



BERGESON & CAMPBELL, P.C.

Predictions and Outlook for
U.S. Federal and International
Chemical Regulatory Policy
2017



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FORECAST 2017

Predictions and Outlook for EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) 2017

2016 was full of surprises, two of which will drive much of the agenda for OCSPP during 2017. First, Congress significantly amended the Toxic Substances Control Act (TSCA). The changes are intended to reform the program to address the widely recognized deficiencies in the law, especially regarding existing chemicals, chemical testing, Confidential Business Information (CBI) claims, and preemption of state actions. Although many thought the chances of successful TSCA legislation were slim, the second surprise event was even more unexpected -- the election of Donald Trump as President.

What the implementation of new TSCA will look like, along with the general environmental program and emphasis of the new Trump Administration, is very unclear this early in the New Year (the new President will not arrive until January 20). What is more predictable is that the operating environment of OCSPP will change significantly, with uncertain impacts on both the U.S. Environmental Protection Agency's (EPA) pesticide and toxic chemical regulatory programs. EPA institutionally may never be the same, and while much of the political debate is likely to concern the climate change issue, all EPA programs will likely see new or different emphasis on how, when, or why to impose any appropriate regulatory controls.

Along with a new Republican President, both the House and Senate remained with Republican majorities. EPA will now be under great pressure to align with the party platform and long-standing calls from Congressional critics to be more flexible and business-oriented in implementing its programs. Current and past policies and interpretations will be under intense scrutiny and likely to change, while Democrats in Congress and environmental advocates who supported Obama Administration policies will resist significant changes. Specific predictions about policies and decisions are purely speculative at this point, but it likely means EPA will be operating in a volatile and often hostile environment (induced by both friends and foes alike).

What is also more predictable is that Non-government Organization (NGO) environmental advocates will need to change their approach in attempting to move their agenda and policy goals away from a now unfriendly Administration. What has happened in the past during a change in Administration like this is that there is a renewed emphasis on litigation and petition challenges to avoid the executive and legislative branches. Advocacy through the judicial branch of government may be slow and uneven, but it will be seen as more likely to be a successful forum.

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OPERATING ENVIRONMENT

Few things can get the attention of federal civil servants more than a promise to eliminate their Agency by the President-elect. Mr. Trump at various times promised to eliminate EPA and change the fundamental direction of the Agency on climate change and, generally, to reduce the regulatory burdens of environmental regulations on businesses. While a new President is unlikely to eliminate EPA, simply stating threats of personnel cuts, a reduced budget, workforce “reform” of changed work conditions or retirement benefits -- initiatives which are also part of the Trump platform -- will have an immediate impact on the EPA operating environment. If budget and personnel cuts are proposed, there will not only be an immediate effect on EPA morale but more specifically could lead to a large increase of staff retirements to avoid proposed changes or even simply to not want to work under the direction of the new leadership.

NEW LEADERSHIP

Mr. Trump has nominated E. Scott Pruitt to be EPA’s next Administrator, who is currently the Attorney General of Oklahoma. Pruitt is on record as opposing the Obama Administration initiatives on climate change and water pollution. For OCSPP, it is not clear what direction any general “stop EPA” rhetoric might mean for the regulation of pesticides and chemicals. Regulated industries will continue to need a credible and competent EPA staff to review and approve applications for both pesticides and new chemicals. The surprise election of Mr. Trump also makes unclear what type of background the new Administration will seek in a new OCSPP Assistant Administrator. Even with an emphasis on being more business friendly, programs will still have to process applications and complete risk assessments.

The regulated community is reported to be informing the incoming leadership on the need for a functional, effective program. Administration-wide initiatives, however, might swamp any pleas for an exception to government-wide budget cuts, personnel policies such

as a hiring freeze, or changes to pay or retirement policies. This could be especially impactful on the toxics program, since with the new TSCA amendments there are many new rules and related initiatives that are due to be completed in 2017 and beyond, and the program is to “ramp up” its hiring and contracting budgets to help implement the new law.

CONGRESSIONAL RELATIONS

Similarly, a new Republican President will complement the Republican Congress, a Congress that has been hostile to many EPA initiatives developed under the Obama Administration. This will be more evident in the pesticide program, especially where the pesticide industry has objected to policies regarding changes to the 10x safety factor and the use of epidemiological data in risk assessments, certain changes to the Worker Protection Standard (WPS), and policies to protect pollinators. In recent years, the registrant community has raised concerns about the “science integrity” of EPA decisions, and has lodged complaints about policies that industry believes have been issued or developed without sufficient transparency or requisite notice and comment rulemaking authority. These subjects generally are certain to be the focus of Congressional oversight and policy lobbying of any new EPA leadership team.

Some of these issues will be discussed in more detail below. Taken together, EPA may face a more engaged and involved Congress since the Committee leadership of the authorizing and Congressional Oversight Committees will now assume they will get more deference to their initiatives. For the toxics program, implementation of new TSCA will be the top priority of both Congress and any constituencies.

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EPA's determinations concerning chlorpyrifos have been controversial, and some of these reach far beyond chlorpyrifos in their potential impact.

OFFICE OF PESTICIDE PROGRAMS (OPP) PREDICTIONS

CHLORPYRIFOS

The pesticide program will face an early test of its emphasis and direction, as the program is under a court order to make a final decision about the future of the organophosphate insecticide chlorpyrifos by **March 31, 2017**, just a few months into the new Trump Administration. 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 that would order EPA to act on that petition. After making an initial determination that EPA had a rational basis for delay, the Ninth Circuit ultimately agreed to grant the writ on August 10, 2015. The Court has stated unequivocally that it will not grant any further extension of the **March 31, 2017**, deadline 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 relies in

support of its current proposal to revoke the food use tolerances for the pesticide. 80 Fed. Reg. 69079 (Nov. 6, 2015). This action is described in more detail on [Bergeson & Campbell, P.C.'s \(B&C[®]\) Pesticide Law and Policy Blog under key word chlorpyrifos.](#)

EPA's determinations concerning chlorpyrifos have been controversial, and some of these reach far beyond chlorpyrifos in their potential impact. For example, EPA has 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 has utilized epidemiological data for chlorpyrifos to select risk endpoints for chlorpyrifos and for all organophosphate pesticides. This FQPA safety factor determination has been the subject of much concern and comment, with industry pointing out numerous scientific, legal, and procedural flaws in the scientific predicate for the determination and the procedure by which it was adopted.

The Trump Administration is not expected to support the chlorpyrifos tolerance revocations as proposed by the Obama Administration. It is unclear at this time, however, how the Trump Administration might change course on the controversial EPA determinations underlying the proposed revocations. The record developed will be the subject of continued legal challenge. Coming so early in the new President's term will also mean that new OCSPP leadership will not yet be in place. This will increase the difficulty of making a final decision before the court deadline, particularly any decision to reverse course.

Adding to the challenge, the court has expressed significant frustration with the pace of EPA's decision-making; any effort to ask for more time in light of the Administration change would almost certainly meet a chilly reception.

ENDANGERED SPECIES

Another key issue that will beset the program continually in 2017 is implementation of the Endangered Species Act (ESA), an issue that has dogged the program for years. The problems of "how much is enough" and how to conduct an assessment have long been concerns. As the issue of endangered species protection has expanded to include legal challenges to new active ingredient registrations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the issues have become even more heated.

In recent years, NGO groups filed challenges in both federal district court and federal appellate court to EPA's registration of new pesticide products with new active ingredients. These challenges are of concern for many reasons, but perhaps most importantly because they were filed to object to a new pesticide active ingredient. New active ingredients typically have been seen as less likely to have an adverse environmental impact, and less likely to jeopardize endangered or threatened species, than the incumbent products they replace. In some cases, EPA has relied on this reasoning explicitly as the rationale for its claim of ESA compliance. If the pending challenges result in long delays or require an administrative record that creates evidentiary impediments to the new pesticide approval

process, this could become the "train wreck" some have predicted for years. If so, that could force Congress to create a more workable process for how ESA and FIFRA should interact.

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

Some of the legal challenges to new active ingredients should be decided soon. If these decisions impose new evidentiary burdens, it is possible that ESA litigation could threaten to undermine the entire current pesticide regulatory system. EPA and the Services (the U.S. Fish and Wildlife Service and the National Marine Fisheries Service) have made recent efforts to improve and more closely coordinate ESA review procedures, and have issued the first biological evaluations under the "improved" assessment approach. This new approach may still be unsustainable and impractical and involve too great a commitment of time and resources, however. With a Republican President and Congress, there may be renewed interest in making legislative changes to create a more practical approach to evaluating impacts on endangered species as part of the pesticide registration process.



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In May 2015, the White House released its “National Strategy to Promote the Health of Honey Bees and Other Pollinators” that led EPA also in May 2015 to publish a “Proposal to Mitigate Exposure to Bees from Acutely Toxic Pesticide Products.”

POLLINATORS

Under the Obama Administration, OPP actions regarding the pollinator issue were discharged through directives and announcements that EPA has made in recent years, starting in 2013 when EPA required significant label changes to lessen any impact on pollinators from insecticide use. Then, in June 2014, the White House issued a “[Presidential Memorandum -- Creating a Federal Strategy to Promote the Health of Honey Bees and Other Pollinators](#).” The strategy is directed to all federal agencies and designed to “expand Federal efforts and take new steps to reverse pollinator losses and help restore populations to healthy levels.”

In May 2015, the White House released its “[National Strategy to Promote the Health of Honey Bees and Other Pollinators](#)” that led EPA also in May 2015 to publish a “[Proposal to Mitigate Exposure to Bees from Acutely Toxic Pesticide Products](#).” The proposal was designed to target pesticide use by those who use contracted pollinator services, and included a list of 76 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 is still in the process of reviewing comments. EPA was expected to respond to these comments sometime in early 2016, but EPA has yet to release a revised proposal. EPA has stated in various communications that it still expects to respond to the comments submitted with a revised proposal before the end of the Obama Administration. The Trump Administration is expected to review, revise, and/or repeal what will likely be known as the “Obama strategy.”

WPS AND CERTIFICATION AND TRAINING

In March 2014, EPA issued a proposed rule to update the WPS that generated a large volume of public comments about various elements of its planned revisions. EPA issued the final rule in September 2015 and it was subsequently published in the *Federal Register* on November 2, 2015. More information is available in B&C’s blog post “[EPA Announces Revisions to Its Worker Protection Standard](#).” Although changes to the WPS have been discussed for years, in some cases since the first regulations were issued over 20 years ago, elements of these changes that EPA proposed, as well as preamble language discussing those changes, were controversial. In its most simple form, critics of increasing the stringency of the current regulations ask why significant changes were needed after 20 years of greater protection offered by the existing regulatory requirements. Others, not surprisingly, cite reported (and unreported) incidents as proof for the need nonetheless to improve the extent and effectiveness of the current regulations. EPA’s final rule represented EPA’s attempt to balance these views, although many in the industry and in the states believe EPA’s rule was a great over-reach. One of the most controversial elements in the final rule allows for third party representatives of farmworkers to ask growers to examine records. Issues about the need for and possible intrusiveness of the requirement have remained controversial, and now with a Republican Administration and Congress it is expected that EPA will revise the rule, or else face a legislative directive to eliminate or change the third-party inspection provisions.

[The final rule is scheduled to be published on January 4, 2017](#), with an effective date of **March 6, 2017**. Please see our memorandum on this final rule

on the [B&C regulatory developments page](#). The proposed rule generated significant controversy and concern from grower groups, registrants, and states who would implement the new requirements. Although EPA has discussed updating these requirements for many years with stakeholder groups, consensus on the types of changes and improvements needed and feasible remains the subject of considerable contention.

REAUTHORIZATION OF THE PESTICIDE REGISTRATION IMPROVEMENT ACT

The Pesticide Registration Improvement Act of 2003 (PRIA) established a fee schedule for pesticide registration- and amendment-related applications, and specified decision time periods in which EPA must make a regulatory decision. PRIA has been reauthorized twice, and currently is scheduled to expire at the end of this 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 are working with Congress to pass what will be “PRIA 4” by the end of the fiscal year.

With each reauthorization of PRIA, there have been increases in the number of fee categories based on the ongoing experience with this pay-for-service program, and increases in the fees themselves (typically five percent). There also have been provisions addressing the federal annual maintenance fees, and money set aside to fund specific projects. Similar changes in PRIA 4 reasonably may be expected.

While PRIA reauthorization is unlikely to be high on Congress’ or the new Administration’s list of priorities, we understand that the House and Senate Agriculture and Appropriates Committees recognize that all stakeholders are counting on Congress to pass this legislation, to allow the pesticide program to continue to function and secure certainty for the regulated community.

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OFFICE OF POLLUTION PREVENTION AND TOXICS (OPPT) PREDICTIONS

One of the big questions posed in our 2016 Predictions memo was resoundingly answered when Congress passed, by large bipartisan majorities, and President Obama signed the Frank R. Lautenberg Chemical Safety for the 21st Century Act on June 22, 2016. The past six months have been a whirlwind of activity for EPA and, given our expectation that the Trump Administration will work to implement new TSCA, 2017 promises to be busier still. The early implementation of such a complex, nuanced statute, presents difficult challenges under the best of circumstances and, as we have noted in our many memoranda and blog posts, there are numerous rules and actions that are [required to be completed by June 2017](#). These and other likely actions for 2017 are summarized and briefly commented upon below. Add to this the challenges presented by a new Administration of a different party and things truly could get interesting.

At the same time, as strong believers in our small “r” republican model of governance, we recognize that

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there can be benefits when legislation is passed under one party but initially administered by the other party. This was the case when old TSCA was enacted under President Ford and first implemented under a different Administration (President Carter) and party. Now, given the surprising electoral outcome, the same type of opportunity for realizing bipartisan progress in dealing with chemical issues is presented in the case of new TSCA.

As faithful readers will know, we have raised concerns with some of the new TSCA interpretations and approaches that have or seem to be coming forward from EPA over the past six months. A new Administration will, at a minimum, allow for a reconsideration of early policies and initial interpretations of new TSCA. We can hope for a carefully considered, measured, and balanced approach to come forward under the new Administration, an approach that can properly address old TSCA's deficiencies and impediments, and serve to realize the potential that we saw when the bipartisan TSCA Amendments were first unveiled by Congress in the Spring of 2016.

ACTIONS EXPECTED TO BE TAKEN/COMPLETED IN 2017

The items listed below are, with one exception, measures required under new TSCA. Since promulgation will occur during the new Administration, the final rules are likely to differ, to a greater or lesser extent, from the proposals. It is also possible that rules could be re-proposed or the comment period re-opened to allow the Trump Administration to get its ideas into play; this, however, could cause such actions to miss their statutory deadlines.

April 2017

- Publication of inventory of mercury supply, use, and trade in the United States (Section 8(b)(10)(B)).

June 2017

- Promulgate procedural rules establishing prioritization and risk evaluations processes and criteria. The proposed rules are expected to issue in **early 2017**. (Section 6(b)(1)(A)).
- Promulgate Inventory reset reporting rule. The proposal is expected to issue in **early 2017**. (Section 8(b)(4)).
- Establish the Science Advisory Committee on Chemicals (Section 26(o)). EPA published a notice requesting comment on a set of 29 candidates for the SACC by **January 9, 2017**, a date that ensures that the final selection will fall to the Trump Administration. See our [TSCA blog post for more information](#).
- Issue guidance document for interested persons to use in preparing draft risk evaluations (Section 26(l)(5)).
- Issue scope documents for the ten risk evaluation chemicals announced by EPA on November 29, 2016. 81 Fed. Reg. 91927 (Dec. 19, 2016). This step is required to be completed within six months of the announcement (Section 6(b)(4)(D)). The chemicals include 1,4-dioxane, 1-bromopropane, asbestos, carbon tetrachloride, cyclic aliphatic bromide cluster, methylene chloride, N-methylpyrrolidone (NMP),



Since promulgation will occur during the new Administration, the final rules are likely to differ, to a greater or lesser extent, from the proposals.

Pigment Violet 29, tetrachloroethylene (perchloroethylene), and trichloroethylene (TCE).

- Complete EPA consultation with the Small Business Administration, review adequacy of the definition of a small manufacturer, and determine, after notice and comment, whether revision of the standard is necessary (Section 8(a)(3)(C)).

We also expect EPA to propose and promulgate, perhaps by **June 2017**, the fees rule at Section 26(b). Although this timeline is not required by new TSCA, EPA has expressed its desire to issue a final rule within one year of new TSCA enactment and we think timely completion of this action in 2017 is likely.

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ACTIONS THAT MAY COME FORWARD IN EARLY 2017

These items are discretionary and if proposed by the Obama Administration, could be allowed to continue or may be withdrawn by the Trump Administration. In addition, the Congressional Review Act (CRA) allows Congress to review, via an expedited legislative process, promulgated federal regulations within 60 legislative days of their issuance and, by passage of a joint resolution, to overrule a regulation. If signed by the President, the action invalidates the regulation. The best known example of the use of this procedure is invalidation

of the ergonomics rule issued by the Occupational Health and Safety Administration in 2001.

- Promulgation of a Significant New Use Rule (SNUR) on long-chain perfluoroalkyl carboxylate and sulfonate chemical substances. The rule could be promulgated in part in 2017, although it appears that under new TSCA, EPA would need to re-propose the rule if it wishes to make imported articles containing such chemicals subject to the SNUR. The issue concerns the requirement at Section 5(a)(5) that EPA make an affirmative finding that the reasonable potential for exposure to the chemical from the article(s) justifies notification.
- Proposed SNUR on use of TCE in non-aerosol spray degreasers. We expect this rule to be proposed sometime in 2017.
- Two proposed Section 6(a) TCE rules. The first rule concerns use as a spotting agent in dry cleaning and in consumer aerosol spray degreasers. The second rule, which is identified as an economically significant rule, concerns use as a vapor degreasing agent. The first rule, [published in the Federal Register on December 16, 2016](#), has some likelihood of proceeding while we believe there is significant potential for the second TCE rule to be withdrawn or be re-proposed.

In addition, we note EPA's decision to conduct a risk evaluation focused on other uses of TCE and observe that this decision could have ripple effects. While the savings provision at Section 26(p)(2) enables EPA to rely on final risk assessments in taking the Section 6 actions discussed in the preceding paragraph, we observe that TCE's risk assessment is quite controversial, particularly regarding the interpretation of certain key adverse effects, and that issues encountered in preparing the new risk evaluation seem likely to "bleed through" and affect at least the vapor degreasing action.



The SNUR procedural rule could be withdrawn or might eventually be promulgated as a narrow rule that avoids some of the issues encountered in the proposal.

- Proposed Section 6(a) rule on use of methylene chloride and NMP in paint strippers. We believe this rule, if issued in final as written is likely to be affected by the new Administration. We believe that EPA's decision to undertake new risk evaluations for these chemicals increases the likelihood that the rule will be withdrawn or at least be re-proposed once the new risk evaluation has been issued in final (**2019** timeframe).
- Promulgation of Section 8(a) reporting and recordkeeping rule on existing chemical nanoscale materials. We believe that if EPA promulgates a narrow rule that, for example, does not require advance notification of manufacture of such nanoscale materials, such a rule could enter into force under the new Administration, depending on the specifics of what is required. If, on the other hand, the rule includes the proposed notification requirement (see our April 6, 2015, memorandum, "[EPA Proposes Reporting and Recordkeeping Requirements for Nanoscale Materials](#)"), we believe it could become the target of consideration under the CRA or an announcement by the Trump Administration that EPA will not enforce this requirement, pending amendment or withdrawal of the action. While the Section 8(a) rule does not meet the \$100 million economic impact criterion to be considered a "major rule" under the CRA, we believe it could be identified by Congress as presenting "significant adverse effects" on competition and innovation and, if so, would be subject to CRA review.

EXPECTED FATE OF OTHER RULES AND ACTIONS

Several other proposed rules seem unlikely to get much traction in the Trump Administration. These include the 2012 proposed SNUR and test rule on certain polybrominated diphenyl ethers (PBDE), the 2014 proposed SNUR on nonylphenol and nonylphenol ethoxylates (NP/NPE), and the 2016 proposed amendments to the SNUR procedural rule to update the hazard communication requirements and other aspects. The PBDEs rules are unlikely to proceed due to the issues presented by the proposals and the requirement under new TSCA for EPA to justify notification for PBDEs in imported articles. The proposed NP/NPEs SNUR also presented a number of issues as discussed in our memo "[EPA Proposes SNUR for Nonylphenols and Nonylphenol Ethoxylates](#)," and we believe it is unlikely that the proposed regulation will be pursued. The SNUR procedural rule could be withdrawn or might eventually be promulgated as a narrow rule that avoids some of the issues encountered in the proposal.

One of the open actions concerns follow-up by EPA on an expected proposed rule for Section 8(a) and 8(d) reporting on oil and gas production (*i.e.*, fracking) chemicals that was occasioned by a Section 21 petition filed in 2011. We do not expect to see this rule pursued in the new Administration.

Our 2016 Predictions memo also noted and discussed several enforcement actions, as well as "clarifications" premised on chemical identity issues as a way to challenge the presence of existing chemicals listed on the

Inventory. Examples discussed included attempts to clarify EPA's existing guidance on statutory mixtures and enforcement actions targeting "fractions" such as chlorinated paraffins (*see* our memorandum "[EPA's Enforcement Actions Target 'Fractions'](#)" and our 2012 article "[Are TSCA Section 8\(b\)\(2\) Statutory Mixture Categories Subject to Reporting Under the Chemical Data Reporting Rule?](#)"); the NP/NPE SNUR discussed also presented a number of nomenclature issues. New TSCA Section 8(b) provisions concerning the legal status of Class 2 nomenclatures and the treatment of the individual members of statutory mixture categories as being "included" on the Inventory have clarified some of these issues, although exactly how things get sorted out is yet to be discerned. At any event, we think that the new Administration is not likely to continue the enforcement approach that previously caused us such heartburn.

NEW CHEMICALS

Notifying new chemical substances and new uses of chemical substances subject to significant new use rules will be challenging in the New Year. New TSCA Section 5 requires EPA OPPT to review and make a determination for all Premanufacture Notification (PMN) new chemicals, and the process OPPT is developing has unduly slowed the review process and raised many questions. EPA wisely convened a stakeholder meeting December 14, 2016, and stakeholders expressed broad discontent with the lack of transparency as well as frustration with the lengthy delays they are experiencing. That said, little was learned on how OPPT intends to address the problems that OPPT's implementation of new TSCA has created, and OPPT remains consumed by new chemical notifications -- the review of which will continue to bring uncertain results and invite costly delays. This is an area which should get the close attention of the incoming Administration, given the need for the ongoing innovation potential provided by new chemical introductions in ensuring the continued competitiveness of the domestic chemical sector.

OTHER NEW TSCA ACTIONS THAT COULD OCCUR IN 2017

We expect EPA to use its new TSCA Section 4 order authority in the coming year. The limitations in data sets available for most TSCA chemicals are relatively significant and we believe that EPA, perhaps starting with chemicals in the 2014 update to the Work Plan, will take steps to require additional testing. While this could include both hazard and exposure information, we think that 2017 actions will most likely focus on the former and possibly on targeted exposure information. We are hopeful that EPA, at the same time, will begin in 2017 to sort out its thinking regarding its approach to tiered exposure testing, a new element under new TSCA.

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NANOMATERIALS FORECAST

The big news for 2017 will be whether and, if so, in what form the TSCA Section 8(a) reporting rule for existing nanoscale materials will be issued in final. The rule cleared the Office of Management and Budget (OMB) review on December 28, 2016, strongly suggesting it will be issued in final before the end of the Obama Administration. Please see our memorandum "[EPA Proposes Reporting and Recordkeeping Requirements for Nanoscale Materials](#)" and our nano blog item "[EPA Submits Final TSCA Rule on Nanomaterials to OMB for Review](#)" for the background information on this reporting rule. We expect OPPT will continue its review of new chemical notifications for nanoscale chemicals and materials in much the same way as before new TSCA was signed into law. There are a number of new TSCA provisions that could be applied in ways that could challenge nano innovators, all of which are discussed in detail in a forthcoming

Bloomberg BNA article scheduled to be published in early January.

In other nanoscale material developments, EPA's OPP May 2015 announcement that it conditionally registered a second nanosilver pesticide product, NSPW-L3oSS, previously known as Nanosilva, was immediately the subject of a federal lawsuit in the U.S. Court of Appeals for the Ninth Circuit. On November 17, 2016, the court heard oral argument in the suit consolidating the petitions filed by NRDC, the Center for Food Safety, and the International Center for Technology Assessment. During oral argument, the court questioned whether EPA could provide data proving that the conditional registration would not increase the amount of silver in the environment and that the registration was in the public interest. The court sought information on the cost to industry to replace silver with a nanosilver product such as NSPW-L3oSS. The court commented that EPA appears to lack data on whether manufacturers would substitute existing uses of silver with NSPW-L3oSS, or if they would create new uses of silver. How the court will rule in 2017 is, of course, still unclear.

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BIOTECH FORECAST

The September 16, 2016, release of the proposed update to the 1986 [Coordinated Framework for the Regulation of Biotechnology](#) (Coordinated Framework) marked a major achievement of the Obama Administration. It provides a comprehensive summary of the roles and responsibilities of EPA, the U.S. Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA) with respect to the

regulation of biotechnology products. The companion document that was released on the same day, the [National Strategy for Modernizing the Regulatory System for Biotechnology Products](#) (National Strategy), sets forth a long-term strategy intended to ensure that the federal regulatory system is equipped to assess efficiently the risks, if any, of the future products of biotechnology. The reports reflect the efforts of many in response to the July 2015 directive from the White House Office of Science and Technology Policy (OSTP), OMB, the U.S. Trade Representative, and the Council on Environmental Quality directing EPA, FDA, and USDA to update the Coordinated Framework for the Regulation of Biotechnology. Public comment on the proposed update was accepted until November 1, 2016.

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B&C PROFESSIONALS are well-known as being at the forefront of legal, regulatory, and science policy deliberation and advocacy in the rapidly-developing field of [industrial biotechnology](#). The Woodrow Wilson International Center for Scholars asked us last year to collaborate in writing and releasing "[The DNA of the U.S. Regulatory System: Are We Getting It Right for Synthetic Biology?](#)" which looks at the current regulatory oversight of synthetic biology in the United States through case studies of synthetic organisms, synthetic chemicals, biopesticides, biomining products, and genetically modified plants, which are regulated by EPA, FDA, and USDA.

The logo for BRAG (Bioscience Resource Action Group) features the word "BRAG" in a bold, white, sans-serif font. To the right of the text is a small green leaf icon with a white outline.

THE BRAG® BIOBASED NEWS AND POLICY REPORT is a terrific source of information on regulatory, legal, policy, and business developments in renewable chemicals, biofuels, and other biobased products. The weekly newsletter is published by B&C for the [Biobased and Renewable Products Advocacy Group \(BRAG®\)](#), managed by [B&C® Consortia Management](#). Subscribe to the BRAG report online at <http://www.braginfo.org/subscribe>, or visit the BRAG blog at blog.braginfo.org.

The National Strategy sets forth a vision for ensuring that the federal regulatory system is equipped to assess efficiently the risks, if any, associated with future products of biotechnology while supporting innovation, protecting health and the environment, maintaining public confidence in the regulatory process, increasing transparency and predictability, and reducing unnecessary costs and burdens. In the National Strategy, the federal agencies demonstrate their sustained commitment to ensuring the safety of future biotechnology products, increasing public confidence in the regulatory system, and preventing unnecessary barriers to future innovation and competitiveness. For more information, [see our memorandum on our website under the key phrase Biobased Products, Biotechnology](#).

The update to the Coordinated Framework represents a useful first step in a process that urgently needs to continue into the next Administration. The work to date nicely lays out a blueprint for action that stakeholders can only hope will be a priority for the next Administration. The White House seeks continued engagement from key stakeholders, including public and private organizations such as companies, universities and research institutes, trade associations, scientific societies, foundations, consumer organizations, non-profits, and individual citizens.

What remains to be seen is how the Trump Administration addresses both documents, or even if it will. We would expect a natural delay occasioned by the transition to the new Administration. Whether incoming

leadership in the White House OSTP and in the federal agencies charged with regulating products of biotechnology pick up where the Obama Administration left off is entirely unclear. We note that the update to the Coordinated Framework was largely driven by the need for clarity by the regulated community. Continued activity to implement the update may resonate with the incoming Administration.

ADMINISTRATION, MANAGEMENT, AND INFRASTRUCTURE FOR INDUSTRY GROUPS

B&C Consortia Management, L.L.C. (BCCM) provides cost effective administrative and support services to consortia. These include capabilities from infrastructure and staff needed for newly organized groups to advocacy and product stewardship programs, communications outreach, research programs, and other activities for industry groups of all kinds.

Learn more about BCCM's services and the consortia we manage at www.bc-cm.com.

The logo for B&C Consortia Management (BCCM) features the letters "BCCM" in a large, bold, serif font. A small "&" symbol is positioned between the "B" and the "C".



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

SIGNIFICANT GLOBAL CHEMICAL MANAGEMENT PREDICTIONS

EUROPEAN UNION (EU)

REACH **2018** is the big news for Europe. The Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) law, which took affect a decade ago on June 1, 2007 (Regulation (EC) No. 1907/2006 of 18 December 2006), is poised in **2018** to enter its final phase-in registration deadline on **May 31, 2018**, and much work will be underway in the new year in preparation for the deadline. Entities that pre-registered substances that they manufacture or import from outside the EU above one tonne but not more than 100 tonnes per year and have not already registered them must do so by the **May 2018** deadline. Late pre-registration may be an option until **May 31, 2017**.

ENDOCRINE DISRUPTORS

The coming year will see ongoing activity focused on how endocrine disruptors are to be identified, a point of some contention among scientists, regulators, and other stakeholders. Endocrine disruptors already factor into the European Commission's (EC) long-range plans and are reflected in existing legislation. The backdrop is the EC's 1999 Strategy on Endocrine Disruptors, with its overall aim of minimizing exposures to these substances. Protective measures (including bans) already are available and deployed through the authorization process for chemical substances in REACH and also when endocrine disruptors are incorporated into plant protection products, biocides, or cosmetics. To date, however, despite the tools

in place to regulate them, formal criteria for identifying substances with endocrine disrupting properties have proven complex and challenging to articulate and have not been specified in the EU or by any other country.

On June 15, 2016 -- already well past a 2013 EU legal deadline for action -- the EC issued two draft acts establishing scientific criteria for identifying endocrine disruptors in the context of the existing Plant Protection Products Regulation (2009) and Biocidal Products Regulation (2012), respectively. The long draft development pathway involved consultation with EU regulators, in-house and independent scientific groups, authorities in other jurisdictions, and stakeholders. Steps toward adoption will go forward under prescribed procedures, including involvement in each case by the European Parliament and the Council. For purposes of the Plant Protection Regulation, Member States will vote on the draft legal text; for the Biocidal Products Regulation, a group of experts from Member States will discuss the draft before the Commission adopts it.

The draft measures build on the World Health Organization's (WHO) definition of an endocrine disruptor, which is generally embraced by the European scientific community, as "an exogenous substance or mixture that alters the function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub) populations." According to the Communication issued by the EC in June 2016, together with the drafts, the proposed identifying criteria embody what the EC terms a "novelty" in the definition, "the introduction of a second element." While the toxicity of a chemical

substance typically is defined in terms of an “end-point” -- the presence or absence of an adverse effect -- the WHO definition adds a “mode of action” element, which accounts for the way in which the chemical substance has an impact. The identification criteria in the June 2016 drafts are meant to capture this endocrine mode of action as a second factor for consideration, separate from adverse effect. Indeed, for purposes of the identification criteria, EC proposes to define an endocrine mode of action as “the inherent ability of a substance to interact or interfere with one or more components of an endocrine system,” *without* necessarily leading to an adverse effect and without necessarily posing an (eco) toxicological hazard in itself. The potentially challenging interplay between the WHO definition, which looks at-risk, and the EC’s hazard-centric, precautionary approach to chemical regulation is a source of considerable criticism.

The EC highlighted a number of additional issues in connection with the proposed identification criteria. These include the following: how “adverse effect” is to be defined, especially in terms of assessing potential adversity at a molecular or cellular level; the concept of “biological plausibility,” *i.e.*, reasonable, rather than conclusive, evidence to determine causality between mode of action and adverse effect; why the EC believes that establishing categories of endocrine disruptors is not useful; why the “threshold” concept is neither necessary nor appropriate when defining the identification criteria for an endocrine disruptor; and why “potency” is unnecessary for identifying an endocrine disruptor and becomes relevant only after a substance has been identified as such.

ACTA'S SCIENTISTS, REGULATORY SPECIALISTS, AND POLICY EXPERTS have extensive and specialized expertise with the EDSP. We assist manufacturers, importers, processors, and users of chemicals identified for endocrine screening to respond efficiently to test orders and to minimize business impacts. Visit our website to explore the services we offer regarding [endocrine disruptors](#).

The existence of EU legislation already in place means that the 2016 draft identification criteria are not an initial step in a regulatory process still to unfold. Under both pieces of existing legislation, active substances that are endocrine disruptors are not to be approved for use, except in the event of negligible exposure from a plant protection product or negligible risk from a biocidal product. Many substances deemed to be endocrine disruptors already have been prohibited in the EU. For products now in use, each approval is in effect for only a limited time period, and renewals involve a reassessment of the product. The renewal process will be one visible place where the rubber will meet the road where the new criteria are concerned.

The EC envisions that the new identification criteria will enhance product assessments, including those for renewed approvals, and anticipates that where possible they will be applied immediately. In addition, the EC has asked the European Food Safety Authority and the European Chemicals Agency to begin revisiting individual approved substances where there are indications that those substances could be endocrine disruptors under the new identification criteria.



The potentially challenging interplay between the WHO definition, which looks at-risk, and the EC’s hazard-centric, precautionary approach to chemical regulation is a source of considerable criticism.

Once the criteria take effect, the regulatory agencies then would be prepared to apply the criteria and take appropriate action more quickly. Given, as noted above, that the Plant Protection Products Regulation and the Biocidal Products Regulation each contain limited derogation provisions, the EC anticipates also that evolving scientific and technical knowledge may enable the grounds for derogation to be updated accordingly. Specifically, the EC has concluded that the basis for possible derogations for plant protection products should be updated to align with the “negligible risk” test for biocidal products. According to the EC, in the context of a hazard-based ban of endocrine disruptors, a revised test for possible derogation of plant protection products could be consistent with overall health and environmental objectives that guide decision-makers’ actions.

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While the identification criteria will apply as a matter of legal obligation only under the plant protection products and biocidal products regulations, the EC expects that the criteria will become a resource for EU bodies that administer other regulatory measures for which endocrine disruptors are a matter of concern. Thus, the criteria may have an eventual impact on the regulation of chemical substances under REACH, as well as on assessing the safety of cosmetic ingredients under the Cosmetics Directive and on the implementation of water quality criteria. Also, the regulatory impacts could extend beyond the EU. Substances deemed to be potential endocrine disruptor candidates are found among the “high priority” substances flagged for EPA to evaluate under a timetable under new TSCA. As such, what is determined to be an endocrine disruptor in the EU could well effect the regulatory treatment of the substance involved in the

United States. Separately, as a business matter, products currently permissible for export from other jurisdictions into the EU could lose their welcome if they were determined to contain endocrine disruptors during a future review under the proposed identification criteria if the latter remain in their current form, and a derogation for the use at issue has not been made.

A group of scientists has raised the concern that the identification criteria will allow some endocrine disruptors to elude identification due to uncertainty or inconsistency of application. Shortly after the draft criteria were announced, an international group of fifteen scientists shared their views in a letter to the EU’s Health and Food Safety Directorate, characterizing the criteria as presenting a “confused set of processes for identifying, evaluating and integrating scientific evidence.” Also, according to these scientists, the criteria place an “under-defined, potentially unprecedentedly high, burden of proof” on identifying problem compounds as having endocrine-disrupting properties, with the result that the identification process will be conducted inconsistently and/or will under-classify candidate substances as endocrine disruptors. Other criticisms have surfaced as well, and despite the EU’s assertion that development of the criteria were based on consultations with a range of experts and stakeholders, their adoption and legal effect, assuming it proceeds as proposed, will neither silence the critics nor simplify the identification of endocrine disruptors going forward.

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BREXIT

On June 23, 2016, more than 30 million people voted in a referendum to decide whether the United Kingdom (UK) should “Leave” or “Remain” in the EU. The referendum turnout was 71.8 percent and the Leave Campaign won by 52 percent to 48 percent, making “Brexit” an important and imminent probability with potentially significant implications for a range of stakeholders, including the chemicals industry.

The following statement from current UK Prime Minister (PM) Theresa May, who replaced former PM David Cameron following his resignation the day after the referendum vote, symbolizes her Government’s strong commitment to Brexit and upholding the result of the referendum:

Let’s state one thing loud and clear: We are not leaving the [EU] only to give up control of immigration all over again and we are not leaving only to return to the jurisdiction of the [European Court of Justice (ECJ)]. That’s not going to happen.

Read our memorandum, “[Brexit -- An Overview of Transformative Developments and Their Potential Impact on European Chemical Laws](#),” on the Acta website, www.actagroup.com.

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CHINA

Chemical regulations continue to evolve in China. For example, the new Environment Protection Law (China EPL) went into effect on January 1, 2015, the Revised Environmental Impact Assessment Law, the Catalogue of Hazardous Chemicals and its Guidance and the new Restriction of Hazardous Substances (RoHS2) took effect in 2016, the Measures for Environmental Administration Registration of Hazardous Chemicals (Ministry of Environmental Protection (MEP) Order No. 22) was abolished in early 2016, the Guidance for New Chemical Substance Notification and Registration (NCSN) is under revision, a List of Priority Existing Chemicals for Management is under development, and a new Toxic and Hazardous Chemical Substances Control Law is under discussion in the National People's Congress. The state of play in China is quite fluid.

THE REVISED GUIDANCE FOR NCSN

The MEP notified a draft revision of the Guidance for NCSN to the World Trade Organization (WTO) Technical Barriers to Trade Committee on March 8, 2016, with proposed date of entry into force of November 1, 2016. The draft revision of [Guidance for NCSN](#) is available online, in Chinese. Based on comments received during the public comment period, further revision is needed and the effective date has been postponed. According to a MEP spokesperson, China could publish the final version of its revised Guidance for NCSN in **early 2017**. The key changes in the draft revision include:

- Elimination of Scientific Research Record (SRR) notification for a substance used solely for scientific research with annual volume ≤ 10 kg;
- Announcement of registration information will include the hazard classification and use of the chemical substances in the category of "Priority Hazardous New Chemicals for Environmental Management";

- Registration is required for substances in a product that will be released under normal or reasonably foreseeable conditions of use of the product and the release of the substance from the product will present a risk to human health or the environment;
- Acute dermal and inhalation toxicity tests will be required based on the physical-chemical properties and potential exposure route of the notified substance for the Level 1 Regular Notification;
- Only adsorption and excretion information is required for the Level 2 Regular Notification and the full toxicokinetics test will be required only if the notified substance has health hazard classification for the Level 3 Regular Notification;
- Criteria for conducting carcinogenicity test are added for the Level 3 Regular Notification. Genotoxicity results and the use and potential exposure scenarios of the notified substance will be considered to justify the carcinogenicity test; and
- Long-term toxicity test to terrestrial organism is added for the Level 4 Regular Notification.

List of Priority Existing Chemicals for Management

The [Action Plan for Water Pollution Prevention](#) published by the State Council on April 16, 2015, authorizes the MEP to lead the initiative of strictly controlling environmental risks and assessment of the environmental and health risks of existing chemicals. A List of Priority Existing Chemicals for Management should be published before the **end of 2017**. The production and use of high-risk chemicals should be strictly controlled and gradually phased out. The Solid Waste and Chemicals Management Center (SCC) of the MEP is currently drafting the technical guidelines for environmental and health risks of existing chemicals and the first batch of Priority Existing Chemicals for Management.



China's Ministry of Agriculture (MOA) published 64 new or revised industry pesticide standards in its announcement No. 2405 on May 23, 2016.

This initiative may extend the current registration requirements for new chemicals to existing chemicals, similar to EU REACH.

Reduction of Production and Uses of Volatile Organic Compounds

China's Ministry of Industry and Information Technology (MIIT) issued an [Action Plan for Reduction of Volatile Organic Compounds \(VOC\) in Key Industries](#) on July 8, 2016. According to the Action Plan, the total industrial emission of VOCs should be reduced by more than 3.3 million tons and the uses of benzene, toluene, xylene, dimethyl formamide, and other solvents and solvent aids should be reduced by more than 20 percent by **2018** than in 2015. Low-VOC/non-VOC green products should consist of more than 70 percent, 60 percent, 70 percent, 85 percent, and 40 percent of pesticide formulations, paintings, inks, adhesives, and tire products, respectively.

The new Toxic and Hazardous Chemical Substances Control Law is under discussion in the National People's Congress. It would significantly change the existing regulatory system of chemicals in China. No details have been made available and no timeline has been set yet for its adoption, however.

ACTA'S EXTENSIVE INVOLVEMENT IN NCSN, and the manufacture, import, and export of chemicals in China, makes us especially well-suited to address client issues that arise under MEP Order No. 7, Decree No. 591, and SAWS Order No. 53. Visit our website for a full description of our services regarding [chemical regulation in China](#); contact lbergeson@actagroup.com if you would like to discuss your needs in the region.

PESTICIDE REGULATION

Chinese Regulation on Pesticide Administration (RPA) has been under revision since 2010. It has been more than five years since the revised draft RPA was released for public comment on July 20, 2011. The revision of the Data Requirements on Pesticide Registration is also under discussion as a part of the new pesticide regulation. The release of the final version of the revised RPA has been postponed several times over the past three years and it is expected that the final version could be published in 2017. The key change in the revised draft RPA is that the temporary registration has been removed. Additionally, many new/revised industry pesticide standards took effect in 2016 and many more are being drafted or under revision. The draft Guidance on Health Risk Assessment of Pesticides was released for public comments on November 23, 2016.

THE NEW AND REVISED STANDARDS FOR PESTICIDES

China's Ministry of Agriculture (MOA) published 64 new or revised industry pesticide standards in its [announcement No. 2405](#) on May 23, 2016. This includes test methods of efficacy and physical-chemical properties, pest resistance assessment, field trial practices, guidelines for full component analysis, validation of analytical method for quality test, quality standard of novel biopesticide, and pesticide environmental risk assessment. These new/revised industry standards took effect on October 1, 2016. Additionally, 11 new/revised industry standards related to pesticides were published in MOA [announcement No. 2466](#) on November 1, 2016, which include the Guideline for the Testing Pesticide Stability at Ambient Temperature

(NY/T 1427-2016), the Guidance on the Establishment of Product Specification for Pesticide Registration (NY/T 2989-2016), and the Methods for Qualitative and Quantitative Determination of Prohibited and Restricted Pesticides (NY/T 2990-2016). These new and revised industrial standards will take effect on **April 1, 2017**. The key change in the NY/T 1427-2016 is the removal of the requirement for testing three consecutive batches of samples.

DRAFT GUIDANCE AND TEST GUIDELINES FOR RISK ASSESSMENT OF PESTICIDES

The Institute for the Control of Agrochemicals, Ministry of Agriculture (ICAMA) released the draft Guidance on Health Risk Assessment of Pesticide Operators and Public Health Pesticides for public comments on November 15, 2016. ICAMA also published for comment draft test guidelines for pesticide registration including the Stability Testing of Pesticide Residue in Stored Commodities, the Processing Test on Pesticide Residue in Commodities, and the Testing of Pesticide Metabolism in Crops on November 28, 2016. Additionally, six draft guidance/guidelines for environmental risk assessment of pesticides were released on September 23, 2016, for public comments, which include Risk Assessment Test Guidelines for Microbial Pesticides; Guidelines for Outdoor Simulated Aquatic Ecosystem (Mesocosm); Test of Pesticides for the Terrestrial Field Dissipation/Degradation Test; the Development and Validation of Analytical Methods for Pesticides in Soil and Water; draft Guidance for Evaluating and Calculating Degradation Kinetics in Environmental Media for pesticide registration; and on

Environmental Risk Assessment for Pesticide Registration-Soil Organisms. Two computation models, China-PRAESS and China-PEARL, are proposed for environmental risk assessment of aquatic ecosystems and soil organisms. These guidance and guidelines are expected to be implemented in the pesticide registration and re-evaluations in 2017, add technical complexity to new pesticide registrations, and accelerate the phase-out of existing high risk pesticides.

THE ADDITIONAL NATIONAL STANDARDS FOR MAXIMUM RESIDUE LIMITS OF PESTICIDES IN FOOD

China's MOA and National Health and Family Planning Commission (NHFPC) released the National Food Safety Standards -- Maximum Residue Limits (MRL) for 132 pesticides in food for public comments on November 2, 2016, which is an addition to the existing pesticide MRLs in food (GB 2763-2014). The final version of the standards is expected to be published in 2017.

Efficacy Data Requirements for Pesticide Registration

The efficacy data requirements for pesticide registration are under discussion in ICAMA. The discussions are focused on the comparative analysis with existing registered pesticides, management of pesticide resistance, efficacy tests by subsequent applicant, justification of combination pesticides, and avoiding unnecessary resource wastes for the registrations of identical products by multiple applicants. The laboratory bioactivity test, crop safety test, and two-year



These guidance and guidelines are expected to be implemented in the pesticide registration and re-evaluations in 2017, add technical complexity to new pesticide registrations, and accelerate the phase-out of existing high risk pesticides.



The Chinese Food Safety Law mandates regulation of food-related products, requires authorities to establish national standards, and requires stakeholders throughout the food supply chain to be responsible for food safety.

field trial are proposed for new pesticide products, including products with new ingredients, against new crop/target, or on new site. One-year field trial at multiple sites should be sufficient for registration of equivalent products with new usage. In addition, the classification code that categorizes the pesticides' mechanism of action should be labeled on all commercial pesticides to promote the alternate use of other pesticides. For pesticides already registered, the subsequent applicant should submit the pesticide resistance survey report.

FOOD REGULATION

The Food Safety Law (China FSL), effective on October 1, 2015, mandates regulation of food-related products, *e.g.*, food packaging, disinfectants, detergents, among other uses, requires the Chinese authorities to establish national food safety standards for food-related products, and requires stakeholders throughout the food supply chain to be responsible for the food safety. The Administrative Measures for Registration of Foods for Special Medical Purpose, the Administrative Measures for Registration of Infant and Young Children Milk Powder Formula Recipes, the Administrative Measures for Registration and Filing of Health Foods, and the Positive List for Commodities Traded through Cross-Border E-Commerce took effect in 2016. The revised draft Implementing Regulation of the China FSL is under final review. The draft Guidance on Building Food Safety Traceability for Food Producers and Operators is released for public comments on November 23, 2016.

DRAFT IMPLEMENTING REGULATION OF THE FOOD SAFETY LAW (FSL)

The revised draft Implementing Regulation of the China FSL was submitted to the State Council by China's Food and Drug Administration (CFDA) for preparation in final, and could be implemented by **early 2017**. The State Council released the revised draft for public comments in its [announcement](#) on October 19, 2016. It has been more than ten months since the [Draft Implementing Regulation](#) was released on December 9, 2015. The revised draft details requirements for raw material management, sale, advertisement and associated registration requirements for food products bearing functional efficacy claims. It also sets forth the regulation and administration of infant formula, health foods, and foods for special medical purposes and requires food manufacturers, distributors, and caterers to establish a food safety traceability system.

THE REVISED STANDARDS FOR FOOD-CONTACT MATERIALS

As of September 2016, there were 590 food additive related standards in effect in China, including a general standard for the labeling of food additive (GB 29924-2013), a general standard for uses of food additives (GB 2760-2014), and 588 quality specification standards. The Chinese Food Safety National Standard Review Committee will review and revise them as needed.

China NHFPC finalized 53 revised National Food Safety Standards for food-contact materials in its [announcement No. 15/2016](#) on November 18, 2016, which include a list of additives (GB 9685), a general safety standard (GB 4806.1), nine material standards (GB 4806.3 – GB 4806.11), and 39 testing standards for individual substances (GB 31604.11 – GB 31604.49). These new National Standards, which are effective on **April 19, 2017** (except GB 4806.1-2016 and GB 9685-2016, which are effect on **October 19, 2017**), serve as a major step forward in the evolution of its food-contact regulatory scheme:

- GB 4806.1-2016 Standard on general safety requirements for food-contact materials and articles;
- GB 4806.3-2016 Enamel articles;
- GB 4806.4-2016 Ceramic articles;
- GB 4806.5-2016 Glass articles;
- GB 4806.6-2016 Standard on food-contact use plastic resins;
- GB 4806.7-2016 Standard on food-contact use plastic materials and products;
- GB 4806.8-2016 Standard on food-contact use paper, paperboard, and paper products;
- GB 4806.9-2016 Standard on food-contact use metal materials and products;
- GB 4806.10-2016 Standard on food-contact use coatings and coating layers;
- GB 4806.11-2016 Standard on food-contact use rubber materials and products;
- GB 4789.15-2016 Microbiological tests; mold and yeast counts;

- GB 5009.156-2016 Standard on pre-treatment methods for migration test of food-contact materials and articles;
- GB 9685-2016 Standard on the uses of additives in food containers and contact materials;
- GB 14934-2016 Disinfection of tableware; and
- GB 31604.11 - GB 31604.49-2016 Testing methods for determination of substances and their migration from food-contact materials and articles.

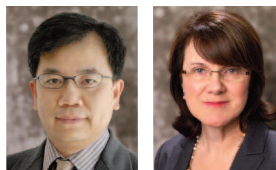
There are 1,294 approved additives listed in GB 9685-2016. The General Safety Standard (GB 4806.1-2016) defines "non-intentionally added substances" and "functional barrier," requires producers of food packaging materials to perform safety assessments to ensure their safety, and permits the use of unlisted substances used behind a barrier -- provided that the substance migrates at less than 0.01 mg/kg, and is not a carcinogen, mutagen, reproductive toxin (CMR), or nano substance. The material standards (GB 4806.3 - GB 4806.11-2016) provide testing requirements for the materials and lists of individual substances permitted for use in the materials. The testing standards (GB 31604.11 - GB 31604.49-2016) generally track international testing methods established by ISO, the Organization for Economic Cooperation and Development (OECD), ASTM, and other recognized standard setting organizations.

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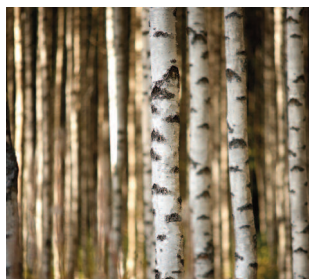
AUSTRALIA

As for other parts of the world, stakeholders should expect to see significant developments in other countries. In Australia in 2017, the Department of Health (DOH) will continue its work on [reforms to the National Industrial Chemicals Notification and Assessment Scheme \(NICNAS\)](#). NICNAS regulates new and existing industrial chemicals, including chemicals used in solvents, adhesives, plastics, paints, inks, fuels, cosmetics, and household cleaning. The NICNAS reforms should reduce the regulatory burden by streamlining the assessment process and refocusing assessment effort on higher risk industrial chemicals, while also maintaining safety standards. To date, DOH has released four [consultation papers](#) for comment and held several public workshops. To implement the reforms, DOH will need to amend the Industrial Chemicals (Notification and Assessment) Act 1989 (ICNA Act) and associated regulations, make changes to the NICNAS information technology (IT) system, and update guidance materials, application forms, standard operating procedures, and other supporting materials. In 2017, subject to agreement by government, DOH will draft and introduce a bill to Parliament that would amend the ICNA Act. Once the bill is passed, DOH will hold a public consultation on draft regulations implementing the reforms. DOH will also develop and consult on all supporting materials. Subject to government agreement and Parliamentary consideration, the NICNAS reforms will be fully implemented by **September 1, 2018**. Some changes to the existing framework could take effect sooner, however.

In a separate initiative, the Department of the Environment and Energy is [consulting](#) on the [Draft National Standard for the Environmental Risk Management of Industrial Chemicals](#) and a supporting [Draft Explanatory Document](#). The National Standard will apply to all industrial chemicals, and is intended to fill a gap identified for the environmental management of industrial chemicals. Therefore, the Draft National Standard does not explicitly manage risks to human health. The National Standard includes three general categories for industrial chemicals -- high, intermediate, and low concern -- that span seven Environment Schedules: Environment Schedules 1 and 2 -- Low Concern; Environment Schedule 3 to 5 -- Intermediate Concern; and Environment Schedules 6 and 7 -- High Concern. The government will convene workshops held in **February 2017** to provide stakeholders with an opportunity to discuss the Draft National Standard and Draft Explanatory Report. Feedback received during these workshops will be used to help inform further development of the Standard. Comments on the Draft National Standard are due **March 3, 2017**.

CANADA

North of the border in Canada in 2017, Environment and Climate Change Canada (ECCC) will continue its work under the Chemicals Management Plan (CMP). On May 30, 2016, ECCC published the [list of substances](#) in the next phase of the CMP (2016-**2020**) and two-year rolling risk assessment publication plan. The [Risk Assessment Toolbox](#) delineates the various types



The Australian National Standard will apply to all industrial chemicals, and is intended to fill a gap identified for the environmental management of industrial chemicals.



The next phase of the Canadian Chemicals Management Plan will include a Domestic Substances List Inventory update to collect information on the commercial status and exposures for a subset of CMP substances.

of approaches that can be considered for assessing a substance or group. The [two-year rolling risk management activities and consultations schedule](#) provides a high level summary of risk management activities, including opportunities for stakeholder consultations and engagement, and is a source of information on risk management activities that are scheduled to occur during the next two years for substances managed under the CMP. Canada will periodically publish more detailed notifications as it updates the work plan to specify the substances for which additional information is needed, the associated timelines, and details on how to provide this information.

The next phase of the CMP will include a Domestic Substances List (DSL) Inventory update to collect information on the commercial status and exposures for a subset of CMP substances. The [list of substances](#) proposed to be included consists of approximately 1,500 substances. The forthcoming Section 71 notice will seek to obtain updated information on the commercial status of listed substances that are remaining priorities and to support any subsequent risk assessment and risk management activities, if applicable. Canada will continue its work to address the remaining 1,550 priority substances out of the original 4,300 substances identified as priorities during the DSL categorization exercise.

As reported in our August 4, 2016, blog item, "[Canada Begins Consultation on Proposed Prioritization Approach for Nanoscale Forms of DSL Substances](#)," Canada released a proposed prioritization approach for nanoscale materials. Under the CMP, Canada plans to establish a list of existing nanomaterials in

Canada, prioritize the existing nanomaterials for action, and take action on nanomaterials identified for further work. Comments on the proposed prioritization approach were due in September 2016. Other planned activities include continuing to re-evaluate food additives, food contaminants, and food packaging material chemicals for which CMP assessments identify potential risks; enhancing food research, monitoring, and surveillance activities; continuing to conduct special reviews and to re-evaluate older pesticides as required under the Pest Control Products Act; and continuing to monitor pesticide health and environmental incidents, taking action as needed.

TAIWAN

In 2017, Taiwan will create a Bureau for Toxics and Chemical Substances. The Bureau's duties are expected to include forming, implementing, and enforcing policies on toxic and chemical substance regulation, chemical accidents and emergency response, and environmental agent regulation. The Bureau will also promote the integration and use of chemical information; technological advances related to toxic chemical regulation; and international cooperation on chemical substance regulation. The Bureau will coordinate the almost dozen government agencies involved in enforcing a number of laws regulating toxic and chemical substances. According to Premier Lin Chuan, a priority for the Bureau will be to improve foods safety by enforcing point of origin controls. Taiwan Environmental Protection Administration (Taiwan EPA) Minister Lee Ying-yuan stated that Taiwan has had recent food scandals due to companies using illegal additives in food processing. The

Bureau, according to Lee, would ensure better management and control of food safety standards. The legislature approved the bill on December 9, 2016, in its third reading.

THAILAND

Thailand is expected to publish a final Thailand Existing Chemicals Inventory in 2017. The first stage nomination deadline for chemicals not listed on the preliminary inventory of existing chemicals ([Preliminary of Thailand Existing Chemicals Inventory](#)) was December 31, 2016. The Department of Industrial Works (DIW) expects to publish a final Thailand Existing Chemicals Inventory in 2017. Chemicals not listed on the final Existing Chemicals Inventory would be considered new chemicals. More information is available, in Thai, on [DIW's website](#).

VIETNAM

In late 2016, Vietnam's Ministry of Industry and Trade (MOIT) published a [draft National Chemicals Inventory](#) for public comment. The draft Inventory included over 3,000 chemicals. After MOIT issues a final National Chemicals Inventory, chemicals not listed will be considered new. Companies will be required to register new chemicals before beginning import to or manufacture in Vietnam. More consultations on the draft Inventory may be held in 2017.

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CHEMICAL SUBSTANCE MANAGEMENT IN MEXICO, CENTRAL, AND SOUTH AMERICA

INDUSTRIAL CHEMICALS

2016 has been a watershed year in Mexico, Central America, and South America, with a variety of chemical substance, pesticide, product stewardship, and worker and workplace safety regulations developing and being implemented at an unprecedented rate. 2017 appears very likely to see these trends continuing, with the "major players" such as Brazil, Argentina, and Mexico implementing key pieces of legislation, while countries such as Chile, Colombia, Costa Rica, and Ecuador are expected to take considerable steps toward a variety of management programs.

Following are key areas of legislative efforts throughout the region.

With respect to chemical substance legislation, the Brazilian Ministry of Environment (*Ministério do Meio Ambiente* (MMA)) has put forth draft legislation titled [Industrial Chemicals Regulation](#) (*Regulação de Substâncias Químicas Industriais*, or *Regulação*). The *Regulação* is expected to be presented for a vote before the Brazilian Congress during the **first quarter of 2017**, but the Brazilian Chemical Industry Association (*Associação Brasileira da Indústria Química* (ABIQUIM)) has indicated that this timeline is fluid, and that due to other legislative priorities, as well as the dynamic political situation in the country, it is conceivable that the presentation could be delayed even further. According to the draft, the MMA must promulgate the *Regulação* within 180 days of its publication in the Official Gazette (*Diário Oficial*), and a three year phase-in period will then ensue. This timeline presumes the relevant portions of the *Regulação* do not change.

Colombia has suggested chemical substance management to be a priority in the coming year. In late 2016,

two bills were put forth in the Chamber of Deputies (*Cámara de Diputados*). The first bill would regulate hazardous substances manufactured or imported in the country, while the second bill specifically addresses two substances, lead (restricting its use in certain products) and asbestos (banning the substance entirely). Since their introduction, however, the bills have been consolidated into a single legislative piece regarding hazardous substance management. The new bill retains many key elements of the two individual proposals, but with some modifications. Three provisions in the combined legislation are particularly important to firms either operating in the country or considering establishing business there: first, the authority (to-be-defined) would develop the “National Hazardous Substance Monitoring System” (*Sistema Nacional de Vigilancia de Sustancias Peligrosas* (SNSN)). Second, the legislation would establish a “take-back” requirement specific to batteries which contain lead or other hazardous substances. Finally, the proposed bill would impose reporting and labeling requirements on producers and sellers of products containing to-be-defined hazardous substances.

Dovetailing with this proposed legislation, the Colombian Ministry of Environment (*Ministerio de Medio Ambiente*) has issued its **2020** [Policy of Risk Management Associated with the Use of Chemical Substances](#) (*Política De Gestión Del Riesgo Asociado Al Uso De Sustancias Químicas*). One of the manifest goals of the Policy is to fill in gaps in the country’s risk management measures during each stage of the chemical substance life cycle. Of particular note, the Policy

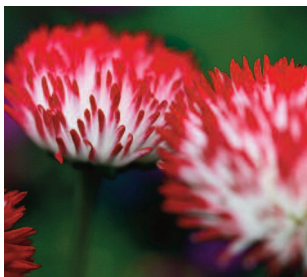
makes a specific recommendation for the Ministries of Health, Labor, Commerce, Agriculture, and Transport to develop implementing regulations to have the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) in place in the country by **December 2020**.

Finally, Costa Rica’s Senate has put forth Executive Decree 28112-S (30718 as amended), “Regulation for the Registration of Hazardous Chemical Products.” The Decree has been proposed in two drafts: Draft 1 includes provisions for the registration and control of hazardous substances, while Draft 2 includes language for the implementation of GHS.

PESTICIDES

Pesticide regulations, whether for agricultural use (more commonly) or for domestic or urban (public health) use, have a long history in Mexican, Central American, and South American chemical legislation, due in large part to the heavy reliance on agricultural production in the respective countries. 2017 is expected to see further expansion of these regulations, as well as the introduction of new ones, as countries seek more robust legislation.

In late 2016, Chile’s Agriculture and Livestock Service (Service) issued [Resolution No. 5482/2016, Establishing Requirements for the Authorization of Pesticides](#). Of particular note is the language of point number three in the “Considering” section of the legislation: “[t]hat, given the new technical and scientific



2017 is expected to see further expansion of pesticide regulations, as well as the introduction of new ones, as countries in the region seek more robust legislation.



A rapidly-emerging trend in Central and South America in the product stewardship arena is the development of a variety of “take back” legislation.

advances on the subject, it is necessary to update the Technical requirements and guidelines for the authorization of pesticides, based on the new requirements and [EU] criteria, and to the new test guidelines of the [OECD].” This clearly suggests that the Service is aware of how pesticide products are managed in other jurisdictions, and its desire, at least with this legislation, to be in concert with both the EU and OECD on the subject.

PRODUCT STEWARDSHIP INITIATIVES

A rapidly-emerging trend in Central and South America in the product stewardship arena is the development of a variety of “take back” legislation. While countries have generally applied such efforts to pesticide containers, regulations are in development that address other applications.

In late 2016, Argentina published the [Plant Protection Products Law No. 27279](#) in the Official Gazette (*Boletín Oficial de la República Argentina*). As per Article 1, “[t]his law establishes the minimum environmental protection for the management of empty containers, under the toxicity of the product contained, requiring a differentiated and conditional management.” The Law requires all entities that hold a Pesticide Certificate of Use and Sale to, per a registration requirement with the Ministry of Agriculture, to put forth for approval a management system for empty containers, and to implement such a system within 270 days of such system’s approval. Additionally, the pesticide containers must be redesigned to minimize their impact on the environment.

Further, the lower house of the Argentine National Congress is considering bill No. 3279-S-2016 that would establish a comprehensive packaging waste management program, and which, at its core, would include requirements for the creation of management systems and labeling requirements for such waste. As presently written, the bill applies only to household packaging wastes, but exempts those already covered by specific waste standards (*e.g.*, packaging for hazardous materials). Producers -- defined as packagers or importers of packaged products and manufacturers and importers of packaging destined for sale and distribution to consumers -- would be required to create national associations to develop and implement Integral Packaging Waste Management Systems (as delineated in Article 7). These management systems would be funded by mandatory fees to be paid by the producers on a per-package basis, thus encouraging a reduction in the overall amount of household packaging generated. Within one year of the bill’s enactment, the Systems would need to be approved by the to-be-defined authority, and will need to meet the packaging recovery targets (*e.g.*, at least 20 percent within the first year, at least 50 percent within ten years, and so forth).

THE ACTA GROUP (ACTA[®]) maintains a deep and expansive understanding of the regulatory landscape in Central and South America, and our professionals can provide strategic, cost-effective, and timely assistance in product registration, CBI management and protection, supply chain management, and more. Visit our website for more information on our services in [Central and South America](#).

Finally, in late October 2016, Bolivia published Supreme Decree No. 2954/2016 in their Official Gazette (*Gaceta Oficial del Estado Plurinacional de Bolivia*), the implementing legislation for [Law No. 755/2015, The Regulation to the Law for the Integrated Management of Wastes](#). Similar in overall concept to the Argentinian packaging waste management program, but specifically directed toward waste electrical and electronic equipment (WEEE), the Bolivian Law requires producers of these materials to: register them in a national registry established by the Ministry of Environment and Water (*Ministerio de Medio Ambiente y Agua*), to develop plans to manage these “post-consumer products,” which will be valid for up to five years, to submit them to the Ministry for approval, and finally to implement them.

Virtually every country in Central and South America has either announced plans to develop similar legislation, or has bills which are already under Congressional discussion. Among these are Brazil, Chile, Colombia, Costa Rica, Ecuador, Mexico, Nicaragua, Panama, Peru, and Uruguay. Notably, Brazil’s São Paulo State’s draft is exceptionally comprehensive, mandating take-back agreements for nine product categories, including certain types of lamps, batteries, automotive filters, vegetable oils, and pesticide packaging. Colombia’s proposed law also addresses WEEE, with the specific requirement that 30 percent of the computers and related peripherals collected annually must be refurbished for reuse in educational and cultural centers. Mexico’s draft specifically identifies products containing Li, Ni, Hg, Cd, Mn, Pb, and Zn, in levels not considered to be hazardous by other regulations, to be “special management waste” subject to management plans. This is particularly noteworthy, as the draft appears to regulate products containing what are traditionally considered to be hazardous materials, even when those levels are below current regulatory limits.

WORKER AND WORKPLACE SAFETY

The most visible developments relative to worker and workplace safety in Mexico, Central America, and South America is occurring with respect to the implementation of GHS. Multiple countries across the region have either implemented GHS or are well on their way to doing so. Argentina’s implementation of GHS for substances is scheduled for January 1, 2017, and for mixtures for **June 1, 2017**. Ecuador will require GHS for both categories on January 1, 2017, while Uruguay presently requires GHS classification for substances, but will require the same for mixtures on **December 31, 2017**. Mexico’s current three year phase-in plan for GHS ends on **October 9, 2018**.

Chile continues development of a GHS regulation: entities may either use the legally-binding NCh 2245:2015 SDS regulation, or may classify to the Fifth Revision of the GHS. Costa Rica has put forth draft proposals for GHS legislation, discussed above, while Colombia has publicly stated its desire to begin the legislative process to implement the System. Colombia is expected to amend its classification and labeling regulation, NTC 1692, and its SDS regulation, NTC 4435, to encompass GHS.

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COMING IN THE FIRST QUARTER OF 2017 FROM ABA BOOKS:

LYNN L. BERGESON, CHARLES M. AUER,

New TSCA: A Guide to the Lautenberg Chemical Safety Act and Its Implementation, American Bar Association (2017).

Congress's substantial revisions to TSCA in 2016 marked the end of a decades-long quest to remedy that which ailed our domestic industrial chemical management law, and the beginning of a new era of TSCA law and regulation. This book written by B&C professionals identifies and explains the substantial revisions to TSCA occasioned by enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, including individual chapters on amended sections of TSCA, plus chapters covering:

- Basic TSCA Provisions
- Key Science Concepts
- Scope of Persons Subject to TSCA
- Microbial Products of Biotechnology
- Nanoscale Chemicals
- Judicial Review
- Timelines and Deadlines