BERGESON & CAMPBELL, P.C.

Predictions and Outlook for U.S. Federal and International Chemical Regulatory Policy 2018

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FORECAST 2018

Bergeson & Campbell, P.C. (B&C®) and its consulting affiliate The Acta Group (Acta®) are pleased to offer you our Forecast 2018. The document distills key trends in U.S. and global chemical law and regulation, and provides a sneak preview of what our legal, scientific, and regulatory professionals believe we are likely to see in the New Year.

Our unique business platform and global team of highly skilled professionals are perfectly suited to offer this focused forecast for the New Year. Our core business is the law, science, regulation, and policy of chemicals of all stripes -- industrial, agricultural, intermediate, specialty, biocidal, manufactured at the bulk or nano scale, and using conventional or innovative technologies including biotechnology, synthetic biology, or bio-based. Our highly acclaimed team of scientists (eight Ph.D.s), including toxicologists, exposure experts, geneticists, and lawyers deeply versed in chemical law, policy, and science, and our business platform leverages and ensures the seamless integration of law and science to achieve success at every level, and in all parts of the globe.

We extend to you our very best wishes for the New Year, and continued commercial success in your business endeavors.

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PREDICTIONS AND OUTLOOK FOR THE U.S. ENVIRONMENTAL PROTECTION AGENCY'S OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION 2018

What a difference a year makes. To some extent, the surprise of 2016 – the election of Donald J. Trump as President – did make many predicted changes about life in Washington, D.C. for 2017 come true. The U.S. Environmental Protection Agency's (EPA) budget proposal reflects serious cuts, climate change policies were radically reversed, rules were withdrawn, several promulgated regulations were Congressionally invalidated, and new leadership positions were filled by appointees who have been harsh critics of past EPA policies. At the same time, much of the anticipated agenda of the new Administration remains unfulfilled, prospective, and fluid at best.

Rancorous and bitter partisan wrangling on Capitol Hill, despite Republican control of the Senate and the House of Representatives (House), has stymied some Administration initiatives and caused nominations to languish, all occurring in the swirl of intensely critical media coverage of EPA actions. Retired EPA staffers are sought out by the media to be profiled as martyred saints who decided to leave rather than stay another day under the new regime. Print and television media outlets openly advertise and invite remaining career staff in agencies to leak documents as part of the "fight" for proper oversight of program activities. Recent punditry has stressed the word "tribalism" to indicate a predictable binary response either for or against the Administration, depending on one's party identification and other political affiliations.

The result has been a mix of wary optimism and fiery opposition by those for or against significant changes to the way EPA has acted in the past and/or the initiatives of the Obama Administration. What new ideas will succeed versus what existing policies will prevail has become less predictable, however. Moreover, despite the difficulties of the first year for the new Administration, there are at least three more years to implement an agenda.

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Operating Environment

The "For Trump/Not For Trump" choice, however simplistic, does not begin to describe the intensity of the rhetoric surrounding virtually all current EPA behavior. The new Administration invites some of this divisiveness when it uses a "not Obama" guideline to determine priorities and initiatives. To some extent this is typical for the arrival of a new Administration. But the level of hostility between opposing camps is extreme, and seems to blanket any idea no matter how routine. Even when the programs issue housekeeping improvement suggestions, there are some who view it as part of the larger de-regulatory agenda.

Regulatory Reform

Among the new priorities is "regulatory reform" both on Capitol Hill and in the White House. 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. On Capitol Hill, various Committees have sought to "reform" and improve EPA science policies to reflect both a more transparent scientific basis for decisions and more consideration of the expected economic costs of regulatory proposals.

Of particular note is EO 13771 issued January 30, 2017, *Reducing Regulation and Controlling Regulatory Costs*, which mandated a "2 for 1" regulation policy. That is, for each new regulation proposed by a federal agency like EPA, two regulations must be eliminated (as measured by the net regulatory burden). The headline is easy to describe, but operationally it is less clear how the mechanics of counting and estimating tradeoffs will be calculated. At a minimum, such directives will further empower the rule review staff in the Office of Management and Budget's (OMB) Office of Information and Regulatory Analysis (OIRA) to question EPA initiatives for increased regulatory costs.

Separate from efforts concerning any future rules or rulemaking, the Administration acted to delay implementation, and announced its intention to revise, a number of rules issued under the Obama Administration. The highest profile examples are the previous actions EPA took to address climate change and the water program rule to define "Waters of the U.S." (WOTUS). The Administration's action on numerous additional rules and policies are also important, even if not as well known. For example, the first Office of Chemical Safety and Pollution Prevention (OCSPP) rules addressing Toxic Substances Control Act (TSCA) policies were significantly different as final rules when compared to the Obama proposal. As another example, the Office of Pesticide Programs (OPP) made efforts to delay and eventually revise regulations on farmworker protection and rules concerning state certification of certain pesticide training programs required under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for the purchase and use of restricted use pesticides. More generally, the Administration openly invited public comment for stakeholders to submit ideas for possible "regulatory relief" as part of its intent to signal strongly to the business and regulated community that such suggestions are welcome.

On Capitol Hill, Republican control of the House and Senate as well as the Presidency opened the door to an unprecedented and wide-ranging application of the Congressional Review Act (CRA) to set aside promulgated EPA regulations. In addition, long sought "reforms" have been proposed to alter EPA regulatory impact analysis and science policies as both the House and Senate are considering legislation to impose new review procedures and analysis on proposed regulations. Both have bills titled "Regulatory Accountability Act" -- H.R. 5 and S. 951 -- both would revise rulemaking procedures intended to make regulations more transparent in their justification and more sensitive to the possible regulatory costs that would be imposed. There are also legislative proposals advancing in the House to "improve EPA science." H.R. 1430 is the "Honest and Open New EPA Science Treatment Act of 2017" or the "HONEST Act." Such bills seek to address criticism that EPA in the past has been selective in its emphasis on what science might justify as 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.

Budget

The first budget proposed by the new Administration for EPA included a 31 percent cut. While this was short of "eliminating EPA," a topic discussed during the election campaign, the proposed cut was significant. There was and remains bipartisan support to keep EPA funding much closer to current levels. The current budget moving through Congress includes a reduction in the range of three to six percent -- still significant -- but far less draconian than the original proposal. Budget cuts at this level, coupled with hiring

The Assistant Administrator position for the OCSPP, which is responsible for implementing both FIFRA and TSCA, is perhaps the most tangled senior appointment vacancy at EPA.

freezes and staffing level reductions, will have an impact on EPA programs. And even as hiring is allowed to replace retired personnel, new hires will not have the same level of expertise and institutional experience, which will also slow things down and present challenges for addressing complicated, longstanding issues.

New Leadership

Typically, more than a year after the Presidential election, the senior appointees of most agencies are in place with few exceptions. This Administration, for whatever reasons, has been exceedingly slow in selecting, moving, and confirming subcabinet positions, especially at EPA. There is still no confirmed Deputy Administrator in place, although the nomination of Andrew Wheeler was approved by the Senate Environment and Public Works Committee on November 29, 2017. The Administration will have to re-nominate him, as it is being reported that his name was not included on the Senate's list of nominees that it agreed to keep active into next year. While Susan Bodine was confirmed on December 7, 2017, to serve as Assistant Administrator (AA) for EPA's Office of Enforcement and Compliance Assurance (OECA), there are few other AAs who have been successfully confirmed. A notable exception is Bill Wehrum, who was narrowly confirmed as AA for EPA's Office of Air and Radiation (OAR) on November 9, 2017, the one Agency position many expected to face the most serious opposition, given the issue of climate change. At this point, the AA position for the OCSPP, which is responsible for implementing both FIFRA and TSCA, is perhaps the most tangled senior appointment vacancy at EPA.

A 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 to opposition by enough senators to challenge the nomination. Press reports in late December suggest that Dr. Dourson has withdrawn his nomination. Regardless, the delay in the arrival of the new AA does materially affect the ability of OCSPP to implement the agenda of the new Administration and hinders even the more routine work of the office (for example, the expeditious resolution of internal budget fights among the media programs).

Congressional Relations

Congressional relations, in general, are not good. They are not good between Democrats and Republicans, not altogether unexpectedly, but the animus and bitterness that exists between the two parties are at a level not seen in decades. The relationships within the party caucuses are not good, and appear to be fractured (Tea Party vs. the establishment Republicans; Progressives vs. centrist Democrats). The White House relationship with Congress is not good; members of both the House and Senate of both parties have regular jousts with the White House -- again at a new level of intensity not seen in years.

There are significant issues that require serious attention, and cooperation, to "make government work." Some semblance of agreement is needed to raise the debt ceiling, to fund the operation of government, and to formulate international policies. This does not include addressing even more controversial issues where partisanship is a given, such as tax policy, health care, and immigration. To date, the prospects for any breakthrough towards compromise or serious cooperation among the constituencies appear to be remote.

On the much smaller scale of OCSPP, as mentioned, there is not even enough agreement on the selection and confirmation of a political appointee, with no timeline for resolution in sight.

Enhanced Media Coverage

Part of the new intensity of the policy debates is fueled by media coverage which also seems to be "tribal." Many supporters of the President watch Fox News, while most liberals prefer MSNBC. CNN, among other outlets, is officially declared "fake news" routinely by the President in the new form of Presidential announcements via Twitter. One can spend hours listening to a constant drumbeat of "for or against" news coverage. *The New York Times*, for example, has repeatedly covered the decision made by Administrator Scott Pruitt in March of 2017 concerning the pesticide chlorpyrifos. More details about the chlorpyrifos controversy are outlined below, but for now, in summary, Mr. Pruitt stopped the course EPA had been on under the Obama Administration to remove the pesticide from the market (which itself was believed by many to be a reversal of the course of the Bush Administration). Not surprisingly, there are arguments for and against either approach, but *The New York Times* has run stories that mention the pesticide 28 times since Mr. Trump was inaugurated. No pesticide or pesticide issue has received such media attention since perhaps 1989 when the pesticide Alar was in the news with a concern about the safety of the pesticide's residues on apples.

The New York Times has also published a profile of the current senior appointee in OCSPP, Nancy B. Beck, Ph.D., who was appointed Deputy Assistant Administrator (DAA) of OCSPP. As DAA, her appointment is not subject to Senate confirmation, and she arrived at EPA in April 2017. On October 21, 2017, *The New York Times* ran a front page story, continuing for two entire pages, about Dr. Beck's background and work at a chemical industry trade association, and how some now-retired EPA senior staff were disappointed in and disagreed with the decisions made by the incoming Trump Administration (as personified by the work of Dr. Beck since her arrival). The point in mentioning this is not to opine on which view is correct, but to illustrate the perhaps unprecedented media scrutiny on the validity of and/or flaws with any decision or policy adopted by the new EPA leadership. This level of media scrutiny about the work of OCSPP is greater now than in any past time in its history (the office was formed after the original TSCA legislation was enacted in 1976).

The New York Times is not alone in intensifying its scrutiny of the new Administration. For example, a Google search for "how government employees can leak documents" produces as the first entry "Here's how to leak government documents to The [Washington] Post." Under *The Washington Post's* banner, in print and online, is the phrase "Democracy Dies in Darkness" -- a slogan added in February 2017. Did democracy not die in darkness before that time?

These and many other examples illustrate the current war, almost literally, between the media and the Administration. The President tweets regularly about "fake news" and the news outlets (fake and otherwise) cover the story with a not surprising tone of skepticism (what media outlet, other than *The Onion*, purposefully prints "fake news"?) Politicians of all stripes have always complained about media coverage, but here again, the animus and conflict have reached a new level of intensity.

All this chaos and volatility makes "predictions" difficult. But as always, we will do our best in the analysis to follow.

PREDICTIONS AND OUTLOOK FOR OCSPP'S OFFICE OF POLLUTION PREVENTION AND TOXICS 2018

Actions or Other Steps Taken by EPA during 2017

In our 2017 Predictions memorandum, we noted the many actions under amended TSCA that EPA's Office of Pollution Prevention and Toxics (OPPT) was required to implement during 2017. We also noted that the election produced a change in the party that would implement the new law following the early implementation steps taken by the Obama Administration.

EPA hit all of its marks in timely promulgating the rules or taking other steps required by new TSCA. These include:

- The framework procedural rules for prioritization and risk evaluation and the TSCA Inventory notification rule were promulgated in June 2017. The rules as issued in final were seen by some as controversial and some stakeholders have pursued legal challenges

One of the challenges in new TSCA was the immediate effect of the new chemical provisions in Section 5. While EPA had made initial determinations for pending chemical notifications, hundreds of Section 5(e) Orders and Significant New Use Rules (SNUR) remain unresolved and the new chemicals they involved are not yet commercial.

(discussed more below). As discussed in our memoranda on the framework rules, we thought the final rules improved upon the proposed rules by adding clarity and specificity where needed and otherwise improved the rules by eliminating provisions or preambular discussion that went beyond the requirements in the new law.

- The Science Advisory Committee on Chemicals (SACC) was established just before January 20, 2017, although EPA has subsequently solicited nominees to "augment" the membership.

- EPA issued scope documents for the ten initial risk evaluation chemicals and a guidance document for use by interested persons in preparing draft risk evaluations.

- EPA initiated its consultation with the Small Business Administration (SBA) on December 7, 2016, concerning the adequacy of its regulatory standards for determining what manufacturers and processors qualify as small manufacturers for purposes of TSCA Section 8(a), and on May 9, 2017, EPA posted the SBA's response. On November 30, 2017, EPA issued its final determination that revision to the current size standards for small manufacturers and processors, which are used in connection with reporting regulations under TSCA Section 8(a), is warranted. 82 Fed. Reg. 56824. EPA did not address the details on how it would be revised, stating that was outside the scope. It will be proposing changes in a subsequent rulemaking.

- EPA also set up a Federal Advisory Committee to negotiate a rulemaking that would limit Chemical Data Reporting (CDR) rule requirements for recycled, reused, or reprocessed inorganic byproducts. Committee members engaged in several two-day meetings, as well as many conference calls, trying to negotiate a rule, but were unable to reach consensus. A key challenge related to scope; some members focused strictly on the statute's directive to reduce the reporting burden, while others believed additional issues of concern related to CDR should be included. In September 2017, Committee members expressed concern that these differing views could not be reconciled, and agreed to terminate the negotiation process.

Regarding areas that did not have a statutory deadline, we were surprised that EPA did not issue a proposed rule to implement the fees provision at TSCA Section 26(b). We understand EPA intends to propose a fees rule early in the New Year. We were also surprised that no steps were taken by EPA during 2017 to use its new authority under Section 4 to require testing.

One of the challenges in new TSCA was the immediate effect of the new chemical provisions in Section 5. Little progress was seen in timely completing new chemical reviews during the first year of new TSCA implementation and EPA, to its credit, implemented an effort to deal with and resolve the backlog of initial determinations by midsummer. While progress has been made on clearing the backlog, much work remains. While EPA had made initial determinations for pending chemical notifications, hundreds of Section 5(e) Orders and Significant New Use Rules (SNUR) remain unresolved and the new chemicals they involved are not yet commercial. We do not believe that Congress intended for EPA to regulate every substance for which it identifies a hazard, and over 80 percent of new chemicals reviewed under the revised law are slated for regulation, an outcome ratio that continues to be seen in the information provided by EPA. A key additional consideration is whether "reasonably foreseeable conditions of use" equates "any possible conditions of use." In our view, if such changes were the legislative intent, Congress would have either used such language in the former instance or specified that the basis for regulation is identified for a potential hazard of a substance, rather than a consideration of risk (being a function of both hazard and potential exposures). During 2017, we redoubled our efforts to engage more effectively with EPA on new chemicals issues by forming

a TSCA New Chemicals Coalition (TSCA NCC) that brings together a broadly based group of companies that have concerns with EPA's approach. We were pleased to see the draft materials that EPA circulated prior to and discussed at its December public meeting on new chemicals, which we discuss in detail below.

Prioritization

Given the demands on EPA to complete risk evaluations over the next several years, we do not expect significant work by EPA on prioritization of chemicals in the coming year. Nonetheless, there could be developments concerning the pre-prioritization process; a concept that, while raised in the proposal, was not included in the final prioritization rule. As discussed in the TSCA Litigation section, there are legal clouds hanging over the prioritization procedural rule. The December 11, 2017, public meeting shed some light on EPA's mindset for how to approach the prioritization process. Dr. Beck, DAA, OCSPP, noted that more than one approach may be considered, but also stated the possibility that a process may not be adopted. Unless EPA has sufficient information to conclude there is no unreasonable risk, EPA must proceed with risk evaluations within the specified timelines with increased uncertainties. This will result in a risk management process that has numerous default assumptions and uncertainty that will be difficult to defend. Such risk management results will likely be subject to litigation, which will be costly in terms of time and resources to both EPA and the stakeholders. EPA noted that it hopes to implement a pre-prioritization approach by **June 2018** to help ensure prioritization can begin in **December 2018**.

More information on the stakeholder meeting is available in our December 14, 2017, blog item "EPA's Approaches for Prioritization under TSCA Discussed at December 11, 2017, Public Meeting."

First Ten Chemicals for Risk Evaluation Under Amended TSCA

In 2017, EPA continued its risk evaluation work on the first ten chemicals selected under Section 6(b)(2)(A). These chemicals were announced in December 2016, pursuant to the legislative mandate to identify such chemicals within 180 days after enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act. In 2017, EPA focused on collecting public input on conditions of use and developing problem formulation documents for the ten chemicals. New TSCA requires that EPA complete a risk evaluation for a chemical substance as soon as practicable, but no later than three years after the date on which EPA initiated the risk evaluation. This means the risk evaluation process should be completed for the first ten chemicals by **December 2019**, although an extension of no more than six months is allowed. If the EPA risk evaluation concludes that one or more condition(s) of use presents an unreasonable risk as defined under TSCA, EPA must propose a risk management rule under TSCA Section 6(a) within one year of the completed risk evaluation; and a final risk management rule one year later (within two years of the completed risk evaluation). There are provisions in the legislation for extensions of no more than two years.

The EPA risk evaluation effort may be a "still waters run deep" scenario in that public stakeholders may not be privy to see exactly what is happening within the existing chemicals risk evaluations. Instead, we likely will have to wait until **2019** to understand better how the EPA risk evaluation process will work in real life. Running in parallel with this activity is the question of the fate of legal challenges files by non-governmental organizations (NGO) to EPA's procedural rule for risk evaluations. These include, among other issues, whether *conditions of use* can be read narrowly (*e.g.*, as excluding legacy, in-place uses) or, as the plaintiffs believe, it includes all uses. *See* the section below on TSCA Litigation for more information on key issues.

Existing Chemical Risk Management

As discussed in our 2017 predictions memo, we were unsure of the fate of a number of the rules on existing chemicals that had been proposed or were planned by the Obama Administration and we update our thoughts below. We also discussed the CRA and its possible use by Congress. While many rules were invalidated under the CRA, none of these actions related to TSCA.

- SNUR on long-chain perfluoroalkyl carboxylate and sulfonate chemical substances. No discernable progress was made in promulgating this rule in 2017. As discussed in our 2017 predictions memo, we questioned whether EPA could proceed without a re-proposal, given the need to satisfy the new requirement at TSCA Section 5(a)(5) that EPA make an affirmative finding that the reasonable potential for exposure to

EPA is expected to issue proposed changes to the CDR rule in May 2018, with changes to be adopted for the 2020 CDR reporting cycle. Should changes be adopted, this will be the fifth modification of reporting for this rule in five reporting cycles.

the chemical from import or processing of the article(s) justifies the significant new use (SNU) notification. We continue to see difficulties for EPA in meeting this requirement and believe that promulgation is unlikely for this reason -- as well as due to the many other actions under amended TSCA that EPA is engaged in. Similarly, the proposed SNURs for nonylphenol and nonylphenol ethoxylates (NP/NPE rule) and toluene diisocyanate (TDI) seem to be on the back burner and will likely remain a low priority as EPA works its way through its statutory requirements for the first ten chemicals and other high-priority rulemakings (such as the fees rule and the small business definition).

- TSCA Section 6(a) rules on trichloroethylene's (TCE) use as a spotting agent in dry cleaning and in consumer aerosol spray degreasers, and its use as a vapor degreasing agent; and EPA's plan to propose a SNUR on use of TCE in non-aerosol spray degreasers. The two Section 6(a) rules were proposed late in the Obama Administration while no action has been forthcoming on the SNUR proposal. As we have noted previously, TCE's risk assessment is quite controversial, particularly regarding the interpretation of certain key adverse effects. In general, we are doubtful that much will happen regarding the regulation of TCE until the revised risk evaluation is completed.

- Proposed Section 6(a) rule on use of methylene chloride and n-methylpyrrolidone (NMP) in paint strippers. As with TCE, we believe that final regulatory action associated with the specific substance in paint strippers will be on hold pending the completion of the larger risk evaluations on these chemicals as part of the first ten chemicals. This is especially true with NMP, which received comments raising some significant scientific issues. (*See First Ten Chemicals for Risk Evaluation under Amended TSCA* above.)

Anticipated Proposal for Changes to CDR

According to the Regulatory Agenda, EPA is expected to issue proposed changes to the CDR rule in **May 2018**, with changes to be adopted for the **2020** CDR reporting cycle. We understand that EPA will be looking to adjust the categories used for reporting under industrial, commercial, and consumer uses to achieve more refined use information and better estimates of exposure potential. Should changes be adopted, this will be the fifth modification of reporting for this rule in five reporting cycles. Major changes were implemented in 2002 under the Inventory Update Rule Amendment (IURA), with further changes added in the 2006, 2012, and 2016 reporting cycles. Presumably, EPA's desire to tweak the CDR is related to the requirements in amended TSCA that EPA implement a prioritization process for existing chemicals, conduct risk evaluations, and, as required, promptly regulate based on the conditions of use.

Several NGOs have submitted their views on needed changes to CDR reporting, including the recommendation to narrow or eliminate several reporting exemptions currently allowed under the CDR and to include processors in the reporting obligations. We would anticipate that these NGO groups will again push for these ideas during the formal rulemaking process. Likewise, it is expected that the

stakeholder groups that were involved with the Negotiated Rulemaking for CDR Requirements for Inorganic Byproducts, which was unable to reach consensus on a proposal to reduce CDR reporting burdens for recycled inorganic byproduct manufacturers, will use the EPA opening of the CDR rule to advocate their particular ideas or proposals.

Although we are sympathetic to the need for EPA to have a better understanding of exposures during processing, it is unclear to us that EPA would agree to expand the CDR reporting universe to include processors. Furthermore, while we recognize the need to refine the information collection under the CDR for amended TSCA purposes, the ever-changing landscape for CDR reporting makes it difficult, if not impossible, for companies to develop and implement standard operating procedures for staff to follow to ensure compliance with the law. Compliance can be especially problematic if potential reporters are not cognizant of the types of records that may be required to support reporting. We would hope that, should changes be implemented for the **2020** reporting cycle, no further changes will be needed for the next few sets of reporting cycles.

Inventory Notification

The reporting of "active" substances by chemical manufacturers and importers, as required under the August 11, 2017, EPA final rule on the TSCA Inventory Notification (Active/Inactive) Requirements, must be completed by **February 7, 2018**. EPA has indicated that there is no option for extension of this deadline -- the statute limits the reporting period to 180 days. Stakeholders are cautioned to submit their notifications early, as we have seen operational problems in EPA's Central Data Exchange related to high volumes of submissions during a short time period in past CDR reporting cycles. EPA will issue an interim list of active substances following the **February 7, 2018**, manufacturer/importer reporting deadline, which processors can use as a basis for their active notification submissions that are due no later than **October 5, 2018**. In theory, there should be very little effort expended by processors, as the chemicals that they use should have been reported during the manufacturer/importer reporting timeframe (an exception concerns the situation with chemicals that are only infrequently produced or imported and that are stockpiled and drawn down over time by a processor). Processors that find themselves submitting multiple active notifications may wish to revisit their existing agreements with chemical suppliers and associated TSCA compliance obligations. EPA states that it will have the final active/inactive chemical lists reflected in the published TSCA Inventory as soon as practicable after the **October 5, 2018**, processor reporting deadline, which we believe will be about two months, or sometime in **December 2018**.

New Chemicals

Major problems and delays continue to challenge efforts by industry to commercialize new chemicals, many of which are less toxic than the existing chemicals they would replace. While we appreciate EPA's challenges in immediately implementing the changes in the law, we continue to believe that some of the problems were self-inflicted (*e.g.*, the decision to apply new TSCA to cases received prior to TSCA's effective date) and that others arose from EPA's overly cautious if not precautionary reading of the new law's requirements. Whereas under old TSCA, ten to 15 percent of new chemicals were regulated, to this point EPA has taken or teed up Section 5(e) consent orders or Section 5(a)(2) SNUR actions on over 80 percent of the new chemicals that have been handled under the new law. As far as we can discern, EPA has proposed a consent order or SNUR for every substance for which EPA has identified a hazard. At the December 5, 2017, stakeholder meeting, Richard E. Engler, Ph.D. requested confirmation on this point, and Jeffery Morris, Ph.D., Director of OPPT, agreed to respond. It is our view that such a profound shift in regulation goes beyond what was contemplated, let alone intended, by the changes in the new law. We believe that EPA is over-interpreting the legal requirements for determinations and regulatory actions and is overly conservative in assessing the potential risks and the need for and nature of the control measures that satisfy the requirement that they be "to the extent necessary to protect against an unreasonable risk." We offer this as a belief rather than any statement based on knowledge because EPA has been singularly unforthcoming in explaining its policy thinking and the legal and scientific basis for its approach to new chemicals.

We are also concerned by EPA's long delay in responding to issues that we have raised in the context of specific new chemicals that are before EPA, as well as more general written comments that we have provided to EPA over the past

The TSCA New Chemicals Coalition provides an effective and broadly based forum for engaging with EPA and other stakeholders regarding implementation of TSCA Section 5.

year: "Bergeson & Campbell, P.C.'s Comments on New Category Documents under the New Chemicals Program," and "Bergeson & Campbell, P.C. Suggests New Approaches to EPA in Managing New Chemical Polymers."

Given this environment, and in response to concerns voiced by our clients and other companies during workshops and webinars we participated in over the past year, we undertook to form the TSCA NCC to provide a more effective and broadly based forum for engaging with and discussing industry's concerns with implementation of TSCA Section 5 with EPA and with other stakeholders.

At the December 6, 2017, OPPT stakeholder meeting on implementing changes to the new chemicals review program under amended TSCA, EPA offered brief prepared remarks and previously solicited questions from stakeholders. Stakeholders expressed their appreciation to EPA for developing the draft Points to Consider and related documents made available in advance of the meeting, and for OPPT's continuing interest in new chemical issues. For more information, see our November 10, 2017, blog item "EPA Posts Agenda and Other Meeting Materials for December 6, 2017, New Chemicals Review Program Implementation Meeting." Below are some key takeaways regarding the meeting as related to EPA's presentations and input from industry and NGOs.

EPA stated that one of its main concerns is when it does not identify unreasonable risk for intended use, but nonetheless has concerns with reasonably foreseen conditions of use; it will assess whether those concerns can be addressed through SNURs that it would promulgate prior to making its TSCA Section 5 finding. EPA stated that, in identifying reasonably foreseeable uses, it will rely on knowledge, experience, and facts to support what is foreseen, not simply what is theoretically possible. Several commenters requested clarification and examples on the information that will support such identifications. This is an area of intense interest and a topic on which EPA pledged to provide additional clarity. EPA confirmed that the SNUR would mirror the premanufacture notice (PMN) in a way that would clearly state what deviations would be permitted to ensure protections for those aspects of the PMN about which EPA had identified concerns. In response to a direct question, Dr. Morris confirmed that he personally is reviewing each new chemical notification decision to ensure a consistent and coherent approach to chemical reviews. Dr. Morris assured stakeholders that his engagement would not slow down the PMN review process.

NGO groups that were ably represented at the meeting expressed disappointment that they were not a part of the pilot testing component of the new chemicals Points to Consider document. OPPT clarified that the purpose of the pilot was to have parties who are actually preparing PMNs pilot use of the document while preparing PMNs and that as a result, non-PMN submitters were not a part of the pilot. Following a request from several NGOs, EPA stated that it would of course make the original and redline versions of the Points to Consider document publicly available to ensure full transparency. Several NGOs also voiced concern with the delay of EPA getting PMN information posted online. Commenters noted the need for access to more content related to the new chemicals review, such as detailed PMN determinations, as the determinations that are publicly available at this point are boilerplate. Interestingly, concerns were expressed on issues not germane to the workshop, such as existing and accidental releases of chemicals (not related to TSCA).

Of the parties that weighed in on the issue, industry representatives who addressed the issue were supportive of using SNURs to cover reasonably foreseeable conditions of use that are not reflected in the submitted PMNs. Some NGOs were supportive of the use of SNURs to reduce consent orders, while others stated that SNURs are not an adequate substitute for consent orders and that Congress intended that TSCA Section 5(e) orders come first and to trigger SNURs. The concern over the use of SNURs, rather than consent orders, may relate to a concern of chemicals being

introduced prior to the SNUR being published in final. Industry representatives also suggested that EPA seek to scale its information needs appropriately. For instance, less detailed exposure information should be required for EPA to determine that it has sufficient information on a low hazard chemical.

Similarly, EPA should adjust the hazard profile requirements for a chemical with low exposure.

EPA reviewed the ongoing effort to develop four new chemical categories that could be used in future new chemical reviews. These are:

1. Lung Effects Categories: Polycationic substances (cationic binding); general surfactants; waterproofing agents; and insoluble polymer lung overload;

2. Photo-Acid Generators (PAG) Category;

3. Tracer Chemicals; and

4. Perfluorinated Chemicals.

EPA asked for input and ideas on how to move forward with chemical categories. It can do so either by updating existing categories or reviewing internal data to identify new categories -- and how the information should be presented (*e.g.*, to publish separately or together in one document).

On behalf of the TSCA NCC, Dr. Engler provided comments that included feedback to EPA that it needs to develop a consultation process with the U.S. Occupational Safety and Health Administration (OSHA) per the Section 5(f) legislative language. Dr. Engler suggested that EPA's assessments could be communicated to submitters and OSHA to inform both on the endpoints of concern and EPA's assessments of safe exposure limits. In this way, employers are obligated under the Occupational Safety and Health Act to assess hazards and exposures, provide information to workers, and ensure that exposures are controlled under OSHA's authority, thereby satisfying EPA's obligation to regulate "to the extent necessary" to protect such workers. The materials from the meeting are available in our December 8, 2017, blog item "EPA's New Chemicals Review Program -- Highlights from the December 6, 2017, Public Meeting."

While we remain optimistic that substantial improvements in the timing and handling of new chemical cases will be forthcoming in 2018, we look to EPA to demonstrate that it can in fact implement a timely and reasonable new chemicals program. We are somewhat doubtful of this given the difficulties and frustrations that we and our colleagues in industry encountered over the past 18 months.

TSCA Litigation

There was an initial flurry of seven petitions for review of the TSCA framework rules in four different jurisdictions. These petitions have subsequently been consolidated into three cases, one per framework rule, but they are now being litigated in two different jurisdictions.

In the Ninth Circuit case on the petition for review of the TSCA framework rule Procedures for Prioritization of Chemicals for Risk Evaluation (*Safer Chemicals Healthy Families v. EPA*, Case Nos. 17-72260, 17-72501, and 17-72968 (consolidated)), on November 27, 2017, the Ninth Circuit issued an order on several pending motions. It granted ACC's (and other industry groups) motion to intervene on behalf of respondent EPA; denied the motions to transfer Case Nos. 17-72260 and 17-72501 to the Fourth Circuit; denied requests to hold Case Nos. 17-72260 and 17-72501 in abeyance; granted the motions to consolidate Case Nos. 17-72260, 17-72501, and 17-72968; and set an amended briefing schedule. The consolidated opening brief is due **January 23, 2018**; the consolidated answering brief and the intervenors' brief are due **February 22, 2018**; and the optional reply brief is due within 21 days after service of the answering and intervenors' briefs.

In the U.S. Court of Appeals for the Fourth Circuit (Fourth Circuit) case on the petition for review of the TSCA framework rule Procedures for Chemical Risk Evaluation under TSCA (*Alliance of Nurses for Healthy Environments v. EPA*, Case Nos. 17-1926, 17-2040, and 17-2244 (consolidated)), the Fourth Circuit granted the petitioners' motions to transfer to the Ninth Circuit on December 11, 2017. This was not entirely unexpected considering the Ninth Circuit's denial

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of respondent EPA's motions to transfer. Now both of these cases will be decided in the Ninth Circuit. ACC and other industry groups were granted leave to intervene on behalf of respondent EPA on September 28, 2017. 17-73290 is now the case number. Petitioner's brief is due **March 1, 2018**, respondent EPA's brief is due **April 2, 2018**, and petitioner's optional reply brief is due 21 days after service of the answering brief.

In the U.S. Court of Appeals for the D.C. Circuit (D.C. Circuit) case on the petition for review of the TSCA framework rule TSCA Inventory Notification (Active-Inactive) Requirement (*EDF v. EPA*, Case No. 17-1201), there are no current delays due to transfers or consolidations. Earlier in the case, EPA filed a request for additional time "in light of the potential for other parties to file additional petitions in this Court until October 24, 2017," which was granted on October 11, 2017. Respondent EPA filed a motion to extend time to file its brief on November 7, 2017; petitioner filed its statement of intent regarding appendix deferral on November 8, 2017, and filed its initial submissions including the statement of issues on November 8-9, 2017; and respondent EPA filed the certified index to record on November 27, 2017. ACC and other industry groups were granted leave to intervene on behalf of respondent on November 13, 2017. The briefing schedule has not been set. Neither the petitioner nor the respondents have moved to transfer this case, so it will in all likelihood stay in the D.C. Circuit.

EPA also recently faced litigation in the form of a complaint filed 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 from 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 the Fluoride Action Network, Food & Water Watch, Inc., the Organic Consumers Association, the American Academy of Environmental Medicine, the International Academy of Oral Medicine and Toxicology, and other individual petitioners. Thus far in the proceedings, defendant EPA filed a motion to dismiss on September 25, 2017, and plaintiff filed its opposition to the motion on October 25, 2017. On November 20, 2017, NRDC and Safer Chemicals, Healthy Families were granted leave to file an amicus brief. The motion to dismiss was heard on November 30, 2017. On December 5, 2017, the D.C. Circuit granted the parties' joint request (also filed on December 5, 2017), to extend the deadlines for EPA's Motion for a Protective Order Briefing Schedule. On December 14, 2017, defendant EPA filed its motion for a protective order to limit review to the administrative record and for an order striking Plaintiffs' jury demand. On December 21, 2017, the court denied respondent EPA's motion to dismiss the petitioner's judicial challenge of EPA's administrative denial of the Section 21 petition and, in so doing, essentially rejected EPA's interpretation that a citizen petition must evaluate all conditions of use of a chemical substance in a TSCA Section 6(b) risk evaluation. More information on this decision is available in our December 22, 2017, blog item "In Case of First Impression, Court Rules EPA Wrongly Dismissed Citizen Group's TSCA Section 21 Petition." The Plaintiffs' response to EPA's motion was filed on January 2, 2018. EPA's reply to the response is due **January 11, 2018**. The updated joint case management conference statement is due **January 18, 2018**, and the hearing and further case management is scheduled for **January 25, 2018**.

U.S. Nanomaterials Forecast

Last year saw EPA's promulgation of a TSCA Section 8(a) reporting rule for certain chemical substances already in commerce as nanoscale materials. The Trump Administration extended the effective date of the January 12, 2017, final rule from May 12, 2017, to August 14, 2017. Persons who manufactured or processed a reporting chemical substance during the three years prior to the final effective date of the final rule must report to EPA within a year of the

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

While the National Institute for Occupational Safety and Health (NIOSH) has several active projects concerning nanomaterials, there may not be significant results in 2018. NIOSH has been developing a "Survey of Engineered Nanomaterial Occupational Safety and Health Practices" in which NIOSH will survey 600 companies that manufacture, distribute, fabricate, formulate, use, or provide services related to engineered nanomaterials. NIOSH anticipates that 500 companies will complete the survey within two years. NIOSH will use the data to inform NIOSH's research agenda to enhance its relevance and impact on worker safety and health in the context of engineered nanomaterials. In addition, NIOSH's Engineering Controls Program is developing three NIOSH engineering control workplace design solution documents that will highlight effective engineering control approaches for the most common nano-manufacturing workplaces.

Strategic Plan to Promote and Implement Alternative Testing Methods

TSCA Section 4(h) requires that EPA take several steps that can contribute to reducing and replacing the use of vertebrate animals in testing "to the extent practicable, scientifically justified, and consistent with the policies" of TSCA. Among others, the provision requires EPA within two years of enactment to develop a strategic plan to promote the development and implementation of alternative test methods and strategies. EPA, in a November 2017 public meeting, proposed to group the array of computational, Structure Activity Relationships (SAR), *in silico, in vitro*, and other alternative methods under the term New Approach Methodologies (NAM). We were pleased to see the results from EPA's early thinking on this issue and look forward to seeing more development of the approaches and concepts. Challenges remain for EPA to sort out issues regarding its scientific acceptance of NAM results for screening versus assessment purposes, and its willingness to accept such test methods to meet legal testing requirements under Sections 4 and 5 of TSCA.

Biobased Forecast

In 2018, we may see some of the recommendations outlined in the 2017 National Academies of Sciences, Engineering, and Medicine report, "Preparing for Future Products of Biotechnology," move forward. While the report was prepared as a result of the Obama Administration's initiative to modernize the biotechnology regulatory biotechnology system, and it remains unclear whether or how far the Trump Administration will carry on with it, progress in 2018 on the following report recommendations would be beneficial for those engaged in biotechnology:

- Agencies involved in regulation of future biotechnology products, such as EPA, the U.S. Food and Drug Administration (FDA), and USDA, to increase scientific capabilities, tools, expertise, and horizon scanning in key areas of expected growth of biotechnology, including natural, regulatory, and social sciences;

- Such agencies to increase their use of pilot projects to advance understanding and use of ecological risk assessments and benefit analyses for future biotechnology products that are unfamiliar and complex and to prototype new approaches for iterative risk analyses that incorporate external peer review and public participation; and

- Agencies that fund biotechnology research with the potential to lead to new biotechnology products to increase their investments in regulatory science and link research and education activities to regulatory-science activities.

Biobased industry stakeholders may wish to express support for the initiative and the allocation of resources to address the recommendations outlined in the report. The next generation of biotechnology products may be on the line if a modernized and efficient regulatory system is not established.

Commercializing new biobased and renewable products continues to remain hampered by complex naming conventions that present challenging regulatory hurdles for chemicals from novel renewable sources. In 2018, the Biobased and Renewable Products Advocacy Group (BRAG®), along with other stakeholders, will continue collaborations with EPA to implement an effective solution to address this commercialization barrier through modifications to the current nomenclature system and chemical equivalence determinations between new and existing biobased chemicals under TSCA.

The biobased industry should plan to remain engaged in all aspects of TSCA implementation to ensure regulatory parity with traditionally-sourced chemicals and to avoid additional obstacles to commercialization.

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Those engaged in biobased chemicals should also keep an eye on the two pieces of bipartisan and bicameral legislation aimed at supporting the biobased industry that were introduced in 2017. On June 29, 2017, Representatives Bill Pascrell (D-NJ), Ryan Costello (R-PA), Brian Fitzpatrick (R-PA), and Linda Sánchez (D-CA) introduced the Renewable Chemicals Act of 2017 (H.R. 3149) to the House. If enacted, the legislation would create a short-term tax credit for the production of qualifying renewable chemicals from biomass and for investments in such production facilities based on job creation, innovation, environmental benefits, commercial viability, and contribution to U.S. energy independence. The bill was referred to the House Committee on Ways and Means. Companion legislation (S. 1980) was introduced to the Senate by Senator Debbie Stabenow (D-MI) on October 18, 2017.

PREDICTIONS AND OUTLOOK FOR THE OCSPP'S OFFICE OF PESTICIDE PROGRAMS 2018

Pesticide Registration Improvement Act

The Pesticide Registration Improvement Act of 2003 (PRIA), as administered by the Office of Pesticide Programs (OPP), established a fee schedule for pesticide registration and amendment applications, and specified decision time periods in which EPA must make a regulatory decision. PRIA has been reauthorized twice, and was scheduled to expire at the end of the 2017 federal fiscal year, on September 30, 2017. As was the case for PRIA and its prior reauthorizations, a coalition of registrants, labor, and environmental advocates were working with Congress relatively smoothly to pass what will be "PRIA 4" before the expiration date. In May 2017, however, EPA announced that as part of its regulatory review efforts there would be delays in implementing recent regulations (that is, regulations issued under the Obama Administration) making changes to worker protection standard (WPS) regulations and requirements of the FIFRA certification and training (C&T) programs run by the states. Some farm advocacy groups, the American Farm Bureau in particular, raised concerns about a few elements of the WPS regulations, and the National Association of State Departments of Agriculture (NASDA) sought more time to make changes to the C&T programs.

When EPA announced these plans, however, farmworker advocacy groups withdrew their support of the PRIA legislation. Along with concerns about possible regulatory changes and delays on the WPS regulations and C&T

programs, environmental groups also raised concerns about the Administration's March 2017 decisions effectively allowing the continued use of chlorpyrifos. The net result of this tumult was a fracture in the PRIA coalition; instead a group of Democratic Senators supporting the environmental and labor advocates' position insisted on blocking the PRIA legislation, seeking to prevent any changes to the current WPS regulations and separately introducing legislation which would effectively end the use of chlorpyrifos (S. 1624).

Suddenly PRIA, expected to be routinely reauthorized as it had been in the past, became a political football in the Senate, with Senate Republicans seeking to reauthorize the legislation, which has already been approved by the House, and a sufficient number of Senate Democrats blocking movement of the legislation. As a result, there is currently an impasse, with discussions reportedly ongoing but with no clear path towards resolution.

PRIA is, however, currently in force, as a short term extension was included in the legislation to fund it through **January 19, 2018**. The expectation is that some kind of resolution will be found, but the specific parameters of any solution have not been identified. PRIA has also included the authorization for the "maintenance fee" provisions first included in the 1988 amendments to FIFRA, designed as general support for the EPA pesticide program budget. Taken together, PRIA reauthorization has become a major contributor to the program budget.

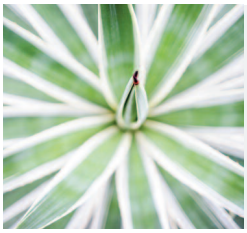
Should PRIA not be reauthorized, then the law now allows for a phase-down of the current submissions that include PRIA fees and are subject to decision deadlines. The larger issue would be the potential for the elimination of approximately 200 positions from the pesticide program workforce, or approximately one-third of the current staff (and is in line with the share of program costs supported by fees).

The final irony, should PRIA fail to be renewed, would be that the severe budget cuts (33 percent) to EPA's pesticide program would be due to the actions of the Democrats in the Senate, who otherwise have decried the specter of EPA budget cuts of 31 percent, as originally proposed by the Administration.

Endangered Species Act

Before the PRIA snafu, at the beginning of 2017, most observers expected the most critical issue that would beset the pesticide program was implementation of the Endangered Species Act (ESA). This issue has dogged the program for many years, since continued litigation challenges first initiated during the Administration of George W. Bush.
A key issue is how extensive EPA's assessment has to be to determine compliance with the ESA, an assessment that is to be done in coordination with the other agencies that have responsibility for implementing ESA. Those agencies are the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (the Services). The problem of "how much is enough" when conducting an assessment, and the degree of coordination of any assessments between EPA and the Services (including "who decides" various issues such as the issues regarding the need for consultation between EPA and the Services), have been debated for more than ten years and are the subject of extensive litigation. The first lawsuits covered older pesticide products that had been on the market for years; more recent lawsuits have challenged EPA's approvals of new active ingredients. The challenge to new products, many of which have a more attractive environmental and health profile, has led to concerns that these new products would be kept off the market with a prolonged or indefinite review process, which could ironically result in greater environmental risks to species compared to the products they would likely replace. Registrants are also very concerned that unpredictable delays in new product reviews would be a disincentive to continue the process of discovery and development of new products, given the enormous costs involved in bringing a new product to the market. Industry estimates of the cost of new product discovery and approval are in the range of $150-250 million.

Efforts have been made to coordinate more closely information and review procedures and policies between EPA and the Services, but delays and litigation continue unabated. With the arrival of the Republican Administration and with Republican majorities in both the House and Senate, there was initially hope that some more practical, or at least predictable, process for ESA compliance could be put into place. Some observers have explored whether legislative action would be possible to tailor how ESA review of pesticide registrations could better fit the goals of the law which originated with a call for review of projects such as building dams or highways. Given the controversies about ESA outside of the pesticide arena, prospects for legislation appear to some to be daunting. Nevertheless, some believe that there may be no alternative but to seek amendments depending on the outcome of various legal challenges (for example, if new registration actions were vacated or otherwise indefinitely suspended).
In lieu of legislative reform, there is also the possibility of



[T]he Farm Bill is one vehicle where legislation might include some attempt to address defects or inefficiencies in the current process. Once legislation is under consideration, proposals affecting greater restrictions on pesticide use or direct regulation of a specific pesticide could be proposed.

policy and regulatory reforms, such as revising and updating regulations to tie the work of EPA and the Services together into a more predictable and shorter assessment framework. Even this approach to finding a solution to the ESA quandary would be no small task.

Any attempt to address ESA concerns is complicated by the slow process of selecting and installing senior political officials at the various programs who would have to be involved in devising proposals for a solution (administrative, legislative, or, at the very least, improvements to the current procedures).

The Farm Bill

One new item on the agenda for 2018 will be legislative consideration of the 2018 Farm Bill. This is considered "must pass" legislation and usually includes a trove of proposals that affect agriculture outside of the more widely known price support, conservation, and research programs of the U.S. Department of Agriculture (USDA). As an example, if PRIA is not reauthorized by the time the new Farm Bill is moving, there would likely be proposals to reauthorize it as a part of the Farm Bill.

Similarly, past Farm Bills have included non-controversial provisions about ESA-FIFRA implementation, such as requesting a National Academy of Sciences review of the assessment procedures of EPA and the Services. Any significant tinkering with duties and jurisdiction would not be non-controversial, but the Farm Bill is one vehicle where legislation might include some attempt to address defects or inefficiencies in the current process.

Once legislation is under consideration, proposals affecting greater restrictions on pesticide use or direct regulation of a specific pesticide could be proposed. Once the legislation is moving, especially in the Senate, unexpected or unlikely amendments might be brought forward as part of the larger agenda of partisanship or simple showmanship (and by the **end of 2018**, the **2020** Presidential election will be on the mind, if not the tongue, of various Senators of both parties).

Chlorpyrifos

Chlorpyrifos is a widely used organophosphate insecticide and has been the target of activist group attention and controversy over many years. Pesticide Action Network North America (PANNA) and the Natural Resources Defense Council (NRDC) filed a petition to revoke the tolerances and cancel the registrations for chlorpyrifos in 2007.

When these groups concluded that EPA in their view had not acted sufficiently timely on their petition, they sought a *writ of mandamus* from the U.S. Circuit Court of Appeals for the Ninth Circuit (Ninth Circuit) that would order EPA to act on that petition. After some additional rounds of legal wrangling through the last years of the Obama Administration, the Court stated unequivocally that it would not grant any further extension beyond March 31, 2017, for final action on the petition.

At the time PANNA and NRDC began the court case, EPA had issued a preliminary decision indicating that it intended to deny the petition, but EPA later reversed course and, in the process, issued several controversial documents upon which it relied in support of the 2015 proposal to revoke the food use tolerances for the pesticide. 80 Fed. Reg. 69080 (Nov. 6, 2015). This action is described in

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more detail on B&C's Pesticide Law and Policy Blog under key word chlorpyrifos. *See also* March 30, 2017, blog item "EPA Denies Petition to Ban Chlorpyrifos."

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

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

This decision has been and remains controversial and subject to continued media scrutiny and it has now become a stumbling block to PRIA reauthorization, as Senator Tom Udall (D-NM) has blocked its renewal. Some avenues of compromise might include a deadline requiring EPA to provide a conclusive determination of whether the pesticide continues to meet the FQPA standards much sooner than **2022**. Additional scrutiny and debate about the appropriate ways to evaluate epidemiological data as part of a regulatory determination are also likely to result from the chlorpyrifos controversy.

Pollinators

To some degree, there has been relatively little movement on the subject of pollinators during 2017. EPA continued its work under directives and initiatives started in 2014 when the Obama White House issued a "Presidential Memorandum -- Creating a Federal Strategy to Promote the Health of Honey Bees and Other Pollinators," eventually followed in 2015 by "EPA's Proposal to Mitigate Exposure to Bees from Acutely Toxic Pesticide Products."

The 2015 plan targeted pesticide use by those who use contracted pollinator services, and included a list of pesticides (not only insecticides) to which the new labeling requirements would apply. EPA received comments from many grower groups and state pesticide officials critical of various elements of the proposal, and did not issue a revised policy until January 12, 2017. *See* "EPA Releases Final Policy to Address Acute Risks to Bees from Pesticides and Three Pollinator-Only Risk Assessments for Neonicotinoid Insecticides." EPA described the 2017 "Policy to Mitigate the Acute Risk to Bees from Pesticide Products" as a revised approach that is "more flexible and practical" and which includes conditions when acutely toxic pesticides might be used while minimizing risks to pollinators.

Since the new policy was announced, EPA has not officially changed its guidance about how it will evaluate pollinator issues. The January policy clarified certain thresholds that may raise concerns, and stated that new labeling would be imposed on products with certain characteristics, but that as of yet there are few reports of mandated label changes for individual pesticides.

The work of state agencies has continued to develop "Managed Pollinator Protection Plans" (MP3) throughout this time period. MP3s present a range of tactics designed to reduce pesticide pollinator hazards. This is consistent with EPA's general approach of urging the state agencies to develop such plans to capture local conditions and avoid an attempt at creating a centralized "one size fits all" approach. It is expected that such plans will be further developed during 2018 and some of the first evaluations of a plans' effectiveness may become available to further evaluate and refine the individual state programs.

[T]he pesticide industry itself must continue to innovate in a less predictable regulatory environment and an always changing political setting across national boundaries.

Among some of the continued concerns of pesticide registrants is the issue of how broadly EPA might attempt to require certain studies of possible risks to bees without clear decision rules for which pesticides need higher tier studies, what questions the data might answer, and the capacity of testing facilities effectively to conduct such studies, especially if the requirements are cast too broadly or without clear decision criteria. The Trump Administration is expected to review any label policies or blanket testing requirements as part of its general regulatory review agenda along with its emphasis on "cooperative federalism" giving more deference to state agencies.

Cooperation with USDA

Another "reform" promised by the Trump Administration is a greater role for, and closer relationship with, the USDA's Office of Pest Management Policy (OPMP). Internal to USDA, the Office is being moved to report directly to the USDA's Office of Chief Economist, which is expected to give OPMP a higher profile and strengthened portfolio when dealing with OPP on pesticide matters. It was widely felt by agricultural producers and registrants during the Obama years that consultation with USDA was diminished or altogether ignored. This reorganization and the rhetorical commitments promise a greater role for USDA input to EPA pesticide activities.

The March of 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. Most decisions about pesticides are not reported in the *The New York Times*, are not subject to Senate scrutiny, and are not even blog-worthy or covered by the trade press.

In part, this is why the questions of EPA staffing and budget are important. EPA continues to process new pesticide product registration applications while conducting registration reviews of the existing active ingredient universe. This takes time, money, and personnel simply to get the job done. Without the fee schemes being reauthorized, some fear that not only would the plain reduction in the budget cause problems, but the impact on morale would be immediate and severe.

EPA, not just the pesticide program, faces a demographic transition from those employees now eligible to retire by the simple passage of time, regardless of any impact of the arrival of new appointees with new agendas. The budget uncertainty currently is impeding recruitment and hiring of new personnel in the pesticide program, yet the workload demands continue as usual. Over time, shortages or even simply uncertainty will likely lead to skills mix issues, organizational capacity problems, and impacts on program morale. This could lead to longer review times and a generally lower scientific quality of the review work, even in cases where there is little controversy and straightforward data evaluations. That would be unfortunate, as the pesticide industry itself must continue to innovate in a less predictable regulatory environment and an always changing political setting across national boundaries; and all of this takes place as the industry itself becomes more consolidated and global due to the financial needs required to be a modern pesticide company.

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II. SIGNIFICANT GLOBAL CHEMICAL MANAGEMENT PREDICTIONS

A. EUROPE: BREXIT FORECAST

On December 1, 2016, Acta published a memorandum entitled "Brexit -- An Overview of Transformative Developments and Their Potential Impact on European Chemical Laws." Since publication of Acta's memorandum, there have been several key developments in case law and statute, resulting in the trigger of Article 50 by the United Kingdom (UK) on March 29, 2017; issuance of a White Paper elaborating the UK's strategy for repealing the European Communities Act 1972 to end the supremacy of European Union (EU) law; and introduction of and parliamentary discussions relating to the EU (Withdrawal) Bill, formerly referred to as the Great Repeal Bill. 2017 has been an interesting and eventful year in the context of Brexit, and it can be expected that 2018 will be instrumental in determining various outcomes and issues for a post-Brexit environment.

The Brexit process and developments pertinent to it are subject to significant change, and many Brexit-related issues are evolving at an exceptionally fast pace. Numerous widespread Brexit matters depend in whole or in part on the outcomes of political negotiations between the UK and the EU, which are evidently presenting on a frequent basis unexpected and novel challenges. Some might suggest making any predictions regarding Brexit or its implications is ill-advised. Considering the global importance of Brexit and potential widespread consequences for the chemicals industry, it is vital that developments are followed closely to prepare comprehensive strategic plans for legal and regulatory compliance, and business prosperity.

UK Members of Parliament (MP) have expressed views on the EU (Withdrawal) Bill that vary significantly and the UK government faces substantial pressure from MPs and the public to reverse, delay, or otherwise alter the UK's planned withdrawal from the EU by **March 29, 2019**, at the latest. Recently, Ireland threatened to block progress of Brexit negotiations unless the UK provides a formal written guarantee that there will be no hard border with Northern Ireland. In terms of the UK's local politics, it would appear that major progress may occur in 2018. Agreement on and progress related to the EU (Withdrawal) Bill appears imperative in 2018 to allow for and facilitate a smooth departure of the UK from the EU, but the current state of affairs raises numerous questions. For example, the Labor Party has tabled a new amendment to the EU (Withdrawal) Bill that would commit the government to giving MPs a vote on the Brexit financial settlement.

Absent agreement among MPs on the EU (Withdrawal) Bill, a variety of potential negative consequences exist for the UK, largely because Article 50 is an EU law issue and the UK would depart from the EU regardless of MPs' agreement on the path forward. Provided the EU (Withdrawal) Bill receives approval from Parliament and Royal assent, the much discussed "transposition" of EU law into the UK's Statute Book is likely to receive important attention in 2018. Transposing EU law to apply in the UK presents a unique challenge because laws would make little or no sense if simply added to the UK's Statute Book (*e.g.*, due to references to EU institutions). Perhaps 2018 will provide important information and clarity regarding the implementation of EU law and European legal judgments in the UK post-Brexit, and related timescales.

To date, both the UK and the EU have been underwhelmed by the negotiating standpoints, opinions, and proposals of one another. On November 28, 2017, *The Guardian* issued a news release entitled "Brexit talks: for all Britain's bluster, the EU has it over a barrel." The news release elaborates the one-sided nature of UK-EU negotiations to date, and states "Brussels no longer pretends it is in 'negotiations' with the UK -- May must either meet its demands or walk off a cliff." Evidently, myriad negotiation challenges lie ahead as we enter the most important timeframe in the Brexit process. 2017 has proven a uniquely challenging year for UK-EU Brexit negotiations, and it can be reasonably expected that 2018 will present numerous challenges of a similar and varying nature.

Although many challenges exist, it can be reasonably expected that 2018 will be a very important year in UK-EU negotiations for Brexit. The clock is ticking and both sides are well aware of the need to secure agreement on important issues for the general public (*e.g.*, citizens' rights). News and discussions evidence that "Hard Brexit" is, in fact, a real possibility, and the UK may be particularly motivated in 2018 to make significant progress on the post-Brexit UK-EU trade deal to avoid trading on World Trade Organization (WTO) terms following Brexit. Of course, it is entirely possible that 2018 may be the year that will display the UK's flex-

[I]ndustrial chemical companies subject to EU REACH may face significant pressure in 2018 -- with one eye on the calendar to monitor the final REACH registration deadline and another on the news to follow Brexit.

ibility and the trend may shift more towards a "Soft Brexit." The outcomes of such issues will likely prove critically important for chemical businesses trading globally, and industrial chemical companies subject to the EU's Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation, in particular, may face significant pressure in 2018 -- with one eye on the calendar to monitor the final REACH registration deadline and another on the news to follow Brexit.

For the chemicals industry, including manufacturers, importers, consultants, and others, 2018 is expected to provide some important information to facilitate strategic planning for the fast approaching post-Brexit environment. Discussions regarding applicability of REACH, the EU's Biocidal Products Regulation (BPR), and the Plant Protection Products (PPP) Regulation in the UK following Brexit currently occur frequently. Recent government consultations, statements by officials, and discussions in the chemicals industry suggest that UK REACH may be on its way. It is possible, of course, that REACH is replaced in the UK by something dissimilar to EU REACH, or repealed entirely.

Transposition of REACH into UK law presents a significant challenge, as the regulation contains over 500 references to EU-specific institutions. The possibility of UK REACH raises numerous questions for industry, including whether a "dynamic" or "non-dynamic" approach will be adopted, whether Substances of Very High Concern (SVHC) will be managed in the same way in the UK and EU after Brexit, and whether EU REACH data sharing agreements will be valid under UK REACH. The UK chemicals industry has expressed a desire for deregulation due to cost burdens; it remains to be seen whether and to what extent such wishes are fulfilled. It can be expected that in 2018 numerous Only Representatives (OR) currently established in the UK will set up offices elsewhere in the European Economic Area, as REACH is clear on scope in this regard and the European Chemicals Agency (ECHA) has provided assistance on the topic. Given the importance of the issues, it can be expected that industry will impose in 2018 substantial pressure on the government and others to obtain at least some insights on UK REACH and Classification, Labelling, and Packaging (CLP) laws in the UK following Brexit. The PPP Regulation raises fewer questions in the context of Brexit than REACH and BPR. It is expected that biocides companies will seek to obtain answers to important questions in 2018. Under BPR and in a post-Brexit environment, biocides companies would be required to appoint an EU representative for purposes of the Article 95 List, and industry will likely be seeking information in addition to that provided by ECHA to facilitate future planning. Currently, many UK companies providing services or operating under REACH and BPR are in a "wait and see" mind-set -- and it is expected such thought patterns will dissipate in 2018 and a trend towards taking more meaningful actions will be seen.

As has been the case in 2017, it can be expected that groups such as the Chemical Industries Association (CIA) and the Chemical Business Association (CBA) will be vocal in expressing the desires of industry. CIA, CBA, and other groups have already expressed that Hard Brexit would have substantial negative repercussions for the chemicals industry, and that an "in REACH" outcome is most desirable. It remains to be seen, perhaps in 2018, whether the efforts of such groups can have a meaningful impact on Brexit processes and outcomes.

To summarize, although the Brexit landscape is challenging, uncertain, evolving, and highly unpredictable, it would appear that 2018 may be the year that will allow many, including chemical companies subject to REACH and BPR, to prepare meaningful, robust plans for years ahead. The UK's departure from the EU will likely be considered a major change in the global political climate for years to come and, due to the implications, it is reasonably expected that all those involved will seek to obtain and provide clarity to facilitate smooth transitions. Any significant weakening of environmental health and safety standards in the UK post-Brexit

would receive strong criticism from the public and involved organizations and, consequently, such drastic changes appear highly unlikely, in 2018 or afterwards.

Endocrine Disrupting Chemicals Identification Criteria to Apply Under BPR Starting June 2018

On November 17, 2017, the European Commission (EC) published in the *Official Journal of the European Union* Commission Delegated Regulation (EU) 2017/2100 regarding scientific criteria for determination of endocrine-disrupting properties pursuant to the EU's BPR. These legal criteria for the identification of endocrine disrupting chemicals (EDC) under the BPR will apply from **June 7, 2018**.

The EDC identification criteria under the BPR and the PPP Regulation were subject to extensive debate and criticism by NGOs and other stakeholders. Typical criticisms of NGOs included that the criteria would effectively delay substantially or prevent identification of chemical substances as EDCs due to the high evidentiary thresholds under the proposed laws. Various groups stated that the EDC identification criteria presented unacceptable risks for human health.

The EDC criteria for the PPP Regulation were rejected by the European Parliament (EP) in October 2017. The criteria for identification of EDCs under the BPR were approved by the EP, however. The BPR will be the first EU regulatory program to apply such EDC criteria, and similar criteria are expected to extend to sectors such as cosmetics, toys, and food contact materials (FCM).

As requested by the EC in the interests of "ensuring for an immediate, consistent and transparent implementation of the new criteria," ECHA and the European Food Safety Authority (EFSA) have issued a draft guidance document for the identification of EDCs. ECHA and EFSA are currently inviting public comment on the draft guidance document, with a deadline of **January 31, 2018**. In its press release, ECHA states "[a]ll received comments will be taken into consideration in [issuing in final] the guidance, which is scheduled to be available by **June 2018**."

B. TURKEY: TURKEY REACH SUMMARY

On January 27, 2016, Acta published a memorandum entitled "Turkey Catching Up with the European Union's (EU) Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Regulation." Since the publication of Acta's memorandum, there have been numerous developments related to Turkey REACH, also referred to as KKDIK. KKDIK was published by Turkey's Ministry of Environment and Urbanization (MoEU) on June 23, 2017, and the law entered into force on December 23, 2017. KKDIK replaces the following Turkish chemical regulations:

- Regulation on the Inventory and Control of Chemicals (CICR):
  - CICR was repealed and replaced by KKDIK upon publication, and no further notifications or updates are required or permitted under CICR;
- Regulation on the Preparation and Distribution of Safety Data Sheets (SDS) for Hazardous Materials and Products
  - KKDIK will replace fully this SDS regulation on **December 31, 2023**;
- Regulation on Restrictions for the Manufacture, Marketing, and Use of Certain Dangerous Substances and Preparations:
  - This regulation was replaced by KKDIK on December 23, 2017.

The principles, rules, and requirements of KKDIK are generally very similar to EU REACH, with few substantive variations. Similar to EU REACH, KKDIK Article 1 provides that the purpose of the regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for the assessment of hazards of substances, while enhancing competitiveness and innovation. KKDIK regulates manufacturing, placing on the market, and use of chemical substances; substances in mixtures; and substances in articles.

The following are covered by KKDIK Article 2 exemptions: (1) radioactive substances and mixtures; (2) substances, mixtures, or articles subject to customs supervision, provided they do not undergo treatment or processing; (3) substances, mixtures, or articles in temporary storage, transit, or in a "free zone or free warehouse with a view to re-exportation"; (4) non-isolated intermediates; (5) carriage of hazardous substances and hazardous mixtures by rail, road, inland waterway, sea, or air; (6) substances manufactured or imported for defense purposes; (7) medicinal products; (8) veterinary products; (9) medical devices; (10) cosmetic products; and (11) food and feeds.

The "Second Part" of KKDIK covers "Registration of Substances." Similar to EU REACH, KKDIK specifies pre-registration and registration deadlines for chemical substances manufactured in or imported into Turkey in quantities of one metric ton per annum or more. Unlike EU REACH, the deadlines do not vary depending on the applicable tonnage band under the law. KKDIK contains the same four annual tonnage bands as EU REACH (*i.e.*, 1-10 metric tons, 10-100 metric tons, 100-1,000 metric tons, and 1,000+ metric tons). The pre-registration deadline is **December 31, 2020**, and the registration deadline is **December 31, 2023**. These deadlines are intended to provide sufficient time for industry to address compliance. KKDIK does not delineate between new and existing substances, and the pre-registration and registration deadlines apply to all substances manufactured in or imported into Turkey in quantities of one metric ton or more annually.

Entities manufacturing in or importing into Turkey chemical substances in quantities of one metric ton per annum or more are required to submit pre-registration dossiers containing information on substance identity and the relevant role in the supply chain, and KKDIK registration dossier requirements, including data requirements, are similar to EU REACH. Similar to EU REACH, joint submission is mandatory for KKDIK registrations. Data sharing under KKDIK is also managed in a similar manner to EU REACH, and the legal text of KKDIK includes the much discussed EU REACH phrase "fair, transparent and non-discriminatory." Unlike CICR, but similar to EU REACH, KKDIK regulates polymers by requiring registration of contained monomers manufactured in or imported into Turkey in quantities of one metric ton per annum or more.

Similar to EU REACH and CICR, non-Turkish manufacturers can address KKDIK compliance through appointment of an OR in Turkey. ORs are addressed under KKDIK Article 9, which provides:

> A natural or legal person established outside Turkey who manufactures a substance on its own, in mixtures or in articles, formulates a mixture or produces an article that is imported into [Turkey] may by mutual agreement appoint a natural or legal person established in [Turkey] to fulfil, as his [OR], the obligations on importers under the scope of this Bylaw ... The [OR] shall have a sufficient background in the practical handling of substances and the information related to them ... If [an OR] is appointed in accordance with paragraphs 1 and 2, the non-resident manufacturer in Turkey shall inform the importer(s) within the same supply chain of the appointment. These importers shall be regarded as downstream users for the purposes of this Bylaw.

As expected, considering the goals and overarching purpose of KKDIK, the OR provisions are very similar to EU REACH. Annex 18 of KKDIK contains qualification requirements for technical experts, as notification, registration, and SDS requirements under KKDIK must be fulfilled by certified Chemical Assessment Experts. KKDIK Annex 18 specifies qualification requirements for such personnel, criteria for trainers, and requirements for the institutions providing such training, including that: (1) Turkish Chemical Assessment Experts for KKDIK purposes shall either obtain a certificate of competency from an institution accredited by the Turkish Accreditation Institution (TÜRKAK), or will have worked "in the Ministry" in the chemicals management field for at least ten years; (2) the "[p]eriod of training shall be at least 64 hours"; (3) persons must score "70 and above in the examination" to receive the Chemical Assessment Competency Certificate; (4) maximum participant numbers shall not exceed 30 persons per training; and (5) trainers must have a "Bachelor degree from chemical engineering, environmental engineering, chemistry, biology,

It can be expected that 2018 will be a busy year for companies subject to KKDIK, and others including consultants and MoEU staff. KKDIK Annex 18 requirements, in particular, have attracted significant attention, and many will likely seek to become certified Chemical Assessment Experts sooner rather than later.

chemistry education or biology education departments" and three years' work experience, or five years' work experience if their degree is "from other departments."

KKDIK Annexes 14 and 17 replace the Turkish Regulation on Restrictions for the Manufacture, Marketing, and Use of Certain Dangerous Substances and Preparations. Annex 17 of KKDIK concerning restrictions closely resembles, but is not identical to, EU REACH Annex XVII. KKDIK Annex 17 is subject to phased implementation, depending on the substance and use in question. In accordance with KKDIK Article 66, authorization processes under KKDIK shall become relevant on **December 31, 2023**, the registration deadline for substances subject to the legislation. Concepts related to restriction and authorization under KKDIK are substantively the same as under EU REACH. Annex 14 is a blank Annex as of the date of publication of KKDIK, and the list of substances to be added to Annex 14 will be determined by MoEU. Based on information available to date, it is reasonably expected that KKDIK Annex 14 will appear very similar to EU REACH Annex XIV.

Rules for preparation of Turkish SDSs are subject to a transition period from December 31, 2017, until **December 31, 2023**. During this timeframe, SDSs can be prepared in accordance with the Regulation on the Preparation and Distribution of SDSs for Hazardous Materials and Products, or in accordance with KKDIK. On **December 31, 2023**, the SDS regulation will be replaced completely by KKDIK. Under KKDIK, SDSs must be authored by a certified Turkish expert. The transition periods under KKDIK for SDSs are intended to provide sufficient time for relevant persons to complete processes to become Chemical Assessment Experts, as required by KKDIK Article 27.

As the KKDIK framework has been formally published and entry into force is imminent, chemical companies globally that are subject to the law should perform various activities to support regulatory compliance, including:

- Determine chemical substances manufactured in or imported into Turkey in quantities of one metric ton per annum or more;
- Determine if an OR, if relevant, is certified for KKDIK compliance;
- Initiate pre-registration steps in 2018; and
- Transition Turkish SDSs to KKDIK requirements by **2023**.

It can be expected that 2018 will be a busy year for companies subject to KKDIK, and others including consultants and MoEU staff. KKDIK Annex 18 requirements, in particular, have attracted significant attention, and many will likely seek to become certified Chemical Assessment Experts sooner rather than later. Industry has expressed concern regarding the availability of experts, and discussed the benefits and pitfalls of permitting EU nationals to serve as Turkish Chemical Assessment Experts. It is also expected that 2018 will provide some clarity on issues regarding which industry has expressed concern, such as data sharing and use of EU REACH data under KKDIK; various matters related to IT tools; and requirements for registrations to be submitted in Turkish. KKDIK guidance documents are already available, and it is expected that further guidance and support will be provided by MoEU in 2018 to facilitate a smooth transition to the new law.

CONTRIBUTORS
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Following significant delays, Turkey has a robust and up-to-date chemical control framework in place that is generally aligned with EU principles. As Turkish regulators have performed their task of developing KKDIK, industry must now take meaningful measures to comply.

C. ASIA: CHEMICAL CONTROL IN ASIA PACIFIC REGION

China

The regulations on chemicals, pesticides, and FCMs continue developing in China. For example, the new Regulation on Pesticide Administration (RPA) and its Implementation Rules took effect in 2017; the Data Requirements for the Guidance for New Chemical Substance Notification and Registration (NCSN) was revised and went into effect on October 15, 2017; the draft of Standard Achieving Management Catalogue for the Restriction of the Use of Hazardous Substances in Electrical Appliances and Electronic Products (First Batch) and Exemption List for the Restriction of Hazardous Substances of the Standard Achieving Management Catalogue under the Rules on the Restriction of the Use of Hazardous Substances in Electrical Appliances and Electronic Products (China RoHS2) were released to the WTO Committee on Technical Barriers to Trade on October 13, 2017; a draft of List of Priority Chemicals for Management (First Batch) was issued for internal consultation, and a revision of the "Order Number 7 of the Ministry of Environmental Protection (MEP) -- Environmental Management of New Chemical Substances in China" (MEP Order No. 7) is under discussion.

Development of Chemical Regulation

Following the Initiative of Jointly Building the Silk Road Economic Belt and the 21st-Century Maritime Silk Road (Belt and Road) in late 2013, MEP released the Belt and Road Ecological and Environmental Cooperation Plan to promote environment-friendly Belt and Road in May 2017. According to the Plan, a series of eco-environmental protection programs from policy coordination to capacity building will be introduced over several years.
MEP is collecting data and exposure information on hazardous chemicals to improve the control of long-term and cumulative environmental risks of hazardous chemicals and wastes. MEP is developing the List of Priority Chemicals for Management, the List of SVHCs, and the List of Restriction and Phase-Out Chemicals. MEP will also establish a preliminary environmental management system by **2020** (the end of China's 13th Five-Year Development Plan). The environmental management system will include a pollutants discharge license, environmental impact assessments, information transparency, environmental monitoring, supervision, and other initiatives to reduce the environmental risks of toxic and hazardous chemicals. A comprehensive environmental management system for the prevention and control of toxic and hazardous chemicals will be established, implemented, and optimized by **2030**.

Revised Data Requirements for NCSN

The Amendment on Data Requirements to the Guidance for NCSN became effective on October 15, 2017. The key changes are on data requirements of regular registrations and include:

- Level 1 Registration (1-10 metric tons/year): Only one of three acute (oral, dermal, or inhalation) toxicity tests is required based on the exposure route. A 28-day repeated dose toxicity test is no longer required. Only a bacterial reverse mutation test (Organization for Economic Co-operation and Development (OECD) 471) is needed unless its test result is positive.

- Level 2 Registration (10-100 metric tons/year): A 90-day repeated dose toxicity test and a 14-day prolonged toxicity test to fish are no longer required.

- Level 4 Registration (> 1000 metric tons/year): A carcinogenicity assessment shall be submitted; conducting carcinogenicity testing shall be based on mutagenicity test results and the potential for human exposure. The earthworm reproduction test is added for chemicals with acute terrestrial hazard classification.
- Mutagenicity Tests for Level 2 and above Registrations: A bacterial reverse mutation test (OECD 471), an *in vitro* mammalian cell chromosome aberration/micronucleus test (OECD 473/487), and an *in vitro* mammalian cell gene mutation test (OECD 476) are required. Additional mutagenicity tests including an *in vivo* gene mutation test (*e.g.*, transgenic rodent somatic and germ cell gene mutation assays (OECD 488)) or a DNA damage and repair test, (*e.g.*, unscheduled DNA synthesis test with mammalian liver cells *in vivo* (OECD 486), and an *in vivo* comet assay (OECD 489) may be required if the test results are positive.

A draft revision of MEP Order No. 7 could be released for public consultation as early as the end of the year and the full revised Guidance for NCSN submitted to the WTO Committee on Technical Barriers to Trade on March 8, 2016, will be issued in final after the MEP Order No. 7 is revised.

- Toxicokinetics (TK) for Registrations at Level 2 and above: TK assessment based on existing data shall be performed, but it is unclear whether a TK study is required when no relevant data exist for the new substance.

Revision of MEP Order No. 7

The MEP Order No. 7 entered into force on October 15, 2010. MEP is currently accepting suggestions from stakeholders for revision of the MEP Order No. 7. Below are preliminary points that were considered according to the Solid Waste and Chemical Management Center (SCC), MEP.

- Clarification of the responsibilities and duties of MEP and other governmental branches in chemical management;
- Information collection of environmental emissions of chemicals;
- NCSN exemptions for cosmetic ingredients;
- Clarification regarding which entity -- Chinese importers, overseas exporters, or the one filing customs clearance -- shall be responsible for filing the NCSN for imported new substances. Chinese importers or overseas exporters are currently required to register the new substances imported into the Chinese market;
- Promote data sharing and revise tonnage accumulation in repeat notifications and joint notifications;
- Simplified and/or reduced notification requirements for new substances that are relatively low risk, such as polymers of low concern (PLC) and small quantity of substances for research and development;
- Reduction of data requirements for isolated intermediates with low exposure potential;
- Focus on the amount instead of concentration of the chemical released to the environment in production or use of chemicals in risk assessment;
- Data requests by MEP for its retrospective review of approved notifications;
- Criteria of priority chemicals for environmental management;
- Criteria and duration for confidential business information (CBI) claim; and
- Improvement and enforcement of the regulations and customs inspection.

A draft revision of MEP Order No. 7 could be released for public consultation as early as the end of the year and the full revised Guidance for NCSN submitted to the WTO Committee on Technical Barriers to Trade on March 8, 2016, will be issued in final after the MEP Order No. 7 is revised.

Draft List of Priority Chemicals for Management

On October 9, 2017, MEP issued a draft List of Priority Chemicals for Management (First Batch) and Risk Management Policy and Measures of the Priority Chemicals for internal consultation to strictly control environmental risks and assessment of the environmental and health risks of existing chemicals based on the mandate by the Action Plan for Water Pollution Prevention published by the State Council on April 16, 2015. The list contains 36 types of chemicals with 59 Chemical Abstracts Service (CAS) Numbers including arsenic (As), lead (Pb), mercury (Hg), chromium (Cr), cadmium (Cd) and their compounds; persistent, bioaccumulative, and toxic (PBT) chemicals identified according to the national standard GB/T 24782-2009 -- *Identification Method of PBT Substances, and Very Persistent and Very Bioaccumulative (vPvB) Substances*; carcinogenic, toxic to reproduction (CMR) chemicals and

chemicals with high aquatic environmental toxicity classified according to the Globally Harmonized System of Classification and Labelling (GHS) and the national standard GB 3000-2013 -- *Rules for Classification and Labelling of Chemicals*; and chemicals manufactured or used in huge quantities in China. The production and use of these high-risk priority chemicals will be strictly controlled and gradually phased out.

Draft Standards for Hazardous Chemicals in Consumer Products

The Standardization Administration of China (SAC) issued a Work Plan for National Standard, *Guidelines on Identification and Evaluation of SVHC*, on April 24, 2017. According to the Plan, China will draft the national standard to provide guidelines for the identification, hazardous classification, and risk assessment of SVHC in 24 months. A draft national standard, *List of SVHC Substances in Consumer Products*, was published by the General Administration of Quality Supervision, Inspection and Quarantine of China (AQSIQ) and SAC in March 2017. The list contains 205 SVHCs similar to substances of similar concepts, such as the list of SVHCs published by ECHA, California's Proposition 65 (Prop 65) in United States, and the Consumer Product Safety Act in Japan. AQSIQ and SAC also published a national standard, *Safety Requirements for Hazardous Chemicals in Consumer Products (Draft)*, for public comment on March 28, 2017. The draft standard introduces restrictions or bans of 103 types of hazardous chemicals in consumer products such as toys, textiles, coatings, paints, decoration materials, and furniture including their components, parts, accessories, and packaging, similar to the consumer restrictions set out in REACH Annex XVII. The restricted/banned substances include heavy metals such as Cd, hexavalent chromium (Cr(IV)), Pb, Hg, and nickel (Ni), phthalates, certain alkanes and alkenes, haloalkenes, phenols, polycyclic aromatic hydrocarbons (PAH), and aldehydes.

Revision of Environmental Protection-Related National Standards

MEP will develop and revise approximately 800 national standards related to environmental protection including about 400 standards on environment quality monitoring and about 100 standards on pollutants emission control according to its Work Plan for Environmental Protection Standards during the Period of China's 13th Five-Year Development Plan (2016 - **2020**) published by MEP on April 10, 2017. The quality of air, water, and soil will be the top priority. The emission control standards will focus on the air and water pollutants and hazardous solid wastes. The standards on noise pollution are also included in the developmental program. These standards will be used to support the newly established pollutants emission permit system and the Environmental Protection Tax Law that took effect on January 1, 2018.

Draft of Standard Achieving Management Catalogue and Exemption List under China RoHS2

The Ministry of Industry and Information Technology (MIIT) notified a draft of the Standard Achieving Management Catalogue for the Restriction of the Use of Hazardous Substances in Electrical Appliances and Electronic Products (First Batch) and Exemption List for the Restriction of the Use of Hazardous Substances of the Standard Achieving Management Catalogue under the China RoHS2 rules to the WTO Committee on Technical Barriers to Trade on October 13, 2017, with no implementation date provided. The drafts of the Standard Achieving Management Catalogue and the Exemption List are available online, in Chinese.

China RoHS2 became effective on July 1, 2016. It requires MIIT to develop a standard achieving management catalogue and its exemptions for its implementation. The draft of the Catalogue (First Batch) includes refrigerators, air conditioners and filters, washing machines, electric water heaters, printers, copy machines, fax machines, television sets, monitors, personal computers, handsets for wireless communication, and telephones, totaling 12 types of products that must comply with the hazardous substance restriction limits, set out in national standard GB/T 26572-2011. The draft of the Exemption List contains details on 39 products or component parts that are exempt from the hazardous substance restrictions of China RoHS2 and their limits if applicable; for example: Hg in certain lamps, Pb in certain glasses, alloys, or lamps, Cd in certain electronic products, and Cr(IV) as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators.

China is establishing a Pesticide Management Agency as the new pesticide authority responsible for industrial planning, approval, surveillance, supervision, and sanctions of pesticides.

Development of Pesticide Regulation

China has been implementing the new RPA (Decree No. 677 of the State Council) since June 1, 2017, and is establishing a Pesticide Management Agency under the Department of Plantation Management, Ministry of Agriculture (MOA) as the new pesticide authority responsible for industrial planning, approval, surveillance, supervision, and sanctions of pesticides. Many new/revised industry pesticide standards took effect in 2017 and many more are being drafted or under revision. Additionally, MOA outlined a work plan to promote food safety, environmental protection, and pesticide industry development in China on June 25, 2017. The key points of the plan are as follows:

- Optimizing manufacture location: 60 percent and 80 percent of production plants of active pesticide ingredients will be moved to chemical or industrial zones by **2020** and **2025**, respectively;

- Optimizing structure of pesticide products: Gradually phase out highly toxic pesticides; promote biopesticides and high efficacy, low toxicity, and environmental friendly pesticides; and reduce new registrations of "me-too" generic pesticide products by 30 percent and 50 percent by **2020** and **2025**, respectively.
- Improving quality of pesticide products: the qualification rate shall be above 95 percent and 96 percent in quality inspection of pesticide products and pesticide residue levels in agricultural products, respectively, by **2020**;

- Improving use efficiency of pesticides: the use efficiency of pesticides shall be above 40 percent, similar to the use efficiency in developed countries by **2025**; and

- Fully optimizing the pesticide management system in the next three to five years.

New and Revised Pesticide Regulation

Since the new RPA was implemented on June 1, 2017, eleven implementation rules of the new RPA took effect that include Pesticide Registration Management Measures (MOA Order No. [2017]3), Measures for the Management of Pesticide Production License (MOA Order No. [2017]4), Measures for the Administration of Pesticide Business License (MOA Order No. [2017]5), Measures for the Management of Tests Used for Pesticide Registration (MOA Order No. [2017]6), and Measures for the Administration of Pesticide Labels and Manuals (MOA Order No. [2017]7) that all became effective on August 1, 2017; List of Pesticides with Restricted Uses (2017) (MOA Proclamation No. 2567) including 32 pesticides that became effective on October 1, 2017; Detailed Rules on Pesticide Production Permit Evaluation (MOA Proclamation No. 2568), Rules on Evaluation of Pesticide Registration Testing Institutes, and Code for Pesticide Registration Testing Quality Management (MOA Proclamation No. 2570) that became effective on October 10, 2017; Data Requirements on Pesticide Registration (MOA Proclamation No. 2569) that became effective on November 1, 2017; and Measures for the Management of QR Code Pesticide Label (MOA Proclamation No. 2579) that became effective on January 1, 2018.

The new RPA and its implementation rules focus on the quality and safety of agricultural products, promote the reduction of pesticide uses, enhance the management of highly toxic pesticides, and clarify the responsibilities of manufacturers, sponsors of the contracted manufacturers, and marketers for the safety, efficacy, and quality of pesticides. The pesticide producers and marketers are primarily responsible for the safety, efficacy, and quality of their pesticide products. MOA becomes the sole regulatory authority with complete control of registration, licensing, and supervision of pesticide production, distribution, and uses. MOA establishes and implements new production and distribution licenses, regulatory enforcement, product recalls, and pesticide waste recycling systems.

The new RPA and its implementation rules significantly changed the registration process and labeling requirements of pesticides, removed temporary pesticide registrations, and included increased fines and blacklisting. The new RPA requires that manufacturers and marketers of pesticides establish a tracking system and maintain the required records for at least two years and that foreign manufacturers obtain the registration for a pesticide in another country before registering it in China.

For pesticide registrations, MOA Order No. [2017]3 requires that chemistry and toxicology tests shall be completed in laboratories located in China approved by MOA or overseas GLP-compliant laboratories from a country that has a mutual or multilateral agreement on data acceptance with China. On November 1, 2017, China stopped unilateral acceptance of overseas GLP data for Chinese pesticide registrations from countries/organizations that have no mutual acceptance of data (MAD) agreement with China. A transitional period is under discussion. The Institute for the Control of Agrochemicals (ICAMA), MOA, has been actively involved in international collaboration on GLP data acceptance. An agrochemical MAD agreement between EPA and MOA has been under discussion since 2014, and a full compatibility evaluation of GLP regulations, guidelines, procedures, and management between the two countries has been conducted. A memorandum of understanding (MOU) on data acceptance would be reached after approval by the U.S. Congress. ICAMA believes that other OECD countries will follow once China and the U.S. achieve a MAD agreement and that it will take less time to sign MAD agreements between China and other OECD countries. Because China has not yet joined the MAD system of OECD, reports from overseas OECD GLP labs that China has recognized for decades will no longer be usable in China. MOA Order No. [2017]3 requires that efficacy, residue, and environmental tests shall be conducted in China, and that literature or data in a foreign language shall be translated to Chinese for pesticide registrations, but is not clear if entire study reports/articles, or only summaries, must be translated into Chinese. Risk assessments and benefit evaluations to demonstrate the safety, efficacy, and economic advantages over existing registered products shall be conducted based on the chemical, toxicological, efficacy, ecotoxicological, and environmental properties of the product. A maximum residue limit (MRL), based on dietary risk assessments, should be proposed for a pesticide registering on a crop in China for the first time. The studies on residue should be repeated in China for a MRL established according to residue data generated outside of China. The *Guideline for Establishment of Pesticide Acute Reference Dose* (ARfD) was published and took effect on September 30, 2017 (MOA Proclamation No. 2586). The guideline provides the precondition, procedure, and parameter selection for the calculation of pesticide ARfD and serves as the technical basis for MRL establishment and dietary risk assessment of pesticides in China.

MOA is responsible for maintaining and updating the List of Restricted/Prohibited Inert Ingredients/Adjuvants according to the hazard and toxicity characters of the inert ingredients. Testing on an inert ingredient will be required when the inert ingredient is exclusively used for a registering product. All registered pesticides are subject to safety surveillance and MOA will periodically re-evaluate active pesticide ingredients that have been registered for over 15 years.

New and Revised Standards for Pesticide Registration

China has established and has revised test guidelines for pesticide storage stability, transformation during food processing. and plant biotransformation of pesticide and pesticide residues that should be used for pesticide registration. The guidelines include NY/T 1427-2016 -- *Guideline for the Testing Pesticide Stability at Ambient Temperature*, NY/T 2989-2016 -- *Guidance on the Establishment of Product Specification for Pesticide Registration*, and NY/T 2990-2016 -- *Methods for Qualitative and Quantitative Determination of Prohibited and Restricted Pesticides* that took effect on April 1, 2017. The guidelines on pesticide residue tests stipulate the conditions, experimental design, sampling, performance, quality control, data processing, and the extrapolation between different crop/food groups including NY/T 3094-2017 -- *Guideline for Storage Stability Testing of*

China implemented the List of Restricted Use Pesticides (2017) (MOA Proclamation No. 2567) on October 1, 2017. The list includes 32 pesticides that are subject to additional labelling requirements.

Pesticide Residue in Food of Plant Origin, NY/T 3095-2017 -- *Guideline for Testing of Pesticide Residue in Processed Agricultural Products*, and NY/T 3096-2017 -- *Guideline for Testing of Pesticide Metabolism in Crops* that took effect on October 1, 2017.

Six new draft voluntary agricultural standards for environmental impact testing of pesticides were issued for public comment in the ICAMA Notice No. [2017]154 on September 20, 2017. The guidelines include *Environmental Reproduction Test Guidelines for Microbial Pesticides -- Soil, Water, and Leaf of Plant (Draft)*; *Guidance Document on Aquatic Toxicity Testing of Difficult Pesticides (Draft)*; *Guideline on Myriophyllum Specatum Toxicity Test for Chemical Pesticides (Draft)*; *Test Guidelines on Chronic Contact Toxicity of Chemical Pesticides to Insect Natural Enemy -- Ladybird and Trichogramma (Draft)*; *Multi-Residue Analytical Methods for Pesticides in Water (Draft)*; and *Guidance on Aquatic (Sediment) Dissipation/Degradation for Chemical Pesticides (Draft)*. Three new draft voluntary agricultural standards for health risk assessment of pesticides, *Guideline on Unit Exposure Test of Pesticide Operators (Draft)*, *Guidance on Neurotoxicity Study of Pesticide (Draft)*, and *Guidance on Assessment of Pesticide Dermal Absorption (Draft)*, were published in the ICAMA Notice No. [2017]188 for public comment on November 2, 2017. A revised draft voluntary agricultural standard, NY/T 788 -- *Guideline on Pesticide Residue Trials on Crops (Draft)*, was published to replace NY/T 788-2004 in the ICAMA Notice No. [2017]194 for public comment on November 10, 2017.

The SAC issued 28 toxicological testing methods for pesticide registration (GB/T 15670.1–.29-2017) covering single and repeated dose toxicity; skin and eye irritations and skin sensitization; genotoxicity; and reproductive and developmental toxicity, neurotoxicity, carcinogenicity, and TK on July 12, 2017, that will become effective on **February 1, 2018**, and replace the GB 15670-1995.

Banned and Restricted Pesticides

China implemented the List of Restricted Use Pesticides (2017) (MOA Proclamation No. 2567) on October 1, 2017. The list includes phorate, isofenphos-methyl, carbofuran, aluminum phosphide, endosulfan, chloropicrin, methomyl, ethoprophos, isocarbophos, aldicarb, methyl bromide, omethoate, paraquat, 2,4-D butylate, botulinum toxin C and D, flocoumafen, sodium diphacinone, warfarin, coumatetralyl, bromadiolone, brodifacoum, carbosulfan, daminozide, chlorpyrifos, flubendiamide, fipronil, dimethoate, fenvalerate, dicofol, triazophos, and acephate -- in total 32 pesticides that are subject to additional labelling requirements. Additionally, the marketing and use of 2,4-D butylate and paraquat are prohibited, and the marketing and use of dicofol, the use of flubendiamide on rice, and the use of carbofuran, phorate, and isofenphos-methyl in sugarcane will be prohibited as of **October 1, 2018** (MOA Proclamation No. 2445). The agricultural use of bromomethane and endosulfan will be banned starting on **January 1, 2019**, and **March 26, 2019**, respectively, and the use of acephate, carbosulfan and dimethoate on vegetables, fruits, tea leaves, fungus, and Chinese medicine herbs will be prohibited starting on **August 1, 2019** (MOA Proclamation No. 2552).

New National Standard for MRLs of Pesticides in Food

China will establish 6000 new MRLs for fruits, vegetables, cash crops, and residue test methods during the period of China's 13th Five-Year Development Plan (2016 – **2027**). *The National Food Safety Standard -- MRL for Pesticides in Food* (GB 2763) has been updated every two years since 2012. The latest version (GB 2763-2016) was implemented on June 18, 2017, and includes 490 newly added MRLs, totaling 4140 MRLs of 433 pesticides in 13 categories of agricultural products, 33 dietary risk-free pesticides exempt from developing MRLs in food, and 184 MRLs of 24 prohibited and restricted pesticides to provide criterion for

determination of illegal uses of prohibited and restricted pesticides. Meanwhile, 106 test methods for pesticide residue detection in agricultural products (GB 23200.1–.106-2016) was also implemented on June 18, 2017. An additional 498 draft MRLs of 130 pesticides to be integrated into the GB 2763 and eight draft determination methods for pesticide residue and/or metabolites in agricultural products were published for public comment in MOA Notice No. [2017]38 on September 30, 2017. The limits for imported commodities will be separately implemented to expand MRL coverage.

Development of Food Contact Regulations

The National Food Safety Standard System of China consists of hundreds of standards for FCM, food additives, nutrition fortification substances, infant formula, foods for special medical purposes, and so on under the Food Safety Law 2015 (China FSL). All previous food contact regulations and standards have been revised and 53 of the revised mandatory national food safety standards regulating the safety of FCM and related products took effect in 2017. These include the two most important new standards, GB 4806.1-2001 on general requirements and GB 9685-2016 on the use of 1,294 approved additives for FCM and articles, and nine material standards (GB 4806.3–.11-2016), 39 testing standards for individual substances (GB 31604.11–.49-2016), and a general principle of migration test pretreatment method (GB 5009.156-2016). The new set of standards have significantly tightened technical criteria in food inspection and oversight, by further aligning with internationally endorsed testing methodology and working mechanism. These standards also offer more detailed and actionable guiding principles from both hygiene and testing perspectives. FCM and the articles have been divided into ten categories: pacifier, enamel ware, ceramic product, glass product, plastic resin, plastic product, paper, metal material, coating, and rubber material. The limit of total migration of plastic FCM such as polypropylene and polyethylene is 60 mg/kg in line with the European level, while restrictions on N-nitrosodimethylamine and heavy metals such as Pb and Cd have also been tightened. A series of parameters in testing such as pH and lipid content, and testing time and temperature have been revised. The National Food Safety Standards GB 2761-2017 *Limits of Mycotoxins in Food* and GB 2762-2017 *Limits of Contaminants in Food* became effective on September 17, 2017, to replace their previous versions GB 2761-2011 and GB 2762-2012, respectively. The new standards specify the limits of aflatoxin B1 and M1, deoxynivalenol, patulin, ochratoxin A, zearalenone, Pb, Cd, Hg, As, Ni, Cr, tin, nitrite, nitrate, benzo[a]pyrene, N-dimethylnitrosamine, polychlorinated biphenyls, and 3-chloro-1,2-propanediol.

A draft *National Food Safety Standard for Composite FCM and Articles* was released for public comment on June 16, 2017. The new standard will replace GB 9683-1988 with increased requirements for raw materials and additives, revised physicochemical indexes, microbiological indexes, and labeling requirements, and the limits of solvent residues and migration amounts of primary aromatic amines and bisphenol A diglycidyl ether (BADGE) and its derivatives.

A draft *General Technical Standard for Metal Container of Canned Food* (GB/T 14251) was released for public comment on April 27, 2017. The new standard will replace GB/T 14251-1993 with stricter requirements on the safety indexes of mental containers including *e.g.*, the requirements on appearance, completeness of inner coating, and the performance of sealing gum of metal containers.

Chinese National Health and Family Planning Commission (NHFPC) issued a *Work Plan for the 2017 Annual Food Safety Standards* for public comment on September 28, 2017. Based on the Plan, 34 national food safety standards will be revised and 46 new ones will be created, that include GB 31604.1 on general principles for migration tests, 47 product standards on eight food products, five complementary food, four FCMs, and quality specifications of 30 food additives, eight guidance on manufacturing or hygiene practices, 23 test guidelines on 20 physiochemical determination methods, two microbiological examination methods, and a toxicological testing method.

Taiwan

The Environmental Protection Administration of Taiwan proposed several changes to the Toxic Chemical Substance Control Act (TCSCA) in April and again in September of this past year. Part of these revisions included additional

In August, the cabinet passed the amended K-REACH. It is expected to come into force on July 1, 2018. The amended K-REACH does not impact the existing deadline to register Priority Existing Chemicals (PEC) imported above 1 ton per year by June 2018.

activities to better align the two agencies responsible for the management of new and existing chemical registrations. The proposed revisions in September included the establishment of an obligatory registration window of six months after the first importation of 100 kilograms or more. In addition, raw materials used in the manufacture of pesticides, medicines, cosmetics, food additives, and other applications would be required to register. The comment periods for both sets of revisions are closed. In November, the draft revisions were approved and sent to the national legislature for review. The TCSCA was renamed to the Toxic and Chemical Substances of Concern Control Act. The expectation is that the changes mentioned above in addition to many others could be issued in final in 2018.

Thailand

The Department of Industrial Works is expected to publish the draft chemical inventory by the end of 2017. The inventory is expected to contain data collected up until the end of 2016.

Vietnam

The Ministry of Industry and Trade continues to develop a chemical inventory. Indications are that a database will be available sometime in **2019**. In October, Decree No 113/2017/ND-CP Detailed Regulations and Guidance on the Implementation of a Number of Articles of the Law on Chemicals was published. The decree regulates the manufacture and importation of chemicals, and includes requirements for GHS classifications, storage, reporting, production, and trading of substances. The decree does allow protection of CBI, except for information relating to protection of health and the environment.

South Korea

The South Korean Ministry of Environment (MoE) and National Institute of Environment Research (NIER) continued this year to develop and revise K-REACH, a very consequential regulatory program for the chemical industry. The MoE proposed changes at the end of 2016 that would drastically alter the current legislation and require all substances imported over 1 ton per year to pre-register and eventually register substances regardless of inventory status. In addition, MoE and NIER continued to address changes to ease registration burdens, including the use of alternative approaches to animal testing for substance registration data requirements, registration approaches that would allow improved data sharing for submitters that have obtained consent for submissions in other regions, and support for small and medium enterprises. In August, the cabinet passed the amended K-REACH. It is expected to come into force on **July 1, 2018**. Expect in 2018 that the MoE will issue a timetable for registration deadlines. The amended K-REACH does not impact the existing deadline to register Priority Existing Chemicals (PEC) imported above 1 ton per year by **June 2018**.

Australia to Begin New Regulatory Scheme for Introducing Industrial Chemicals in 2018

The Australian government began work in 2015 to reform the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). NICNAS regulates new and existing chemicals, including chemicals used in solvents, adhesives, plastics, paints, inks, fuels, cosmetics, and household cleaning. As reported in our November 9, 2015, memorandum, "Australia Implementing Reforms to the National Industrial Chemicals Notification and Assessment Scheme (NICNAS)," the aim of the reforms is to rebalance post- and pre-market requirements to reflect the

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risk of a new chemical, to streamline the current risk assessment process for new and existing chemicals, to better use international assessment materials, and to create a more appropriate compliance tool, among other things. After releasing five consultation papers and holding a number of public stakeholder meetings, the Australian government submitted to Parliament a package of six bills that will establish a new national regulatory scheme for industrial chemicals. The Industrial Chemicals Bill 2017 describes the Australian Industrial Chemicals Introduction Scheme (AICIS), a legislative framework for a reformed, risk-based regulatory scheme for Australia to continue to regulate the introduction of industrial chemicals. The House of Representatives passed the legislation without amendment on October 17, 2017, and the legislation has now been introduced in the Senate. The government anticipated that the legislation would pass quickly and that the new scheme would commence on **July 1, 2018**, with full implementation by **July 2019**. The bill did not pass within the expected timeframe, however, and the government is now considering how to manage issues posed by the delay. Once the package has been passed, NICNAS will publish further information, including on the early changes and the draft rules to be made under the new legislation on its website, and provide it directly to affected stakeholders and via monthly stakeholder updates. NICNAS expects to release drafts of the delegated legislation and associated guidelines for public consultation in **late January 2018**, with comments due in **March 2018**.

D. MEXICO AND CENTRAL AND SOUTH AMERICA: CHEMICAL SUBSTANCE MANAGEMENT

Industrial Chemicals

2017 was a watershed year in many countries in Central and South America and Mexico with respect to the development and implementation of a wide variety of chemical substance regulations. 2018 is expected to continue this trend, and the pace of these developments is expected to increase. Among the trends being seen across the region are the recognition of various environmental aspects such as biodiversity, clean water, and the protection of natural ' resources expanding from legal obligations to those that have a moral human rights component. In addition, countries have either passed GHS legislation, or are in the process of doing so, with full implementation expected in 2018. International conventions are being joined as well, expanding the list of chemical substances that are regulated in the region. Finally, product stewardship initiatives, in a variety of forms, are gaining substantial traction across numerous countries. 2018 should see a marked rise in the passage, enactment, and enforcement of legislation designed to reduce waste and related aspects.

Following are key areas of legislative efforts throughout the region.

Chemical Substances

As noted in our July 5, 2016, publication, "A Critical Review of Brazil's Just-Published Industrial Chemicals Regulation *(Regulação de Substâncias Químicas Industriais)*," Brazil's *Ministério do Meio Ambiente* (Ministry of Environment, or MME) published its draft legislation titled *Regulação de Substâncias Químicas Industriais*) (Industrial Chemicals Regulation, or *Regulação*) on June 30, 2016. The publication began an almost-eighteen-month attempt, a process which still continues, to enact the legislation into national law. Throughout much of 2017, due in part to changes in the National government that delayed discussion and related actions on the draft and the solicitation of comments on the document, the draft remained virtually untouched.

On June 28, 2017, Acta published "Brazil Inches Forward On Industrial Chemicals Regulation Implementation" that discussed the major themes of the over 800 comments received on the draft document, comments that the MME must evaluate. Thus far, only the issues considered out of scope in the comments and the issues related to the regulation of the law have been reviewed.

Once the remaining comments are addressed, the draft law must be amended as appropriate, debated, and presented for a vote before the Brazilian Congress. Brazil will also hold its general election in **October 2018**, which may delay consideration. Once approved, according to the draft, the MMA must promulgate the *Regulação* within 180 days of its publication in the *Diário Oficial* (Official Gazette), and a three year phase-in period will then ensue.

Given all of the complexities, implementation of the *Regulação* in 2018 is likely aspirational at best.

Multiple countries across Mexico and Central and South America have either implemented GHS or are well on their way to doing so. In an August 23, 2017 Chemical Watch article, Acta presciently forecasted an uptick in GHS implementation in the region that was borne out by Costa Rica's implementation of the System in late 2017.

Colombia is rapidly emerging as one of the most progressive, from a chemical substance management perspective, countries in the region. Colombia worked toward the development of a chemical "risk management" bill in the *Senado de la República de Colombia* (Senate of the Republic of Colombia). At the close of 2017, the *Senado* passed draft legislation that would identify chemical substances that may pose risks to human health and would develop a system to monitor and control their use. The bill now advances to the Colombian *Cámara de Representantes* (House of Representatives), for its consideration. The legislation is of particular importance because, if signed into law, the *Ministerio de Salud y de Protección Social* (Ministry of Health and Social Protection) could conceivably use the law to enforce a wide variety of restrictions on the substances, such as banning their import, sale, or specific applications, or conditions of use.

With respect to moral obligations toward environmental aspects, Argentina has proposed legislation in its Senate (*Honorable Senado de la Nación Argentina*) that would make access to potable water and sanitation be "essential human rights." Bill No. 3952/17, "Pereyra: Project Of Law That Declares The Right To Drinking Water And Sanitation As An Essential Human Right" (*Pereyra: Proyecto De Ley Que Declara El Derecho Al Agua Potable Y Saneamiento Como Un Derecho Humano Esencial*) would additionally provide for a means of governmental assistance to citizens to ensure their access. Because the bill defines these aspects as fundamental rights, it must additionally be considered by the Committee on Rights and Guarantees, as well as the Committee on Environment and Sustainable Development. If the bill is passed into national law, it would likely upend the traditional way of regulating these aspects, and potentially open up new legal areas to challenge violators.

GHS

Multiple countries across the region have either implemented GHS or are well on their way to doing so. In 2017, Argentina joined Brazil as the second country in the region to implement the system for hazardous chemical products (System). In an August 23, 2017 *Chemical Watch* article, Acta presciently forecasted an uptick in GHS implementation in the region that was borne out by Costa Rica's implementation of the System in late 2017. Now that three countries in the region, including two of the major economic powerhouses, have implemented GHS, thereby doing the "heavy lifting," this trend is expected to continue into 2018 as more countries realize the value and feasibility of employing the System.

Also in 2017, the Costa Rican *Ministerio de Trabajo* (Ministry of Labor) issued its final regulation that required use of the Sixth Edition of GHS, Technical Regulation RTCR 481:2015 , effective as of December 30, 2017. Products that are currently sold in Costa Rica have a five year transition period to come into compliance with the GHS regulation, particularly with respect to labeling. As with many other regions of the globe who have adopted GHS, there are several customizations to the Sixth Edition that are specific to Colombia. Of particular note is that the technical regulation expands the types of products that are subject to GHS requirements, such as consumer goods, which were previously outside the scope. In addition, the label must identify that the product has been registered with the Ministry of Health.

Also with respect to GHS implementation, the Colombian *Ministerio de Trabajo* (Ministry of Labor) has issued draft legislation that would also require conformance to the Sixth Edition of GHS. The scope of the draft is extremely broad, applying to all natural and legal persons, both public and private, who carry out a wide range of activities relating to pure chemical substances, dilute solutions, and mixtures. Further, the draft would reach into spaces where GHS has not typically been applied, such as for pesticides and consumer products (again similar to Costa Rica). The draft also requires a mandatory update of labels and SDSs every three years, even if there is no new or significant information. Colombia also provides a transition period of 36 months after final publication for substances, and 48 months after final publication for mixtures.

Product Stewardship Initiatives

Waste reduction, especially via packaging "take back" -- a concept where manufacturers are required by law either to set up local collection points where consumers can return product packaging or to accept these items directly for reuse or recycling -- is a rapidly developing area of law in the region. In addition, countries continue to pass "end of life" legislation requiring manufacturers to accept the return of a wide range of items at the end of their useful life, and to propose legislation which requires the overall reduction in waste generated.

On September 26, 2017, the Brazilian Ministry of the Environment published the "Reverse Logistics System and Management Plans of Solid Waste" (*Sistemas de Logística Reversa e os Planos de Gerenciamento de Resíduos Sólidos*) in the *Diário Oficial*. The resolution, which went into effect with that publication, requires manufacturers to accept products such as electrical products, electrical components, batteries, and other items. The implicit purpose of the regulation is to reduce the overall volume of solid waste generated.

In a similar vein, the lower house of the Brazilian National Congress (*Câmara dos Deputados*) is proposing to amend the country's National Solid Waste Policy (Law No. 12.305/2010) to require those entities who manufacture and/or import electric or electronic products into the country to follow a wide-range of directives regarding packaging and labeling requirements, specific recycling goals, design-for-environment (also known as DfE) criteria, collection, and reuse, among other goals.

As an indication as to how widespread the concept of legislating waste reduction and "take back" is within Central and South America, it is also being proposed at the local and State levels. Indeed, the Brazilian State of São Paulo, through its Legislative Assembly (*Assembléia Legislativa do Estado de São Paulo*), has taken this concept to a relative "extreme." It has a bill that would require all commercial establishments that sell packaged goods to develop collection areas throughout the city for all types of their used packaging. The establishments would then ensure the material is collected and sent for recycling, using their own resources to fund the establishment of the collection areas.

With respect to international conventions being joined -- and thereby expanding the list of chemical substances that are regulated in the region -- perhaps the most prominent convention for 2018 is the United Nation's (UN) Minamata Convention on Mercury (Convention), "a global treaty to protect human health and the environment from the adverse effects of mercury," by managing the anthropogenic releases of the element throughout its lifecycle. The close of 2017 saw several Central and South American countries becoming signatories. Argentina ratified the Convention on September 25, 2017, Brazil on August 8, 2017, Costa Rica on January 19, 2017, El Salvador on June 20, 2017, and Honduras on March 22, 2017. Of particular note is the requirement to phase down and phase out the use of mercury in a number of processes and products, which is very likely to restrict the import and use of this element in the countries at issue. As with GHS, it is likely that other countries in the region will see the value in participating in these types of international agreements, both in 2018 and beyond.

Also at the end of 2017, the UN Climate Change (UNCC) conference "COP 23/ CMP 13/ CMA 1-2" convened in Bonn, Germany. While this conference primarily aimed to advance the ambitions of the Paris Agreement, many South American countries have used the UNCC as a basis for developing their own climate change regulations nationally. Argentina currently has a bill in its Chamber of Deputies, Chile is expected to present a bill in its National Congress at some point in 2018, Colombia has had legislation under consideration in its National Congress since August of 2017, and Peru has a bill pending (PL 1314/2016). These legislative efforts are expected to reach fruition in 2018 and those countries will potentially join Brazil, which enacted a climate change law (Law 12.187) in 2009, and Mexico (General Law on Climate Change), which promulgated its law in 2012, in enacting climate change regulations.

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The thirty-fourth session of the UN Sub-Committee of Experts on GHS took place in December of 2017. It is expected that the eighth revised edition will contain a new annex specifically to address dust explosion hazards.

E. GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS FORECAST

The UN GHS

The UN GHS Purple book was developed over a period of ten years from a 1992 mandate from the UN Conference on Environment and Development. The UN-developed system establishes harmonized criteria for classification associated communications tools and recommendations for labeling and SDSs. It was adopted in 2002 and published in 2003. The UN GHS is not a regulation, it is a model system used for hazard determination. The UN GHS is not a regulation, it is a model system used for hazard determination. The model is based on the concept of "building blocks" and is organized in parts, chapters, and annexes. Each chapter in Parts 2, 3, and 4 contain various hazard classes. Each hazard class contains categories that further define and/or refine the hazard class. The system includes several communication tools in addition to hazard classification. These tools include hazard statements, pictograms, and precautionary statements. The system is updated and revised every two years.

In 2017, the seventh revised edition (Rev 7) was published. Rev 7 contains changes to categories for Chapter 2.2 -- Flammable Gases. Category 1 is expanded to include sub-categories. Annex 3 contains further rationalization of precautionary phrases. Annex 4 contains new guidance to address transport in bulk in Section 14 of the SDS. Finally, Annex 7 includes new examples for fold out labels for small packages.

The thirty-fourth session of the UN Sub-Committee of Experts on GHS took place in December of 2017. The agenda included discussions on Chapter 2.1, dust explosion hazards, use of non-animal testing methods for classification of health hazards, aspiration hazard, nanomaterials, and labeling of small packaging. It is expected that the eighth revised edition will contain a new annex specifically to address dust explosion hazards. This long anticipated annex will help to align the combustible dust labeling requirements that are part of the U.S. and Canadian regulations.

Canada GHS Implementation

On February 11, 2015, Health Canada published the Hazardous Products Regulation (HPR). The HPR revised and updated the Workplace Hazardous Materials Information System (WHMIS). WHMIS 2015 significantly altered the previous system (WHMIS 1988) and is a modified criteria-based approach following Rev 5 of the UN model. Health Canada worked with the U.S. to align, as much as possible, each countries' GHS implementation. WHMIS 2015 does not include environmental hazard classes or certain health hazard categories (*e.g.*, acute toxicity category 5, skin corrosion/irritation, category 3, and aspiration hazard category 2). WHMIS 2015 does include the additional hazards in OSHA Hazard Communication Standard (HCS 2012). In addition, WHMIS 2015 retains elements from WHMIS 1988 that are unique to Health Canada's program (*i.e.*, Biohazardous Infectious Materials). The WHMIS 2015 transition period was scheduled to end on June 1, 2017, but was extended from May 31, 2017, to **June 1, 2018**, to address additional complexities within the updated system. Health Canada continues to provide guidance for addressing the implementation.

Mexico GHS Implementation

Mexico's Ministry of Labor and Social Welfare published The Harmonized System for the Identification and

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In 2017, the EC issued its long-awaited draft regulation to amend the REACH annexes to address nanoforms of substances. The EC's October 9, 2017, draft regulation is intended to clarify the registration requirements and downstream user obligations for substances with nanoforms.

Communications of Hazards and Risks from Hazardous Chemicals in the Workplace (NOM-018-STPS-2015) on October 9, 2015. NOM-018-STPS-2015 is a complete UN GHS Rev 5 implementation. No additional hazards were added and all hazard classes and categories are included. The transition period for mandatory compliance ends **October 9, 2018**. Currently, Mexico will accept a HCS 2012-compliant SDS and label as long as it is provided in Spanish. The labeling and SDS requirements are not aligned between the U.S. and Mexico and, it is important to note, HCS 2012 is based on UN GHS Rev 3 whereas Mexico adopted Rev 5 of the UN model. There are elements that are not included in the U.S. or Canadian approach that are required for Mexico.

Costa Rica GHS Implementation

The Costa Rican *Ministerio de Trabajo* (Ministry of Labor) issued its final regulation that requires use of the Sixth Edition of GHS, Technical Regulation RTCR 481:2015, which entered into force on December 30, 2017. Products currently sold in Costa Rica have a five-year transition period to come into compliance with the GHS regulation, particularly with respect to labeling. There are several customizations to the Sixth Edition that are specific to Colombia. Of particular note is that the technical regulation expands the types of products that are subject to GHS requirements, such as consumer goods, which were previously outside the scope. In addition, the label must state that the product has been registered with the Ministry of Health when such registration is required.

F. INTERNATIONAL NANOMATERIALS FORECAST

Canada Continues Process to Evaluate Existing Nanomaterials

Canada is taking a stepwise approach to evaluate nanoscale forms of substances listed on the Domestic Substances List (DSL) to determine if they pose potential risks to the environment or human health. The first step is to establish a list of existing nanomaterials in Canada, and in 2015, Canada began a mandatory information-gathering survey under Section 71 of the Canadian Environmental Protection Act, 1999 (CEPA). According to Canada, it identified 53 substances as being manufactured and/or imported at the nanoscale in Canada. Canada has not publicly identified the 53 substances. The second step is the prioritization of existing nanomaterials for action. In 2016, Canada published a proposed prioritization approach for nanoscale forms of substances on the DSL. Canada expects to publish the results of prioritization in **spring 2018**. The third step will be action on substances identified for further work. Canada intends the initiative to ensure that the potential human health and ecological risks of nanomaterials will be adequately identified and addressed. It will also serve to identify data needs and provide input to the mechanism for prioritizing research activities in the area of nanomaterials.

Nano Developments in the EU

In 2017, the EC issued its long-awaited draft regulation to amend the REACH annexes to address nanoforms of substances. The EC's October 9, 2017, draft regulation is intended to clarify the registration requirements and downstream user obligations for substances with nanoforms. It would impose additional testing and reporting requirements. As drafted, the requirements would not apply until **January 1, 2020**. More information is available in our October 11, 2017, blog item, "EC Proposes to Amend REACH Annexes to Address Nanomaterials." The EC has posted the comments online. In all, 36 comments were submitted. The comments received fall into the following categories: business associations; public authorities; NGOs; company/business organizations; environmental organizations; academic/research institutions; and other. According to the EC's notification to WTO, the proposed date of adoption is **March 31, 2018**.

As reported in our September 20, 2017, blog item, "EC Begins Consultation on Revising Recommendation on Definition of Nanomaterial," the EC held a public consultation on the revision of the 2011 EC recommendation on the definition of nanomaterial. The Roadmap identifies problems that the initiative intends to address, including the need to clarify some terms in use and how the criteria are applied, as well as issues of scope. According to the Roadmap, the intention now is to prepare a revised recommendation to be adopted by the EC, accompanied by a Staff Working Document that will report on the review undertaken and the rationale for the modifications. The draft changes to the recommendation will be subject to a 12-week online public consultation.

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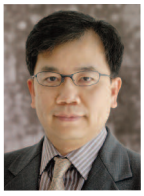

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