A. Introduction

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

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

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

1. Elections Have Consequences

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

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

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

2. EPA Leadership

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

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

Finally, in August 2018, a second nominee was announced: Ms. Alexandra Dapolito Dunn who currently serves as the Regional Administrator (RA) of EPA’s Region 1. This region covers EPA program activities in New England including the states of Connecticut, Massachusetts, Rhode Island, Vermont, New Hampshire, and Maine. Ms. Dunn has also served as the Executive Director of the Environmental Council of the States (ECOS), an organization of state environmental regulatory agencies. The AA positions are subject to Senate confirmation (the RA positions are not), so Ms. Dunn could not simply be transferred into the OCSPP position. Ms. Dunn had to undergo the process of consideration by the Senate Environment and Public Works Committee and will undergo a vote by the Senate. On November 29, 2018, the Senate Environment and Public Works Committee convened a confirmation hearing on the nomination of Ms. Dunn, and the full Senate approved the confirmation on January 2, 2019.

3. Administration Initiatives

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

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

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

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

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

4. Operating Environment

4.1 Congress

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

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

4.2 Media Coverage

As we noted last year, media coverage of EPA actions under the Trump Administration has been intense and mostly critical. News in the current era is described as “tribal” -- consumers can pick from many sources and receive a constant stream of information tuned to their personal biases without necessarily receiving many contrary views. One problem with media coverage of media coverage is that it is covered by the media. One
person’s “fake news” is another person’s important stand of telling truth to power.

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

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

### 4.3 Litigation

Litigation is a time-tested tool of advocacy, either to support or to prevent change to a desired policy position. As soon as the new Administration arrived, environmental advocacy groups planned on using litigation as a key strategy since advocacy through both the Executive and Legislative branches of government was considered to be ineffective. Two years later, that plan has been executed, and it has been effective in both delaying some changes in rules and policies sought by the Administration and in ensuring that proper tools and procedures are followed in making changes to established regulations. For example, using Executive Orders to “make it happen” and other means simply to impose changes have been slowed or reversed due to procedural defects. Similarly, even when the appropriate procedures were followed to propose changes, challenges to the development process or judicial challenges to the final decision have been filed to delay or reverse the outcome. Litigation is also not a new tool, but here again the frequency and intensity of using the tool has been emphasized.

### B. TOXIC SUBSTANCES CONTROL ACT (TSCA)

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

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

##### 1.1 Section 4 -- Testing

(a) Regulatory Actions

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

EPA might use the Section 4 tools (particularly the new order authority) to fill critical data needs as part of the ongoing risk evaluations under Section 6. At the same time, the short deadline for completing risk evaluations will affect EPA’s ability to obtain completed studies that can be timely reviewed and incorporated in risk evaluations. EPA has indicated that it may not proceed with prioritization for chemicals that do not have sufficient data. Section 4 is the tool available to address that issue, although to use order authority in such cases (rather than a rule or an enforceable consent agreement (ECA)), EPA would need to support a “may present” conclusion. Another complication in requiring prioritization testing is that EPA must make a prioritization designation within 90 days after receiving the Section 4 information.

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

1.2 Section 5 -- New Chemicals

Return to equilibrium on new chemicals.

**Table 2. Section 5(a) Case Statistics under New TSCA from June 22, 2016 - November 27, 2018**

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

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-tsca/statistics-new-chemicals-review#stats. It includes premanufacture notices (PMN), Microbial Commercial Activity Notices (MCAN), and Significant New Use Notices (SNUN), but excludes exemption notices, that were within the 90-day review period as of June 22, 2016 — cases in which EPA restarted the 90-day clock and re-reviewed regardless of the outcome of its initial review.

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

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

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

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

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

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

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

(b) Non-order SNURs Proposed

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

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

(c) New Chemicals Litigation

In January 2018, the Natural Resources Defense Council (NRDC) petitioned the U.S. Court of Appeals for the Second Circuit for review of EPA’s "New Chemicals Decision-Making Framework: Working Approach to Making Determinations under Section 5 of TSCA" (Framework Document). NRDC v. EPA, No. 18-25. In its petition for review, NRDC described the Framework Document as a final rule, and argued in its May 1, 2018, opening brief that, based on the Framework Document, EPA “limits its review of a new chemical substance to the manufacturer’s intended conditions of use and disregards Congress’s instruction to address risk concerns through enforceable orders and regulations.” EPA’s July 31, 2018, opening brief included a declaration from Office of Pollution Prevention and Toxics (OPPT) Director Jeffery Morris, Ph.D. According to Morris, EPA considers the “conditions of use” of the PMN when making determinations under TSCA Section 5(a)(3).

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

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

1.3 Section 6 -- Existing Chemicals

(a) Prioritization

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

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

Once candidate chemicals have been identified, EPA will initiate the prioritization process, as outlined in the procedural rule, including two 90-day comment periods, and complete the final prioritization designations in nine to 12 months, but no later than December 22, 2019. Thus, 2019 will be an important year for stakeholders to participate in and consider EPA’s efforts throughout the prioritization process and in its designations.

(b) Risk Evaluations

EPA is in the process of developing risk evaluations for the first ten chemicals selected from the 2014 update to the TSCA Work Plan. Under new TSCA, EPA has three years to complete a risk evaluation, extendable for six months. EPA released its first draft risk evaluation in November 2018 concerning the chemical Colour Index (C.I.) Pigment Violet 29. EPA’s draft concluded that the chemical does not present an unreasonable risk. As discussed below, the Science Advisory Committee on Chemicals (SACC) will hold its first public meeting in January 2019, when it will take public comment and conduct a peer review of this draft risk evaluation.
During 2019, EPA will be releasing additional draft risk evaluations for peer review and public comment prior to preparing the final risk evaluations by the December 16, 2019, deadline (extendable to June 16, 2020). Presumably, for most of these cases, EPA will be working behind closed doors during 2019 on the evaluations, which means there may not be heightened media coverage or public discourse on the ongoing EPA work. Nonetheless, release of the draft and possibly final risk evaluations will be one of the more important developments expected to occur in 2019.

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

New TSCA also requires that, by the end of calendar year 2019, EPA must have at least 20 chemical risk evaluations ongoing at any given time on high-priority substances. In addition, as allowed under Section 6(h)(5), EPA has initiated manufacturer-requested risk evaluations on two persistent, bioaccumulative, and toxic (PBT) chemicals.

(c) Risk Management, including of Certain PBT Chemicals

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

There is, in addition, a 2019 statutory deadline for regulatory action on certain PBT chemicals. TSCA Section 6(h) requires EPA to propose Section 6(a) regulatory action by June 22, 2019, on chemicals from the 2014 update of the TSCA Work Plan that meet the PBT requirements laid out in Section 6(h). The proposed Section 6(a) rules must, pursuant to Section 6(h)(4), “address the risks” presented by the chemicals and reduce exposure “to the extent practicable.” EPA identified five PBT chemicals that meet the statutory criteria (decabromodiphenyl ethers (DecaBDE); hexachlorobutadiene (HCBD); pentachlorothiophenol (PCTP); phenol, isopropylated, phosphate (3:1); and 2,4,6-tris(tert-butyl) phenol). The proposed rules that must be issued by June 2019 will represent another of the important developments in 2019, as they will be the first use by the Trump Administration of the new regulatory authority and requirements under Sections 6(a) and (c) of the amended law.

(d) Prioritization and Risk Evaluation Litigation

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

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

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

Petitioners argued in their November 9, 2018, reply brief that new TSCA requires EPA to consider “so-called” legacy activities in its risk evaluations. According to the petitioners, EPA’s justifications for eliminating legacy use, associated disposal, and legacy disposal from the “conditions of use” definition are “divorced from the statutory text” and must be rejected. The petitioners maintain that EPA fails to show how excluding conditions of use from risk evaluations comports with new TSCA’s “text, structure, and purposes.” In addition, petitioners assert that EPA fails to show how use-by-use “no unreasonable risk” determinations “can be squared with the text or health-protective purpose of TSCA.” The petitioners claimed that EPA will fail to ensure that it has adequate information for risk evaluation by failing to obtain “often-vital information that can be generated only through longer-term testing.” The petitioners stated that such information may be “reasonably available” because EPA “can reasonably generate” it “considering the deadlines” for both prioritization and risk evaluation.

(e) Proposed SNURs on Existing Chemicals

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

In addition, the Trump Administration issued a proposed SNUR on June 11, 2018 (83 Fed. Reg. 26922), on certain non-ongoing uses of asbestos and the Fall 2018 Regulatory Agenda states that the rule is scheduled to be issued in final by January 2019. This SNUR received a fair amount of attention in the popular press, although it was interpreted as permitting, rather than regulating, that is, requiring a SNUN prior to initiating these legacy uses. Given all the issues and attention focused on asbestos under TSCA, we expect that this rule will be promulgated during the first quarter of 2019.

1.4 Sections 8 and 14

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

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

- Reporting from the 2012 and 2016 Chemical Data Reporting (CDR) cycles;
- Notices of Commencement (NOC) received by EPA since June 21, 2006; and
- Notice of Activity (NOA) Form As received by EPA through the February 7, 2018, deadline, submitted under
As of April 2018, the Inventory lists approximately 38,303 total active substances, or about 44.5 percent of the substances listed on the Inventory. It is somewhat surprising that a greater percentage of the non-confidential substances were notified as active (45.6 percent of non-confidential business information (CBI) substances compared to 40.5 percent of confidential substances). Because most substances added to the Inventory through the PMN process were added with CBI identities (62.7 percent), we interpret this statistic as supporting B&C’s contention, as articulated in articles and in communications to EPA from the TSCA NCC, that, as a general matter, new chemicals do not necessarily remain long term in the market, thus fewer are active over time. This may be because they are overtaken by even newer chemicals, or because they fail to gain sufficient hold on the market.

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

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

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

(b) CBI Inventory Review Rule

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

(c) Inventory Notification Rule Litigation

On October 12, 2018, the U.S. Court of Appeals for the District of Columbia Circuit heard oral argument in the Environmental Defense Fund’s (EDF) challenge to the final rule. EDF v. EPA, No. 17-1201. According to EDF, in promulgating the final rule, EPA “repeatedly violated the statutory text and erred in favor of concealment instead of disclosure.” TSCA Section 8(b)(f)(B)(ii) states that the Inventory rule must require manufacturers or processors that “seek[] to maintain an existing claim for protection against disclosure of the specific chemical identity” to submit a request to maintain that claim. EPA allowed a manufacturer or processor to assert confidentiality claims even if that manufacturer or processor had never asserted such a claim in the past, as long as someone had. EDF maintains that confidentiality claims are person-specific and a person cannot “maintain an existing claim” if the person has never asserted the claim before. New TSCA Section 14 now requires that confidentiality claims meet numerous substantive and procedural requirements beyond those required by Exemption 4 of the Freedom of Information Act (FOIA). According to EDF, the final rule fails to incorporate several of Section 14’s requirements and instead directs EPA to follow its general FOIA regulations. EPA will therefore process confidentiality claims without complying with all of the requirements in new TSCA Section 14.

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

During the oral argument, the three-judge panel focused on the Trump Administration’s revisions to the proposed rule released in the final days of the Obama Administration. The judges noted that new TSCA specifies criteria for substantiating CBI claims, including whether the information is readily attainable through reverse engineering. While this was part of the proposed rule, the Trump Administration removed this criterion from its final rule. EPA responded that while the final rule does not specifically require consideration of whether data are readily
attainable through reverse engineering, the final rule's remaining criteria for substantiating claims capture that concern. EPA argued that if the judges find in favor of EDF, the proper remedy would be to remand the final rule to EPA without vacatur to allow it to explain better why certain criteria were dropped from the rule's provisions for substantiating CBI claims. EDF requested partial vacatur and remand. According to EDF, a complete vacatur would postpone the release of some of the “very information” sought by EDF, allowing EPA to postpone the published TSCA Inventory based on the information that it has already collected. EPA could still explicitly include a consideration of “reverse engineering” in the upcoming review plan that EPA must promulgate under Section 8(b)(4)(C) that must include the provisions for substantiating a CBI claim.

(d) Unique ID Implementation

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

(e) Mercury Rule

On June 27, 2018, EPA promulgated a final rule regarding reporting requirements for applicable persons to provide information to assist in the preparation of an “inventory of mercury supply, use, and trade in the United States,” where “mercury” is defined as “elemental mercury” and “a mercury compound.” 83 Fed. Reg. 30054. The final rule applies to any person who manufactures (including imports) mercury or mercury-added products, or otherwise intentionally uses mercury in a manufacturing process (including uses traditionally not subject to TSCA, such as for the manufacture of pharmaceuticals and pesticides). EPA will use data from the 2018 reporting year for the 2020 mercury inventory. The 2018 reporting year is from January 1, 2018, to December 31, 2018, and the submission deadline for the 2018 reporting year is July 1, 2019.

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

(f) Mercury Rule Litigation

On July 19, 2018, NRDC petitioned the U.S. Court of Appeals for the Second Circuit to review and set aside the final mercury rule. NRDC v. EPA, No. 18-2121. On October 15, 2018, the court granted a joint motion filed by NRDC, EPA, and Vermont to consolidate NRDC’s case with Vermont v. EPA, No. 18-2670. NRDC and Vermont filed separate opening briefs on December 7, 2018. NRDC’s statement of issues includes: (1) whether the reporting rule is unlawful because it exempts manufacturers and importers of products with mercury-added component parts, despite TSCA’s instruction that EPA require reporting from “any person who manufactures [or imports] mercury or mercury-added products”; and (2) whether the reporting rule is unlawful because it exempts manufacturers and importers of mercury in amounts (i) greater than or equal to 2,500 pounds per year for elemental mercury, or (ii) greater than or equal to 25,000 pounds per year for mercury compounds despite TSCA’s requirement that EPA require reporting from “any person” who manufactures or imports mercury and that EPA prepare an accurate and comprehensive “inventory” of mercury supply and trade. Vermont’s statement of issues includes these issues, as well as whether EPA’s decision to exempt certain entities from the reporting requirements is contrary to Congress’ intent to create a detailed and complete inventory of the relevant mercury activities involving mercury supply, use, and trade under TSCA. On December 14, 2018, 11 states -- Oregon,
Connecticut, Hawaii, Massachusetts, Maine, Maryland, Minnesota, New Jersey, Pennsylvania, Rhode Island, and Washington -- filed an *amicus* brief in support of NRDC and Vermont. EPA's brief is due *March 8, 2019*.

(g) Nomenclature

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

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

(h) CDR Rule Changes

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

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

1.5 Section 21

(a) Litigation

EPA is still wrestling with a complaint filed on April 18, 2017, to compel it to initiate a rulemaking under TSCA Section 6 to prohibit the addition of fluoridation chemicals to drinking water supplies (*Food & Water Watch, Inc. v. EPA*, Case No. 3:17-cv-02162-EMC (N.D. Cal.)). This complaint was filed as an appeal following EPA's denial of a TSCA Section 21 petition requesting it to exercise its Section 6 authority to prohibit the purposeful addition of fluoridation chemicals to U.S. water supplies filed by several organizations and individuals. On February 7, 2018, the court denied EPA's motion for a protective order to limit review to the administrative record, stating that the "text of the TSCA, its structure, its purpose, and the legislative history make clear that Congress did not intend to impose such a limitation in judicial review of Section 21 citizen petitions," and, therefore, allowed for the plaintiffs' case to be heard *de novo* – a decision that will allow plaintiffs to introduce evidence above and beyond what was included in the administrative record when EPA responded to plaintiffs' petition. The case is scheduled for an eight court day Bench Trial beginning *August 5, 2019*, and ending *August 16, 2019*, per the court's April 14, 2018, order and discovery is currently ongoing.

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

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

### 1.6 Section 26

**Section 26**

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

EPA issued the final Section 26(b) fees rule on October 18, 2018. [83 Fed. Reg. 52694](https://www.federalregister.gov/articles/2018/10/18/2018-24230). 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. EPA is soon expected to issue its list of chemicals subject to prioritization under Section 6, and then has nine to twelve months to determine if those chemicals are high or low priority. If a chemical is deemed high priority, EPA must initiate a risk evaluation, including publication of the scope, within six months. Thus, by **mid-2020**, EPA will likely be assessing fees for these chemicals and, per the final rule, the entire risk evaluation fee of $1,350,000 for TSCA Work Plan chemicals will be required sixty days after the scope is published.

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

(b) SACC

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

EPA announced in November that it will convene the first public meeting of the SACC in January 2019, to review the draft risk evaluation of C.I. Pigment Violet 29. This meeting will be preceded by a SACC teleconference to discuss and receive public comments on the draft charge questions for the peer review. We expect a number of additional meetings of the SACC to review risk evaluations as they are released by EPA over the course of the year.

### 1.7 Other Topics

(a) OPPT Staffing and Reorganization

The final fees rule, issued in October 2018, opened the door for OPPT to obtain the much needed resources to meet its new obligations under amended TSCA. [83 Fed. Reg. 52694 (Oct. 17, 2018)](https://www.federalregister.gov/articles/2018/10/17/2018-24230). The new fees apply to Section 5 notices received after October 1, 2018, and to future Section 4 testing actions and Section 6 risk evaluations. We expect that during 2019, OPPT will work to use the new resources to increase its staff and contractor capabilities as the fees begin to flow into EPA's budget.

Another consideration is the pending reorganization of OPPT. EPA took steps during Spring 2018 to delay its pending reorganization to consider a six division structure that has separate new and existing chemical risk management divisions complemented by separate new and existing chemical risk assessment divisions. Under this scheme, OPPT's other functions were to be distributed into a mission operations division and a division that sweeps together chemical right-to-know, economics, information reporting, and the Safer Choice/Design for the Environment (DfE) program.

While we like the concept of parallel risk assessment divisions, critical questions and issues concern us regarding OPPT's ability to obtain both adequate hiring authority to meet its scientific needs and then being able to locate and hire the needed technical experts. While the first may be satisfactorily resolved, based on our experience, the second will be challenging, as expertise is in short supply in areas such as toxicology, environmental fate, exposure assessment, biotechnology, and nanotechnology. A related and critical reorganization issue that could be joined in earnest in 2019 is the process to select the four Division Directors needed to manage and lead the separate new and existing chemical risk assessment and risk management divisions. These selections will be critical in determining the near-term path forward and potentially affecting the long-term direction and
implementation of TSCA Sections 4, 5, 6, and 8.

(b) International

(i) OECD Chemicals

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

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

OECD updated its guidance document on standardized test guidelines for endocrine disruption.

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

Potential deliverables in 2019 include the following:

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

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

(ii) SAICM

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

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