCA SACC. EPA released its first draft risk evaluation in November 2018 concerning the chemical PV29, which

stated that the chemical did not present an unreasonable risk. This risk evaluation was reviewed by the SACC in June 2019. Subsequently, draft risk evaluations for the cyclic aliphatic bromides cluster of flame retardants (HBCD) (which did not find unreasonable risk), 1,4-dioxane (which found unreasonable risk to workers), and 1-bromopropane (1-BP) (which found unreasonable risk to workers, occupational non-users, and consumers under certain conditions of use) were peer reviewed between July and September.

EPA published the SACC meeting minutes and final peer review report for PV29 on September 30, 2019, and the SACC meeting minutes and final peer review report for 1,4-dioxane and HBCD in November 2019. Preparation of the corresponding documents for the remaining risk evaluations is in progress. SACC identified a number of issues and concerns with EPA's risk evaluation of PV29 and concluded that SACC members generally agreed that the information presented to support the risk characterization conclusions was not sufficiently robust for this purpose. SACC indicated that the risk evaluation required additional text and information, including targeted testing, to improve clarity and transparency. In general, SACC believed that significantly more detail needed to be provided to better support the conclusions and improve transparency of the decision-making. SACC went further to provide specific guidance for the different components of the risk evaluation and also requested that the additional material include a short description of why PV29 was originally selected for the TSCA Work Plan. SACC was particularly critical of the physicochemical properties section of the document, as it appears that solubility and hence bioavailability, which are critical and central to support the risk evaluation conclusions, were not supported by measured data. SACC noted that inconsistencies in the available physical-chemical properties data and/or lack of high-quality solubility studies in water and octanol, or equivalent tools, such as absorption/distribution/metabolism/excretion (ADME) studies, needed to produce estimates of solubility with sufficiently high confidence to justify their use in establishing exposure and absorption potential. SACC requested an improved discussion on why available study data are adequate to reach the conclusions of "no unreasonable risk" from exposure to PV29. This discussion should also justify why additional testing is not necessary to confirm this conclusion. EPA will need to address these SACC concerns and criticisms in the final risk evaluation and, absent critical new test data, it may be difficult for EPA to support adequately its conclu-

sions that PV29 does not present an unreasonable risk. Such a determination must be issued by order and is subject to legal challenge.

Regarding 1,4-dioxane, SACC noted issues with both EPA's design and implementation of the systematic review. SACC generally agreed that the environmental fate, exposure, and effects assessment was inadequate. According to SACC, even for exposure routes that were considered, inadequate data are included. SACC noted that "many of the inadequacies" of the draft risk evaluation "have their genesis in a faulty problem formulation." The problem formulation strayed from basic risk assessment principles by omitting well-known exposure routes such as water consumption and occupationally and non-occupationally-exposed humans, as well as similar exposures to other biological receptors. SACC concluded that EPA's characterization of occupational inhalation exposure, which led to the finding that 1,4-dioxane, as used in manufacturing (import), processing (repackaging), and distribution in other considered downstream uses, does not present an unreasonable risk of injury to health, is not adequately supported in the draft risk evaluation. SACC agreed that EPA's preliminary determination that 1,4-dioxane represents an unreasonable risk to workers in certain specified conditions of use is adequate, and unlikely to change with SACC's recommendations. Many SACC members deemed EPA's decision to defer concerns of consumer exposure, or exposure of the general public, through ambient water or air because "other environmental statutes administered by EPA adequately assess and effectively manage these exposures" was unacceptable. According to SACC, it was not clear that other statutes are being used to evaluate the health risks of 1,4-dioxane exposure to the general public. In general, SACC found the identification of the cancer and non-cancer endpoints to be mostly appropriate. Regarding risk characterization, SACC agreed that there is a lack of quantitative uncertainty analyses in the draft risk evaluation. Individual SACC members had a wide array of responses to the question of whether the information presented supports the findings outlined in the risk characterization section. Three issues that were noted by several members were: the use of personal protective equipment (PPE) to reduce risk to levels below exposure limits, which may be an unreasonable assumption; the lack of inclusion of pregnant women; and the lack of inclusion of the general population exposure via pathways such as drinking water.



EPA has expressed confidence that it will meet the statutory deadline of June 2020 to issue the initial set of ten final risk evaluations.

In reviewing HBCD, SACC members generally agreed that they could not assimilate the full content of the HBCD systematic review in the time allotted and had to approach this review by selective query in their area of expertise. SACC noted that the fate and transport (Section 2.1) introduced estimated values of critical environmental properties. These are subsequently used in the prediction of HBCD exposure of humans and wildlife later in the draft risk evaluation. As such, uncertainties in these values will propagate into these higher-level predictions. SACC states that this is problematic in terms of associated confidence in their estimates. While methods and approaches to estimate environmental release were generally appropriate, SACC expressed concerns that estimations of environmental concentrations associated with demolition and disposal are not adequately addressed. Approaches, methods, and rationale for occupational inhalation exposure estimation were presented and described clearly. SACC questioned whether particles of the size of commercially-available HBCD would be expected to reach the lower airway, and a consensus of SACC believes that PPE may not be consistently and properly worn, as EPA assumed. SACC states that the models used for environmental, general population, and consumer exposure are complex in construction and incorporate multiple assumptions. Beyond the recommendations for the draft risk evaluation, SACC expressed a need for additional peer review expertise to assess the adequacy and appropriateness of use for each complex model that EPA uses for the evaluation of chemicals under TSCA. SACC recommended that EPA convene a panel of modeling experts to assess the conservativeness of model estimates. There is sufficient information in relation to environmental hazards to expect that exposures to higher trophic level wildlife species will be of the greatest concern. The human health hazard assessment indicates data from human epidemiological studies is limited, and EPA considered whichever data are available to be inadequate for conducting a risk assessment. Overall, according to SACC, for the environmental risk characterization, appropriate methods were used to assess risk quotients for water and sediment exposure. SACC had

concerns that the threshold used for soil was inappropriate, however. SACC considered the lack of quantification of uncertainties as a “lingering concern for EPA’s process of risk assessment/evaluation, leading to EPA needing to develop a practical and sensible process where uncertainties can be quantified systematically and consistently.”

For the remaining six chemicals -- asbestos, carbon tetrachloride, methylene chloride, N-methylpyrrolidone (NMP), perchloroethylene (PCE), and trichloroethylene (TCE) -- EPA released the draft risk evaluations for methylene chloride in October and NMP in November. EPA has indicated that it will release two of the remaining draft risk evaluations by the end of 2019 and the other two in **January 2020**, but it is likely that all will be released in 2020. SACC is expected to review the remaining four draft risk evaluations in 2020.

EPA has expressed confidence that it will meet the statutory deadline of **June 2020** to issue the initial set of ten final risk evaluations. In response to complaints and concerns from the public about the short time allowed to review the large, hundreds of pages long, draft risk evaluation documents, EPA extended the pre-SACC public comment period to 30 days. SACC members had also expressed interest in learning the public’s perspective(s) going into their review. The challenge of maintaining the schedule is compounded by the scope and complexity of the remaining risk evaluations that involve chemicals most of which have been under regulatory scrutiny for decades, have robust databases, and do not infrequently present difficult and controversial scientific interpretive issues. EPA also needs to cement its approach to a number of risk evaluation policy issues before preparing final evaluations.

EPA has yet to issue in final its approach to preparing manufacturer-requested risk evaluations of two persistent, bioaccumulative, and toxic (PBT) chemicals (ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,5,5-tetramethyl-2-naphthalenyl); and ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-

2,3,8,8-tetramethyl-2-naphthalenyl)) that would otherwise have been subject to expedited risk management as required by Section 6(h). EPA announced on December 2, 2019, that it granted manufacturer-requested risk evaluations of two phthalate chemicals (diisodecyl phthalate (DIDP) and diisononyl phthalate (DINP)), both of which were listed in the 2014 Update to the TSCA Work Plan. These phthalates are used in children's toys, among other uses, and this particular use was previously restricted by the Consumer Product Safety Commission (CPSC) based on a risk assessment conducted by that agency. The manufacturers specifically request that exposure to children from toys and childcare articles, among other uses, be evaluated in conducting the risk evaluation. As reported in our August 19, 2019, memorandum, "[EPA Begins Comment Period on Manufacturer Requests for Risk Evaluation of DIDP and DINP, and Identifies Additional Conditions of Use](#)," EPA commenced a public comment period on the requests and on additional conditions of use that EPA identified to include in the risk evaluations.

We believe that EPA, despite its best efforts and its success in hitting all other statutory deadlines to date, will be challenged to complete all ten required risk evaluations by **June 2020**. The challenges are many, including: legal risks if EPA determines that PV29 and HBCD do not present unreasonable risks without addressing the weaknesses identified by SACC; the difficult scientific issues that EPA will need to sort through in completing risk evaluations on chemicals with a wide variety of uses and exposures; the need for sufficient time for notice and comment of the remaining draft risk assessment and to develop the responses to comments, the need to navigate a way through often highly controversial and long-standing scientific disagreements associated with several of the chemicals at play; and the need for EPA to sort out the many policy issues presented before issuing in final the first risk evaluation determinations under amended TSCA, all in a little more than six months.

(c) Risk Management, Including Certain PBT Chemicals

Under the Obama Administration, EPA proposed a Section 6(a) ban on methylene chloride in consumer and commercial paint and coating removal uses. In March 2019, EPA issued a final Section 6(a) rule banning use of methylene chloride in consumer paint and coating removal products ([84 Fed. Reg. 11420](#); 40 C.F.R. Part 751). Around the same time, EPA chose

to not promulgate the proposed unreasonable risk determination and Section 6(a) rule concerning commercial paint and coating removal uses of methylene chloride, but instead issued an advance notice of proposed rulemaking (ANPRM) for such uses ([84 Fed. Reg. 11466](#)). This notice requests input on approaches including training, certification, and limited access programs that could be an alternative to the ban action in the proposed rule. Although EPA has been criticized for delaying the commercial ban, it is important to recognize that, while the training and certification approach was described in EPA's proposed rule, it received only limited comment and EPA decided on the need to solicit additional public input.

EPA met the June 2019 statutory deadline for proposing regulatory action on five PBT chemicals and a **December 2020** deadline looms for issuance of the final rule. The chemicals at play and the proposed actions are as follows:

- Hexachlorobutadiene (HBCD), used as a solvent and functional fluid:
 - > EPA proposed no action.
- Phenol, isopropylated phosphate (3:1) (PIP (3:1)), used as a flame retardant, functional fluid, and in other uses:
 - > EPA proposed to ban processing and distribution except for certain uses, including aviation hydraulic fluid, lubricants and greases, new and replacement parts for automobiles and other motor vehicles, and distribution of automotive parts to which PIP (3:1) has been added.
- 2,4,6-Tris(tert-butyl)phenol, (2,4,6-TTBP), antioxidant used as fuel/lubricant additive:
 - > EPA proposed to ban distribution in commerce of 2,4,6-TTBP and products containing 2,4,6-TTBP in any container with a volume of less than 55 gallons for any use to prevent consumer and small commercial uses.
- Pentachlorothiophenol (PCTP), used as cross-linking agent in rubber:
 - > EPA proposed to ban the manufacture, processing, and distribution in commerce of any product containing a concentration of PCTP greater than one percent by weight.



Looking to 2020, EPA will confront the need to initiate Section 6(a) actions on those of the “first 10” risk evaluation chemicals for which it finds an unreasonable risk.

- Decabromodiphenyl ether (decaBDE), used as a flame retardant:
 - EPA proposed to ban manufacturing, processing, and distribution, including in most articles.

Looking to 2020, EPA will confront the need to initiate Section 6(a) actions on those of the “first 10” risk evaluation chemicals for which it finds an unreasonable risk. The statute requires that EPA propose such Section 6(a) rules within one year after the final risk evaluation is published (this deadline likely works out to be sometime in **2021**) and must promulgate the final rules within one additional year, with a two-year extension possible. Given the likelihood that EPA will need to prepare Section 6(a) rules for most of the “first 10” risk evaluation chemicals, as well as the logistical, policy, and legal challenges in preparing multiple complex *de novo* rules under new TSCA on these chemicals, the next several years will be daunting ones for EPA.

(d) Risk Management Litigation

Multiple challenges to EPA’s final methylene chloride rule were filed in the U.S. Court of Appeals for the Second Circuit, and the court has consolidated the cases. *Labor Council for Latin Am. Advancement v. EPA*, No. 19-1042. Several public interest groups and two mothers are challenging the final rule for allowing commercial use of methylene chloride to continue. According to their October 16, 2019, opening brief, EPA’s final rule fails to regulate methylene chloride’s paint stripping uses “to the extent necessary so that [they] no longer present[]” unreasonable risk, as required by TSCA Section 6(a). The petitioners cite EPA’s risk assessment for methylene chloride, noting that it shows that workers face the greatest risks from methylene chloride and that delayed protections may result in additional deaths. Petitioners ask that the methylene chloride rule be remanded to EPA with instructions to issue final requirements for commercial uses consistent with its risk assessment. The Halogenated Solvents Industry Association

(HSIA) also challenged EPA’s final rule for making it “effectively impossible” for small businesses to obtain methylene chloride paint strippers in practical quantities. HSIA asks the court to “overturn the parts of the rule that have so disrupted the supply chain.” Briefing will continue in 2020.

(e) Prioritization and Risk Evaluation Litigation

On November 14, 2019, the U.S. Court of Appeals for the Ninth Circuit [issued its decision](#) in a case filed in 2017 challenging EPA’s prioritization and risk evaluation rules. *Safer Chemicals, Healthy Families v. EPA*, No. 17-72260. The court heard oral arguments on May 16, 2019. During oral arguments, the court asked the petitioners whether they had standing to be before the court. The court suggested that petitioners could wait to see whether EPA will ignore certain uses of chemicals in its risk evaluations. EPA maintained that petitioners were raising a challenge to a hypothetical scenario and that EPA has the legal discretion to study whichever chemical uses it sees fit. Following oral argument, the court ordered petitioners to file a supplemental brief addressing why they should be allowed to bring suit against EPA. The petitioners argued in their supplemental brief that they have standing because the TSCA Framework Rules threaten their members’ concrete interests in minimizing toxic chemical exposures; they have information standing for each of their challenges to the Framework Rules; and their claims are ripe. EPA responded that petitioners “have plausibly alleged standing to challenge only the definitional interpretation of ‘conditions of use’ and the two provisions still subject to EPA’s motion for voluntary remand.” As to the remainder of petitioners’ claims, EPA maintains that petitioners’ allegations “are based on hypotheticals and other non-final agency actions currently being considered by the agency.” EPA states that if it “ever takes final agency actions based on the decisions Petitioners hypothesize, those would be the proper actions for Petitioners’ challenges.” In its November 14, 2019, decision, the court held that it lacks jurisdiction to review petitioners’ claim that TSCA requires EPA to evaluate risks associated with a chemical’s uses collectively before determining that the chemical is safe.

The court held that petitioners' claim that EPA must consider all of a chemical's conditions of use in that evaluation fails on the merits. The court granted in part the petition for review with respect to petitioners' challenge to EPA's exclusion of "legacy uses" and "associated disposals" from the definition of "conditions of use," and those portions of the risk evaluation rule's preamble are vacated. The court noted that because petitioners' challenges to EPA's prioritization rule are "entirely encompassed" within their challenges to the risk evaluation rule, the challenges rise or fall together. The court thus focused only on the risk evaluation rule.

(f) Proposed SNURs on Existing Chemicals

In April 2019, EPA issued a [final SNUR](#) regulating the discontinued uses of asbestos. The rule requires that, prior to engaging in a discontinued use (or other new use), an entity must submit a SNUN that EPA must review under Section 5 and take any necessary regulatory measures under Section 5(e) or 5(f). This rule was significant as it closed a regulatory loophole that could have allowed old uses of asbestos to come back into the market without EPA review and regulation. We note that the proposed rule and its legal effect were widely misunderstood by the public. This was likely due to inaccurate advocacy by some stakeholders as somehow "allowing" or "encouraging" new uses of asbestos. Over 90 percent (5,386) of the individual comments received on the proposed SNUR were anonymous and the majority were generally considered not germane to the proposed rule considering the purpose and effect of the action, but, where appropriate, they were addressed in EPA's Response to Comments document on the rulemaking.

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. Because of the significant burden of the required Framework Rules, the risk evaluations and risk management actions related to the "first 10" existing chemicals, and the PBTs, EPA has not had the bandwidth to move these SNUR actions forward.

In our view it is not surprising that nothing has been issued yet, and B&C would not be surprised if the dates slip further for several of these actions. The one exception is the SNUR on LCPFACs that, based on EPA's PFAS Action Plan (discussed further below), we would expect to be published in 2020 as a supplemental proposal to make inapplicable the



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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."

1.4 Sections 8 and 14 -- Reporting and Confidential Information

(a) TSCA Inventory and Active Chemical Designation

As of August 2019, only chemicals designated as active on the TSCA Inventory can be manufactured, imported, or processed for a nonexempt commercial purpose. Chemicals designated as inactive on the TSCA Inventory can be reintroduced into commerce for nonexempt commercial purposes following notification to EPA via a Notice of Activity (NOA) Form B, found in EPA's Central Data Exchange (CDX). Upon receiving such notification, EPA will change the designation of substances from inactive to active. The effective date of an NOA Form B submission is the date that it is received by EPA electronically.

(b) EPA Policy on Deficient Confidential Business Information (CBI) Claims

Stakeholders are urged to be aware that the former EPA policy, to send notices of deficiency to submitters that submitted procedurally flawed CBI claims, no longer applies. EPA's new policy went into effect on August 15, 2019. Companies that do not properly sign or substantiate CBI claims will not be informed of their error and EPA will disclose the information claimed as CBI without notice.



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(c) CBI Inventory Review Rule

TSCA Section 8(b) requires EPA to issue a rulemaking on CBI claims made when chemicals were reported as "active" in response to the Inventory Notification process in 2018. EPA issued a proposed rule in April 2019 on the anticipated

procedures for CBI substantiation on chemical identity and subsequent EPA review. EPA must issue the final rule on review of chemical CBI claims one year after the publication of the updated TSCA Inventory. Although the updated Inventory was available on February 19, 2019, the *Federal Register* notice was not published until May 15, 2019; therefore, the EPA CBI rule must be issued by **May 15, 2020**. The CBI reviews covered in the rule must occur within five years of the date of the TSCA Inventory publication, or no later than **May 15, 2024**.

Note that the lawsuit on the Inventory notification rule (discussed below) impacts the CBI review rulemaking process. In response to the court order, EPA is working to address substantiation questions regarding reverse engineering applicable to persons claiming a specific chemical identity as CBI. EPA published a supplemental notice of proposed rulemaking (NPRM) in the *Federal Register* on November 8, 2019. The supplemental notice includes two additional questions about “reverse engineering” that manufacturers and processors would be required to answer when making CBI claims. According to EPA, these questions would help provide additional information on CBI claims for specific chemical identities and would ensure that chemical companies are fully supporting their CBI claims. EPA is also proposing a process for manufacturers and processors to use to amend and update certain previously submitted claims to include responses to these additional questions, as required to be addressed by the court’s decision.

EPA notes that the supplemental notice is limited in scope and that “[i]t impacts only the universe of CBI claims made for specific chemical identities for chemicals reported as ‘active’ in response to the Active-Inactive Rule.” Comments were due December 9, 2019.

(d) Inventory Notification Rule Litigation

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

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

(e) Unique Identifier (UID) Implementation

TSCA Section 14(g)(4) requires that EPA develop a system to assign a 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 expect that EPA will include UIDs for all substances on the confidential por-

tion of the Inventory for which EPA has reviewed and approved the CBI claim.

(f) Mercury Rule

In 2019, companies that produced, imported, stored, used, sold or exported mercury were subject to reporting under the June 27, 2018, EPA final rule to provide information to assist in the preparation of an “inventory of mercury supply, use, and trade in the United States” [83 Fed. Reg. 30054](#). In March 2019, EPA posted a compliance guide for impacted stakeholders, “[Reporting Requirements for the Mercury Inventory of the Toxic Substances Control Act](#).” The deadline for reporting was July 2019.

Information elements included on the mercury inventory reporting were amounts of mercury produced, imported, stored, used, sold, or exported; types of mercury-added products made; types of manufacturing processes; information on how the mercury is used; industry sectors where mercury-added products were sold; country of origin for products; and destination country for exported products. Information was reported via EPA’s CDX.

The updated mercury inventory should be published in 2020, reflecting the data compiled in 2019. EPA will reportedly use the information collected to identify processes or products that intentionally add mercury and determine if actions are needed to achieve further reductions.

While EPA states that mercury inventory reporting records must be retained for a period of three years beginning on the last day of the reporting year, submitters are encouraged to retain their records longer than three years. Reporting occurs every three years, so the next reporting cycle will be in **2022** for mercury information for calendar year **2021**.

(g) Mercury Rule Litigation

The U.S. Court of Appeals for the Second Circuit heard oral arguments on November 20, 2019, in the challenge to EPA’s mercury inventory reporting rule. *NRDC v. EPA*, No. 18-2121. In its May 22, 2019, final brief, NRDC argued that the exceptions in EPA’s mercury rule are unlawful and must be set aside. According to NRDC, the component exception contravenes TSCA’s requirement that EPA require reporting on mercury-added products. NRDC states that the Chemical Data Reporting (CDR) ex-

ception is contrary to TSCA and “the product of irrational decision making.” EPA filed its final brief on May 22, 2019, arguing that the mercury rule’s approach to product manufacturers, including assembled product importers and product assemblers, is consistent with TSCA. According to EPA, its treatment of CDR rule reporters was “logical, well-explained, and neither arbitrary nor capricious.” Vermont filed its final brief on May 22, 2019, arguing that the mercury rule’s exemptions contravene the purposes of TSCA and they should be vacated under the APA and that the mercury rule’s exemptions impede it and other Interstate Mercury Education and Reduction Clearinghouse (IMERC) states from enforcing their own laws enacted to prevent mercury contamination. During oral argument, the court questioned whether EPA could still make a reasonable estimate to guide its mercury reduction decisions, despite the “less than optimal” exemptions described by NRDC. The court asked EPA if it has the discretion to make a judgment that Congress “doesn’t want to know” if an imported product contains mercury. EPA maintained that Congress did not ask for a general inventory.

(h) Nomenclature

We know that a novel biobased source for complex chemical substance leads to a new chemical identity under current EPA nomenclature policies, even though the chemical constituents of this new biobased chemical are indistinguishable from similar existing chemistries. Further, as a result of the new chemical identity, the biobased chemical is subject to Section 5 new chemical reviews that can and do result in EPA applying risk management conditions on the production and distribution in commerce of these renewable chemicals; restrictions that may not apply to older chemistries (whether from petroleum or traditional bio sources, such as vegetable oils). This results in an uneven regulatory playing field for these newer, more benign chemistries.

B&C staff, in coordination with the [Biobased and Renewable Products Advocacy Group \(BRAG®\)](#), will be continuing to advocate for equivalency determinations for certain biobased chemicals. Given the goal of developing chemicals that might offer a more benign environmental impact, it is imperative that this issue -- in which chemicals developed as potential substitutes for existing chemicals are not listed on the TSCA Inventory because substance identity specifies the source of the substance -- be discussed in a thorough and thoughtful manner by EPA.



By mid-2020, EPA will likely be assessing fees, as appropriate for high-priority chemicals and, per the final rule, the entire risk evaluation fee of \$1,350,000 for TSCA Work Plan chemicals will be required 60 days after the scope is published.

(i) CDR Rule Changes

A new round of CDR reporting will begin on **June 1, 2020**, with a final deadline of **September 30, 2020**. Unfortunately, the timing of EPA's proposed changes to CDR in April 2019 have once again left the regulatory community in flux prior to this next reporting cycle. While the modifications proposed were not necessarily significant, it was the fifth round of changes in as many reporting cycles for CDR (or its predecessor the Inventory Update Reporting (IUR) rule). As of October 28, 2019, stakeholders are still waiting on the final rulemaking that could include changes on how processing and use information will be categorized. Without knowing this type of information, companies that opt to automate information collection or otherwise wish to begin the process of identifying reporting categories cannot move forward. As noted in past Forecasts, we hope that these upcoming adjustments arising from the April 2019 proposal will be the last for a while, so companies can set their internal processes with the confidence that no further changes are forthcoming.

Critical for small businesses is the proposal to reset the small manufacturer definition for purposes of CDR. EPA is expected to raise the annual sales thresholds from \$4M for any reporting and \$40M for chemicals less than 100,000 pounds per site to \$11M and \$110M, respectfully. These proposed increases will provide important relief for those companies that would, by all other accounts, be viewed as small businesses, but were above the outdated sales thresholds in previous CDR cycles. Yet again, until EPA issues a final rule on these changes, companies that might benefit from the small business definition change are left in limbo - not knowing if they will be required to report or not.

EPA is expected to rely on information reported on the 2020 CDR in its next round of Section 6 prioritization. With the 2019 prioritization process completed, and a three to three and a half year window for completing risk evaluations on the designated high-priority chemicals, the next round of prioritization would be expected in **2022**.

1.5 Section 26 -- Administration of TSCA

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

EPA issued the final Section 26(b) fees rule on October 17, 2018. [83 Fed. Reg. 52694](#). The final rule calls for EPA to collect fees for Section 6 risk evaluation work in conjunction with the publication of the risk evaluation scope. As discussed above, EPA was required to issue the next 20 high-priority designations in final by December 22, 2019 (which it did on December 20, 2019). Once a chemical is designated as 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, as appropriate for such chemicals and, per the final rule, the entire risk evaluation fee of \$1,350,000 for TSCA Work Plan chemicals will be required 60 days after the scope is published.

This timeline requires that industry stakeholders be prepared to organize into consortia quickly in 2020 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.

1.6 Section 21 -- Litigation and Petitions

EPA continues to wrestle with a complaint filed on April 18, 2017, in the U.S. District Court for the Northern District of California 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. The complaint was filed following EPA's denial of a [TSCA Section 21 petition](#) requesting it to exercise its Section 6 authority to prohibit the purposeful addition of fluoridation chemicals to U.S.

water supplies filed by several organizations and individuals. On November 15, 2019, the court held a motion hearing to determine whether the case will proceed to oral argument. On December 30, 2019, the court denied the plaintiffs' and the defendant's motions for summary judgment. A bench trial is scheduled to begin on **April 20, 2020**. More information on the TSCA Section 21 petition is available in our March 7, 2017, blog item, "[EPA Denies TSCA Section 21 Petition on Fluoride Chemicals in Drinking Water; Provides Response to Petition.](#)"

Other suits challenging EPA's denial of TSCA Section 21 petitions have continued. Two suits in the U.S. District Court for the Northern District of California concern EPA's dismissal of TSCA Section 21 petitions regarding asbestos. In the first case, the Asbestos Disease Awareness Organization (ADAO) and five other non-governmental organizations (NGO) [petitioned EPA](#) on September 27, 2018, requesting that EPA initiate rulemaking under TSCA Section 8(a) to amend the CDR rule to increase reporting of asbestos to CDR. EPA denied the petition on December 21, 2018, on the grounds that the petitioners did not demonstrate that it is necessary to amend the CDR rule. On February 18, 2019, ADAO filed suit regarding EPA's denial of its petition. *ADAO v. EPA*, 3:19-cv-871. On September 5, 2019, the court held a hearing on EPA's motion to dismiss for lack of jurisdiction. Parties filed briefs on September 27, 2019, addressing whether the underlying Section 21 petition constituted a request to initiate a proceeding for the issuance of a new rule (and thus subject to Section 21(b)(4)(B)) or an amendment of an existing rule (and thus subject only to Section 21(b)(4)(A)). On November 15, 2019, the court denied EPA's motion to dismiss. The court dismissed with prejudice ADAO's Section 21 claim for *de novo* review. The court noted that because ADAO's petition "expressly requests the EPA to modify the CDR rule for stricter asbestos-reporting, by its terms, it does not fall under Section 21(b)(4)(B)." According to the court, because ADAO's petition seeks an amendment to the existing CDR rule, "APA review is appropriate, and *de novo* review under Section 21(b)(4)(B) does not apply." Because ADAO sought an amendment to the existing CDR rule, the court concluded that its APA claim is properly before the court. More information on EPA's denial of the Section 21 petition is available in our January 4, 2019, [blog item](#).

In the second related case in the U.S. District Court for the Northern District of California, following EPA's dismissal

of a January 31, 2019, petition, a coalition of 11 state attorneys general filed a lawsuit on June 28, 2019, against EPA for its failure to initiate an asbestos reporting rule under TSCA Section 8(a). *California v. EPA*, No. 3:19-cv-3807. The coalition argues that EPA wrongfully denied the states' [January 31, 2019, petition](#) asking EPA to issue a rule for the reporting of the manufacture, import, and processing of asbestos. The coalition includes the Attorneys General of California, Connecticut, Hawaii, Maine, Maryland, Massachusetts, Minnesota, New Jersey, Oregon, Washington, and the District of Columbia. According to the coalition, the rulemaking they requested is necessary under TSCA, and the denial of their petition was arbitrary and capricious and violates EPA's obligations under TSCA. On September 9, 2019, the court granted the parties' stipulation to stay EPA's responsive pleading deadline pending resolution of the motion to dismiss in *ADAO*. More information on the suit is available in our July 3, 2019, [blog item](#).

On August 7, 2019, the Public Employees for Environmental Responsibility (PEER) filed a [petition for rulemaking](#), asking that oil refineries be prohibited from using hydrofluoric acid in their manufacturing processes and that oil refineries be required to phase out the use of hydrofluoric acid within two years. According to PEER, TSCA and CAA regulate hydrofluoric acid and provide the statutory authority for EPA to issue a regulation prohibiting the use of hydrofluoric acid in oil refineries. PEER states that under TSCA, EPA "possesses the power to promulgate rules banning chemicals that pose an unreasonable risk to human health." On November 4, 2019, EPA [denied PEER's petition](#), based on the petition's lack of sufficient facts establishing that it is necessary for EPA to issue a rule under TSCA Section 6(a). According to EPA, the petition lacks the analysis that would be expected in a TSCA risk evaluation preceding a Section 6(a) rulemaking. Whether PEER will challenge EPA's dismissal of its Section 21 petition in court is unclear.

1.7 Other Topics

(a) OPPT Staffing and Reorganization

EPA shelved its plan to reorganize OPPT. It is not clear if the plan has been withdrawn or is simply on the back burner. The delay may simply be a response to the reality that the new organization requires an expansion in the number of staff and management to be fruitful. OPPT is currently operating with acting Directors for both the

Chemical Control Division and Risk Assessment Division. The new organization would require two additional Division Directors, as well as additional supervisors and staff. Given EPA's current staffing shortages, and the pending departure of Dr. Jeffery Morris, the OPPT Office Director, EPA will have its hands full filling current positions in the current organization. EPA has been hiring new, largely junior staffers, but getting OPPT up to its full complement of staff and management will take some time.

(b) PFAS

Congressional scrutiny of PFAS significantly ramped up in 2019 and legislative activity is expected to continue in 2020. PFAS has a broad range of applications across a number of industries, including automotive, aeronautics, medical, and electronic technologies. With increased public awareness of drinking water contamination from historic use of long-chain PFAS substances (*i.e.*, perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS)), as well as ongoing attention on GenX detections in drinking water sources in North Carolina, legislators face mounting pressure to direct agency action on regulating PFAS. Environmental advocates are calling for broad regulation of PFAS as a class in spite of the vast differences in the chemical properties and behavior of the substances that are considered PFAS under the broad definition, including substances that are used in small quantities as process chemicals and that have not been detected in the environment. Legislators introduced dozens of bills in 2019 aimed at regulating PFAS through a broad swath of environmental statutes, including Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) hazardous substance designations, Toxics Release Inventory (TRI) listings, CAA hazardous air pollutant (HAP) listings, and drinking water maximum contaminant levels (MCL).

In the TSCA realm, a legislative package marked up in the House E&C Committee in the fall includes legislation, that if enacted would: (1) prohibit EPA approval of PMNs for new PFAS substances (H.R. 2596); (2) prohibit the manufacture or process of any PFAS substance as a significant new use (H.R. 2600); and (3) require TSCA Section 4(a) testing for all PFAS manufactured or processed unless such testing would be duplicative as determined by the EPA Administrator (H.R. 2608). In addition to the E&C package, a bundle of PFAS-related amendments are attached to both the House and Senate versions of

the National Defense Authorization Act (NDAA) -- *i.e.*, the U.S. Department of Defense (DOD) spending bill. DOD is one of the largest users of PFAS-containing firefighting foams, and military installations are a common place where PFAS is detected at levels of concern. The Senate version of the NDAA is narrower in scope, while the House version takes a broad "class approach" to regulation. It is unclear at this time where NDAA negotiations will go and it is possible that all amendments will be stripped in the final version. As for the E&C package, it will need to hitch a ride on another "must pass" legislative vehicle and is unlikely to pass as "stand alone" legislation.

Meanwhile, EPA is poised to issue some of the first proposals outlined in its PFAS Action Plan released in February 2019. The initial regulatory actions will include a re-proposal of a long-chain SNUR, as the earlier proposal issued in 2015, pre-Lautenberg, did not address the new SNUR requirements for articles. As reported in our December 5, 2019, memorandum, ["EPA Seeks Information on PFAS for Possible Addition to TRI List of Toxic Chemicals,"](#) EPA also issued an ANPRM to collect input on potential TRI listing additions for PFAS substances. Finally, EPA is expected to release proposed MCLs for PFOA and PFOS, and likewise propose to designate PFOA and PFOS as hazardous substances under CERCLA. The latter action is of particular concern for manufacturing sites where legacy PFAS was once made.

The slow pace of the rulemaking process is unlikely to alleviate pressure for Congress to act before EPA can carry out its regulatory process. We expect Congressional interest and the likelihood of legislative action to continue into and through 2020.

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C. FIFRA

1. Predictions and Outlook for the OCSPP's Office of Pesticide Programs (OPP) 2020

1.1 Pesticide Registration Improvement Act (PRIA)

In January 2019, the short-term continuing resolution (CR) that ended the federal government shutdown and re-opened the government included an extension of the Pesticide Registration Improvement Extension Act (PRIA 3) through the duration of the funding measure, February 15, 2019. This was yet another extension in the protracted effort to renew statutory authorization for the fee-for-service program that has underpinned the federal pesticide regulatory program for more than 15 years. After considerable activity in the Senate and House in the second half of February 2019, PRIA 4 was passed and then signed into law on March 8, 2019, reauthorizing PRIA through FY **2023**. See our blogs titled "[Continuing Resolution to Re-open the Government Includes PRIA Extension](#)," "[Federal Budget Deal Negotiations Fail to Advance PRIA Reauthorization](#)," "[House and Senate Approve PRIA 4 Legislation](#)," and "[President Trump Signs PRIA 4 Reauthorization Bill](#)."

As with preceding reauthorizations, PRIA 4 contained a range of revisions based on OPP's ongoing experience implementing its program. In addition to increasing the number of registration action categories from 189 to 212, PRIA 4 increased the total fee amount that OPP may collect annually in maintenance fees from \$27.8 million to \$31 million. PRIA 4 explicitly authorized use of the maintenance fees in the registration review process to offset costs for endangered species assessment. OPP must complete the current registration review cycle by **October 1, 2022**.

PRIA and its reauthorizations have directed set-asides for funding specific projects. Of note, PRIA 4 created a new set-aside to support inspections for compliance with the Good Laboratory Practice (GLP) standards. Another set-aside will

support development and related rulemaking for efficacy guidelines for invertebrate pests of significant public health or economic importance, with a mandatory schedule of deliverables. PRIA 4 authorizes up to \$500,000 annually for these projects through **2023**. EPA, including OPP and the Office of Enforcement and Compliance Assurance (OECA), are expected to engage on these projects in 2020 and beyond.

In PRIA 4, Congress directed EPA no later than **October 1, 2021**, to implement the Agricultural WPS revision published on November 2, 2015, and the Certification of Pesticide Applicators final rule published on January 4, 2017. [80 Fed. Reg. 67496](#); [82 Fed. Reg. 952](#). PRIA 4 precludes revisions to these rules, except after notice and comment of at least 90 days, and revisions to the AEZ provisions. As noted elsewhere in this Forecast, EPA has followed up on these directives.

Finally, OPP increased PRIA 4 fees on October 1, 2019, by five percent, consistent with past increases. The revised fees will remain in effect until **September 30, 2021**. [84 Fed. Reg. 52085](#).



PODCAST:

[Pesticides: Navigating New Technologies](#)

1.2 Chlorpyrifos

Chlorpyrifos is a widely used organophosphate (OP) 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 2007 petition.

Although EPA had issued a preliminary decision indicating that it intended to deny parts of the 2007 petition, EPA decided in 2015 to propose revocation of the tolerances and cancellation of the registrations for chlorpyrifos. This proposal was materially based on a controversial decision to retain the ten-fold Food Quality Protection Act (FQPA) safety factor for all OP pesticides because of neurodevelopmental effects that were reported in some epidemiology studies for chlorpyrifos. This action is described in more

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Instead of stating that the chlorpyrifos review will continue until 2022, EPA has now stated it will expedite the review and issue a proposed registration review decision by October 2020.

detail on [B&C's Pesticide Law and Policy Blog® under key word chlorpyrifos](#). See also the 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 concerning chlorpyrifos had a significant potential to reach far beyond chlorpyrifos in their potential impact. For example, EPA utilized epidemiology data in making a decision to retain the FQPA safety factor, and EPA assumed without knowing the mode of action for the effects attributed to chlorpyrifos that such effects would be pertinent to all other OP pesticides as well. 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 may have important implications for other OP insecticides, even to the extent that some fear (and others advocate) a complete elimination of all OP product registrations.

The Trump Administration arrived long after the beginning of this controversy and only a few months before the court-ordered March 31 deadline for final EPA action on chlorpyrifos. As many expected, in meeting the deadline for a decision on the petition, the Trump EPA declined to act on EPA's prior proposal to revoke chlorpyrifos tolerances and instead denied the petition, stating that it would continue to review the safety of chlorpyrifos and would make a further determination as part of the registration review of the pesticide, due by **2022**.

In response to what was described as EPA inaction, Senator Udall (D-NM) and others introduced legislation to eliminate chlorpyrifos uses ([S. 1624](#)). The legislation was not acted upon during 2018, but not surprisingly, in 2019,

Senator Udall reintroduced his bill as [S. 921](#), essentially with the same requirement for EPA to ban chlorpyrifos. In the meantime, as part of the trail of continued litigation over the EPA response to the original petition, on July 19, 2019, the final order denying objections to EPA's 2017 refusal to revoke chlorpyrifos tolerances was signed by AA Alexandra Dunn. In this order, the arguments supporting denial of the original petition were more fully articulated. See our blog titled "[EPA Issues Final Order Denying Objections to EPA's March 2017 Order Denying PANNA's and NRDC's 2007 Petition to Revoke All Tolerances and Cancel All Registrations for Chlorpyrifos](#)." The State of California, which had previously utilized new animal studies that report neurodevelopmental effects from chlorpyrifos exposure below the level that inhibits cholinesterase to designate chlorpyrifos as a Toxic Air Contaminant, subsequently became more involved in the chlorpyrifos debate by relying in part on the same animal studies to issue cancellation notices for chlorpyrifos under California state law. See B&C's FIFRA blog titled "[California DPR Issues Cancellation Notices for Chlorpyrifos, and Establishes a Work Group to Recommend and to Develop Alternatives to Chlorpyrifos](#)."

As of now, the federal registrations and tolerances for chlorpyrifos remain in place, but EPA is still reviewing the pesticide as part of its registration review process. Instead of stating that the review will continue until **2022**, EPA has now stated it will expedite the review and issue a proposed registration review decision by **October 2020**. EPA has also stated that this decision will include a review of the new animal studies on which California has relied.

In the meantime, judicial review of EPA's refusal to revoke the tolerances for chlorpyrifos, including the EPA order denying objections to that refusal issued in July, will proceed in the U.S. Court of Appeals for the Ninth Circuit. On October 16, 2019, the court decided that judicial review of EPA's final decision will proceed as a new case, but this new case has been referred to the same three-judge

appellate panel that issued an adverse decision directing EPA to proceed with revocation of all tolerances and cancellation of all registrations for chlorpyrifos. Now EPA will have to persuade that panel that EPA's latest refusal to take immediate action to revoke the tolerances for chlorpyrifos was not a circumvention of the court order requiring EPA to take final action disposing of the 2007 NRDC and PANNA petition. Regardless of the outcome of the continued chlorpyrifos litigation, EPA's evaluation of the new animal studies for chlorpyrifos for the registration review decision, and EPA's retention of the ten-fold FQPA safety factor for other OP pesticides, will undoubtedly be a source for continued controversy.

1.3 ESA

As in past years, the 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 remains unresolved. The pivotal question essentially remains how extensive EPA's assessment must be to determine compliance with the ESA, and how that assessment is to be addressed with and by the other agencies that have responsibility for implementing ESA. Those agencies are USFWS and NMFS.

In a significant development affecting ESA generally, with specific repercussions for ESA review under FIFRA as well, three final rules were issued by the Services on August 27, 2019, amending ESA implementing regulations. [84 Fed. Reg. 44753](#); [84 Fed. Reg. 44976](#); [84 Fed. Reg. 45020](#). The three rules (one rule issued by USFWS and two rules issued jointly by USFWS and NMFS) include nearly all of the changes to the regulations proposed in July 2018. While not specifically limited to FIFRA actions, there are, for example, changes to the standards under which listings, delistings, reclassifications, and critical habitat designations are made. Thus, these new rules may affect when and how EPA and the Services are required to assess potential effects of a pesticide's registration on endangered or threatened species or their designated critical habitats. Two lawsuits were filed against the Services almost immediately following the issuance of these final rules, one by a coalition of environmental NGOs and another by a coalition of U.S. states and the District of Columbia. How these lawsuits are resolved and how the Services implement these changes are likely to be a significant focus in 2020.

Issues related to the conduct of ESA assessments 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 many years. These issues are the subject of extensive litigation against EPA and the Services alleging violations of substantive and procedural duties under the ESA Section 7 consultation process. Several lawsuits initially filed years ago continue their briefing schedules. Of some note is a stipulated partial settlement published on August 23, 2019, that sets deadlines in **2021** and **2024** for EPA's completion of ESA Section 7(a)(2) effects determinations for several pesticides, and a new lawsuit filed in 2019 alleging EPA violated ESA with regard to its decision that the dicamba use authorized by EPA can have absolutely "no effect" on hundreds of species or their critical habitat.

In 2020, EPA will likely continue its efforts addressing these lawsuits, and also continue to fulfill other ESA obligations, including but not limited to the completion of its ESA evaluation of the effects of four pesticides -- atrazine, simazine, propazine, and glyphosate -- on listed species as part of the registration review under FIFRA. Such review may include initiation of any necessary ESA consultations for these four pesticides, as required pursuant to a settlement agreement reached with the Center for Biological Diversity (CBD).

One other development worth noting is EPA's May 16, 2019, issuance of a proposed rule seeking comment on its Draft Revised Method for National Level Endangered Species Risk Assessment Process for Biological Evaluations of Pesticides (Draft Revised Method). [84 Fed. Reg. 22120](#). EPA further hosted a public meeting on June 10, 2019,

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.



Since the January 2017 policy was announced during the last days of the Obama Administration, EPA has not officially changed much of its guidance about pollinator issues.

where it presented the Draft Revised Method. The Draft Revised Method states it is intended to be “used in the evaluation of potential risks from pesticides to listed species” and that it will be “used by EPA for making effects determinations under registration review, which will also be used to inform biological opinions from the Fish and Wildlife Service and the National Marine Fisheries Service [(the Services)].” See our blog titled [“EPA Issues Draft Revised Method for ESA Pesticide Assessments.”](#)

This is the latest chapter in the long saga of coordination between ESA review by the Services and EPA registration activities. The steps outlined in the Draft Revised Method are designed to improve the coordination of work between the agencies and represent an important step in designing a framework that might make the current situation more reliable, predictable, and efficient. The current process has been subject to criticism on a number of fronts, with the current biological evaluation process seen as unsustainable given the amount of resources and time consumed by the first biological evaluations.

The goal is eventually to have the Services and EPA “play nice together” and implement a leaner and more efficient process, which is considered absolutely necessary if EPA hopes ever to complete appropriate ESA assessments on hundreds of active ingredients formulated into thousands of end-use pesticide products. Such efforts could also represent a cornerstone of the agencies’ meeting provisions in the 2018 Farm Bill (Section 10115), which includes requirements for the agencies to “... increase the accuracy and timeliness” of the ESA consultation process, as well as implement these same policies stated in the Memorandum of Agreement (MOA) between EPA, the Department of the Interior (DOI), and the Department of Commerce (DOC) on [“Establishment of an Interagency Working Group to Coordinate Endangered Species Act Consultations for Pesticide Registrations and Registration Review.”](#)

1.4 Pollinators

During the Trump Administration, there continues to be relatively slow movement on the subject of pollinators. EPA has continued its work under an initiative announced in 2013 when EPA issued revised labeling requirements for neonicotinoid insecticides, which was followed in 2015 by [“EPA’s Proposal to Mitigate Exposure to Bees from Acutely Toxic Pesticide Products.”](#)

The 2015 plan targeted pesticide use by those who use contracted pollinator services and included a list of pesticides (not only insecticides) to which the new labeling requirements would apply. EPA received comments from many grower groups and state pesticide officials critical of various elements of the proposal and did not issue a revised policy until January 12, 2017. See [“EPA Releases Final Policy to Address Acute Risks to Bees from Pesticides and Three Pollinator-Only Risk Assessments for Neonicotinoid Insecticides.”](#)

EPA described the 2017 “Policy to Mitigate the Acute Risk to Bees from Pesticide Products” as a revised approach that is “more flexible and practical” and identified instances where acutely toxic pesticides might be used while minimizing risks to pollinators. The 2017 policy clarified certain thresholds that may indicate risk concerns, and also stated that EPA would impose new labeling on products with certain characteristics.

Since the January 2017 policy was announced during the last days of the Obama Administration, EPA has not officially changed much of its guidance about pollinator issues. On the EPA website for the [“Protecting Bees and Other Pollinators from Pesticides,”](#) almost all of the content is the same as it was during the last days of the Obama Administration.

A bit more behind the scenes is the accumulating data and review experience of both EPA and registrants regarding appropriate pollinator risk assessment requirements. There is some concern among pesticide registrants that EPA may 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. 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.

On March 21, 2019, EPA announced it was updating the “Residual Time to 25% Bee Mortality Data Table.” See our blog titled [“EPA Updates New RT25 Data to Help Beekeepers and Farmers Protect Pollinators.”](#) Updating 2017 guidance, this information indicates how long a specific pesticide may remain toxic to bees and other pollinators following foliar application of the pesticide. EPA uses it as an important indicator of possible risks to pollinators that can help fashion label instructions and best practices advice to help farmers and applicators avoid pollinator risks.

Another ongoing element of EPA’s pollinator strategy is the evaluation of state-managed pollinator protection plans. These are intended to be part of the general approach to EPA’s pollinator protection strategy.

For 2020, registrants, farmers, and other stakeholders await the release of the proposed registration review decisions that are scheduled to be completed, according to the EPA website, “by the end of 2019.” This deadline appears to be slipping into sometime in **early 2020**. The current plan would see release of the proposed interim registration review decisions for the major neonicotinoid pesticides (imidacloprid, clothianidin, thiamethoxam, dinotefuran, and acetamiprid).

In the meantime, a broad challenge to registration of 59 neonicotinoid pesticidal active ingredients that was brought by NRDC in 2017 in the D.C. District Court is pending. NRDC has asked the court to vacate the registrations of all of these pesticides, which it asserts pose a special and unacceptable risk to pollinators. The court denied motions by EPA and industry intervenors to dismiss the case or to issue a judgment on the pleadings on September 24, 2019, and briefing on the merits will commence in the **first half of 2020**.

1.5 Duplicative Permitting under FIFRA and the Clean Water Act (CWA)

A 2009 U.S. Court of Appeals for the Sixth Circuit Court decision resulted in CWA National Pollutant Discharge Elimination System (NPDES) permitting aerial spraying of pesticides into, over, and near federal jurisdictional waters, or “Waters of the United States” (WOTUS). Agriculture stakeholders assert that CWA permitting is duplicative, burdensome, and unnecessary for FIFRA-compliant pesticide applications. In fact, 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, legislators have introduced bills in the House and Senate that would amend both the CWA and FIFRA to exempt FIFRA-compliant pesticide applications from NPDES permitting. Proponents were successful in passing legislation in the Republican-controlled House and even garnered the support of over two dozen Democrats, but legislation stalled in the Senate each time. In the 116th Congress, Representative Robert Gibbs (R-OH) again reintroduced the NPDES “fix” legislation ([H.R. 890](#)). With a Democratic majority in the House and shrinking bipartisan support, however, it is unlikely to advance. EPA and the U.S. Army Corps of Engineers’ (USACE) joint proposal to revise and replace the WOTUS definition further complicates efforts to exempt pesticide permitting as many see the replacement WOTUS definition as less protective of waters nationwide. For this reason, legislative efforts that some view as stripping layers of environmental protection, even if redundant, face an uphill battle.

1.6 Dicamba

An issue of increasing notice throughout 2018 was EPA’s decision whether and to what extent to allow continued use of new formulations of dicamba herbicide designed to be used on cotton and soybean crops that have been genetically engineered (GE) to resist dicamba exposure. The new formulations were specifically formulated to reduce potential off-site movement of the herbicide after application. The “old” formulations of dicamba, that are still in wide use for certain applications, historically have been considered to have greater potential for application “drift,” which may cause injury to nearby non-target crops. Many growers were eager for the arrival of the new dicamba formulations and genetically modified organism

(GMO) seeds to control weeds that have become resistant to glyphosate and causing significant reductions in yield.

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 may have been attributable to misuse of older dicamba products, difficulty in following new application and stewardship requirements (buffer zones, wind speeds, and related factors), or unanticipated properties of the new formulations. In addition, the first approvals of the new dicamba formulations were time-limited and subject to renewal by the end of 2018.

On October 31, 2018, EPA announced that it is extending the registration of the new dicamba products for an additional two years. As part of this decision, EPA added further requirements designed to reduce the likelihood of drift problems and non-target crop injury. These requirements include additional training, timing, recordkeeping, and stewardship when using the new formulations. Some of the new requirements are novel, including a requirement that all applicators must be certified applicators (not allowing use by applicators “under the supervision” of a certified applicator). Once again, EPA imposed a time-limit (two years) to the registration.

During the now ongoing two-year renewal period, EPA is expected to be monitoring closely injury and misuse reports, as well as academic and registrant research into the likely cause of any reported problems. EPA will also rely on state officials to report and evaluate the experience of users in their state, especially concerning whether the additional training and stewardship requirements significantly reduce local injury reports.

The National Family Farm Coalition sought judicial review in 2017 in the U.S. Court of Appeals for the Ninth Circuit concerning EPA's decision to register the new dicamba products, but that action was subsequently dismissed as moot. A new case was filed in 2019 after the decision to extend the registration of the new dicamba formulations in late 2018. Due to the short duration of the latest extension, it is questionable whether the matter can be briefed and decided before the new case becomes moot as well.

In 2020, EPA will have to decide once again about whether to extend or to modify the new dicamba formulations. Reports and research about any new drift incidents and possible explanations for any non-target crop injury will be the focus of EPA's 2020 decision.

1.7 Glyphosate

Glyphosate is one of the most widely used herbicides world-wide. Use of glyphosate has greatly expanded since the advent of GMO crops in the mid-1990s designed to be tolerant to glyphosate. Those stakeholders who raise safety concerns about the development and use of genetically modified crops have also taken a strong interest in the safety of any glyphosate exposure.

In 2015, the International Agency for Research on Cancer (IARC) issued a report using its assessment nomenclature and evaluation methods that stated that exposure to glyphosate is “probably carcinogenic to humans.” Although the scientific basis for this IARC classification has been broadly criticized, it was an important factor in several tort decisions in California linking glyphosate exposure to non-Hodgkins lymphoma. These decisions have resulted in increased media visibility and further fueled public concern regarding the safety of glyphosate.

EPA assessments for many years have not identified any concerns about human risks from glyphosate exposure, thereby rebutting inferences based on the IARC classification. On May 6, 2019, EPA released its Proposed Interim Registration Review Decision on glyphosate. [See our blog titled “EPA Releases Proposed Interim Registration Review Decision for Glyphosate; ATSDR Announces Availability of Draft Toxicological Profile for Glyphosate.”](#) In that document, EPA states once again that it has not identified any human health risks from exposure to any use of glyphosate.

Despite EPA's conclusions, the Office of Environmental Health Hazard Assessment (OEHHHA) in 2017 listed



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On August 7, 2019, EPA issued a sharply worded letter to glyphosate registrants, stating that EPA “will no longer approve labeling that includes the Proposition 65 warning statement for glyphosate containing products.”

glyphosate under Proposition 65 (Prop 65) based on the IARC finding. This sparked a lawsuit challenging OEHHA’s listing of glyphosate as a chemical known to cause cancer, and a developing controversy concerning the application of OEHHA’s Prop 65 warning requirements to FIFRA-regulated pesticide labels, an issue that, once resolved, will encompass potential state requirements for FIFRA pesticide labels in all 50 states. Warning requirements on products containing glyphosate have been on hold since February 2018, when the U.S. District Court for the Eastern District of California in *National Association of Wheat Growers et al. v. Becerra* enjoined 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.”

That case was in abeyance pending decisions to be reached in two related First Amendment compelled commercial speech cases (i.e., *en banc* Ninth Circuit case in *American Beverage Ass’n v. City and County of San Francisco*, No. 16-16072 (Ninth Cir. 2018); Ninth Circuit case in *CTIA-The Wireless Ass’n v. City of Berkeley, CA*, No. 16-15141 (Ninth Cir. 2018)). The court agreed with OEHHA to await these decisions since the rulings in those cases could provide useful guidance on the interpretation of the First Amendment in compelled commercial speech cases involving issues of health and safety.

With decisions in those two cases reached on January 31, 2019, and July 2, 2019, respectively, a briefing schedule is again in place for *National Association of Wheat Growers v. Becerra*. Plaintiffs filed a motion for summary judgment on September 25, 2019, where plaintiffs argue that this case “presents a simple question: Can a State force private parties to defame their own products by reciting a cancer warning with which they vehemently disagree, in circumstances where the primary federal regulatory authority body -- in agreement with a nearly unanimous worldwide scientific consensus -- has determined that the state-mandated warning would be ‘false and misleading’?”

Plaintiffs further argue that the recent decisions in the two cases noted above do nothing to “undermine[] this Court’s earlier conclusion that the State cannot compel Plaintiffs to spread a controversial and misleading warning message on the State’s behalf.” A hearing is scheduled for **March 23, 2020**.

While that case proceeds, EPA and OEHHA have issued mutually inflammatory statements regarding their positions on Prop 65 warnings on glyphosate labels. See our blog titled [“EPA Issues Guidance Regarding Prop 65 Labeling Requirements for Glyphosate Products and OEHHA Responds.”](#) On August 7, 2019, EPA issued a sharply worded letter to glyphosate registrants, stating that EPA “will no longer approve labeling that includes the Proposition 65 warning statement for glyphosate-containing products.” EPA stated further that “[t]he warning statement must also be removed from all product labels where the only basis for the warning is glyphosate and from any materials considered labeling under FIFRA for those products.” Moreover, EPA unequivocally stated that “pesticide products bearing the Proposition 65 warning statement due to the presence of glyphosate are misbranded” under FIFRA Section 2(q)(1)(A). Registrants with glyphosate products currently bearing Prop 65 warning language, where the exclusive basis for such warning is based on the presence of glyphosate, were required to submit draft amended labeling that removes Prop 65 warning language by November 5, 2019.

OEHHA immediately released its own press release on August 13, 2019, in which it “objects to US EPA’s characterization of any warning concerning glyphosate’s carcinogenicity as a false claim.” After reiterating OEHHA’s listing glyphosate based on the IARC determination, OEHHA states that EPA’s position “conflicts with the determination made by IARC” and that “it is disrespectful of the scientific process for US EPA to categorically dismiss any warnings based on IARC’s determinations as false.”

While the glyphosate case is based on a specific fact pattern regarding the divergent conclusions of the glyphosate data reached by EPA and OEHHA, the case raises issues regarding express and implied preemption of California duty to warn claims on pesticide labels generally. Final resolution of this case, thus, could set precedent for other challenges related to pesticides listed under Prop 65, whether based on conflicts in data review or more broadly affecting EPA approval of Prop 65 warnings on pesticide labels.

On that note, OEHHA and EPA also remain at odds regarding pesticide label amendments other than glyphosate. OEHHA in 2018 previously provided a very modest accommodation for Prop 65 warnings required on EPA-approved pesticide labels, allowing the word “ATTENTION” instead of “WARNING” 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)). There have been issues, however, with EPA’s consistent approval of label amendment applications involving Prop 65 warning language, continuing the controversy between these two agencies.

1.8 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 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. OPP has had a substantial surplus of fees over the past few years, and the program reports that in recent years hiring has been affected by hiring freezes and decisions to not spend the available funds. Partly, this may be due to the uncertainty surrounding reauthorization of PRIA, now resolved, and OPP has been allowed to fill available positions.

But in a larger sense, government-wide personnel policies, budget uncertainty, and threats to pension and promotion practices as mentioned earlier, nonetheless, have had 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 of the more controversial or widely used active ingredients remain to be completed. And once EPA has issued its conclusions, by definition, the more controversial pesticides are likely to face litigation challenges over touchstone disagreements about ESA assessments, including 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 workforce of EPA and federal government generally presents a serious issue. Estimates are that over 40 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.

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D. U.S. NANOTECHNOLOGY

1. American Conference of Governmental Industrial Hygienists (ACGIH[®])

In 2020, the ACGIH[®] Threshold Limit Values for Chemical Substances (TLV[®]-CS) Committee could include carbon nanotubes on its list of chemical substances and other issues under study. If carbon nanotubes are on the list, then stakeholders will have an opportunity to submit substantive data and comments. The TLV[®]-CS Committee has included carbon nanotubes on its 2018 and 2019 lists of chemicals substances and other issues under study.

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2. National Institute for Occupational Safety and Health (NIOSH)

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

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PODCAST

[All Things Nano with Lisa E. Friedersdorf, Ph.D.](#)

In 2019, NIOSH began working with RTI International to distribute a survey to companies that manufacture, distribute, fabricate, formulate, use, or provide services related to engineered nanomaterials (ENM). The goal of the survey is to assess the impact of NIOSH's contribution to guidelines and risk mitigation practices for the safe handling of ENMs in the workplace. NIOSH will use feedback from the survey to inform its research agenda, enhancing the relevance of guidance intended to manage nanomaterial workers' safety and health.

NIOSH published a *Federal Register* notice on December 17, 2019, requesting information on toxicological and physicochemical data of ENMs to evaluate in developing categorical occupational exposure limits (OEL). [84 Fed. Reg. 68935](#). NIOSH seeks to obtain information, including published and unpublished reports and research findings, to evaluate the possible adverse health risks of occupational exposure to ENMs. Information is due by **February 18, 2020**. NIOSH intends to publish a Technical Report that describes the data, methods, and findings for the development of categorical OELs for ENMs that may include relevant information submitted in response to this request. NIOSH will make the draft Technical Report available for public comment in a subsequent *Federal Register* notice.

E. BIOTECHNOLOGY

In 2020, the U.S. Food and Drug Administration (FDA) will continue to implement its [Plant and Animal Biotechnology Innovation Action Plan](#), pursuing actions intended to support innovation in plant and animal biotechnology and to advance FDA's public health mission. Most recently, FDA introduced the [Veterinary Innovation Program \(VIP\)](#). VIP is a pilot program intended to facilitate advancements in the development of innovative animal products by providing greater certainty in the regulatory process, encouraging development and research, and supporting an efficient and predictable pathway to approval.

In March 2019, FDA and the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) announced a [formal agreement](#) to regulate cell-cultured food products from cell lines of livestock and poultry. In 2020, the agencies will continue to oversee jointly the production of human food products derived from the cells of livestock and

poultry. The formal agreement describes how the agencies will collaborate to regulate the development and entry of these products into commerce. The shared regulatory approach is intended to ensure that cell-cultured products derived from the cell lines of livestock and poultry are produced safely and are accurately labeled.

USDA's National Bioengineered (BE) Food Disclosure Standard (Standard) requires food manufacturers, importers, and retailers who package and label food for retail sale or sell bulk food items to disclose information about BE food and BE food ingredient content. [83 Fed. Reg. 65814](#) (Dec. 21, 2018). The Standard is intended to provide a mandatory uniform national standard for disclosure of information to consumers about the BE status of foods. The Standard defines BE foods as those that contain detectable genetic material that has been modified through lab techniques and cannot be created through conventional breeding or found in nature. The Standard was implemented on January 1, 2020, but small food manufacturers have until **January 1, 2021**, to implement the Standard. The Standard includes a voluntary compliance period that ends on **December 31, 2021**. Mandatory compliance begins on **January 1, 2022**.

USDA's Animal and Plant Health Inspection Service (APHIS) could publish a final rule in **April 2020** on the movement of certain GE organisms. APHIS' June 6, 2019, proposed rule would revise the regulations regarding the movement, including the importation, interstate movement, and environmental release of certain GE organisms in response to advances in genetic engineering and APHIS' understanding of the plant pest risk posed by them, "thereby reducing regulatory burden for developers of organisms that are unlikely to pose plant pest risks." [84 Fed. Reg. 26514](#). The proposed rule would significantly update and modernize the federal government's approach to evaluating and assessing risks posed by GE organisms. APHIS proposes to revise its regulatory approach to align with current scientific knowledge and to base its decision to regulate on the plant-trait-mechanism of action set of considerations. The focus on the inherent risks of a particular product, as opposed to the method by which the product was made, is correct and aligns with other federal agency approaches to assessing risks. The approach set forth in the proposal is a step in the right direction to addressing some of the challenges innovators in this space have faced in commercializing new technologies, as discussed in our report from the Synthetic Biology Project, [The DNA of the U.S. Regulatory System: Are We Getting It Right for Synthetic Biology?](#) As discussed there, the pathway to market for new products

utilizing evolving technologies can be difficult to navigate, posing a challenge for companies in their efforts to commercialize new ideas. Similarly, the novelty posed by some of these evolving products can make it difficult for regulatory agencies to evaluate risks. More information on APHIS's proposed rule is available in our June 7, 2019, memorandum, "[APHIS Proposes Revised Regulatory Framework Regarding the Movement of Certain Genetically Engineered Organisms](#)."

In 2020, EPA will continue to implement its maturing regulatory systems for managing review of biotech innovations for pesticides and industrial chemicals. According to EPA's [New Chemicals Notice Status website](#), EPA reviewed 25 MCANs in FY 2019. Of those 25 MCANs, three were determined to be invalid. Cases may be declared invalid if there is not sufficient detail in the MCAN, but may also be invalid if the organism's manufacture has already been commenced by another submitter, although for MCANs, that is unlikely. Of the remaining cases, EPA found that 19 are not likely to present an unreasonable risk under the conditions of use (including reasonably foreseeable conditions of use). Despite the fact that MCAN review requires an in-depth look at all aspects of the organism including the host organisms, the specific genetic changes, the functions of the various modifications, and the fate of the organisms after use, EPA made its determinations within the 90-day review period without suspensions. The only instances in which cases were suspended were the cases submitted in November 2018 and those cases were extended only about three weeks total, across a period that included the holidays and a three-week government shutdown. Organisms reviewed included: yeast modified to produce biofuels; other microbes to produce enzymes; and microbes used to produce an unspecified chemical substance. This pace of submissions was down from FY 2018, in which EPA reviewed a total of 47 MCANs, 17 of which were deemed invalid. Four of the 30 valid cases are still pending review 13 months after submission. B&C expects no change in EPA's review and approval of MCANs in 2020. Industry continues to invent novel engineered microorganisms and EPA continues to review MCAN submissions in a timely fashion.

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BRAG

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.

F. BRAG

The biobased chemicals industry continues to play an important role in progressing [Goal 9: Build resilient infrastructure, promote sustainable industrialization, and foster innovation](#) under the [2015 United Nations \(UN\) 17 sustainable development goals](#). As recognized by the UN, technological progress in industrial sectors, including developing and embracing renewable chemical options, is the basis for achieving energy efficiency and resource conservation. As noted on the UN web page, "[w]ithout technology and innovation, industrialization will not happen, and without industrialization, development will not happen.



PODCAST

[Biobased Product Regulation](#)

To achieve the larger sustainability promise, biobased chemicals must progress quickly and efficiently from research and development (R&D) platforms to commercially available products -- and that is where [BRAG](#) comes in. BRAG works with its member companies, regulatory groups, and other stakeholders to identify and address challenges associated with commercialization of these new chemical products. In 2020, BRAG will continue its efforts to move the needle on the unique challenge of market impacts based on how a chemical is named, as further described in BRAG's white paper ["Proposal for a Toxic Substances Control Act \(TSCA\) Inventory Representation and Equivalency Determinations for Renewable and Sustainable Bio-based Chemicals."](#) Progress on this important project will be contingent on leaders in the biobased industry taking up this important cause. In addition to the nomenclature challenge, BRAG will also engage with EPA to incorporate further the inherent sustainable nature of biobased chemicals into ongoing TSCA programs, such as its Section 5 new chemical review and prioritization evaluations under Section 6.

Although EPA will play an important regulatory role in the evolution of biobased chemical products in 2020, there are other U.S. federal agencies involved as well. The U.S. Department of Energy (DOE) Bioenergy Technologies Office (BETO), for example, is expected to continue its funding in incentivizing biotechnology and energy efficiency through renewable and sustainable sources. FDA and the USDA will also be looking to increase growth of biotechnology under their respective domains.

Stakeholders in the biobased chemical industry should also plan to monitor activities on Capitol Hill, including the Sustainable Chemistry Research and Development Act, introduced into the House by Congressman Dan Lipinski (D-IL) and co-sponsored by Representative John Moolenaar (R-MI). The bill, which passed the House on December 9, 2019, seeks to address the important need to coordinate R&D efforts among the many federal agencies involved with progressing sustainability in the United States. The Senate has a companion bill that was introduced by Senators Chris Coons (D-DE), Susan Collins (R-ME), Amy Klobuchar (D-MN), and Shelley Moore Capito (R-WV). This type of government coordination will be vital for increasingly moving the biobased chemicals market forward in the new decade, which will, in turn, help achieve the UN sustainability goals by the **2030** deadline.

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G. HAZARDOUS MATERIALS TRANSPORTATION

1. Predictions and Outlook for the U.S. Department of Transportation's (DOT) Pipeline and Hazardous Materials Safety Administration (PHMSA) for 2020

The United States is undergoing an energy renaissance, propelled largely by new oil and gas production technologies and an insatiable global appetite for United States sourced energy. The DOT's PHMSA occupies a central oversight role in this new, booming energy era. PHMSA oversees the safe movement of hazardous materials and energy-related products in all modes of transportation -- ground, rail, air, water, and pipeline. The consistent safe delivery of these commodities provides economic growth, supporting packagers, shippers, and pipeline operators as they move these products to the homes and businesses that rely on them. PHMSA executes its mission by developing safety standards to protect the public, advancing industry safety systems, encouraging innovation and research, providing comprehensive safety inspections, and executing enforcement actions.

PHMSA lacks some of the "glamor" of its sister federal agencies. Despite the perception of a less prominent status among its peer agencies, PHMSA's efforts are of vital national importance. Fatal train derailments, pipeline explosions, fires aboard aircraft caused by improperly packaged or undeclared hazardous materials, and spills of toxic materials are all potential consequences if PHMSA fails to exercise its duty effectively, or if regulated entities fail to adhere to the Hazardous Materials Regulations (HMR).

Safety is PHMSA's primary mission and its paramount priority. PHMSA's simple, but difficult, institutional goal is zero safety incidents. In addition to its regulatory programs that help achieve advancement towards this goal, PHMSA uses outreach programs, R&D efforts, and voluntary compliance initiatives.

PHMSA's FY 2020 funding request demonstrates this dedication to safety. It includes, among others, the following safety investments:

- Funding for 572 positions that directly execute and support standards development, safety inspections, incident investigation, data analysis, and safety support functions;

- Providing \$19.60 million for R&D that supports innovative safety inspection outcomes, advances in safer packaging and transportation methods, and insight into emerging issues such as the safe transportation of liquefied natural gas (LNG);
- Supporting contract safety programs with \$20.54 million to extend and advance systems and technology, data analysis, and information for effective safety programs; and
- Making available \$84.33 million for grants to states, local communities, safety organizations, and not-for-profits to help prevent, plan and prepare for, and respond to hazardous materials incidents.

PHMSA's safety mission extends to more than 40,000 companies involved in the transportation of regulated hazardous materials. PHMSA's oversight includes the expansive U.S. pipeline network of more than 2.7 million miles that moves more than 16 billion barrels of hazardous liquids and gases safely annually. Oversight also extends to the surface, air, and vessel transportation of hazardous materials, which accounts for more than 2.7 billion tons of regulated hazardous products valued at more than \$3.1 trillion, annually.

Each day, hundreds of trucks, trains, aircraft, and pipelines carry hazardous materials across the national transportation network. Despite the dizzying volume of hazardous materials traffic, safe delivery occurs the vast majority of the time. In 2020, PHMSA will continue to devote its resources to ensure this success remains the case.

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

1.1 Regulatory Reform

PHMSA, like every other federal regulatory agency, is pursuing an agenda of regulatory reform. These reform activities are intended to make it more efficient and responsive to changes in the industries that PHMSA regulates. It will continue its regulatory reform efforts in 2020.

While PHMSA works to complete its regulatory agenda, it is also committed to improving the effectiveness of its regula-



Consistent with its regulatory reform push, we expect a proposed rule from PHMSA in 2020 to amend the HMR to adopt a number of actions that would reduce certain unnecessary regulatory burdens on hazardous material transportation without compromising safety.

tory program by conducting a comprehensive evaluation of current, in-progress, and planned regulations. PHMSA's rulemaking efforts are guided by the themes of EOs 13771, 13777, and 13783 and other legal authorities, espousing that there should be no more regulations than necessary, and those regulations should be straightforward, clear, and designed to minimize burdens, without sacrificing safety.

In 2020, PHMSA will continue to confer with the public and other stakeholders to ensure that its regulations are "right-sized." This will allow operators to put additional resources where they will have the maximum safety impact, such as greater investment in safety R&D and technology-based safety enhancements.

Consistent with its regulatory reform push, we expect a proposed rule from PHMSA in 2020 to amend the HMR to adopt a number of actions that would reduce certain unnecessary regulatory burdens on hazardous material transportation without compromising safety. These amendments include deregulatory actions identified by internal agency review and public comments on DOT's regulatory reform and infrastructure notices. PHMSA has identified a number of complex deregulatory opportunities to include package design, regulatory updates, and incident reporting and data. Through this forthcoming proposal, PHMSA seeks to ensure the HMR are amended as necessary to reflect new technologies, improved manufacturing methods, and current economic conditions.

An example of PHMSA's actions on the regulatory reform front is an August 2019 proposal. Specifically, on August 14, 2019, PHMSA proposed several revisions to the HMR. [84 Fed. Reg. 41556](#). PHMSA is responding to numerous petitions for rulemaking submitted by the regulated community that request PHMSA address a variety of provisions, including but not limited to those addressing packaging, hazardous communication, and incorporation by reference documents. The proposed amendments include the following:

- Phasing out the use of non-normalized tank cars to transport poison-by-inhalation (PIH) materials;
- Creating a limited quantity exemption for hydrogen peroxide;
- Revising marking requirements for portable tanks;
- Relaxing standards for metal drums sent for reconditioning;
- Harmonizing limited quantity provisions;
- Revising standards for mobile refrigeration units;
- Removing special provisions for four explosives;
- Issuing a final standard for HM-246 tank cars;
- Phasing out the use of non-HM-246 compliant rail tank cars;
- Allowing non-Resource Conservation and Recovery Act (RCRA) wastes to take advantage of the lab pack exception; and
- Incorporating by reference several industry standards.

1.2 Expanding Rail Cars Eligible for Transporting LNG

Another effort by PHMSA demonstrating its focus on regulatory reform and responding to the U.S. energy boom is an October 24, 2019, proposed rule on the transportation of LNG by rail. On that date, PHMSA and the Federal Railroad Administration (FRA) issued a proposed rule broadening the types of rail cars that are eligible for transporting LNG. [84 Fed. Reg. 56964](#). The rule proposes to revise the HMR to allow rail transportation of LNG in DOT-113 speci-



A risk PHMSA intends to address in 2020 is the issue of undeclared hazardous materials. This occurs when hazardous materials are shipped without being declared as such.

fication tank cars. The proposal is a result of President Trump's April 2019 "Executive Order on Promoting Energy Infrastructure and Economic Growth." The EO recognizes the leading role the United States plays in producing and supplying LNG and the need to continue to transport LNG safely and efficiently.

Currently, the HMR does not authorize the use of DOT-113 tank cars for the rail transportation of LNG. Instead, LNG may only be transported by rail in a portable tank with an approval from FRA. The HMR does, however, authorize the use of DOT-113 specification tank cars for other flammable cryogenic liquids. According to PHMSA, DOT-113 tank cars are specifically designed for the transportation of refrigerated liquefied gases. This design specification may be similarly suitable for the transport of LNG, the proposal states. PHMSA also believes that there are many potential benefits of transporting LNG by rail, including the safety benefits inherent to rail transport and the use of approved tank cars, fuel efficiency, fuel accessibility to remote regions, increased U.S. energy competitiveness, and fewer emissions. We anticipate PHMSA to promulgate this rulemaking in final in 2020.

1.3 Closing the Undeclared Hazardous Materials Gap

A risk PHMSA intends to address in 2020 is the issue of undeclared hazardous materials. This occurs when hazardous materials are shipped without being declared as such. Indeed, closing the undeclared hazardous materials gap is a matter of some urgency for PHMSA. For example, the significant consumer demand for lithium batteries has resulted in rapid expansion in their production, supply, and proliferation. Consequently, this hazard is increasing exponentially, as lithium battery production capacity is set to double by **2021**.

A thought no passenger or crewmember on an aircraft wishes to ponder is whether undeclared hazardous materials are in the cargo hold of the aircraft. This chilling thought, however, can be a reality. According to PHMSA, undeclared

hazardous materials are ending up on passenger and cargo aircraft. Alarming, this issue is not just isolated within the airline industry as the harmful impacts caused by undeclared hazardous materials filter through many other modes of transportation. PHMSA is expected in 2020 to provide information alerts to instill greater awareness in the industry and public about the hazards associated with undeclared and improperly packaged hazardous materials.

The shipment of lithium batteries is a prime example of this hazard. The lack of industry and public awareness on the rules governing the shipment of lithium batteries poses additional risk across multiple transportation modes, and particularly to shipment of batteries on commercial airliners. Consequently, PHMSA and the Federal Aviation Administration (FAA) are rolling out an important new safety awareness initiative called [Check the Box](#) to address these shortcomings.

Shipping dangerous goods without proper designation, packaging, and handling instructions puts people's lives at risk. In many cases, people shipping dangerous goods are unaware that their package is going to be onboard an aircraft -- which makes it unlikely that they will have packaged or prepared it as safely as they should have for that leg of its journey using this means of transport.

Through Check the Box, PHMSA hopes to achieve greater public and industry awareness of common household items that are classified as hazardous materials and how to ship them safely by educating industry and the public through new dedicated content on PHMSA's website, social media, and at engagement events throughout the country.

PHMSA also added a new reporting portal to its website that makes it easier for undeclared hazardous materials shipments -- and other incidents -- to be reported by the public and regulated entities.

We expect to continue to see enhanced focus in 2020 by PHMSA on undeclared hazardous materials shipments and to take steps to reduce their incidence.



PHMSA is considering revising the 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.

1.4 FAST Act Implementation

In 2020, 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 by rail of LNG and crude oil. On December 4, 2015, President Obama signed the FAST Act into law. The 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 Act was catalyzed by a number of incidents involving so-called “high hazard flammable trains.”

In 2020, PHMSA will continue to implement its statutory mandates under the FAST Act. For example, on February 28, 2019, PHMSA issued a final rule pursuant to the FAST Act that expands the applicability of comprehensive oil spill response plans based on thresholds of liquid petroleum that apply to an entire train. [84 Fed. Reg. 6910](#). The rule-making also requires railroads to share information about high-hazard flammable train operations with state and tribal emergency response commissions.

PHMSA also is considering revising the 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 ANPRM in response to the petition. [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.

1.5 Transportation of Lithium Batteries by Air

The transportation of lithium batteries, particularly by air, has been and in 2020 will continue to be an area of concern and focus for PHMSA. To that end, on March 6, 2019, PHMSA issued an interim final rule (IFR) revising the HMR for the transportation of lithium batteries by aircraft. [84 Fed. Reg. 8006](#). The IFR imposes three main requirements:

1. It prohibits the transport of lithium ion cells and batteries as cargo on passenger aircraft;
2. It requires that lithium ion cells and batteries be shipped at not more than a 30 percent state of charge aboard cargo-only aircraft when not packed with or contained in equipment; and
3. It limits the use of alternative provisions for small lithium cell or battery shipments to one package per consignment.

The IFR does not restrict passengers or crewmembers from bringing personal items or electronic devices containing lithium cells or batteries aboard aircraft, nor does it restrict cargo-only aircraft from transporting lithium ion cells or batteries at a state of charge exceeding 30 percent when packed with or contained in equipment or devices. PHMSA made the rule immediately effective and we expect it to devote resources in 2020 to its implementation and enforcement.

1.6 Conversion of Special Permits

PHMSA will continue to convert special permits into the text of the HMR. 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 HMR 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 the need for numerous renewal requests. The rulemaking action, which we expect to be issued in 2020, 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.

1.7 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 on November 27, 2018, proposed revisions to the HMR 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 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 International Civil Aviation Organization Technical Instructions for the Safe Transport of

Dangerous Goods by Air (ICAO Technical Instructions), and the International Organization for Standardization (ISO) technical standards applicable to cylinders. We expect PHMSA to issue this rule in final in 2020.

On December 18, 2018, PHMSA issued a [Notice of Enforcement Policy](#) regarding compliance with international standards. In the policy, PHMSA states that it understands that many offerors and carriers of hazardous materials in international transport will soon be adhering to requirements in the 2019-2020 ICAO Technical Instructions and Amendment 39-18 of the International Maritime Organization (IMO) IMDG Code. In the notice, PHMSA states that it will not take enforcement action against any offeror or carrier using these standards when transporting hazardous materials by certain modes.

1.8 Research Gaps and Priorities

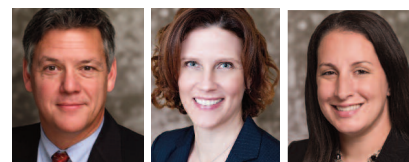
PHMSA has given significant attention to identifying perceived research gaps and prioritizing projects for research. Based on an October 2019 public meeting on R&D needs convened by PHMSA, in 2020, we expect it to focus on research gaps associated with: development of new standards for bulk and non-bulk packaging; proved materials and designs for hazardous materials packaging; classification of hazardous materials; improvements to the Emergency Response Guidebook (ERG) (see below); battery storage device transportation safety; and innovative technologies to improve hazmat transportation safety.

1.9 Revising the ERG

DOT's ERG is the standard for emergency responders. PHMSA developed the ERG for use by emergency services personnel to provide guidance for initial response to hazardous materials transportation incidents. PHMSA has not, however, updated the ERG in several years. We expect that to change in 2020.

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In June 2019, PHMSA held a public meeting discussing the methodology used to determine the appropriate response protective distances for poisonous vapors resulting from spills involving dangerous goods considered toxic by inhalation. PHMSA also solicited comments related to new methodologies and considerations for future editions of the ERG. Additionally, the meeting included discussions on the outcomes of field experiments, ongoing research efforts to understand environmental effects on airborne toxic gas concentrations, and updates to be published in the ERG in 2020.

PHMSA will continue on its course of regulatory reform, closing safety gaps, and buttressing its R&D needs in 2020. We anticipate seeing many revisions to the HMR issued in final form, with PHMSA's continued emphasis on ensuring the safe transportation of hazardous materials.

H. TRADE

1. Introduction

Trying to synthesize concisely all that has happened on the trade front in the past year and cast a light into the darkness of what might occur in 2020 is difficult. The trade wars launched by the Trump Administration have raged for some 18 months, with little substantive achievements and seemingly no positive impact from the fighting. As with many conflicts, casualties abound and no parties have benefited. That is likely to continue into 2020 and as long as the trade skirmishes arise.

There is, however, some reason to hope the trade disputes will abate in 2020. Casting a giant shadow over this terrain is the ongoing trade conflict between the U.S. and China. The dispute has shunted global economic growth into a backwater eddy and rattled financial markets. The two nations have hammered each other with tariffs on hundreds of billions of dollars of goods, with global ramifications, none of them positive. Approximately \$360 billion worth of Chinese goods are now subject to U.S. tariffs, with \$110 billion of U.S. goods slapped with Chinese tariffs. Largely as a result of the tariffs, agriculture and manufacturing in the U.S. are sputtering. Economies across the globe are suffering. The White House's announcement that a "Phase One" deal had been reached with China buoyed the markets and hopes, but as of the writing of this Forecast, the details of the deal are nonexistent and the deal has not been signed. In short, there appear to be no win-

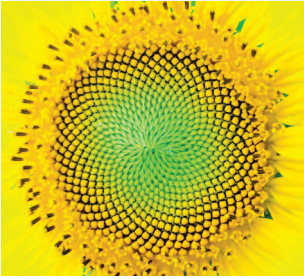
ners at this stage, nor are there likely to be, irrespective of whether, how, and when these disputes end. With the year-end announcement that a Phase One deal has been reached between the two nations, 2020 promises at least some return to normalization and, perhaps, less battering by tariffs.

Other developments contribute to a less than rosy trade prognosis for 2020. The U.S. won a World Trade Organization (WTO) ruling allowing it to impose some \$7.5 billion on tariffs on aircraft and associated parts imported from the European Union (EU), but the EU is poised to respond in kind and to impose several billion dollars in tariffs on the U.S. In addition, the U.S. has withdrawn from several multi-lateral trade agreements and instead is trying to negotiate unilateral deals, with little progress in those areas.

Economic data and indicators presage a worrisome picture for 2020. Perhaps no single indicator describes better the negative impact the trade wars are having than the WTO's revision of its global trade forecast. On October 1, 2019, the WTO scaled back its growth forecast for global trade to 1.2 percent this year and 2.7 percent in 2020. These are the lowest growth rates in a decade. (This spring, the WTO had predicted 2.6 percent and three percent growth, respectively.) The WTO points to several factors for the forecasted declines, chief among them are trade conflicts (especially U.S. vs. China), Brexit uncertainty, and global shifts in monetary policy.

Manufacturing is always an early victim of trade disputes. On October 1, 2019, the U.S. announced that domestic manufacturing activity in September hit its lowest level in a decade. The WTO frets that trouble may spill over to job creation and business investments. Also in September, the U.S. trade deficit fell to its lowest level in five months as imports dropped sharply. DOC stated that the monthly trade gap fell to \$52.5 billion. The data indicate that the tariffs are resulting in fewer U.S. exports, and many economists predict that the trade deficit will continue to be a drag on growth as the continued weakness in the global economy further depresses demand for American goods. Meanwhile, tariffs continue to mount and take their toll, borne on the backs of U.S. businesses and consumers. In September 2019, the U.S. paid a record \$7.1 billion in tariffs, a 59 percent increase compared with a year ago.

As 2019 wanes, the bottom line is that the trade wars are hurting global economies and that there has been no substantive movement on major U.S. trade agreements. There



“America First” remains the banner under which President Trump and his Administration marshal their rhetoric, forces, and actions. This is perhaps no plainer than in his approach to trade issues.

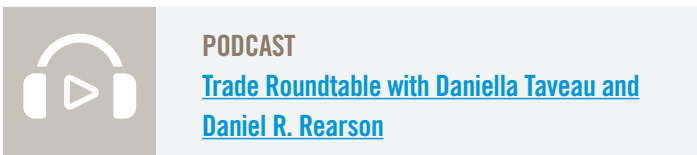
similarly appears to be no imminent seismic agreement or change that would signal an armistice on global trade sniping. As of the writing of this Forecast, the U.S. and China may have reached a “Phase One deal” that could result in both sides suspending tariffs, although even that basic byte of information is disputed by President Trump. In the most significant trade development of 2019, the U.S., Mexico, and Canada reached agreement on the U.S.-Mexico-Canada Agreement (USMCA), the replacement for the North American Free Trade Agreement (NAFTA). On December 19, 2019, after months of negotiations between House Democrats and the United States Trade Representative (USTR), the House of Representatives passed the USMCA. The U.S. and Japan reached an agreement on a narrow sliver of issues, but many argue that the U.S. would have gained more under the Trans-Pacific Partnership (TPP). Negotiations continue on multiple fronts, and that is likely to continue into 2020.

gain that goal, although success there depends upon the Republican Party retaking the House of Representatives.

In his book “The Art of the Deal,” Donald Trump describes his negotiating style as walking into a negotiation meeting and punching the first person he sees in the face. This approach is reflected in his approach towards trade issues, particularly in the dispute with China. He has punched hard, and China and other nations are jabbing back.

A 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 to 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 NAFTA “the worst deal ever,” he vowed to dismantle it. Decrying multi-lateral trade agreements, Mr. Trump claimed that he would withdraw from the TPP, cease negotiations on the Transatlantic Trade and Investment Partnership (T-TIP), and focus instead on securing bilateral agreements. He has done this, and more.

Putting aside political bents, President Trump is following through on his pledge to fight for fair and reciprocal trade. “While past administrations failed to protect hardworking Americans against unfair trade, President Trump is making sure other countries are held accountable,” the White House claims. There is no question that China’s trade practices are unfair, including its theft of American intellectual property (IP). His negotiations to reform our trade relationship with China are intended to blunt those unfair trade practices. President Trump also is calling on Congress to pass the United States Reciprocal Trade Act, giving him the authority to take strong action to pressure countries to lower their



PODCAST

[Trade Roundtable with Daniella Taveau and Daniel R. Rearson](#)

2. President Trump’s Approach to Trade Negotiations

“America First” remains the banner under which President Trump and his Administration marshal their rhetoric, forces, and actions. This is perhaps no plainer than in his approach to trade issues. During his campaign, he directed his ire at “disastrous” trade deals inked by his predecessors. His fury has not waned since his inauguration. For example, during a speech on November 12, 2019, to the Economic Club of New York, President Trump railed that these trade deals have disenfranchised Americans and encouraged the shuttering of U.S. manufacturing plants and the “off-shoring” of American labor. He added that the deals sold out the American worker and diluted the American Dream.

President Trump’s main thrust is to ensure that trade with the U.S. is fair, reciprocal, and that the U.S. is no longer taken advantage of by its trading partners. He is pushing for Congressional passage of the Reciprocal Trade Act to help

trade barriers and open their markets to U.S. goods. Specifically, the legislation would give the President more authority to increase tariffs if other countries' tariff and non-tariff barriers are too restrictive.

There have been some reasons for celebration. In addition to renegotiating NAFTA, President Trump renegotiated the United States-Korea Free Trade Agreement, the Administration is also opening new negotiations with the EU and the United Kingdom (UK), and has reached a slim trade accord with Japan. These achievements, however, are, at best, sideshows: the center ring of the circus for 2020 will continue to be the trade war with China.

3. Pillars of U.S. Trade Policy

President Trump's trade agenda is driven by a determination to use the leverage available to the world's largest economy to obtain fairer treatment for American workers. As we reported last year in our annual Forecast, this policy rests on the following five major pillars:

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

3.1 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 2020, 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.

3.2 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 markets that are more efficient and make it easier for American workers and companies to succeed.

3.3 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 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 and 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.

3.4 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



President Trump continued to levy tariffs against Chinese goods throughout 2019. As of this time, almost every good imported into the U.S. -- valued at some \$360 billion worth of goods -- is subject to tariffs or will be shortly.

WTO disputes, helping force countries to abandon unfair practices and preserving the U.S. right to enact fair laws.

3.5 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. The win in 2019 from the WTO on EU airplane subsidies is proof that the strategy is effective.

4. Two Toughest Kids on the Block: The U.S.-China Trade Dispute

In the 1984 classic movie "Red Dawn," Air Force Lieutenant Colonel Andrew Tanner (portrayed by Powers Boothe) explains to the "Wolverines" what sparked the Communist invasion of the U.S. When asked "[w]hat started it?," he replies, "[t]wo toughest kids on the block, I guess. Sooner or later they're bound to fight."

Although the U.S. and China are the largest economies in the world -- Tanner's "two toughest kids on the block" -- a trade war between the U.S. and China was not inevitable. The election of Donald Trump to the White House, however, raised the prospects to a near certainty. 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, and China is counter-punching.

The arc of the trade dispute spans back to at least June 2016. While campaigning for President, Mr. Trump described his plans for countering China's unfair trade practices. He previewed his moves to apply tariffs and calls China's entrance into the WTO the "greatest jobs theft in history." After his election, in March 2017, he then signed two EOs, one calling for tighter tariff enforcement and the other ordering a review of U.S. trade deficits and their causes. In April 2017, Presidents Trump and Xi Jinping met and agreed to a 100-day plan for trade talks. At the end of that period, however, the

two sides had failed to reach common ground on how to reduce the U.S. trade deficit with China.

In August 2017, President Trump issued a memorandum directing the 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 warranting 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."

On March 22, 2018, the USTR released its report, finding that China's policies result in harm to the U.S. economy at a cost of at least \$50 billion per year. What followed has been a blow-by-blow tariff bout. Following the report, in April 2018, President Trump 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 then he dropped the hammer -- setting a ten percent tariff on \$200 billion worth of imported Chinese products, which he raised to 25 percent on August 1, 2018. A week later, he imposed 25 percent tariffs on \$16 billion worth of goods. China punched back and imposed 25 percent duties on \$16 billion worth of U.S. goods.

President Trump continued to levy tariffs against Chinese goods throughout 2019. As of this time, almost every good imported into the U.S. -- valued at some \$360 billion worth of goods -- is subject to tariffs or will be shortly.

At the June meeting of the G20 in Osaka, Japan, the U.S. and China agreed formally to restart trade talks. After a mere two days of discussions, however, the talks broke down and the

two sides retreated to their corners but talks resumed in October. After their conclusion, President Trump announced that the U.S. and China had agreed to a “Phase One” deal.

The U.S. and China now seem to be aligned publicly when it comes to acknowledging that they have reached some form of an initial trade agreement. Beijing’s description of what President Trump announced could give the President some cover to tout a deal. China likely realized Trump needed to have some credibility with the American people, and hence concurred that a “deal” had been reached. In the days after Trump announced a “Phase One” deal, Beijing hesitated to call what was reportedly agreed upon an “agreement.” On October 16, 2019, however, a Chinese Foreign Ministry spokesman confirmed what Trump stated as true, “and it is the same with our understanding on this agreement.” As part of the deal, China would get a reprieve on another tariff hike in exchange for buying \$50 billion worth of U.S. farm goods.

Recent action by the House of Representatives, however, put the outlook for a meaningful U.S.-China trade deal in less certain waters. The House passed legislation supporting protesters in Hong Kong. In the wake of that action, China reportedly backtracked on part of the deal. The House bill would require an annual review of whether Hong Kong is truly separate from Beijing to the point that it justifies the special trading status it receives under U.S. law and would implement sanctions against officials “responsible for undermining fundamental freedoms and autonomy in Hong Kong.” Chinese officials unsurprisingly did not take the news well, accusing the U.S. of a “political plot” to thwart China’s development. The Chinese Ministry of Foreign Affairs stated that it would [take strong measures](#) against the U.S. if the bill passed.

Tensions have eased somewhat in the wake of the announcement that the U.S. and China, on December 13, 2019, reached a “Phase One” agreement on trade. As part of this Phase One agreement, the U.S. suspended tariffs that were planned on \$160 billion in Chinese imports that were set to take effect. The U.S. also halved the September 1 tariffs from 15 percent to 7.5 percent -- they included all kinds of consumer products such as clothing and sports equipment. Under the deal, China will purchase an unspecified amount of American products and has also agreed to other changes, although details are scant. In a tweet, President Trump stated the U.S. has agreed to a “very large Phase One trade deal with China” and that he has delayed tariffs on imported Chinese products that were set to take effect. Trump also

stated Beijing has agreed “to many structural changes and massive purchases of Agricultural Product, Energy, and Manufactured Goods, plus much more” and that the two countries will begin negotiations over the second phase of a trade deal right away. China too confirmed in a press conference in Beijing that a deal was reached. Both sides have yet to sign the deal. Officials stated the agreement would cover agricultural products, IP protection, currency manipulation, and forced technology transfers by U.S. companies doing business in China. All are issues that Washington has been pressing China to address for years, with limited success.

The U.S. and China enter 2020 with the tariff war in somewhat abated fury. With the Phase One deal reached and tariffs on hold, a sigh of relief from the U.S. manufacturing and agricultural sectors can be heard.

5. Renegotiating NAFTA: USMCA

President Trump has called NAFTA the worst trade deal in history. As a candidate, he vowed to dismantle and renegotiate it in a manner that yields better returns for the U.S. against its North American neighbors. The USMCA attempts to do just that. Although Congress has not yet approved the pact, we anticipate that it will do so in 2020.

The NAFTA negotiations concluded on September 30, 2018, when the U.S., Mexico, and Canada reached agreement on the revamped accord. Now dubbed 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.

Soon after the pact was reached, House Democrats began to strategize how to shape the new agreement. Since its passage, House Democrats have always had four main concerns with the USMCA: its provisions on labor, the environment, pharmaceutical, and general enforcement provisions. Lawmakers also are unlikely to push the deal through Congress unless the White House lifts steel tariffs against Canada and Mexico.

The resolve of Democratic lawmakers stiffened in April 2019 when the International Trade Commission (ITC) released its highly anticipated report on the potential economic benefits of the USMCA. The ITC found, as many expected, that the new

deal will provide modest gains to the U.S. economy and labor market. The report estimates that the USMCA would increase the U.S. Gross Domestic Product (GDP) by \$68.2 billion, or 0.35 percent, by its sixth year. USMCA would also create 176,000 U.S. jobs, increasing domestic employment by 0.12 percent. In short, the USMCA would have a minimal effect on the \$20 trillion U.S. economy. But, compared with other free trade agreements, it would generate a higher growth rate. The ITC estimated the U.S.-Korea Free Trade Agreement would result in U.S. GDP growing by 0.10 percent once fully implemented. It also forecast that the TPP would have increased U.S. GDP by 0.15 percent over 15 years. USTR Robert Lighthizer noted that the ITC's forecast for U.S. GDP growth under USMCA is more than double what the independent panel projected for TPP. "These findings validate President Trump's action to withdraw from TPP and renegotiate the disastrous NAFTA," Lighthizer stated. Democratic lawmakers, already demanding updates to USMCA, seized on the analysis as evidence that the deal does not go much further than its predecessor. Senator Ron Wyden (D-OR), ranking member on the Senate Finance Committee, stated the report confirms USMCA "represents at best a minor update to NAFTA." House Ways and Means Chair Richard Neal (D-MA) stated nothing in the report alleviates concerns over the pact's labor, environment, IP, and enforcement provisions. Neal stated he remains "concerned that these portions of the renegotiated deal are not yet acceptable." One area where ITC's estimates contradict those of the USTR is auto imports. The ITC report stated the agreement's stricter rules of origin would boost auto sector employment by 28,000 jobs over the **next five years**, while also raising prices paid by consumers. USTR also released its own analysis projecting 76,000 job gains, however, due to an anticipated \$34 billion in new investments.

After the ITC report, on May 30, USTR Lighthizer submitted a Statement of Administrative Action to House Speaker Nancy Pelosi (D-CA) to begin the process for seeking Congressional approval of the USMCA. The letter allowed the White House to submit formally the deal to Congress within 30 days. Once the draft deal itself is submitted to Congress, the House must vote on it in 60 days. In addition, at the same time, the White House also announced new tariffs on Mexico, ranging from five to 25 percent on an escalating basis.

USTR Lighthizer spent the summer and fall working with House Democrats trying to iron out differences. On December 10, 2019, the parties signed a revised version of the agreement the House passed the legislation on December 19, 2019.

With the House's passage of the USMCA and the Senate poised to do so **early in 2020**, President Trump has achieved one of his most prominent campaign promises. This next year will be consumed with implementing the details of the trade pact revisions and understanding better the impact it will have on U.S. trade between its two North American neighbors.

6. Abandoning Multi-Lateral Trade Agreements

When President Trump took office, the U.S. was hip deep in negotiations with the EU on T-TIP and with Pacific Rim countries on TPP. President Trump wasted little time in following up on his pledge to abandon these multi-lateral trade agreements. Just three days after taking office, on January 23, 2017, President Trump announced the U.S. withdrawal from the TPP. 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. Most prominent among these are trade accords with Japan, the EU, and the UK. In 2020, the Trump Administration will continue to push forward on trying to reach agreement with these nations.

7. U.S.-Japan Trade Agreement

On October 7, 2019, USTR Lighthizer and Ambassador of Japan to the United States Shinsuke J. Sugiyama signed the U.S.-Japan Trade Agreement and U.S.-Japan Digital Trade Agreement. The U.S.-Japan Trade Agreement will eliminate or reduce tariffs on certain agricultural and industrial products to enhance bilateral trade in a robust, stable, and mutually beneficial manner between our nations, which together account for approximately 30 percent of global GDP.

There is much promise in the agreement, and the U.S. is likely to see it yield benefits in 2020. The agreement will eliminate or lower tariffs for certain U.S. agricultural products. For other agricultural goods, Japan will provide preferential U.S.-specific quotas. Once this agreement is implemented, over 90 percent of U.S. food and agricultural products imported into Japan will either be duty free or receive preferential tariff access. Moreover, when the agreement is implemented by Japan, American farmers and ranchers will have the same advantage as Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CP-TPP) countries selling into the Japanese market. On the U.S. side, it will provide tariff elimination or reduction on 42 tariff lines for agricultural imports from Japan.

valued at \$40 million, including products such as certain perennial plants and cut flowers, persimmons, green tea, chewing gum, and soy sauce. The U.S. will also reduce or eliminate tariffs on certain industrial goods from Japan such as certain machine tools, fasteners, steam turbines, bicycles, bicycle parts, and musical instruments.

The two nations struck a separate accord on a high-standard and comprehensive set of provisions addressing priority areas of digital trade. These areas include:

- Prohibitions on imposing customs duties on digital products transmitted electronically such as videos, music, e-books, software, and games.
- Ensuring non-discriminatory treatment of digital products, including coverage of tax measures.
- Ensuring barrier-free cross-border data transfers in all sectors.
- Prohibiting data localization requirements, including for financial service suppliers.
- Prohibiting arbitrary access to computer source codes and algorithms.
- Ensuring firms' flexibility to use innovative encryption technology in their products.

The digital trade agreement with Japan meets the gold standard on digital trade rules set by the USMCA and will expand trade in an area where the U.S. is a leader.

8. U.S.-EU Trade Agreement

In 2020, we expect to see significant movement on trade negotiations between the U.S. and the EU. Much progress had been made under the Obama Administration on T-TIP, and those negotiations showed promise. With the withdrawal of the U.S. from T-TIP, the U.S. essentially began anew under President Trump. He has not been shy in expressing his antipathy towards the EU on trade. President Trump believes that the EU may be "worse than China" when it comes to trade issues. He has also stated that the EU is "difficult" and that it has raised significant barriers to fair and reciprocal trade.

Under the Trump Administration, the U.S. and EU have made progress. The basic approach and goals for the U.S.-EU trade talks were set forth in a 2018 joint declaration from both parties. Both sides have agreed to work toward zero tariffs, zero non-tariff barriers, and zero subsidies on non-auto industrial goods. Both sides also agreed to work to reduce barriers and increase trade in services, chemicals, pharmaceuticals, medical products, and soybeans. This will open markets for farmers and workers, increase investment, and lead to greater prosperity in both the U.S. and the EU. It should also make trade fairer and more reciprocal.

Both sides also agreed to strengthen their strategic cooperation with respect to energy. In particular, the EU wants to import more LNG from the U.S. to diversify its energy supply. In addition, the U.S. and EU agreed to launch a close dialogue on standards to ease trade, reduce bureaucratic obstacles, and slash costs. A fourth point of agreement is to join forces to protect American and European companies better from unfair global trade practices. The U.S. and EU will, therefore, work closely together with like-minded partners to reform the WTO and to address unfair trading practices, including IP theft, forced technology transfer, industrial subsidies, distortions created by state-owned enterprises, and overcapacity.

In the latter half of 2019, talks stalled. Newly elected European Commission (EC) President Ursula von der Leyen may breathe new life into the talks. The Trump Administration has made it clear, however, that it remains ready to slap auto tariffs onto the EU or to take other actions if there is no progress in the negotiations.

9. Conclusion

Trade issues will continue their raucous ride in 2020. Given the volatility of many of the Trump Administration's actions, it is impossible to predict anything other than there is some hope that USMCA will be enacted and that China and the U.S. may reach common ground on trade.

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The possibility of future OEHHA rulemakings for targeted businesses and exposures may continue, as businesses seek to clarify their compliance with particular exposure scenarios not easily addressed through the general regulatory provisions.

I. PROP 65

For the most part, companies have settled in to the new labeling requirements imposed by California's OEHHA revisions to its Prop 65 Article 6 "clear and reasonable warnings" regulations, effective as of August 31, 2018. Issues remain, however, that are being addressed.

In particular, to address issues with OEHHA's regulations set forth at Section 25600.2 regarding who is responsible for providing warnings between manufacturers and "retail sellers," OEHHA has proposed to revise its regulations to clarify those relationships and the circumstances when warning requirements can be transferred to such retail sellers. Industry stakeholders initially requested that OEHHA clarify retail seller responsibilities, and expressed concern with OEHHA's proposal. On October 4, 2019, OEHHA [proposed](#) modifications to the amendments it initially proposed on November 16, 2018. The 2019 proposed revisions seek to: clarify that compliance may be met so long as the business to which the authorized agent for a retail seller provides the written notice is subject to Section 25249.6 of Prop 65; provide that written notices to retail sellers must be renewed annually during the period in which the product is sold in California by a retail seller; clarify that entering into a written agreement is not limited to retail sellers, but that other intermediate parties -- businesses to which they are selling or transferring product -- may also enter into a written agreement; and modify the definition of "actual knowledge" to remove knowledge of "sufficient specificity" and instead define "actual knowledge" as when the retail seller "receives information from any reliable source that allows it to identify the specific product or products that cause the consumer product exposure."

This last revision defining "actual knowledge" is of interest. Although there was general recognition that the definition for "actual knowledge" needed clarification, concerns were raised regarding OEHHA's definition proposed in November 2018. OEHHA's [prior guidance](#) regarding the scope of "actual knowledge" states that "a retail seller may acquire knowledge of an exposure that requires a warning through news media,



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[Prop 65: Exposure Assessments and Compliance Implications](#)

its customers or a trade association." If the sources stated in OEHHA's guidance are the "reliable sources" from which actual knowledge can be derived, the revised definition may provide a more objective standard against which to determine when "actual knowledge" has occurred.

OEHHA also issued amendments to its warning regulations to address specific scenarios, particularly: new regulations to address the exposures that can occur at residential rental properties and provide safe harbor guidance on message content and warning methods for those exposures; and new regulatory provisions to provide more specificity regarding the content of safe harbor warnings for rental vehicle exposures, and the corresponding methods for providing those warnings that are specific and appropriate for rental-car businesses. The possibility of future rulemakings for targeted businesses and exposures may continue, as businesses seek to clarify their compliance with particular exposure scenarios not easily addressed through the general regulatory provisions.

A significant issue throughout 2019 that will continue in the New Year (and beyond) is the applicability of Prop 65 warning requirements for pesticide products registered under FIFRA. These issues are discussed in the FIFRA Section of our Forecast.

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J. INGREDIENT DISCLOSURE

In early 2019, companies were poised to begin 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). Those responsibilities took a dramatic turn on August 27, 2019, when the State of New York Supreme Court invalidated the Disclosure Program. See our TSCAblog™ titled "[Court Rules NYDEC Household Cleansing Product Information Disclosure Program Is 'Null and Void.'](#)" In a significant victory for industry petitioners, the court found that the Disclosure Program was in fact a "rule" and had to be remitted to the New York Department of Environmental Conservation (NYDEC) with the directive to comply with the State Administrative Procedure Act (SAPA) rulemaking procedures.

New York has yet to propose the ingredient disclosure requirement through official rulemaking procedures. In fact, the New York legislature in April 2019 proposed a 2020 budget package that did not address the "Consumer Right to Know Act" intended to expand New York's cleaning product ingredient disclosure requirements to personal care products and to introduce new labeling requirements for a variety of consumer products. New York Governor Andrew Cuomo did, however, sign one piece of legislation (S.2387 B/A 164-B) on October 11, 2019, that is specifically intended to require a "plain and conspicuous printed list of all the ingredients" in menstrual product packages or boxes. See our memorandum titled "[New York Requires Disclosure of Ingredients in Menstrual Products.](#)"

Although the status of New York's broader cleaning product ingredient disclosure requirements remains unclear, Governor Cuomo signed [S.4389-B](#) into law on December 9, 2019. This law will, as of **January 1, 2022**, prohibit the sale of household cleaning products, cosmetic products, and personal care products that have certain levels of 1,4-dioxane. Specifically, the level of 1,4-dioxane permissible in household cleansing products and personal care products will be two parts per million (ppm) by **December 31, 2022**, and then one ppm by **December 31, 2023**. 1,4-dioxane in cosmetic products is limited to ten ppm by December 31, 2022. The terms cosmetic product and personal care product are defined as follows:

- The term "cosmetic product" shall mean any article (a) intended to be rubbed, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for beautifying, promoting attractiveness, or altering the appearance, and (b) intended for use as a component of any such article. The term "cosmetic product" shall not include any personal care product as defined in this section for which a prescription is required for distribution or dispensation as provided in section two hundred eighty-one of the public health law or section sixty-eight hundred ten of the education law.
- The term "personal care product" shall mean any product intended for cleaning or cleansing any part of the body, such as the skin and hair, and including but not limited to, hair shampoo, hair conditioner, soap, bath gels and other bath products. The term "personal care product" shall not include any product for which a prescription is required for distribution or dispensation as provided in section two hundred eighty-one of the public health law or section sixty-eight hundred ten of the education law.

The law includes an enforcement provision stating that any person that violates these provisions shall be liable for a civil penalty not to exceed \$1,000 for each day the violation continues, as well as a second violation to "be liable to the people of the state" for a civil penalty up to \$2,500 each day during which such violation continues.

The law was enacted in an effort to prevent 1,4-dioxane from contaminating New York's water systems. Industry has been critical of the legislation, stating that since levels of 1,4-dioxane in these products are already very low, this legislation will have little to no impact on contamination of New York's water systems. Instead, manufacturers that cannot reformulate or ensure compliance may stop selling some of these otherwise commonly available products in New York.

Even with its 1,4-dioxane legislation, New York's potential development of a broader cleaning product ingredient disclosure regulation will be an issue to monitor in 2020, as NYDEC has the option to initiate a rulemaking at any time. If NYDEC proceeds, industry stakeholders hope that it will work with pertinent trade associations to develop a workable program, and that NYDEC will consider a program that



Ingredient disclosure requirements set forth under California's law remain active, with online requirements applicable to designated products sold in California effective as of January 1, 2020, and product label disclosure requirements applicable to designated products sold in California on or after January 1, 2021.

aligns with California's law setting forth the ingredient disclosure requirements for similar cleaning products. On that note, California's requirements under S.B. 258 are unaffected by the New York court's decision. Ingredient disclosure requirements set forth under California's law remain active, with online requirements applicable to designated products sold in California effective as of January 1, 2020, and product label disclosure requirements applicable 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 general parameters of California's requirements are as follows:

- **Scope of Products Covered:** S.B. 258 applies to manufacturers of "designated products" sold in California. A "designated product" is defined as "a finished product that is an air care product, automotive product, general cleaning product, or a polish or floor maintenance product used primarily for janitorial, domestic, or institutional cleaning purposes." Products that are excluded from the definition of "designated products" include foods, drugs, and cosmetics and a variety of personal care products, including toothpaste, shampoo, and hand soap. Importantly, while FIFRA-regulated products are exempt from label disclosure requirements, they are subject to website disclosure requirements. In addition, California excludes products used primarily in industrial manufacturing, production, and assembling processes, including oil and gas production; steel production; heavy industry manufacturing; industrial water treatment; industrial textile maintenance and processing other than industrial laundering; and food and beverage processing and packaging.

- **Ingredient Disclosure Requirements:** The required disclosure elements (unless the ingredient is CBI) include:
 - > A list of each "intentionally added ingredient" (which can be limited for labels to only those contained in a product that is included on a "designated list" (i.e., one of more than 20 state, federal, and international lists (the so-called "list of lists")));
 - > A list of any of 34 "nonfunctional constituents" identified in the regulations;
 - > A list of each specified fragrance allergen, when present in the product at a concentration at or above 0.01 percent (100 ppm); and
 - > An intentionally added ingredient that is listed on California's Prop 65 list (although this element is not enforceable until **January 1, 2023**).
- **Website Disclosure Elements:** To be compliant with the website disclosure requirements, in addition to determining the ingredients to be disclosed, companies must also:
 - > Include the functional purpose of each ingredient.
 - > List ingredients in descending order of predominance by weight in the product. If concentration of an ingredient is below one percent, a company can list them following the other ingredients without respect to the order of predominance by weight.
 - > Include a link to a safety data sheet (SDS) for the covered product.
- **Label Disclosure Elements:** California provides two options for complying with the label disclosure requirements:

➤ **Option 1:** Provide: (1) a list of each intentionally added ingredient contained in the product that is included on a Designated List (~25,000 substances); and (2) a list of each fragrance allergen 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, when present in the product at a concentration at or above 0.01 percent (100 ppm).

➤ **Option 2:** Provide (1) a list of all intentionally added ingredients contained in the designated product unless it is CBI. Fragrance ingredients or colorants may be listed on the product label as “fragrances” or “colorants,” respectively; and (2) a statement that reads “Contains fragrance allergen(s)” shall be included on the product label when a fragrance allergen 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, or subsequent updates to those regulations, is present in the product at a concentration at or above 0.01 percent (100 ppm).

Under either option, California requires manufacturers also to provide on the label: (1) the manufacturer’s toll-free telephone number and (2) an Internet website address. If a full list of intentionally added ingredients is not provided, then the label must also include: (1) a statement that reads: “For more ingredient information visit”; (2) an Internet website that provides all information required for online communications (Section 108954.5); and (3) a toll-free number.

- **CBI:** CBI includes any intentionally added ingredient for which a claim has been approved by EPA for inclusion on the TSCA Confidential Inventory, or for which the manufacturer, or its supplier, claims protection under the Uniform Trade Secrets Act.

- **Requirements for Employers:** S.B. 258 also contains an amendment to Section 6398.5 of the Labor Code, providing that employers that are required to make SDSs readily accessible to employees must now also make the ingredient information listed on a manufacturer’s website available to employees in the workplace.

While the status of the New York program is unknown, any developments in New York, as well as potential additional state laws of this type, remain an area to watch. Companies affected by S.B. 258 should also have completed their review of covered cleaning products to ensure, at a minimum, compliance with the online requirements before the January 1, 2020, deadline.

K. FDA FOOD AND COSMETICS REGULATION

2019 saw the continued implementation of the FDA’s Food Safety Modernization Act (FSMA). FDA continues to develop substantial guidance for industry to address the seven foundational rules that are collectively known as FSMA. These rules will continue, in 2020, to have many significant impacts on industry and on the evolution of policy and procedures for safe food handling, contact, and distribution.



WEBINAR

[FDA FSMA Food Defense Plan Requirements](#)

March of 2019 was the deadline for very small businesses, the last group impacted by the Foreign Supplier Verification Program (FVSP) FSMA rule, to comply; the first compliance deadline was 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](#).

In July of 2019, the Food Defense Plan (FDP) became effective for business not meeting the definitions of very small or small. The FDP is FSMA’s final rule on Mitigation Strategies to Protect Food Against Intentional Adulteration, issued in May 2016, and may be the most impactful. 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.” Details of the specific content of the FDP are codified at 21 C.F.R. Section 121.126.

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Manufacturers should take the opportunity in 2020 to review FDA definitions, and any existing facility registrations to ensure FDA has a clear understanding of the operations being conducted.

The full requirements of the FDP 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.

FDA continues to develop guidance documents for all seven foundational rules. Most FSMA specific guidance, at this time, exists in “draft” but provides substantial details that industry should consider, as enforcement measures are expected to increase as these final rules are implemented. Manufacturers should take the opportunity in 2020 to review FDA definitions, and any existing facility registrations to ensure FDA has a clear understanding of the operations being conducted. In addition, as FDA jurisdiction is use-specific, industry should ensure that the intended uses specified in any FDA facility registration or company documentation are in alignment, and compliant with all FDA regulations for the intended use.

1. FDA Regulatory Agenda

The following items were listed on the Fall 2019 Regulatory Agenda. Each could have substantial impacts on businesses in the New Year.

1.1 Proposed Rule Stage

Sunscreen Drug Products for Over-the-Counter-Human Use; Tentative Final Monograph, [0910-AF43](#). FDA issued a proposed rule ([84 Fed. Reg. 6204](#)) on February 26, 2019, detailing the Tentative Final Monograph (TFM) for nonprescription, over-the-counter (OTC) sunscreen drug products. The TFM

describes the conditions under which the FDA proposes that OTC sunscreen monograph products are generally recognized as safe and effective (GRASE). According to the provisions of the 2014 Sunscreen Innovation Act (SIA), the statutory deadline for issuing the final monograph was November 26, 2019, but FDA has not yet issued the final monograph. The comment period for the proposed rule, originally scheduled to end on May 28, 2019, was extended to June 27, 2019, to accommodate extensive public comments. As the final monograph is expected to have unprecedented and far-reaching impacts on both manufacturers and consumers of OTC sunscreen drug products in 2020, and as FDA is still reviewing the extensive public comments it received regarding the TFM, FDA has not yet provided a timeline for release of either the final monograph, or a revised TFM. FDA is working with stakeholder groups to address the serious concerns raised by physicians, consumers, and OTC sunscreen manufacturers. Among the extensive changes that have raised significant and widespread concerns, the TFM considers only two of the 16 existing sunscreen monograph ingredients, titanium dioxide and zinc oxide, to be GRASE, and places 12 ingredients in Category III -- insufficient data to make a GRASE determination. Among these 12 ingredients, two are not in common use, and six, avobenzone, homosalate, octinoxate, octisalate, octocrylene, and oxybenzone, are used alone or in combination of two or more active ingredients in many sunscreen products. The timelines for generating the additional data FDA is requesting are short considering the duration and complexity of the studies. While approval of a new sunscreen drug product through the new drug application process remains an option, the frequent, market-driven changes in sunscreen products makes this option too time consuming and costly, and the OTC drug monograph process the most viable option. Consistent with the SIA, FDA also expects to address sunscreen dosage forms and maximum sun protection factor (SPF) values. More information regarding FDA’s intended path forward is expected **early in 2020**.

Food Standards: General Principles and Food Standards Modernization (Reopening of Comment Period), [0910-AC54](#). FDA is reopening the comment period on a proposed rule, is-

sued jointly with the USDA's 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 in **January 2020**.

Investigational New Drug Applications Requirements for Drug Studies of 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 was scheduled to issue a NPRM by November 2019.

Streamlining Provisions Requiring Disclosure to and Receipt of Written Assurances from Commercial Customers in the Preventative Control for Human Food Rule, [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 preventative 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 NPRM was scheduled to be issued by November 2019.

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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 2020**.

Food Additives: Food Contact Substance Notification That Is No Longer Effective, [0910-AI01](#). FDA proposed 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 **April 2020**.

Permanent Listing of Color Additive Lakes, [0910-AH80](#). FDA proposes to streamline and clarify the regulations for insoluble pigments prepared by chemically reacting water-soluble dyes with water insoluble substances. The proposed rule would consolidate current requirements and permanently list these color additives for use in food, drugs, and cosmetics. FDA is scheduled to issue the NPRM by **April 2020**.

Streamlining Provisions Requiring Disclosure to and Receipt of Written Assurances from Commercial Customers in the Foreign Supplier Verification Programs Rule, [0910-AI23](#). FDA proposes to remove or revise certain written assurance requirements that currently apply to importers of human or animal food to align with the requirements that apply to manufacturing/processing facilities under the preventive control regulations and the requirements that apply to farms under the produce safety regulation. FDA is scheduled to issue a NPRM by **July 2020**.

L. OSHA, WHMIS, AND GHS

1. OSHA

On May 25, 2012, the Occupational Safety and Health Administration (OSHA) revised and updated the Hazard Communication Standard (HCS). Currently, all substances and mixtures are required to comply with HCS 2012, as the transition period ended 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 contin-



2019 saw the publication of the eighth revised edition (Rev. 8) of the UN's GHS. The publication of Rev. 8 is certain to inspire discussion on next steps for many nations currently striving to develop or revise their own adaptations of the UN GHS model.

ues 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 2018 Regulatory Agenda stated that OSHA intended 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. As stated above, however, the proposed rule has yet to be published and OSHA officials now expect it to be issued sometime in **mid-2020**, with the final rule out by the **end of the year**. With the publication of Rev. 8 of the UN Globally Harmonized System of Classification and Labeling of Chemicals (GHS) model, it would be logical for OSHA to consider how best to incorporate the changes into any future rulemaking initiatives.

2. 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 GHS model. Health Canada worked with the U.S. to align, as much as possible, each countries' 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 ended on June 1, 2018, to address additional complexities with the updated system. There were no significant changes in 2019. It is expected, if OSHA does issue the proposed rule in 2020, that Health Canada would consider updating WHMIS shortly thereafter to ensure the two countries remain as closely aligned as possible.

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 RCC met in September of 2019 and is expected to continue discussing mechanisms for managing the variances between the two approaches, which are not as substantial as other countries' approaches to GHS. In addition, OSHA/Health Canada have published three new guidance documents that address [labeling requirements](#), [regulatory processes in the workplace](#), and [labeling hazards not otherwise classified, physical hazards not otherwise classified, and health hazards not otherwise classified](#).

3. GHS Initiatives

2019 saw the publication of the eighth revised edition ([Rev. 8](#)) of the UN's GHS. The publication of Rev. 8 is certain to inspire discussion on next steps for many nations currently striving to develop or revise their own adaptations of the UN GHS model.

Earlier in 2019, OSHA indicated it was going to issue a NPRM to update the HCS by December 2019. OSHA has since indicated that the revision is not expected in final until the **end of 2020**.

Summaries of the current state of GHS are provided in more detail in the UN GHS section under Key Global Chemical Management Predictions.

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With offices in the U.S., Europe, and China, The Acta Group (Acta®) offers expertise with regulatory programs and chemical product approvals in North America, Europe, South and Central America, Asia, the Middle East, and the Pacific Rim. Acta is the consulting affiliate of B&C, established to complement B&C's legal services by providing a full-range of global support for our clients' products from concept to approval, so they get to market quickly and efficiently and stay there when challenged by a new issue or set of rules.

II. KEY GLOBAL CHEMICAL MANAGEMENT PREDICTIONS

A. ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT (OECD)

Among the key deliverables from 2019 for the OECD chemicals program are the following:

- In an important development, OECD updated its [report](#) estimating the savings to industry and countries due to the work of the OECD Environment, Health and Safety Program. This report provides an overview of the benefits and estimates the total savings from OECD work to be more than EUR 309 million per year.
- In February 2019, the OECD Council adopted the [Recommendation on Countering the Illegal Trade of Pesticides](#) to strengthen cooperation between countries and inspectors and to identify illegal pesticides throughout their lifecycle with a Best Practice Guidance. The work of the OECD Network on Countering the Illegal Trade of Pesticides (ONIP) is now focusing on the implementation of this recommendation.
- [Version 4.3 of the OECD QSAR Toolbox](#) was launched along with an updated website. New features of the QSAR Toolbox include two new Databases (pKa OASIS and ADME database), five New Profilers (Acute Oral Toxicity, Blood brain barrier (beta), Oral absorption (beta), Skin permeability (beta), Uncouplers (MITOTOX)), new methods for assessing pKa, and 159 new (Q)SAR models, including the pre-calculated online Danish QSAR DB models. A Toolbox Application Program Interface (API) is now publicly available allowing for enrichment of the Toolbox tools library with additional parameter calculators, profilers, (Q)SAR models, and metabolism simulators.
- OECD also published two guidance documents on the exposure assessment for children:

- > Estimating Mouthing Exposure in Children -- Compilation of Case Studies, 2019 [ENV/JM/MONO(2019)24]; and
- > Considerations when Assessing Children's Exposure to Chemicals from Products, 2019 [ENV/JM/MONO(2019)29].

Among the key deliverables foreseen for 2020 are:

- Guiding Principles and Key Elements for establishing weight of evidence (WoE) for chemicals assessment. This document is intended to provide universal Guiding Principles that should be considered when developing or augmenting systematic approaches to WoE for chemical evaluation and Key Elements to formulating a systematic approach to WoE. The ultimate goal is to facilitate that regulators follow a consistent, clear, and transparent delivery of evidence using the Principles and Elements described in this document.
- Release of Version 3.0 of eChemPortal, the Global Portal to Information on Chemical Substances with a new User Interface.
- On the scientific front, in 2020, OECD plans to adopt 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.

B. STRATEGIC APPROACH TO INTERNATIONAL CHEMICALS MANAGEMENT (SAICM)

SAICM is a voluntary policy framework to promote chemical safety around the world that was agreed to internationally in 2006. Its key objective is achieving sound management of chemicals throughout their life cycle by the year 2020. Over the past several years, SAICM's existing policy framework has been revisited and possible changes considered through an international process under the auspices of the UN Environment Programme and the World Health Organization (WHO). In 2020, this effort will culminate with an international decision on SAICM's future arrangements **beyond 2020**, which is scheduled to occur at the next session of the International Conference on Chemicals Management (ICCM5) to be held in Bonn, Germany, in **October 2020**.

C. EU

1. REACH

The May 31, 2018, registration deadline for "phase-in" chemical substances under EU's Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation marked the beginning of a new phase for REACH, with the European Chemicals Agency (ECHA) and the EC placing increased emphasis on compliance. Understanding of, and engagement in, the REACH evaluation processes is increasingly important for registrants. In addition to maintaining compliance with various REACH rules and addressing evaluation-related requests from ECHA and Member State Competent Authorities, entities affected by REACH are expected to remain busy in 2020 due to: evolving rules for phase-in substances and nanomaterials; activities of ECHA's Forum for Exchange of Information on Enforcement (Enforcement Forum); Brexit-related considerations; and the need to manage suitably cost sharing.

REACH dossier and substance evaluation processes are expected to keep industry occupied in 2020, and have potentially substantial implications for companies' product portfolios in terms of regulatory risk management, resources, testing requirements, desirability, marketability, and profitability. For these reasons and others, companies can benefit significantly from devoting adequate resources towards managing REACH evaluation processes in 2020-2021. Chemical companies globally that have registered sub-

stances need to understand properly ECHA's dossier evaluation procedures, review available information and guidance, and correspond with ECHA appropriately. Emphasizing the importance of dossier compliance, ECHA issued a press release on June 24, 2019, entitled "[ECHA to scrutinise all REACH registrations by 2027](#)." In its press release, ECHA indicates that the "[EC] will propose an amendment to REACH to raise the current [five percent] minimum target for compliance checks to 20 [percent] of registration dossiers in each tonnage band." ECHA indicates this would result in "checks for about 30 [percent] of all registered substances." This increased target is part of the [REACH Evaluation Joint Action Plan](#), developed by ECHA and the EC, "to address the lack of compliance in registration dossiers and encourage industry to improve their safety data on chemicals." ECHA indicates that its aim is to screen "all registration dossiers submitted by the 2018 deadline: by **2023** for substances registered over 100 tonnes per year and by **2027** for substances in the tonnage band 1-100 tonnes per year."

Priority will be placed upon evaluation of substances with high tonnage, hazardous properties, or circumstances such as widespread exposure -- where more data are needed to evaluate potential risk. ECHA indicates that similar substances will be assessed in groups to gain efficiency and ensure that proposals for further regulatory action are consistent. By the **end of 2020**, ECHA will prioritize high tonnage substances and conclude for each whether it is a high-priority for risk management or data generation, or whether it is of low-priority for further action. Priority substances are key candidates for compliance checks and/or substance evaluation, either of which could lead to requests for additional data generation. ECHA indicates that it will re-allocate staff from other functions to meet its targets. Other important actions on ECHA's radar include simplifying compliance check decisions and interacting with industry associations to ensure registrants "step up their compliance efforts." Entities must be prepared to address ECHA's concerns, coordinate suitably, organize additional testing if required, and advocate their interests.

Member States are scheduled to evaluate [74 substances in 2020-2022](#) under the [draft Community Rolling Action Plan \(CoRAP\)](#), with 14 substances scheduled for evaluation in 2020, and 60 substances listed for evaluation in **2021-2022**. ECHA suggests that registrants of a listed substance coordinate their actions, and contact the evaluating Member

State Competent Authority. Downstream users of a listed substance are advised to review “the information they have available and share it with the registrants.”

ECHA’s Member State Committee is expected to prepare an opinion on the draft CoRAP in **February 2020** and, based on the opinion, it is anticipated that ECHA will adopt and publish the CoRAP Update for 2020-2022 in **March 2020**. ECHA emphasizes the importance of up-to-date information on uses, clear documentation of exposure scenarios in registrants’ Chemical Safety Reports (CSR), and performing any dossier updates before **March 2020**. Entities subject to REACH substance evaluation processes can benefit from reviewing ECHA’s guidance document entitled “[Registrant’s guide - How to act in substance evaluation](#).”

Beyond evaluation, active entities in the REACH sphere need to ensure compliance with their ongoing obligations. For example, REACH Article 22 requires that registrants update their registrations “without undue delay” if there is relevant new information (e.g., change in registrant status, change in composition of the substance, or change in classification and labeling). ECHA’s increased emphasis on timely voluntary dossier updates and compliance with other REACH obligations is visible to industry, and REACH registrants worldwide are expected in 2020 to devote increased resources towards ensuring timely dossier updates and “general” REACH compliance. Such ongoing REACH obligations are expected to keep industry occupied in 2020.

As indicated by ECHA in its press release entitled “[Rules for registration of phase-in substances clarified](#),” EC Implementing Regulation (EU) 2019/1692 clarifies that certain REACH provisions applicable to phase-in substances, for which the transitional regime ended in 2018, were applied until December 31, 2019. ECHA states that “[after this] cut-off date, [companies] need to calculate their manufactured or imported volume per calendar year for each of their substances.” In its press release, ECHA states “[f]rom the cut-

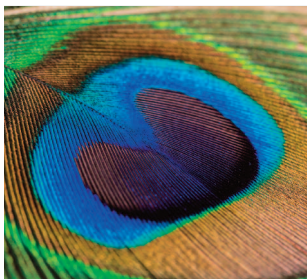
off date, companies that plan to register a substance will need to submit an inquiry to ECHA to get information on other registrants in order to begin data-sharing negotiations, and they can no longer rely on their pre-registrations.”

ECHA indicates further that if data sharing negotiations started within a Substance Information Exchange Forum (SIEF), respective data sharing disputes could only be submitted according to REACH Article 30(3) until December 31, 2019. ECHA indicates “[a]fter this date, all data-sharing disputes will be handled according to Article 27.” Implementing Regulation 2019/1692 addresses a number of important points, and requires timely review and attention from industry for maintenance of suitable REACH compliance strategies in 2020 and beyond. The Implementing Regulation also encourages use of “informal communication platforms” similar to SIEFs to manage continuing data-sharing and registration obligations, and it is expected that numerous companies will display, in 2020, compliance plans that account for and address the Implementing Regulation.

As indicated in ECHA’s press release entitled “[Get ready for new REACH requirements for nanomaterials](#),” new information requirements apply to all new and existing REACH registrations covering nanoforms beginning January 1, 2020. The revised REACH Annexes addressing nanoforms provide clarifications and introduce new provisions for: (1) characterization of nanoforms or sets of nanoforms covered by the registration (Annex VI); (2) the chemical safety assessment (Annex I); (3) registration information requirements (Annexes III and VII-XI); and (4) downstream user obligations (Annex XII), “to make sure companies provide enough information to demonstrate the safe use of their nanoforms for human health and the environment.” Numerous registrants submitted updates to their existing registrations for nanoforms prior to January 1, 2020. All new registrations in 2020 and beyond for nanomaterials must comply with the revised framework. This is expected to require extensive efforts from regulatory, scientific, and technical professionals.

An array of enforcement activities at the Member State level, coordinated through ECHA’s Enforcement Forum’s REACH-EN-FORCE (REF) projects, are expected to require attention from industry in 2020. REF’s seventh enforcement project, REF-7, covers enforcement of registration obligations after the last registration deadline in cooperation with customs authorities, and has a “reporting phase” of “Q1 2020,” an “evaluation phase” of “**Q3 2020**,” and “adoption of the re-

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It is expected that the connection between enforcement and the REACH Evaluation Joint Action Plan will continue to strengthen in 2020, and that REACH enforcement through the year will be comprehensive.

port” in “Q4 2020.” REF-8, the eighth enforcement project, addresses enforcement of the Classification, Labeling, and Packaging (CLP) regulation ((EC) No 1272/2008, REACH, and Biocidal Products Regulation (BPR) duties related to substances, mixtures, and articles sold online, and has an “operational phase” in 2020. It is expected that the connection between enforcement and the REACH Evaluation Joint Action Plan will continue to strengthen in 2020, and that REACH enforcement through the year will be comprehensive. Entities can benefit substantially in 2020 from understanding fully enforcement processes, maintaining compliance, and devoting adequate resources to manage potential enforcement activities.

Lawyers and regulatory personnel are expected to remain busy throughout 2020 addressing numerous legal and data compensation activities under REACH. In addition to the usual array of commercial and confidentiality agreements that cover a range of matters, including REACH-compliant supply of products, substance sameness, and registration, various legal agreements among co-registrants may require amendment or reissue. Cost sharing activities, including cost reconciliation for registered substances, updating Letter of Access (LoA) costs, issuing reimbursements, engaging external service providers, and sharing new costs arising from dossier or substance evaluation can benefit from allocating adequate and suitable resources in 2020.

Last but not least, Brexit is expected to require time and attention from chemical companies in 2020. The chemicals industry needs to remain attentive, respond to ongoing developments, and engage as needed to refine compliance plans, revise legal agreements, transfer registrations, and perform various other Brexit-related activities. The chemicals industry understands well the potentially disastrous supply chain consequences that can result from inaction in the Brexit context, and is expected to remain busy in 2020 to support its commercial interests and comply with applicable regulations in the EU and the UK.

A plethora of ongoing matters in the REACH arena suggests that 2020 will be an interesting and busy year. It is expected

that companies’ technical, scientific, regulatory, and legal personnel will remain busy supporting compliance under various REACH processes. Well-informed and up-to-date approaches to compliance, and suitable assistance from recognized specialists, can assist companies in the REACH space to achieve their commercial and product stewardship goals in 2020.

2. EU -- Endocrine Disruptors

In 2020, the EC will build on work that it began in 2019 to address actions anticipated by its 2018 Communication “[Towards a comprehensive EU framework on endocrine disruptors](#).” The Communication calls for a comprehensive screening of current legislation applicable to endocrine disruptors through a Fitness Check that will build on the data already collected and analyzed. The Communication also outlines initiatives currently considered by the EC to ensure that the implementation of existing policies on endocrine disruptors reaches its full potential, including the identification of endocrine disruptors, improving communication throughout supply chains by using SDSs as established under the REACH regulation, and taking forward the scientific assessment of endocrine disruptors with further regulatory action.

As reported in our June 20, 2019, memorandum, “[EC Begins Public Consultation on Fitness Check Roadmap on Endocrine Disruptors](#),” the EC began a public consultation on the [Fitness Check Roadmap on Endocrine Disruptors](#) in June 2019. The Fitness Check will focus on legislation that does not contain specific provisions for endocrine disruptors, such as the legislation on toys, cosmetics, and food contact materials (FCM). A particular focus of the Fitness Check will be on whether the different pieces of legislation take into account the protection of vulnerable population groups that may be particularly sensitive to endocrine disruptors when assessing and regulating such substances. It is intended to help assess whether legislation is fit for purpose and analyze whether there is potential to improve regulatory efficiency. The Fitness Check

will assess the current situation in the EU and compare it with the situation in 1999, when the EC adopted its first Strategy on endocrine disruptors. It will also assess the international dimension, taking into account the impact of EU provisions on products imported into the EU. As part of its Fitness Check, in December 2019, the EC began two public consultations: a public consultation (designed from a citizen's perspective), and a stakeholder consultation (designed for stakeholders and experts). The [public consultation](#) will close **March 9, 2020**, and targets the general public. The [stakeholder survey](#) will close on **January 31, 2020**, and targets stakeholder organizations such as businesses, public authorities, academic research and NGOs, and experts working in such areas responding in their professional capacity. More information is available in our December 18, 2019, memorandum, "[EC Begins Public Consultations on Fitness Check of EU Legislation Regarding Endocrine Disruptors](#)."

The EC consulted key stakeholders and public authorities through targeted consultations. Importantly, it convened the [first annual forum on endocrine disruptors](#), announced in the 2018 Communication, on November 8, 2019. The forum brought together public and private stakeholders and scientists with expertise on endocrine disruptors to exchange information, identify challenges, and build synergies to inform the EC's reflections. The EC will publish a synopsis report, summarizing the results of all consultation activities once the activities are closed.

The 2018 Communication includes criteria for the identification of endocrine disruptors as applied to biocides and pesticides. To provide ECHA the data necessary to assess active biocidal substances against these criteria, the EC will amend Annexes II and III of the BPR. The EC and the competent authorities began discussing amendments to the data requirements in Spring 2019, and they reached agreement in September 2019. The amendments will require more data on reproductive toxicity, developmental neurotoxicity, and developmental immunotoxicity.

The EC held a [public consultation](#) in Fall 2019 on a draft regulation that would amend the SDS requirements under REACH. The draft regulation would amend REACH Annex II to include information that reflects the identification of relevant and specific SDS requirements for substances and mixtures with endocrine disrupting properties. On November 19-20, 2019, members of the

REACH Committee voted unanimously in favor of the draft regulation. The draft regulation provides for a transition period from **January 1, 2021**, until **December 31, 2022**. During this time frame, SDSs may continue to be provided in accordance with current requirements.

During the July 2019 meeting, the Competent Authorities for REACH and CLP (CARACAL) discussed updating several REACH Annexes to improve the data requirements and support the identification of endocrine disruptors under REACH. The changes discussed include integrating endocrine disruptor assessment in human health hazard assessment and environmental hazard assessment in Annex I and developing a tiered approach for endocrine disruptor information and testing requirements in Annexes VII to X. The EC will prepare proposals with different options for amending the Annexes to find possible solutions for registration dossiers at different tonnage levels to provide information on endocrine disruption while considering issues such as proportionality and animal welfare. After obtaining input from a CARACAL subgroup with toxicological and ecotoxicological expertise, the EC will further develop its proposals with different options for amending the Annexes that will be used to conduct an impact assessment. The EC will also prepare a draft amendment of Annexes VII to X to include new standard tests (*in silico*, *in vitro*, and *in vivo*) for evaluating endocrine disrupting properties.

3. EU -- FCMs

In 2020, the EC intends to continue its evaluation of how the current EU legislative framework for FCMs has performed in relation to its original objectives. As reported in our February 14, 2019, memorandum, "[EC Begins Public Consultation on Evaluation of FCMs](#)," the EC convened a public consultation in early 2019 on Regulation (EC) No 1935/2004 (Regulation) in its entirety and the rules and tools provided for by the legislation, such as specific implementing measures. The consultation also examined the situation concerning materials for which there are no EU measures and that are subject to permitted national measures. The Regulation provides the legislative framework for FCMs and has done so since its adoption in October 2004 with varying degrees of success, given the divergence of national standards sprinkled throughout the EU. The framework provides for special rules on active and intelligent materials; powers to enact additional EU measures for specific materials; a procedure to



The EC has wisely (and bravely given the complexity of the process) concluded there is a need to evaluate how Regulation (EC) No 1935/2004 has performed in relation to its original objectives. A staff working document that will give the EC a review of what steps, if any, to take is due in Spring 2020.

perform safety assessments of substances used to manufacture FCMs involving the European Food Safety Authority (EFSA); rules on labeling, including an indication for use, either by language or the appropriate symbol; and compliance documentation and traceability. The EC has wisely (and bravely given the complexity of the process) concluded there is a need to evaluate how the current Regulation has performed in relation to its original objectives, which were (1) to facilitate the free movement of FCMs and articles within the European Economic Community (EEC); and (2) to expand the scope of the previous legislation (Directives 80/590/EEC and 89/109/EEC) to include new types of materials and articles, such as active ingredients and intelligent FCMs, “for reasons of clarity and legal certainty,” all while protecting public health and the interests of consumers. A staff working document that will give the EC a review of what steps, if any, to take is due in **Spring 2020**.

While the EC is evaluating the framework regulating FCMs, its Directorate-General (DG) Sante [conducted a survey](#) in 2019 to gain a better oversight of the current use of phthalates in FCMs, or other non-phthalate substances that provide the same function in the material. The consultation primarily aimed to obtain information on the use and occurrence of the five phthalates that are authorized as additives for use in plastic FCM -- (DBP, BBP, DEHP, DINP, and DIDP) -- as well as substances that provide the same function in the material, alone or in combination, in plastic FCMs and the technical function they perform. The consultation also sought information on the use and occurrence of these five phthalates or other phthalates, or substances that provide the same function in the material, alone or in combination, in non-plastic FCMs and the technical function they perform.

In December 2019, EFSA updated its [risk assessment of five phthalates used in plastic FCMs](#). EFSA set a group tolerable daily intake (TDI) for four of the five phthalates (DBP,

BBP, DEHP, and DINP) of 50 micrograms per kilogram of body weight (µg/kg bw) per day based on their effects on the reproductive system. According to EFSA, the fifth phthalate in the assessment, DIDP, does not affect testosterone levels in fetuses, therefore it set a separate TDI of 150 µg/kg bw per day based on its effects on the liver. EFSA states that based on the limited scope of the EC’s mandate and the uncertainties identified, the EFSA Panel on FCMs, Enzymes and Processing Aids considered that the current assessment of the five phthalates, individually and collectively, should be on a temporary basis.

On September 9, 2019, the EC and its contracted consultancy Ecorys organized a Stakeholder Workshop to present the findings of the review so far. Whereas many specifics as to the functioning of the current regulatory framework are still missing due to a lack of hard data, the overall conclusion is that stakeholders are in support of an overhaul and the establishment of harmonized rules applicable across the EU. The EC is now working on an internal Commission Staff Document that should lead to a legislative proposal in the **first quarter of 2020**. During this period, there are still opportunities for stakeholders to provide input to the EC on the future legislation.

D. UK/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,” as this campaign has been dubbed colloquially, has become an important matter globally for a wide range of stakeholders. Numerous, and often contentious Brexit-related political and legal developments have ensued, culminating in the UK’s General Election on December 12, 2019. Based upon the Conservative Party’s decisive victory and strong majority in Parliament, Prime Minister Boris Johnson’s Government has a clear mandate to “get Brexit done” and approve UK legislation implementing the deal by **January 31, 2020**, the extended deadline for the UK’s departure granted by the EU. With subsequent approval by the European Parliament (EP)



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expected, 2020 is expected to be a busy year, as industry now has meaningful clarity regarding the next Brexit-related steps and timeframes for their completion.

The [Withdrawal Agreement](#) and [Political Declaration](#) agreed between the UK and EU in October 2019 include a number of important issues. The Withdrawal Agreement covers the following areas, among others: (1) common provisions; (2) citizens' rights; (3) separation provisions; (4) transition; (5) financial settlement; and (6) institutional and final provisions. The Political Declaration addresses a wide array of post-Brexit issues, including economic cooperation, security, intelligence, migration, and "regulatory aspects." The Political Declaration indicates that the UK and EU will "explore the possibility" of cooperation of UK authorities with EU agencies such as ECHA. Article 126 of the Withdrawal Agreement provides for a "transition" or "implementation" period until **December 31, 2020**. Subject to certain exceptions, the Withdrawal Agreement provides that EU law shall continue to "be applicable to and in the [UK]" during the implementation period. If the negotiated Brexit deal cannot receive timely approval in the UK and EU, and if a further extension for exit day is not agreed, the default remains a "no-deal Brexit" on **January 31, 2020**.

The UK's departure from the EU will open a new chapter of challenging negotiations related to the UK's post-Brexit trade deal with the EU. Prime Minister Boris Johnson has represented that a trade deal with the EU can be agreed by **December 2020**, but much remains to be seen in terms of pressure the EU may place on the UK for post-Brexit alignment with the EU on several fronts. Given the Conservative Party's representations of "taking back control," it is unclear how the UK will respond to such potential EU suggestions.

Entities worldwide are well aware of the significant implications of Brexit for chemical regulatory compliance under several regimes, including the EU's REACH regulation and BPR. If the Withdrawal Agreement is ratified by the UK Parliament

and the EP prior to **January 31, 2020**, EU REACH and BPR will continue to apply in the UK during the transition period until **December 31, 2020**. Under these circumstances, UK-based entities' registrations under EU REACH and biocidal product authorizations under BPR would remain valid until the end of the transition period, but would be "non-existent" thereafter. ECHA has indicated that the UK will be unable to act as an Evaluating Competent Authority or Reference Member State under BPR as of exit day, irrespective of whether or not a transition period is applicable.

Time is of the essence. Companies worldwide need to anticipate and manage the game-changing consequences of Brexit on their businesses throughout 2020, including the following, among others:

- UK-based Lead Registrants will be outside the scope of EU REACH;
- UK-based Only Representatives (OR) will be unable to provide services under EU REACH;
- UK-based suppliers will be removed from the Article 95 List under BPR;
- Importation of chemical products from the UK to the EU-27 will give rise to regulatory obligations; and
- Importation of chemical products from the European Economic Area (EEA) to the UK will give rise to new regulatory obligations in the UK.

Actions required by affected businesses include establishment of their own manufacturers/importers or appointment of an OR in the EU-27, suitable correspondence with Lead Registrants, and the review and update of legal documents. In addition to understanding consequences of Brexit for products under EU chemical laws and taking actions timely to support compliance in the EU-27, entities with business interests in the UK need to follow closely developments pertaining to the UK's post-Brexit chemical regulatory framework, including [UK REACH](#). UK REACH provides transitional arrangements for certain supply chain actors, and companies with interests in the UK market should review and understand the UK REACH Statutory Instrument, engage specialists as required, and prepare now to address UK REACH requirements. Although EU REACH and UK REACH rules and requirements are similar, it is important

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Brexit has significant consequences for the interpretation and enforceability of various legal agreements, and companies are expected to require substantial resources in 2020 to support the review, negotiation, and update of such documentation.

for entities to understand comprehensively nuances and procedural differences under the laws in support of continuous compliance.

Entities engaged in the biocides sector are expected to complete various Brexit-related adjustments to compliance plans in 2020. Under BPR, holders of authorizations for biocidal products must be based within the EEA or Switzerland. As the UK will be outside the EEA upon Brexit, it is expected that numerous UK entities holding biocidal product authorizations will seek to transfer these authorizations to EEA-based companies in **early 2020**. Additionally, BPR requires entities that are included in the Article 95 List of Active Biocidal Substance and Product Suppliers to be established within the EEA or Switzerland. As a consequence of Brexit, UK-based suppliers will be removed from the Article 95 List, and biocidal products from UK suppliers will no longer be allowed to be made available on EEA and Swiss markets. Numerous suppliers based outside the EEA and Switzerland that have appointed Article 95 List representatives in the UK, and wish to maintain post-Brexit access to EEA and Swiss markets, are expected to appoint in **early 2020** new representatives within the EEA or Switzerland. The UK will implement its own jurisdiction-specific rules, modeled in line with EU BPR, for [post-Brexit regulation of biocides](#). Biocide companies with business interests in the UK need to follow such developments and review legislation closely to support post-Brexit compliance and commercial affairs in the UK. Brexit raises numerous complex questions regarding chemical regulatory compliance, and entities affected by Brexit can benefit from reviewing Acta's [responses to frequently asked questions](#).

Chemical companies are expected to devote extensive efforts, in 2020, to maintain post-Brexit compliance and support supply chains. Such efforts are expected to include measures to retain EU-27 market access (e.g., establishment of importer or appointment of OR in EU-27 under EU REACH). Chemical companies are also likely to follow in 2020 UK REACH-related developments closely, including those pertaining to the Health and Safety Executive's functions and

UK REACH-IT. It is expected that, in 2020, numerous companies will engage in "grandfathering" processes under UK REACH. Further measures expected through the year in the context of UK REACH include establishment of ORs under the regulation and preparations for submission of full datasets.

Brexit has significant consequences for the interpretation and enforceability of various legal agreements, and companies are expected to require substantial resources in 2020 to support the review, negotiation, and update of such documentation. The divergence of chemical regulations in the UK and EU-27 gives rise to data sharing needs for post-Brexit regulatory compliance in the UK, and it is expected that numerous entities will seek access to necessary data for UK REACH submissions in 2020. Such data sharing negotiations are expected to present the usual array of challenges, including reaching agreement on the scope of data rights and compensation.

Brexit is fast approaching, and companies globally with business interests in the UK and EU-27 need to implement suitable compliance plans timely to avoid supply chain disruption, maintain market access, support product portfolios, and achieve desired goals. Those that have not yet reviewed and updated their European regulatory compliance strategies in consideration of Brexit need to start now.

E. BIOCIDES

The EU's BPR, which aims to improve the functioning of the biocidal products market in the EU while ensuring a high level of protection for humans and the environment, covers the "placing on the market" and use of biocidal products to protect humans, animals, materials, or articles against harmful organisms (e.g., pests). BPR is a complex framework that includes a number of distinct and well-defined processes. Entities addressing BPR compliance need to follow closely ongoing regulatory developments pertinent to their product portfolios in 2020. The regulation includes numerous actors and interested parties, and has widespread implications for the development and use of biocidal products and treated articles within the EEA.

One of the most challenging developments is the implementation of the criteria for endocrine-disrupting properties under the BPR, which could result in the exclusion of biocidal active substances and co-formulants in biocidal products. The criteria have significant implications for entities addressing BPR compliance. A substance is considered to have endocrine-disrupting properties if the following criteria are met:

- It shows an adverse effect in an intact organism or its progeny;
- It has an endocrine mode of action (*i.e.*, alters the function(s) of the endocrine system); and
- The adverse effect is a consequence of the endocrine mode of action.

Interpretation and application of the endocrine disruptor criteria have already caused significant compliance issues for industry in 2019, particularly in terms of determining whether the observed “adverse effect” is a consequence of the endocrine mode of action. Such regulatory challenges are expected to continue throughout and beyond 2020, and ECHA has established an Endocrine Disruptor Expert Group to assist industry in managing compliance with the new criteria. The Expert Group assists industry at various stages (*e.g.*, confirmation of determination of endocrine disrupting properties) and has three meetings scheduled for 2020. ECHA stated at its 2019 Biocides Day that most assessments related to the endocrine disruptor criteria are transparent, follow applicable guidance, account for relevant data, and “allow to follow from underlying data to final conclusion.” ECHA highlighted specifically, as areas for improvement, that data gaps prevented conclusions on endocrine disrupting properties and that assessments “struggle with the assessment of *in vitro* data.”

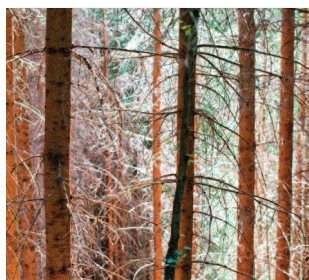
Implementation of these criteria at this late stage in the BPR timeline presents compliance and commercial challenges in 2020 and beyond. As companies seek to bring biocidal products to market, the endocrine disruptor criteria will continue to attract substantial attention and give rise to further testing, critical analysis, and important regulatory and commercial decision-making. As application of the endocrine disruptor criteria under BPR continues, further development of guidance and clarifications, as well as advocacy related to the criteria are expected.

The BPR data sharing rules and compensation are expected to remain contentious and challenging in 2020, and the longstanding requirements of fairness, transparency, and non-discrimination are expected to keep regulatory and legal professionals busy.

There are numerous important deadlines in 2020 under BPR. These include deadlines for notification to ECHA to include substances in the Review Program, which was established under the Biocidal Products Directive, and continues under the BPR. Transitional provisions in the BPR allow biocidal products containing active substances included in the Review Program, for a given product-type (PT), to be made available and used, subject to national rules, until three years after the date of their approval. ECHA intends to complete the Review Program by **2024**. Notifications must be submitted to ECHA by **June 12, 2020**, to include metam sodium (PT 9 and 11) and thiram (PT 9) in the Review Program. Several PT 19 substances are subject to a notification deadline of **October 18, 2020**, for inclusion in the Review Program. ECHA’s Biocidal Products Committee (BPC) has a busy Work Program in 2020, and companies with affected product portfolios will likely follow closely regulatory consideration of their active substances, including glyoxal (PT 2, 3, and 4), creosote (PT 8), and carbon dioxide generated from propane, butane, or a mixture of both by combustion (PT 19).

Although enforcement of BPR is in the sole competence of Member States, the Enforcement Forum’s BPR Subgroup (BPRS) plays an important role in coordinating strategies, enforcement projects, and joint inspections. In 2019, BPRS launched a coordinated enforcement project, the Biocides Enforcement Project (BEF), dedicated solely to BPR requirements regarding compliance of treated articles throughout the supply chain (BEF-1). A report on BEF-1 that will provide important information in an area with limited enforcement experience is expected in 2020. BPRS’ next enforcement project, BEF-2, will focus on approved substances in biocidal products and is expected to start in **2021**.

In addition to BPRS’ projects, the Enforcement Forum’s REACH-EN-FORCE-8 (REF-8) project covers enforcement of CLP, REACH, and BPR duties related to substances, mixtures, and articles sold online. The operational phase of REF-8 is scheduled for 2020, and further REF-8 activities (*e.g.*, evaluation phase and draft report) are scheduled for **2021**.



2019 saw substantial changes in approaches to chemical control legislation in Asia. South Korea's amended legislation is laying the groundwork for sweeping changes in the approaches countries in this region are taking to chemical management.

Entities globally are well aware of the significance of Brexit in management of chemical regulatory compliance approaches. Entities worldwide have implemented regulatory compliance plans that consider widespread Brexit consequences. Those that have not already implemented business and compliance strategies that account for Brexit should start efforts now. As of today, an “orderly Brexit” with a deal and a “disorderly” Brexit with “no-deal” are both possible. There are numerous ongoing political developments that can significantly affect the Brexit outcome, and it is clear that entities will need to remain engaged in 2020 to maintain compliance and achieve goals.

Companies with interests in EU-27 and UK markets face the challenge of preparing appropriately for multiple potential Brexit outcomes and implementing plans timely. Biocidal products cannot be made available on the EU market unless the product supplier or the substance supplier is included in the “Article 95 List” for the relevant PT. The purpose of the Article 95 List, which is updated by ECHA regularly, is to “ensure the equal treatment of persons placing active substances on the market.” It is important to note, as of this writing, that UK suppliers currently on the Article 95 List will be removed on the day the UK leaves the EU.

As reported extensively, among other changes, due to 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 important roles to play in

2020. Well-informed and comprehensive regulatory approaches, and suitable assistance from external specialists, can assist entities in the biocides sector to achieve their compliance and business goals in 2020.

F. ASIA

2019 saw substantial changes in approaches to chemical control legislation in Asia. South Korea’s amended legislation is laying the groundwork for sweeping changes in the approaches countries in this region are taking to chemical management. This trend is expected to continue in 2020 with the emergence of additional amendments, the development of new legislation, and a variety of approaches in developing processes for chemical control.

1. South Korea

As expected, the amended Act on the Registration and Evaluation of Chemicals (K-REACH) entered into force on January 1, 2019, and marked the beginning of the pre-registration period that ended on June 30, 2019. After the pre-registration period closed, South Korea provided a mechanism to submit late pre-registrations. Late pre-registration is only available for phase-in substances that meet very specific criteria, including no importation above one metric ton from 2016 to 2018.

Under the current framework, entities that manufacture or import a non-phase-in substance must submit a full registration when volumes exceed 100 kilograms (kg) per year. Entities may continue to import or manufacture up to one ton per year of eligible phase-in substances before a late pre-registration is required. An entity that wishes to manufacture or import more than one metric ton per year of a phase-in



PODCAST

[South Korea's K-REACH: Why it Matters for Everyone](#)

substance must submit a full registration prior to commencement of that activity if it has not pre-registered, and is not eligible to submit a late pre-registration for the substance. It is not clear, in this situation, how the SIEF and data sharing activities will take place if the lead registrant's registration deadline is later than that of other registrants that did not qualify for late pre-registration. This is a gap that South Korea will need to address as entities prepare substance registrations.

The South Korean National Institute of Environmental Research (NIER) is currently conducting risk assessments for the list of 510 priority existing chemicals (PEC) that required registration prior to June 2018. The Ministry of the Environment (MoE) is expected to evaluate and, as appropriate, propose restrictions and/or authorizations for these substances.

2. Vietnam

Vietnam's effort to strengthen chemical management began as a cooperative effort between Vietnam and Japan's Ministry of Economy, Trade and Industry (METI) in 2012 under a three-year memorandum of cooperation between the two countries that was extended for five years in 2015. Vietnam's National Chemical Inventory has been developed through a succession of three nomination periods in 2016, 2017, and 2018. The most recent draft, released in September 2018, contains over 31,000 chemical substances.

A white paper released by Vietnam's Ministry of Industry and Trade (MoIT) and the UN Industrial Development Organization (UNIDO) highlights the importance of the domestic chemicals industry to support growth in Vietnam's high value industries such as textiles and apparel and telecommunications, which is necessary to increase Vietnam's competitive position in these market sectors.

In 2020, Vietnam is expected to prepare in final a chemical inventory and to develop the regulations that outline the process for substances that are not listed on the inventory.

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 ibergeson@actagroup.com if you would like to discuss your needs in the region.

3. Taiwan

In Taiwan, on December 21, 2018, a bill amending the Toxic Chemical Substance Control Act (TCSCA) passed, and TCSCA was renamed as the Toxic and Chemical Substances of Concern Control Act (TCSCCA). A rider to the legislation called for the Taiwan Environmental Protection Administration (Taiwan EPA) to draft a bill within one year to regulate the existing chemicals manufactured, imported, and/or used in Taiwan. The Taiwan EPA issued on March 11, 2019, a revision to the Regulation of New and Existing Chemical Substance Registration.

Taiwan's first list of 106 PECs is final; substances on this list are subject to registration and annual volume reporting. Registration of these substances began January 1, 2020. Guidance on and potential refinements to the requirements are expected in 2020 as the new regulations enter into force. In addition, expansion of the PEC list is expected, with the addition of the next batch of substances in 2020.

Annual volume reporting of registered new and existing substances manufactured or imported in the previous calendar year begins **April 1, 2020**, with the reporting window running through **September 30, 2020**. This annual reporting provides the Taiwan EPA with exposure and use information that may be used to develop and issue restrictions, or require special permitting for the use or handling of certain substances.

A "substances of concern" list, to be published by the Taiwan Ministry of Labor (MoL) by the end of 2019, will provide the basis for the MoL to require special permitting to handle these substances at industrial sites. The Taiwan EPA and MoL are expected to continue to review subordinate laws and propose updates as part of the implementation of TCSCCA.

4. Thailand

Thailand's current chemicals management scheme consists of many related laws and agencies controlling chemicals under the Hazardous Substance Act, B.E. 2535 (1992) (HSA). Unfortunately, the current framework has resulted in oversight duplication in some areas and gaps in enforcement in other areas. Concerns over continuing environmental contamination, chemical incidents, and lack of public information about chemicals have driven Thailand's decision to make improvements to the existing scheme while working to create a new framework.



The implementation date for the Eurasian Economic Union (EAEU) regional chemical framework is June 1, 2021. It contemplates the registration of mixtures as well as substances.

Thailand's National Legislative Assembly approved on February 1, 2019, several revisions to the HSA. The revisions provide more clarity for imports and exports, and simpler processes related to the shipment of hazardous substances. Thailand published the amendments in the *Royal Thai Government Gazette* on April 30, 2019, and they entered into force on October 27, 2019.

In September 2019, Thailand approved the List of Hazardous Substances No. 5 that modifies the hazardous substance type for several substances, adds exemption conditions for two substances, and adds a number of existing substances to the List of Hazardous Substances. On November 6, 2019, Thailand notified the WTO of proposed revisions to the List of Hazardous Substances that would reclassify several listed pesticides as type 4, effective December 1, 2019. Type 4 substances are hazardous substances whose production, import, export, or possession is prohibited. In response to comments opposing the proposed revisions, Thailand has postponed the effective date to **June 1, 2020**, for paraquat and chlorpyrifos, and dropped the proposed prohibition of glyphosate, which will instead be restricted.

In addition to the above amendments intended to update the HSA, Thailand continues the work that it began several years ago toward an improved chemicals framework: achieving a more unified chemical management approach that aligns with international guidelines and requires responsibility for the entire life cycle of chemicals. As part of this work, Thailand's Department of Industrial Works (DIW) created a preliminary existing chemical inventory from data on hazardous substances notified to DIW between 2012 and 2015. The inventory, on-line since 2016, includes approximately 16,000 substances. Release of Thailand's inventory in final, previously expected by the end of 2017, is now expected in 2020.

A joint committee consisting of government, enterprise, civil service, and legal experts has drafted a new chemicals law. Between April and October 2019, two drafts have been issued, and two public meetings have occurred in which the new requirements have been introduced and discussed. The

expectation is that the momentum this new law has will carry it forward into 2020 with the potential for additional drafts and opportunities for stakeholder engagement that will lead to a new approach for managing chemicals in Thailand.

The preamble to the first draft of the new chemicals law as well as a recent second draft refer to "precautionary principles," "risk assessment principles," and the life cycle of chemicals. When the final chemicals law is adopted, it will replace the HSA.

5. Eurasia

In 2017, the Eurasian Economic Union (EAEU) member countries issued in final a regional chemical framework. Member countries of the EAEU include the Republic of Armenia, the Republic of Belarus, the Republic of Kazakhstan, the Republic of Kyrgyzstan, and the Russian Federation. The member countries are developing two implementing sub-regulations that reportedly have been drafted, but did not enter into force by the 2018 target deadline. A few of the key elements that are not yet agreed upon include a list of chemicals to be restricted or banned, criteria for denying registration of chemicals, and rules for completing CSRs.

The implementation date for the chemical framework is **June 1, 2021**. It contemplates the registration of mixtures as well as substances. To begin, the Member States are each to develop an inventory of the chemicals in commerce in each of their countries by **January 1, 2021**. These are to be consolidated into a regional inventory by **June 1, 2021**.

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There is a provision for late nominations to the inventory until **June 1, 2023**, for substances or mixtures on the market prior to **June 1, 2021**. The nomination process is to begin after the sub-regulations are agreed. Some Member States, such as the Republic of Belarus, the Republic of Kazakhstan, and the Russian Federation, have already begun compiling their inventories and taking nominations. This inventory activity and the near-term deadlines suggest that additional actions could be taken to release the EAEU sub-regulations in final in 2020.

The framework draws from both TSCA, with the formation of an initial inventory, and from the EU's REACH regulation, with the registration of existing as well as new substances. The details are to be framed in the sub-regulations. Submissions can be made in any language, but must be accompanied by a Russian translation.

Russia Federation Government Decree No. 1019 issued in final the Technical Regulation on the Safety of Chemical Products in October 2016 to establish a chemicals framework with similar implementation dates. The process to submit substance information to the inventory of the Russian Federation began in late 2019, and is expected to extend to **mid-2020**. The Russian regulation is expected to be rescinded when/if the EAEU sub-regulations are implemented. Until then, entities exporting products to the Russian market should nominate their substances and mixtures to the Russian chemical inventory to ensure continued access to the Russian market and to avoid the requirement to submit a full registration after the inventory nomination process closes.

G. MIDDLE EAST

1. Chemical Substance Management in the Middle East

Chemical regulation in the Middle East continues to lack the level of harmonization businesses seek. While the region continues to be slow to develop a comprehensive approach to chemicals management, two initiatives are expected to advance in 2020 and help promote a clearer chemical picture. First, Saudi Arabia is expected to publish a draft national chemical safety program. Second, the Gulf Standards Organization (GSO) is expected to publish in final a harmonized standard to align hazard communication in the region with the fifth revised edition (Rev. 5) of the GHS.

2. Saudi Arabia

Saudi Arabia has begun drafting a national chemical safety program that will include the development of a chemical inventory as a first step. The initial plan, to be introduced by **mid-2020**, is not expected to propose a comprehensive chemicals framework like the EU REACH regulation or TSCA. The information gathered in the process of creating the inventory is to be used, instead, to assess the chemicals in commerce and inform Saudi Arabia's decisions to develop chemical regulations to address risks and chemicals of concern.

3. GHS

The Gulf Cooperation Council (GCC), whose members are comprised of the governments of the State of the United Arab Emirates (UAE), The Kingdom of Bahrain, The Kingdom of Saudi Arabia, The Sultanate of Oman, The State of Qatar, and The State of Kuwait, continues with its plans to implement GHS in the region. The GCC Standardization Organization published a first draft of a Technical Regulation to adopt GHS in the GCC member countries. The draft Technical Regulation aligns to Rev. 5 of GHS, proposes to adopt the list of harmonized substance classifications in Annex VI of the EU CLP regulation, and is expected to be published in final by **mid-2020**. The Technical Regulation will move toward a more harmonized approach to hazard communication in the region as each member country assesses its existing regulations and adopts the details of the GCC Technical Regulation into its own country-specific requirements.

H. UN GHS

Rev. 8 of the UN GHS model includes updates to Chapter 2.3 *Aerosols* to include *Chemicals Under Pressure* as a separate hazard class with definitions, classification criteria, and label elements in a separate subsection (2.3.2). Rev. 8 includes an entirely new annex (Annex 11 *Guidance on Other Hazards*

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Rev. 8 of the UN GHS model contains “new provisions for the use of in vitro/ex vivo data and non-animal test methods to assess skin corrosion and skin irritation,” clarification on classification criteria for Specific Target Organ Toxicity, and further rationalization of precautionary statements.

Not Resulting in Classification) 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 guidance on combustible dusts including flow charts and extensive details that could be beneficial to those seeking guidance on how to address potential dust explosions hazards. Rev. 8 contains “new provisions for the use of *in vitro/ex vivo* data and non-animal test methods to assess skin corrosion and skin irritation,” clarification on classification criteria for Specific Target Organ Toxicity, and further rationalization of precautionary statements.

The UN GHS model is adopted by countries in several different ways. Some countries choose to adopt all the building blocks (physical, health, and environmental hazard classes and categories) “as is” into their legislation. The edition adopted will determine the details implemented into the legislative framework. Some countries will adopt the criteria based approach of the UN GHS 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 self-evaluation of the hazards, based on the criteria, to determine the classification. Other countries have chosen to adopt the basic UN GHS 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 already have adopted the GHS standards.

1. Mexico

Mexico’s Ministry of Labor and Social Welfare published the Harmonized System for the Identification and Communica-

tions 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 on October 9, 2018. With the continued renegotiating of NAFTA, many are eager to see if North America’s regulatory framework will influence Mexico’s chemical regulation scheme. Changes in 2020 are highly unlikely.

2. Malaysia

Malaysia introduced GHS in 2008 through the Department of Health and Safety. The implementation of GHS was formally issued by the Malaysian Occupational Safety and Health (Classification, Labeling and Safety Data Sheet of Hazardous Chemicals (CLASS)) Regulation 2013, published October 11, 2013. The implementation of CLASS is a criteria based approach following Rev. 3 of the UN GHS model. All hazard classes and categories were not included; flammable liquid category 4, acute toxicity category 5, skin corrosion/irritation category 3, aspiration hazard category 2, and hazardous to the environment, acute categories 2 and 3 were excluded. The transition period for implementation ended April 17, 2015. Currently, the regulations on classification, labeling, and packaging are being examined. Malaysia is considering changes to the national legislation to require companies to obtain classification approvals for hazardous chemicals before they are imported. In 2020, Malaysia may revise the list of pre-classified chemicals in the industry code of practice for hazard communication. If the list is revised, companies will need to consider how the changes will impact current hazard communication documentation and required revisions.

3. New Zealand

New Zealand was the first country to implement GHS in 2001 by modifying its Hazardous Substance and New Organisms (HSNO) Act of 1996. New Zealand’s approach is very

unique and was originally based on Rev. 1 of the UN GHS model. It has been revised and is currently based on Rev. 5 of the UN GHS model. HSNO uses nomenclature that is not in alignment with the UN GHS model. Hazard classes and sub-classes are assigned using a numeric class and a lettered category. The system somewhat resembles a merging of GHS with the UN system for the classification of dangerous goods for transportation purposes. HSNO provides a list of classified substances as guidance. The meaning of the alpha-numeric system does not always align with the hazard classes and categories of the UN GHS model. In December of 2017, the New Zealand Environmental Protection Authority (New Zealand EPA) published several notices regarding changes to the management of hazardous substances. The changes include, in Schedule 7 of the Hazardous Substances (Classification) Notice 2017, tools for interpretation from the alpha-numeric system to the UN GHS classification. Not all alpha-numeric classifications have associated GHS classifications, as noted in the substance specific spreadsheet provided. In addition, New Zealand will accept SDSs and labels that are compliant with other GHS schemes, provided that the UN elements applicable in New Zealand are included.

On October 29, 2019, the New Zealand EPA proposed to update the HSNO classification system by adopting Rev. 7 of the UN GHS model. New Zealand EPA has identified a number of benefits in updating to a later version of the GHS, including reducing complexity for stakeholders; international alignment that facilitates trades; and enhanced effectiveness of the HSNO. The change in classification system would be achieved by issuing a new Classification Notice that incorporates Rev. 7 by reference. Adopting Rev. 7 would mean that the new Classification Notice will align with the Labeling and SDS Notices, which already require compliance with the GHS requirements. New Zealand EPA proposes transitional provisions to give stakeholders time to adjust to the new classification system. The public consultation closed January 9, 2020. If New Zealand EPA updates the HSNO classification system, it states that it will need to update all HSNO approvals (including group standards) to convert their HSNO classifications to GHS classifications. New Zealand EPA plans to revoke a large number of individual approvals (approximately 5,600), as they are covered by group standard approvals, i.e., their individual approval is essentially redundant. This part of the project will involve a second public consultation exercise planned for the **first quarter of 2020** to request feedback on:

- Proposed GHS classifications for all individual approvals (derived from their existing HSNO classifications); and
- The list of individual substance approvals that New Zealand EPA plans to revoke and the name of the group standard(s) they could be covered by.

4. Singapore

Singapore first implemented GHS in 2005. The Workplace Safety and Health Advisory Committee standards were updated in 2014 (SS 586: Part 1 - 4 of 2014). These standards are criteria based according to Rev. 4 of the UN GHS model. Not all the building blocks are included; flammable liquids category 4, acute toxicity category 5, skin corrosion/irritation category 3, aspiration hazard category 2, acute aquatic category 2 and 3, and chronic aquatic category 3 and 4 are not included in the standards. Singapore will accept later revisions of GHS. The Singapore Chemical Industry Council (SCIC) plans to implement Rev. 7. The timing is not clear, however, as there have been indications that this may occur in 2020, **2021**, or **within the next five years**. As Singapore is willing to accept later revisions, the implementation of Rev. 7 appears to have little impact on those wishing to use Rev. 8. It is unclear if Singapore will consider in its plan the inclusion of previously excluded building blocks.

5. Australia

Australia implemented Rev. 3 of UN GHS model into its Work Health and Safety Laws (WHS) on January 1, 2012. The transition period ended in January of 2017. In July of 2019, Safe Work Australia began seeking comments on a consultation to update to Rev. 7 of the UN GHS model to “ensure Australia’s requirements for workplace hazardous chemicals reflect the most up to date approach and remain aligned with our key chemicals trading partners.” The Consultation paper included several key questions that note timing to begin transitioning (**October of 2020** was mentioned), and a potential to have a staged transition period (12 months for manufacturers/importers with an additional 12 months to sell down existing stock). The main changes are not viewed as substantive but would include new hazard classes, new/revised hazard categories, and changes to precautionary statements. As the changes are not viewed as substantive, the transition period is expected to be significantly reduced from the original five-year transition plan that was part of

the implementation of Rev. 3 of the UN GHS model in 2012.

6. Taiwan

Taiwan's Council of Labor Affairs (CLA) first adopted GHS in 2006. The MoL's Occupation Health and Safety Act revised the previous implementation and updated to Rev. 4 of the UN GHS model under the National Standard CNS 15030. Environmental hazards were not included in the National Standard. In 2008, CLA began issuing lists of substances in phases that required self-classification, similar to Japan's approach. There were three phases ending in 2013. All substances on the list must comply with the National Standard as of January 2017. In addition, advisory classifications for these substances were provided by the CLA and the MoL Occupational Safety and Health Administration. Taiwan has indicated they will accept later revisions of GHS. Taiwan plans to update to Rev. 7 of the UN GHS model. The timing is not clear, however, as there have been indications that this may occur in 2020, **2021**, or **within the next five years**.

7. South Korea

The South Korean Industrial Safety and Health Act Notice No 2006-36 implemented GHS in 2006. This was updated in 2009 (Notice No 2009-68). The South Korean approach is currently based on Rev. 3 of the UN GHS model. Not all of the UN building blocks were adopted, including flammable liquid category 4, acute toxicity category 5, skin corrosion/irritation category 3, aspiration hazard category 2 and acute aquatic toxicity category 2 and 3. The MoE issued and updates a list of required substance classifications. The last updates occurred in 2016. In addition, the Ministry of Employment and Labor (MoEL), the Korea Occupational Safety and Health Agency (KOSHA), and the National Emergency Management Agency (NEMA) provide non-mandatory substance level classifications.

In February of 2018, the MoEL announced amendments to the Korean Occupational Safety and Health Act. The amendments include provisions that would require manufacturers and importers of hazardous substances to submit their SDSs to the MoEL. In addition, companies claiming confidential protection for the disclosure of hazardous ingredients would be subject to approval from the MoEL prior to providing the SDS. The final revised bill was originally expected to be issued in September of 2019, and is now expected to be issued

in final at the end of 2019 or in the **beginning of 2020**. A grace period will be provided for those who prepare and update SDSs prior to the implementation. The grace periods will be based on the annual manufacturing and import volume. Chemical and chemical products greater than or equal to 100 tons will have a submission period within one year, ten to less than 100 tons will have a submission period within two years, one to less than ten tons will have three years, 100 kilograms to less than one ton will have four years, and finally, under 100 kilograms will have a submission period of five years. A newly prepared SDS after the implementation will not be subject to the grace periods but will need to be submitted to the MoEL. South Korea will introduce an Only Representative (OR) system. A foreign manufacturer may appoint an OR that meets the requirements set out by the Ministry Decree to submit a prepared SDS. This approach has caused much discussion and contention, especially in competitive business sectors that seek to protect CBI. The enactment and process for review by the MoEL will require substantial resources and could result in business delays if enforcement provisions are implemented/coordinated with customs in South Korea.

8. Turkey

Turkey's implementation of the Classification, Labeling and Packaging (CLP, abbreviated as SEA in Turkish) was published on December 11, 2013, in the Official Gazette, number 28848 and came into force on the date of publication. SEA provided obligatory transition periods that would fully repeal the former Turkish classification regulation. Classification and labeling according to SEA became obligatory in June 2015 for substances and June 2016 for mixtures. Products that were placed on the market before publication had a two year transition period. Legal representatives are appointed on behalf of importers in Turkey. This unique point to the SEA was created to avoid issues with exporters and CBI concerns. Turkey is planning to update the classification and labeling regulation in the upcoming months to follow the EU's CLP regulation. A draft of this update was produced by the Ministry of Environment and Urbanization (MoEU) in 2018. Turkey reviewed the burden of the poison centre provisions in the EU CLP regulation and, due to the lack of Turkey's infrastructure, the draft will exclude this provision. The regulation in Turkey provides substance specific classifications and concentration limits in Annex VI similar to the EU. The draft includes changes from the CLP up to the thirteenth adaptation to technical and scientific



On March 27, 2019, the twelfth adaptation to technical and scientific progress (ATP) was published in the EU Official Journal. It aligns CLP with Rev. 6 and Rev. 7 of the UN GHS model. The changes will apply from October 17, 2020.

progress (ATP). Companies with interests in Turkey should note that as Turkey attempts to align with the EU, disconnects between updates to the ATP and differences in substance specific classifications and concentrations will occur. The Ministry was expected to publish the revisions by the end of 2019.

9. EU REACH/CLP

In January of 2009, the CLP regulation 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 was originally based on a combination of Rev. 3 and Rev. 4 of the UN GHS model. The eighth ATP notes that CLP was reviewed against Rev. 5 of the UN GHS model and updated accordingly. On March 27, 2019, the twelfth ATP was published in the EU *Official Journal*. It aligns CLP with Rev. 6 and Rev. 7 of the UN GHS model. The twelfth ATP 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. The changes will apply from **October 17, 2020**. Stakeholders may wish to consider earlier application as needed. 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 published on October 4, 2018, in the EU *Official Journal* 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 2020, manufacturers and importers will need to review the changes for both the twelfth and thirteenth ATP 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, SDSs and labels will require updates as specified in the regulation.

10. Brazil

Brazil first implemented GHS in 2009. The Brazilian Association of Technical Standards (ABNT) of August 2009 contains the specific details. The Standard is broken into four parts. ABNT NBT 14725-1 contains details on the classification. The implementation includes all building blocks and the deadlines were established in stages. Substances were to be completed by 2010. Mixtures were to be completed by June of 2015. In June of 2019, Brazil amended the ABNT Standards to incorporate Rev. 7 of the UN GHS model. This amendment includes changes in some of the thresholds and classification groupings for chemicals. This includes changes to serious eye damage/eye irritation, respiratory or skin sensitization, carcinogenicity, reproductive toxicity or for effects via lactation, and specific target organ toxicity. In addition, Brazil is currently reviewing the Chemical Management Bill. This bill will establish a national chemical registry and may possibly be passed in the **second half of 2020**.

11. Chile

Chile has not officially adopted GHS. The draft version of the GHS regulation, *Draft Reglamento de Clasificación, Etiquetado y Notificación de Sustancias Químicas y Mezclas* (Regulations on the classification, labeling and notification of chemical substances and mixtures), was finished and published by the Health Ministry in 2017. The Health Ministry was to propose a public comment period followed by issuance of the regulation in final. Implementation was expected no later than the second half of 2019, as requested by OECD. Chile became a member of the OECD in 2010. The OECD recently made GHS mandatory for all member countries. The draft GHS regulations have been revised multiple times and the Secretariat-General of the Presidency (SEG-

RES) has reviewed and provided comments on the latest draft. This has resulted in delays to publication.

The regulation established implementation deadlines for substances and mixtures in industrial uses and non-industrial uses. Substances for industrial use will have a one-year deadline after publication, while non-industrial substances will have a two-year deadline after publication. Mixtures, industrial and non-industrial, also have two separate deadlines. Industrial mixtures will have a four-year deadline after publication and non-industrial mixtures will have a six-year deadline after publication. The publication will face challenges with the current political unrest in the region. Expect that, if political issues can be resolved, the regulation will be formally adopted. Companies with stakes in Chile should plan, in 2020, to begin developing compliant SDSs and labels. Chile will accept GHS classifications in accordance with Chilean Standard NCh2245:2015. NCh2245:2015 indicates that GHS classification, including the appropriate pictograms, signal words, hazard statements, and precautionary statements are allowed in Section 2 of SDSs and on labels, but additional standards should be consulted to determine if additional information specific to Chile is required.

12. China

The National Registration Centre for Chemicals (NRCC) under the Ministry of Emergency Management (MEM) collected public input for revision of the Implementing Guidance (Trial) for the Catalog of Hazardous Chemicals (2015) in 2019 and is expected to release the revised Implementing Guidance in 2020. This catalog contains mandatory substance classifications and changes will impact SDSs and labels. There is no indication that China, in 2020, intends to propose revisions to the Guobiao (GB) standards that are currently based on Rev. 4 of the UN GHS model.

CONTRIBUTORS

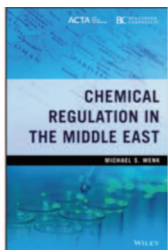
JANE S. VERGNES, PH.D., KARIN F. BARON, MSPH, SCOTT J. BURYA, PH.D., KAREN L. LORUSSO, HEATHER J. BLANKINSHIP



APPENDIX A: SPEECHES AND WRITINGS

BOOKS AND REPORTS

Chemical Regulation in the Middle East



This handbook offers an essential guide to the patchwork of chemical regulatory programs and the complex system of permits and licenses that manage chemicals in the countries of the Middle East.

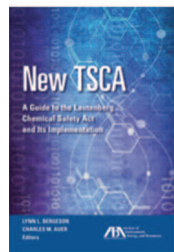
See also the [Chemical Regulation in the Middle East Webinar recording](#).

Available for purchase at

<https://www.wiley.com/enus/Chemical+Regulation+in+the+Middle+East-p-9781119223641>

New TSCA: A Guide to the Lautenberg Chemical Safety Act and Its Implementation

This book is a comprehensive guide to the substantial revisions to the Toxic Substances Control Act (TSCA) occasioned by enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act on June 22, 2016, to produce “new TSCA,” amending and replacing “old TSCA” as of that date.



B&C[®] Managing Partner Lynn L. Bergeson and Senior Regulatory and Policy Advisor

Charles M. Auer are editors and co-authors, with contributions from B&C’s outstanding TSCA practice group, including 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, and Kathleen M. Roberts. Available for purchase at <https://www.americanbar.org/products/inv/book/277092448/>

ABA Year in Review

Lynn L. Bergeson, co-author, “[Pesticides, Chemical Regulation, and Right-to-Know 2018 Annual Report](#),” in [The Year in Review 2018: Environment, Energy, and Resources Law](#), American Bar Association (2019).

Susan M. Kirsch, co-author, “[Water Quality and Wetlands 2018 Annual Report](#),” in [The Year in Review 2018: Environment, Energy, and Resources Law](#), American Bar Association (2019).

ARTICLES

Recent articles on critical issues:

Lynn L. Bergeson, “[SEC Proposes Changes To Reporting Rules](#),” *Chemical Processing*, October 16, 2019.

Lynn L. Bergeson, “[The Growing Influence of Chemical Risk Evaluation on the M&A Market](#),” *Financier World-wide*, October 2019.

Lynn L. Bergeson, “[Chemical Restrictions and TSCA’s Growing Commercial Influence](#),” *Environmental Quality Management*, Volume 29, Issue 1, Fall 2019.

Lynn L. Bergeson, Kathleen M. Roberts, and Richard E. Engler, Ph.D., “[Protecting the Value of Health, Safety Studies—Emerging TSCA Issues](#),” *Bloomberg Environment Insights*, August 22-23, 2019.

J. Brian Xu, Jane S. Vergnes, and Carla N. Hutton, “[China Drafts Changes to Chemical Registration Rules](#),” *Bloomberg Environment Insights*, July 29, 2019.

Lynn L. Bergeson, “[EPA Prioritizes Chemicals for Risk Evaluation: Why This Matters](#),” *Environmental Quality Management*, Volume 28, Issue 4, Summer 2019.

Lynn L. Bergeson, “[Protecting Confidential Business Information: An Evolving Challenge](#),” *International Chemical Regulatory and Law Review*, Volume 2, Issue 2, Summer 2019.

Lynn L. Bergeson, “[Expert Focus: TSCA and Liability under the False Claims Act – a Potentially Promising Area](#),” *Chemical Watch*, July 26, 2019.

Zameer Qureshi, “[EU REACH: How’s Life After the Registration Deadlines?](#),” *Elements, the Magazine of Chemicals Northwest*, Spring 2019.

Lynn L. Bergeson, “[The Rise of Ingredient Disclosure: The California and New York Experience](#),” *Environmental Quality Management*, Volume 28, Issue 3, Spring 2019.

ARTICLES

Lynn L. Bergeson, "[EPA Updates the TSCA Inventory: Impact on Chemical Importers](#)," *Elements, the Magazine of Chemicals Northwest*, Spring 2019.

Lynn L. Bergeson, "[Regulatory Opportunities and Challenges in Commercialising Biobased Chemicals](#)," *International Chemical Regulatory and Law Review*, Volume 2, Issue 1, Spring 2019.

Cheryl B. Cleveland, Carrie R. Fleming, Jason E. Johnston, Angela S. Klemens, and Bruce M. Young, "[Benchmarking the Current Codex Alimentarius International Estimated Short-Term Intake Equations and the Proposed New Equations](#)," *Journal of Agricultural and Food Chemistry*, March 14, 2019.

Lynn L. Bergeson and Karin F. Baron, "[Expert Focus: A Glimpse at US OSHA's Updated Hazard Communication Standard](#)," *Chemical Watch*, March 11, 2019.

Lynn L. Bergeson, "[Changing of the Guard](#)," *Specialty Chemicals Magazine*, March 2019.

PRESENTATIONS

Materials from recent presentations are available by request - email hlewis@lawbc.com.

"Worker Protection under the Toxic Substances Control Act," Richard E. Engler, Ph.D., Society for Risk Analysis 2019, Arlington, Virginia (December 8, 2019)

"GHS Overview and Implications of an Update to HCS 2012," Karin F. Baron, MSPH, 2019 Automotive Specialty Product Alliance (ASPA) Winter Meeting, Ft. Lauderdale, Florida (December 10, 2019)

"Update on SNURs and Nanomaterials," Society for Chemical Hazard Communication (SCHC) Fall Meeting, Arlington, Virginia (September 21, 2019)

"TSCA Risk Evaluation and Regulatory Issues: Do You Feel Me Now?" Lynn L. Bergeson, [Household & Commercial Products Association's \(HCPA\) IMPACT2019](#), Washington, D.C. (May 1, 2019)

"Data for Chemical Evaluations: Secret or Otherwise," Jane S. Vergnes, Ph.D., Society of Toxicology 38th Annual Meeting, Baltimore, Maryland (March 10, 2019)

"Legal & Regulatory Considerations for Renewable Chemical Production," Richard E. Engler, Ph.D., Nebraska Ethanol Board 2019 Emerging Issues Forum, La Vista, NE (March 8, 2019)

"Exporting Chemicals And Hazardous Material," Karin F. Baron, MSPH, Cleveland State University Global Business Center Program, Cleveland, Ohio (March 7, 2019)

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

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

WEBINARS

Value Chain Communications Required under TSCA Consent Orders and SNURs: How to Formulate Them and Optimize Their Value

[Lynn L. Bergeson](#), Managing Partner, B&C, and [Richard E. Engler, Ph.D.](#), Director of Chemistry, B&C, discuss the categories of legally required risk communications to value chain participants required under TSCA Consent Orders and SNURs, and analyze these communications through a legal, product stewardship, and practical lens.

Turkey REACH (KKDIK): Achieving Timely Compliance with New Chemicals Requirements

Turkey's Registration (*Kayıt*), Evaluation (*Değerlendirilme*), Authorization (*İzni*) and Restriction (*Kısıtlanma*) of Chemicals (*Kimyasalların*) (Turkey REACH/KKDIK) regulation was published by Turkey's Ministry of Environment and Urbanization (MoEU) on June 23, 2017. The Acta Group (Acta®) and CRAD Çevre Risk Analiz Denetim A.Ş. provided an overview of the framework, key similarities and differences with EU REACH, technical resources, and instruction on Turkish Safety Data Sheet (SDS) requirements.

RCRA Improvements Rule: An Update and Discussion

[Christopher R. Bryant](#), Senior Regulatory Consultant, B&C, and [Lynn L. Bergeson](#), B&C's Managing Partner, presented an overview of the significant regulatory changes, including transferring waste between generators, new requirements, and episodic generation standards, reorganization of the regulations and new standards for LQGs, SQGs, and VSQGs, and practical aspects of complying with the regulatory changes.

New TSCA at 3: Key Implementation Issues

[Alexandra Dapolito Dunn](#), Assistant Administrator, EPA Office of Chemical Safety and Pollution Prevention; [Lynn L. Bergeson](#), Managing Partner, B&C; and [Richard E. Engler, Ph.D.](#), Director of Chemistry, B&C, drilled-down on key implementation challenges facing industry and the EPA three years into navigating the legal, regulatory, and science policy issues arising under the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

FDA FSMA Food Defense Plan Requirements

One of the Food Safety Modernization Act (FSMA) foundational rules, Mitigation Strategies to Protect against Intentional Adulteration, requires non-exempt entities to have developed the appropriate preventive measures by July 26, 2019. [Karin F. Baron, MSPH](#), Senior Regulatory Consultant, B&C, and [Scott J. Burya, Ph.D.](#), Regulatory Chemist, B&C, covered key aspects of the rule, reviewed strategies for ensuring compliance with major provisions of the rule, including preparation of a Food Defense Plan, and suggested measures to ensure businesses were prepared for the July 26, 2019, deadline.

TSCA: Three Years Later

Leading panelists, including [Lynn R. Goldman](#), Michael and Lori Milken Dean and Professor, Environmental and Occupational Health, Milken Institute School of Public Health, George Washington University; [Alexandra Dunn](#), Assistant Administrator, OCSPP, EPA; and [Jeffery Morris](#), Director, OPPT, EPA, reflected on the accomplishments and challenges since the implementation of the 2016 Lautenberg Amendments and where the Toxic Substances Control Act (TSCA) stands today. Panelists explored a host of topics, including the current impacts of TSCA on science policies, challenges faced by industry, and the impacts of TSCA on regulatory policies, especially those concerning ensuring compliance and enforcement.

This one-day conference was hosted by The Environmental Law Institute (ELI), the George Washington University Milken Institute School of Public Health, and B&C.

Preserving Cosmetics on a Global Scale: It is Harder than You Think

The regulatory requirements that product manufacturers must adhere to when incorporating preservatives into their products and what claims are permissible on their product labels is far from harmonized globally, and the path is not getting easier. [Karin F. Baron, MSPH](#), Senior Regulatory Consultant, Acta; [Scott J. Burya, Ph.D.](#), Regulatory Chemist, Acta; and [Jane S. Vergnes, Ph.D., DABT®](#), Vice President, Scientific Affairs and Director of Toxicology, Acta, provided an overview of cosmetic ingredient regulations in the U.S., the European Union (EU), Canada, and China, focusing on how preservatives are regulated in cosmetic formulations. A special focus was on cosmetic claims specific to preservatives and how certain claims impact the product's regulatory jurisdiction.

WEBINARS

[Sustainable Investment in Agriculture](#)

The concept of "sustainability" elicits a range of interpretations and diverse legal, regulatory, and practical implications. Anchoring "sustainability" within a legal construct and limiting the fluidity of the concept is well underway, but very much a work in progress, in particular in the context of Agenda 2030 and the Sustainable Development Goals. Presenters discussed emerging tools and legal models for ensuring sustainable investment in agriculture, with a focus on the UNIDROIT initiative; due diligence for proposed investments; financial instruments; and where we go from here.

This webinar was presented by the IBA Agricultural Law Section, supported by the ABA Section of Environment Energy and Resources, Committee on Pesticides, Chemical Regulation and Right-to-Know, the Environmental Law Institute, and the National Agricultural Law Center. [Lynn L. Bergeson](#), Managing Partner, Bergeson & Campbell, P.C. (B&C®), and Vice Chair, International Bar Association, Agricultural Law Section, moderated.

[FIFRA Hot Topics in Pesticide, Biocides, and Other Agricultural Chemicals Regulation and Litigation](#)

[Richard P. Keigwin, Jr.](#), Director, Office of Pesticide Programs (OPP), Office of Chemical Safety and Pollution Prevention (OCSPP), U.S. Environmental Protection Agency (EPA); [Amy Plato Roberts](#), Regulatory Affairs Manager, Lallemand Plant Care, North America; [Lisa M. Campbell](#), Partner, B&C; and [James V. Aidala](#), Senior Government Affairs Consultant, B&C, discussed critical legal, science, and policy issues affecting pesticides and other agricultural chemicals.

[Prop 65: Exposure Assessments and Compliance Implications](#)

The webinar discussed legal, scientific, and practical considerations for companies to evaluate before deciding to conduct and rely upon exposure assessments determinations that Prop 65 warning requirements do not apply. The webinar consisted of 45 minutes of presentation, followed by a 15-minute Q&A period. [Lisa R. Burchi](#), Of Counsel, B&C, and [Jason E. Johnston, M.S.](#), Senior Scientist, B&C, presented.

PODCASTS



All Things Chemical™ engages listeners in intelligent, insightful conversation about everything related to industrial, pesticidal, and specialty chemicals and the law and business issues surrounding chemicals. B&C's talented team of

lawyers, scientists, and consultants keep listeners abreast of the changing world of both domestic and international chemical regulation and provide analysis of the many intriguing and complicated issues surrounding this space. The issues that B&C pursues in its day-to-day business are unfailingly interesting and we wish to share our knowledge, our insights, and our enthusiasm for these issues with you through our All Things Chemical podcast.

All Things Chemical is available now on [iTunes](#), [Spotify](#), [Stitcher](#), and [Google Play Music](#) with new episodes released approximately every two weeks. Subscribe so you never miss an episode. All Things Chemical is recorded and produced by [Bierfeldt Audio, LLC](#).

[RCRA Rundown: Hazardous Waste and Sustainable Removal](#)

Christopher R. Bryant and Lynn L. Bergeson discuss RCRA, what it is, how the law has developed, what is covered under it, and how we might expect -- or hope -- it to change for the better. Chris hits upon the subject of plastics and PFAS materials, and explains the evolution of EPA's thinking about waste over the last few decades, including how RCRA has adapted to a business world that is becoming increasingly more sustainability-oriented.

[Waiting for Lautenberg: A Conversation with Jim Jones](#)

Jim Jones, Executive Vice President Strategic Alliances & Industry Relations at the Household & Commercial Products Association (HCPA) and Lynn L. Bergeson discuss Jim's career as Assistant Administrator of the Office of Chemical Safety and Pollution Prevention in the Obama Administration and what it felt like to watch with anticipation as the political proceedings surrounding the TSCA amendment unfolded. In addition to talking about TSCA's recent history and EPA's implementation of it, Jim shares career advice, tips for other industry groups, and first-hand experiences about the difference between the private and public sectors of this industry.

PODCASTS

[How Do We Know if a New Technology Is Safe?](#)

Sheryl Lindros Dolan, Dr. Richard E. Engler, and Lynn L. Bergeson walk through what it takes to bring a new technology to EPA (or any other regulatory authority) and to help the regulators understand the benefits and safety of the new technology, especially when dealing with older regulatory frameworks that are sometimes ill-suited to anticipate the challenges posed by cutting edge technologies.

[Food Quality, New TSCA, and Much More: A Conversation with Lynn R. Goldman, Dean, Milken Institute School of Public Health at GWU](#)

Lynn R. Goldman, M.D., M.S., M.P.H., Michael and Lori Milken Dean, Milken Institute School of Public Health; Professor of Environmental and Occupational Health, and Lynn L. Bergeson discuss new TSCA's roots as the "Kids Safe Chemicals Act," as well as about how Dr. Goldman and others built upon Senator Lautenberg's interest in TSCA reform legislation, the parallels with implementing new TSCA, and Dr. Goldman's experience implementing what was then considered the "new FIFRA."

[South Korea's K-REACH: Why it Matters for Everyone with Karin Baron](#)

Karin F. Baron and Lynn L. Bergeson discuss K-REACH, the South Korean government's industrial chemical substance registration program, its recent amendment, and potential harmonization of chemical regulations in the region.

[Celebrating the Environmental Law Institute's 50th Anniversary with President Scott Fulton](#)

Scott Fulton, President of the Environmental Law Institute (ELI), and Lynn L. Bergeson discuss the various lines of work in which ELI is currently engaged, how the Institute has evolved over its 50-year history, and how it maintains its status as a well-respected, internationally recognized, non-partisan organization. They talk about the impact of the current federal Administration on the legal infrastructure, ELI's judicial training efforts around the world, the concept of "soft law," as well as the role that new technologies will play in the future of environmental monitoring and law.

[All Things Nano with Lisa E. Friedersdorf, Ph.D.](#)

Dr. Lisa E. Friedersdorf, the Director of the National Nanotechnology Coordination Office (NNCO), and Lynn L. Bergeson break down the central goals and challenges of the

National Nano Initiative, a governmental program designed to facilitate research and development in nanotechnology, educate people about nanotechnology, and ensure the responsible development of nano by understanding nano's potential environmental, safety, and health implications. They also talk about some of the wonderfully surprising and unique applications for nanotechnology existing currently in our daily lives, and potential future applications of the technology for the field of agricultural and chemical production.

[Food Security and World Hunger with Katherine Meighan, International Fund for Agricultural Development](#)

Katherine Meighan, the General Counsel of the International Fund for Agricultural Development (IFAD), and Lynn L. Bergeson discuss IFAD's efforts to address the issue of food security and world hunger, as well as the important social issues affecting global agriculture, including climate change and mass migration.

[Environmental Compliance and Enforcement with Environmental Integrity Projects' Eric Schaeffer](#)

Eric Schaeffer, Executive Director of the Environmental Integrity Project, and Lynn L. Bergeson touch on EPA's evolving enforcement strategy, how ideally to address non-compliant companies, voluntary disclosures by businesses that discover indiscretions, remote pollution monitoring techniques, and even the much-discussed idea of cooperative federalism.

[Inside OCSPP with EPA Assistant Administrator Alexandra Dapolito Dunn](#)

Alexandra Dunn, Assistant Administrator for EPA's Office of Chemical Safety and Pollution Prevention (OCSPP), and Lynn L. Bergeson discuss priorities and challenges inside the OCSPP, and what to expect from it in the coming months.

[Innovation and New Chemicals in the TSCA Program](#)

Lynn L. Bergeson and Dr. Richard E. Engler discuss so-called "New Chemicals" and the challenges faced by not only new chemical manufacturers, but also by the U.S. Environmental Protection Agency (EPA) in trying to fulfill its duties as a regulatory gatekeeper.

[Ambassador Howard Gutman on What Every CEO Needs to Know Right Now](#)

Former U.S. Ambassador to Belgium Howard Gutman and

Lynn L. Bergeson discuss what every CEO needs to know about the world right now. Howard provides his perspective on what to pay attention to with regard to Brexit, energy policy, climate change, trade, the globalized economy, and the 2020 Presidential election. Howard also provides advice on how to manage business perception, create opportunities from regulatory changes, and even shares some helpful thoughts on how to fill board seats to be more innovative.

Look Ahead at 2019 with Lynn Bergeson and Jim Aidala

Lynn L. Bergeson and James V. Aidala discuss 2019 and the state of industrial and agricultural chemical regulation: what is to come, what to expect, and how we can prepare for it. This touches on the updated TSCA chemical inventory, issues arising under the Endangered Species Act, and what it means to be identified as a high- or low-priority chemical under EPA's newly implemented chemical prioritization process.

Trade Roundtable with Daniella Taveau and Daniel R. Pearson

Daniella Taveau, a Regulatory and Global Trade Strategist and founder of Bold Text Strategies; Daniel Pearson, a principal at Pearson International Trade Services, LLC; and Christopher R. Bryant, Senior Regulatory Consultant with B&C, discuss all aspects of the trade discussion which might be relevant to anyone working in the chemical manufacturing space. Listeners will hear about developing a historical context in which to understand the U.S.' shifting trade policies; analysis and speculation about current and possible future trade policies as well as their philosophical underpinnings (or lack thereof); and specific discussion about practical current issues such as re-negotiating NAFTA, the effects of the trade war with China, the automobile industry, and what stakeholders should be doing in this moment of protectionist policies.

Pesticides: Navigating New Technologies under FIFRA

Lynn L. Bergeson and Sheryl Lindros Dolan discuss all things pesticides: past, present, and future, including the historical and legal/regulatory background necessary to understand the current state of pesticide regulation, which the U.S. Environmental Protection Agency (EPA) manages under the Federal Insecticide, Fungicide, and Rodenticide Act, or FIFRA, as it is colloquially known.

EU Food Contact Materials Legislation

Renato Addis, of the Brussels-based regulatory consulting firm EPPA, and Lynn L. Bergeson discuss the European Commission process to evaluate and likely revise the current

EU Food Contact Materials (FCM) legislation. This is a big deal for any stakeholders in this space -- domestic or European -- as the current legislation has been in-place for many years and the proliferation of national standards has greatly complicated an already complex area.

Biobased Product Regulation

Lynn L. Bergeson, Kathleen M. Roberts, and Dr. Richard E. Engler discuss the commercial challenges of bringing renewable, biobased chemicals to market, why the EPA has, in most cases, "pre market approval authority" over the commercialization of these chemicals, and get down into the science of what exactly constitutes a "biobased" chemical anyway.

"Dis-harmonization" of GHS

Lynn L. Bergeson and Karin F. Baron discuss recent developments pertinent to the United States Hazard Communication Standard (HCS). These regulatory developments have been proposed to bring the HCS more in line with GHS, the Global Hazard Communication Standard. Karin unpacks this complex but important area of the law and focuses on the aspirational and important goals of harmonization, in a way that focuses on the realities of a world that actually ensures dis-harmonization.

TSCA and Stalled Innovation

Lynn L. Bergeson, Charles M. Auer, and Dr. Richard E. Engler discuss their Bloomberg *Environment Insights* article "[New Chemicals Under New TSCA—Stalled Commercialization](#)" in greater detail. The thesis is simple: EPA's interpretation of our brand new industrial chemical law, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, signed into law in June 2016, needs to change. They believe that Congress never intended fundamentally to overhaul the new chemical review process and to require that EPA regulate north of 80% of all new chemicals. Ironically, that is exactly what the new law is being interpreted to do, in contrast to old law that regulated, appropriately, about 10-15% of new chemicals. The article and podcast explain the new law, contrasts it with the old law, and critically reviews the numbers -- the new chemical statistics from EPA's database, to prove the point. They then offer some suggestions to fix the problem.

Confidential Business Information under TSCA

Lynn L. Bergeson and Dr. Richard E. Engler discuss Confidential Business Information (CBI). CBI is both a term of art under the Toxic Substances Control Act (TSCA) and can be understood broadly to be anything from trade secrets to, you know, the secret sauce of a chemical formulation that makes a

product profitable. In their conversation, they focused on how this concept of CBI functions under TSCA and how businesses need to handle CBI during the EPA's chemical review process.

Chemical Regulation in the Middle East

Lynn L. Bergeson and Michael S. Wenk discuss his book "[Chemical Regulation in the Middle East](#)." Michael's book focuses on eight countries in the Middle East that have a combination of well-developed and emerging chemical regulatory schemes. The book provides a comprehensive examination of the main chemical management laws in force for each particular country, and summarizes general trends and issues facing the region as a whole.

Animal Testing and New TSCA

Lynn L. Bergeson leads a roundtable discussion with colleagues about a Strategic Research Plan released by EPA in 2019, outlining an approach to reduce and replace "vertebrate" testing. In keeping with the commitment outlined in 2016's Frank R. Lautenberg Chemical Safety for the 21st Century Act, EPA proposes several so-called New Approach Methodologies, or NAMs, which they hope will be able to replace and reduce animal testing. Weighing in on this hot topic are B&C's Dr. Richard E. Engler, Director of Chemistry, Dr. Jane S. Vergnes, Senior Toxicologist, and Dr. Oscar Hernandez, Senior Regulatory Chemist.

APPENDIX C: GLOSSARY

1-BP -- 1-Bromopropane	CR -- Continuing Resolution
2,4,6-TTBP -- 2,4,6-Tris(tert-butyl)phenol	CRS -- Congressional Research Service
µg/m³ -- Micrograms Per Cubic Meter	CSR -- Chemical Safety Report
µg/kg bw -- Micrograms Per Kilogram of Body Weight	CWA -- Clean Water Act
AA -- Assistant Administrator	DBP -- Dibutyl Phthalate
ABNT -- Brazilian Association of Technical Standards	decaBDE -- Decabromodiphenyl Ether
ACC -- American Chemistry Council	DEHP -- Di-ethylhexyl Phthalate
ACGIH ® -- American Conference of Governmental Industrial Hygienists	DG -- Directorate-General
Acta ® -- The Acta Group	DIBP -- Di-isobutyl Phthalate
ADAO -- Asbestos Disease Awareness Association	DIDP -- Di-isodecylphthalate
ADME -- Absorption/Distribution/Metabolism/Excretion	DINP -- Di-isononylphthalate
AEZ -- Application Exclusion Zone	DIW -- Department of Industrial Works (Thailand)
ANPRM -- Advanced Notice of Proposed Rulemaking	DOC -- U.S. Department of Commerce
APA -- Administrative Procedure Act	DOD -- U.S. Department of Defense
APHIS -- Animal and Plant Health Inspection Service	DOE -- U.S. Department of Energy
API -- Application Program Interface	DOI -- U.S. Department of the Interior
ATP -- Adaptation to Technical Progress	DOT -- U.S. Department of Transportation
B&C ® -- Bergeson & Campbell, P.C.	E&C -- Energy and Commerce
BBP -- Butylbenzylphthalate (BBP)	EAEU -- Eurasian Economic Union
BCCM -- B&C® Consortia Management, L.L.C.	EC -- European Commission
BE -- Bioengineered	ECHA -- European Chemicals Agency
BEF -- Biocides Enforcement Project	EDB -- Ethylene Dibromide
BETO -- Bioenergy Technologies Office	EDF -- Environmental Defense Fund
BPC -- Biocidal Products Committee	EEA -- European Economic Area
BPR -- Biocidal Products Regulation	EEC -- European Economic Community
BPRS -- BPR Subgroup	EFSA -- European Food Safety Authority
BRAG ® -- Biobased and Renewable Products Advocacy Group	Enforcement Forum -- Forum for Exchange of Information on Enforcement
CAA -- Clean Air Act	EO -- Executive Order
CARACAL -- Competent Authorities for REACH and CLP	ENM -- Engineered Nanomaterials
CBD -- Center for Biological Diversity	EP -- European Parliament
CBI -- Confidential Business Information	EPA -- U.S. Environmental Protection Agency
CDR -- Chemical Data Reporting	EPW -- Environment and Public Works Committee
CDX -- Central Data Exchange	ERG -- Emergency Response Guidebook
CERCLA -- Comprehensive Environmental Response, Compensation, and Liability Act	ESA -- Endangered Species Act
ChAMP -- Chemical Assessment Management Program	EU -- European Union
CIB -- Current Intelligence Bulletin	EUH -- EU Specific Hazard Statements
CLA -- Council of Labor Affairs (Taiwan)	FAA -- Federal Aviation Administration
CLASS -- Classification, Labeling and Safety Data Sheet of Hazardous Chemicals (Malaysia)	FAST Act -- Fixing America's Surface Transportation Act of 2015
CLP -- Classification, Labeling and Packaging	FCM -- Food Contact Material
CoRAP -- Community Rolling Action Plan	FCN -- Food Contact Notification
CP-TPP -- Comprehensive and Progressive Agreement for Trans-Pacific Partnership	FDA -- U.S. Food and Drug Administration
CPSC -- Consumer Product Safety Commission	FDP -- Food Defense Plan
	FFDCA -- Federal Food, Drug, and Cosmetic Act
	FIFRA -- Federal Insecticide, Fungicide, and Rodenticide Act
	FQPA -- Food Quality Protection Act
	FRA -- Federal Railroad Administration
	FSIS -- Food Safety and Inspection Service

FSMA -- Food Safety Modernization Act	LNG -- Liquefied Natural Gas
FSVP -- Foreign Supplier Verification Program	LoA -- Letter of Access
FY -- Fiscal Year	LVE -- Low Volume Exemption
GAO -- Government Accountability Office	MAD -- Mutual Acceptance of Data
GB -- Guobiao	MAP-21 -- Moving Ahead for Progress in the 21st Century Act
GCC -- Gulf Cooperation Council	MCAN -- Microbial Commercial Activity Notice
GDP -- Gross Domestic Product	MCL -- Maximum Contaminant Levels
GE -- Genetically Engineered	MEM -- Ministry of Emergency Management (China)
GHS -- Globally Harmonized System of Classification and Labeling of Chemicals	METI -- Ministry of Economy, Trade and Industry (Japan)
GLP -- Good Laboratory Practice	MOA -- Memorandum of Agreement
GMO -- Genetically Modified Organism	MoE -- Ministry of Environment (South Korea)
GRASE -- General Recognition of Safety and Effectiveness	MoEL -- Ministry of Employment and Labor (South Korea)
GSO -- Gulf Standards Organization	MoEU -- Ministry of Environment and Urbanization (Turkey)
HAP -- Hazardous Air Pollutant	MoIT -- Ministry of Industry and Trade (Vietnam)
HBBD -- Cyclic Aliphatic Bromides Cluster of Flame Retardants	MoL -- Ministry of Labor (Taiwan)
HCBD -- Hexachlorobutadiene	MOU -- Memorandum of Understanding
HCS -- Hazard Communication Standard	NAFTA -- North American Free Trade Agreement
HHCB -- 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran	NAM -- New Approach Methodologies
HMR -- Hazardous Materials Regulations	NDAA -- National Defense Authorization Act
HPR -- Hazardous Products Regulation	NDRC -- National Development and Reform Commission
HSA -- Hazardous Substance Act (Thailand)	NEMA -- National Emergency Management Agency
HSIA -- Halogenated Solvents Industry Association	New Zealand EPA -- New Zealand Environmental Protection Authority
HSNO -- Hazardous Substances and New Organisms	NGO -- Non-governmental Organization
IARC -- International Agency for Research on Cancer	NIER -- National Institute of Environmental Research (South Korea)
ICAO Technical Instructions -- International Civil Aviation Organization's Technical Instructions for the Safe Transport of Dangerous Goods by Air	NIOSH -- National Institute for Occupational Safety and Health
ICCM5 -- International Conference on Chemicals Management	Nm -- Nanometers
IFR -- Interim Final Rule	NMFS -- National Marine Fisheries Service
IMDG Code -- International Maritime Dangerous Goods Code	NMP -- N-methylpyrrolidone
IMERC -- Interstate Mercury Education and Reduction Clearinghouse	NOA -- Notice of Activity
IMO -- International Maritime Organization	NOI -- Notice of Intent
IND -- Investigational New Drug	NPDES -- National Pollutant Discharge Elimination System
IP -- Intellectual Property	NP/NPE -- Nonylphenols and Nonylphenol Ethoxylates
ISO -- International Organization for Standardization	NPRM -- Notice of Proposed Rulemaking
ITC -- International Trade Commission	NRDC -- Natural Resources Defense Council
IUR -- Inventory Update Reporting	NRCC -- National Registration Centre for Chemicals (China)
Kg -- Kilogram	NYDEC -- New York Department of Environmental Conservation
KOSHA -- Korea Occupational Safety and Health Agency	OCSPP -- Office of Chemical Safety and Pollution Prevention
K-REACH -- Act on the Registration and Evaluation of Chemicals (South Korea)	OECA -- Office of Enforcement and Compliance Assurance
Lautenberg -- Frank R. Lautenberg Chemical Safety for the 21st Century Act	OECD -- Organization for Economic Cooperation and Development
LCPFAC -- Long-chain Perfluoroalkyl Carboxylates	OEHHA -- Office of Environmental Health Hazard Assessment
LCPFAS -- Long-chain Perfluoroalkyl Sulfonates	OEL -- Occupational Exposure Limit
	OMB -- Office of Management and Budget

ONIP -- OECD Network on Countering the Illegal Trade of Pesticides	SCIC -- Singapore Chemical Industry Council
OP -- Organophosphate	SCIL -- Safer Chemical Ingredients List
OPP -- Office of Pesticide Programs	SDS -- Safety Data Sheet
OPPT -- Office of Pollution Prevention and Toxics	SEA -- Turkey Implementation of CLP Regulation
OR -- Only Representative	SEGRES -- Secretariat-General of the Presidency Services -- USFWS and NMFS
ORD -- Office of Research and Development	SIA -- Sunscreen Innovation Act
OSHA -- U.S. Occupational Safety and Health Administration	SIEF -- Substance Information Exchange Forum
OTC -- Over-the-Counter	SNUN -- Significant New Use Notice
PANNA -- Pesticide Action Network North America	SNUR -- Significant New Use Rule
PBT -- Persistent, Bioaccumulative, and Toxic	SPF -- Sun Protection Factor
PCE -- Perchloroethylene	Taiwan EPA -- Taiwan Environmental Protection Administration
PCTP -- Pentachlorothiophenol	TBBPA -- 4,4'-(1-Methylethylidene)bis[2,6-dibromophenol]
PEC -- Priority Existing Chemical	TCE -- Trichloroethylene
PEER -- Public Employees for Environmental Responsibility	TCEP -- Tris(2-chloroethyl) Phosphate
PFAS -- Perfluoroalkyl Substances	TCSCA -- Toxic Chemical Substance Control Act (Taiwan)
PFOA -- Perfluorooctanoic Acid	TCSCCA -- Toxic and Chemical Substances of Concern Control Act (Taiwan)
PFOS -- Perfluorooctanesulfonic Acid	TDI -- Tolerable Daily Intake
PHMSA -- Pipeline and Hazardous Materials Safety Administration	TFM -- Tentative Final Monograph
PIH -- Poison-by-Inhalation	TLV[®]-CS -- Threshold Limit Values for Chemical Substances
PIP (3:1) -- Phenol, Isopropylated Phosphate (3:1)	TME -- Test Marketing Exemption
PMN -- Premanufacture Notice	TPP -- Trans-Pacific Partnership
PPE -- Personal Protective Equipment	TPP (chemical) -- Phosphoric Acid, Triphenyl Ester
PPM -- Parts Per Million	TRI -- Toxics Release Inventory
PRIA -- Pesticide Registration Improvement Act	TSCA -- Toxic Substances Control Act
PRIA 3 -- Pesticide Registration Improvement Extension Act	T-TIP -- Transatlantic Trade and Investment Partnership
PRIA 4 -- Pesticide Registration Improvement Extension Act of 2018	TPP -- Trans-Pacific Partnership
Prop 65 -- Proposition 65	TWA -- Time-Weighted Average
PSI -- Per Square Inch	UAE -- United Arab Emirates
PT -- Product-Type	UID -- Unique Identifier
PV29 -- Pigment Violet 29	UK -- United Kingdom
Q1 -- First Quarter	UN -- United Nations
Q3 -- Third Quarter	UNIDO -- United Nations Industrial Development Organization
Q4 -- Fourth Quarter	U.S. -- United States
R&D -- Research and Development	USACE -- U.S. Army Corps of Engineers
RAC -- Risk Assessment Committee	USDA -- U.S. Department of Agriculture
RCC -- Regulatory Cooperation Council	USFWS -- U.S. Fish and Wildlife Services
RCRA -- Resource Conservation and Recovery Act	USMCA -- United States-Mexico-Canada Agreement
REACH -- Registration, Evaluation, Authorization and Restriction of Chemicals	USTR -- U.S. Trade Representative
REF -- REACH-EN-FORCE	VIP -- Veterinary Innovation Program
Rev. -- Revision	WHMIS -- Workplace Hazardous Materials Information System
REL -- Recommended Exposure Limit	WHO -- World Health Organization
RVP -- Reid Vapor Pressure	WoE -- Weight of Evidence
SACC -- Science Advisory Committee on Chemicals	WHS -- Work Health and Safety Laws (Australia)
SAICM -- Strategic Approach to International Chemicals Management	WOTUS -- Waters of the U.S.
SAPA -- State Administrative Procedure Act	WPS -- Worker Protection Standard
	WTO -- World Trade Organization



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