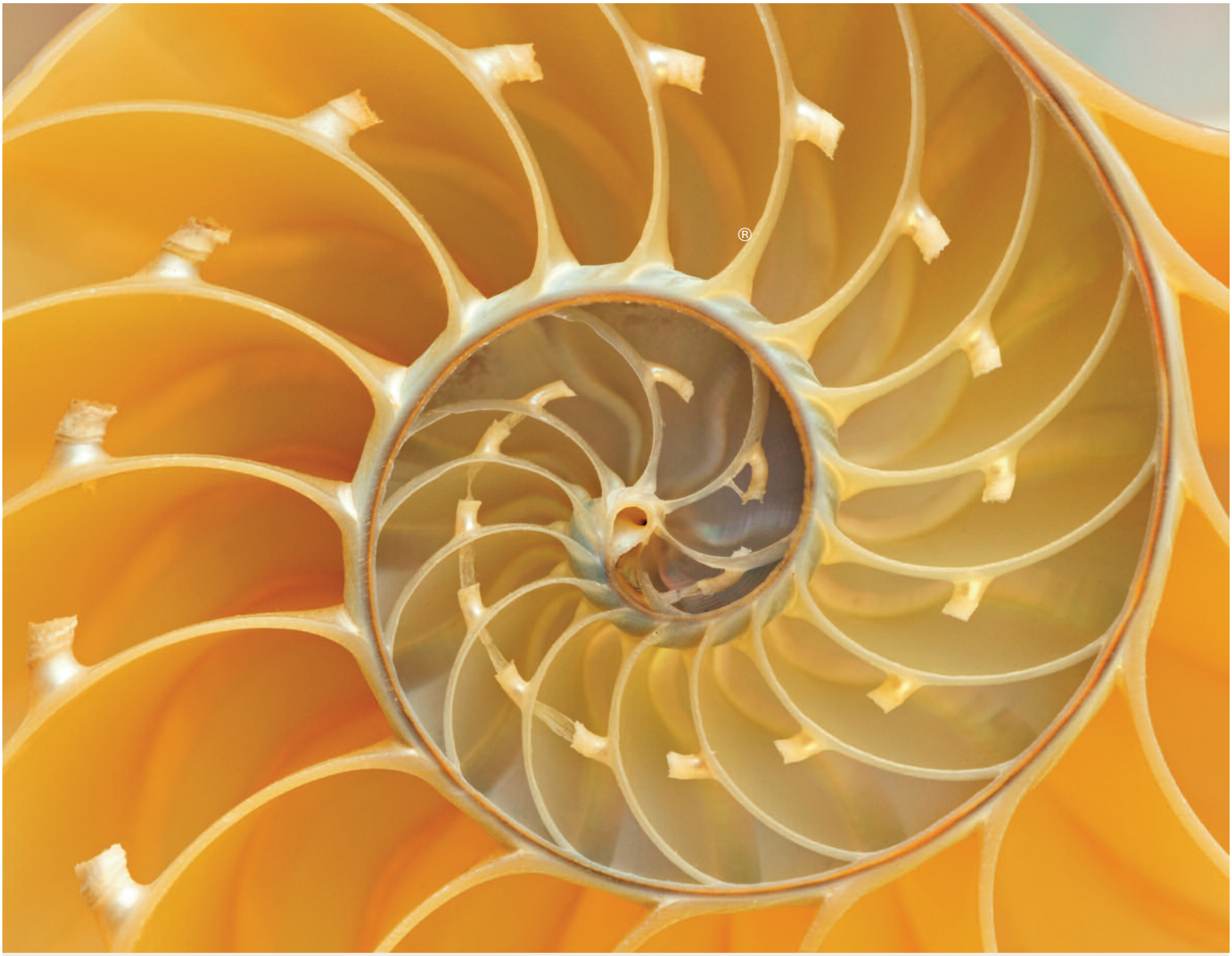

BERGESON & CAMPBELL, P.C.

Predictions and Outlook for EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) 2016

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FORECAST 2016

Predictions and Outlook for EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) 2016

Even if Toxic Substances Control Act (TSCA) legislation is not enacted, 2016 will be a momentous year. As the curtain closes on eight years of the Obama Administration, there are a number of items expected to be among the "legacy" issues in the chemical and pesticide regulation space. Enhanced protections for farmworkers, more protective assessment policies, and a re-energized toxic chemical assessment program are among the short list of notable achievements that will have some remaining work to complete as we enter the New Year. At the same time, there are significant issues over which the U.S. Environmental Protection Agency (EPA) has little control but that could, nonetheless, drive the program's agenda for years to come. Specifically, there are two large unknowns for OCSPP: (1) will there be enactment of substantial amendments to TSCA; and (2) will litigation over implementation of the Endangered Species Act (ESA) result in a virtual halt to new pesticide active ingredient registrations. And all of this for 2016 will take place in the context of a Presidential Election Year with some of the leading party candidates declaring their commitment to doing away with EPA altogether if elected. For a political junkie, it may not get better than this; for an interested stakeholder in the world of pesticide and chemical regulation, the uncertainty could be bruising.

2016 will also be the last year of the Obama Administration. In addition to Election Year dynamics -- oversight hearings, candidate jockeying, party platform positioning -- we will see attempts to complete various "legacy issues" by completing or attaining objectives set out earlier in the Administration.

Like 2015, most of the fireworks concerning EPA will not directly involve the regulation of industrial chemicals and pesticides. Most of the rhetoric and high profile activities will center on climate change policies and initiatives, the World Climate Change Conference 2015 (COP21) Paris agreement, and attempts to hinder or foster Administration positions. At the same time, for OCSPP, we expect the most important initiatives to include what now appears to be the serious possibility of legislative reform of TSCA and continued attempts to revitalize the toxic chemicals program even without legislation, along with continued emphasis on various pesticide issues, such as pollinator protection, endangered species, worker protection standards, and endocrine testing requirements.

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CONGRESSIONAL RELATIONS

There is little reason to expect the recent trend of bitter partisan rancor to diminish in Congress during 2016 with the continued presence of a Republican majority on both sides of Capitol Hill, although House Speaker Paul Ryan (R-WI) shows signs of a greater capacity for compromise. Election years mean more posturing, so some hearings and oversight questions will be geared to buttress likely campaign claims about the costs of regulation, the "overreach" of the Administration and "bureaucracy," and the general adverse impact of EPA and other regulatory agencies on "jobs and the economy." The one exception to this hostility, however genuine, is the possibility of significant TSCA legislative amendments.

PROSPECTS FOR TSCA LEGISLATION

Starting in late 2014, there was a compromise bill endorsed by Senator Tom Udall (D-NM) and then ranking member Senator David Vitter (R-LA). Unlike earlier bills introduced over the many years, that draft late in the previous session of Congress showed significant progress in attempting to address the concerns of most of the identified TSCA stakeholders, including significant concerns raised about deadlines, the risk standard, testing requirements and priorities, confidential business information (CBI), and other key issues. The most outstanding issue, and the largest hurdle in coming to agreement among the parties, was the issue of state preemption. Even with the change in party control of the Senate, which saw Senator Jim Inhofe (R-OK) take over the Senate Environment Committee, work continued towards a successful compromise. The House approved a compromise bill (H.R. 2576) with a surprisingly large bipartisan vote of 398-1 on June 23, 2015. Very late in the year, on December 17, 2015, a new version of a compromise bill (S.697) was approved by voice vote in the Senate. The text of the new bill and our analysis of it are available online. It contains new language regarding preemption of state actions, and it is unclear now if the House and Senate managers of the bill will seek a conference committee on the bills, or simply see the Senate language as the "grand compromise" and ready to be accepted by the House (which will require another House vote on the Senate-approved text). This approach, avoiding a conference, would be the most straightforward path to successful legislation, assuming the President would sign the bill as is expected. It would also present the quickest path to enactment, which also means this Administration would have some significant time to begin the early implementation of the provisions before a new Administration arrives. This could prove important as new EPA appointees, regardless of party, often are delayed in being confirmed in the Senate.

BUDGET

Another surprising bipartisan agreement in late 2015 covered the Fiscal Year (FY) 2016 federal budget, including EPA -- which held EPA's total budget the same as the previous year. Since there is a small increase in federal salaries (1.3 percent), this will erode slightly the EPA operating funds since the increase will have to be covered by cutting other current activities. The pattern of little or no increase while granting a cost of living increase is helpful to today's employees but these "small" cuts (as costs) that generally increase over time can have a cumulative impact on staff hiring and morale due to cuts in other program activities (such as staff travel and training, or hiring new staff to replace retiring employees).

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Litigation outcomes driven by endangered species and pollinator protection issues threaten to undermine the entire current pesticide regulatory system.

Generally, EPA's budget may continue to be in the cross-hairs. As Congress has the power of the purse, attempts to control policy outcomes are expected to take the form of appropriation amendments as part of the EPA budget process. These attempts, along with continued hearings on any number of issues, could consume significant amounts of senior management time and attention. EPA might also face budget cuts as one way to "rein-in EPA," a popular agenda item for some of the more conservative members of Congress. Congress has aggressively cut the Internal Revenue Services' (IRS) budget, purportedly to "rein-in" the IRS, with significant negative impact on the IRS' ability to assist tax payers or collect unpaid taxes. Although EPA avoided similar targeted budget cuts in FY2016 and EPA enjoys popular support much more so than does the IRS, cuts that substantially impact EPA's ability to function effectively are a possibility in **FY2017**, which begins on the eve of the elections.

EPA has recently seen cuts in personnel allotments, even if budget dollars are available to substitute contractor support for some level of permanent staffing positions. OCSPP reportedly has reduced its personnel allotment over the past year by close to 100 positions. This could allow more budget flexibility in the future for insulation against future budget reductions. Given the demographics of the EPA workforce (many hired in the early days of EPA are now eligible to retire), and the prospect of dealing with a Presidential transition, many staff are considering retirement before the end of 2016. Such retirements and subtle budget cutbacks could lead to skills-mix personnel issues and a general loss of institutional knowledge and history. Delays in new and existing chemicals review and inconsistent decision-making are both a possibility if a number of key scientific staff retire before being able to train replacements.

For the pesticide industry, budget concerns and personnel reductions continue to stretch Pesticide Registration Improvement Act (PRIA) resources, which are dedicated theoretically to ensure predictable timelines for registration decisions. Delays have been encountered over the need for resolution of additional ESA issues, among other complications. Deadlines for decisions in many cases have slipped and required PRIA extensions to the point where it may become a matter of Congressional concern. Delays and staff resources are also being discussed among stakeholders as part of the discussions about the next PRIA authorization.

OFFICE OF PESTICIDE PROGRAMS (OPP) ISSUES

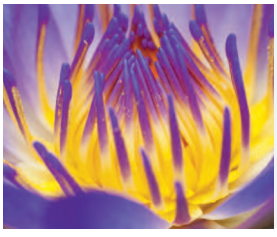
Two issues will continue to dominate pesticide regulatory activity during 2016: endangered species and pollinator protection. In 2015, there has been an additional twist: litigation outcomes driven by these two issues threaten to undermine the entire current pesticide regulatory system. This dramatic rhetoric is not overblown: legal challenges concerning pollinator concerns resulted in one case where the United States Court of Appeals for the Ninth Circuit vacated a recently issued registration for a new active ingredient (sulfoxaflor) and another case, not yet decided, where EPA asked the Ninth Circuit to vacate a recently issued registration, based on EPA's position that recently received new information warranted this

action (Enlist). The Enlist case raises the issue for some of EPA's ability to sidestep Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) statutory procedures for cancelling or suspending a product. The cases additionally are believed by some to establish a new standard for adverse effects reporting under FIFRA Section 6(a)(2), based on patent application information that could have far-reaching impacts on any pesticide registrant that has filed a patent application for the product at issue. EPA's recent actions seeking to vacate registrations, instead of cancelling or suspending those registrations under the well-established statutory FIFRA procedures, are consistent with other recent EPA actions relating to pesticide registrations that also seem to ignore or skirt long-established statutory and regulatory procedures. These novel EPA approaches to addressing issues with pesticide registrations have led some registrant stakeholders to fear EPA is pursuing a "new normal" to avoid the statutory procedures and opportunities for contesting EPA decisions. These issues will likely be the focus of significant debate through 2016.

These two cases and the procedural issues they present are not the only items likely to prove controversial -- there are a number of others. For example, EPA has promulgated new rules implementing far-reaching new farmworker protections and is currently accepting comment on expansive new requirements for certified applicators, both of which have generated considerable controversy and concern within the registrant community, growers, and the states. Another example is EPA's efforts to revoke the tolerances for the organophosphate (OP) insecticide chlorpyrifos. Although EPA's effort to use the tolerance revocation process in lieu of a cancellation process is not a new tactic in 2015, it remains a controversial one. Moreover, as part of the chlorpyrifos effort and, potentially applicable to all OPs, is EPA's issuance of what many in the registrant community believe amounts to a new rule in the form of a "literature review" document placed in the docket relating to individual OP products. This approach, intended to tighten the standards that must be met to maintain the Food Quality Protection Act (FQPA) 10x safety factor in individual pesticide assessments, leads some critics to believe that EPA is applying the precautionary principle, contrary to the underlying statutory requirements. It is yet another procedural foul according to its critics.

In general, this has led to increased fears that "rushing" to complete things before the end of the Obama Administration, as part of a legacy issue push, or a push simply to get decisions out the door, will result in significant market uncertainty for registrants. On top of Election Year antics with a Republican Congress trying to help set an agenda or to push certain issues seen as helpful to their constituencies, "regulatory impacts," "appropriate procedures," and "science integrity" will likely be issues of Congressional concern.

Other issues will be important (*e.g.*, implementing the Worker Protection Standard (WPS) rule and promulgating and implementing the new certified applicator requirements), but ESA and pollinator issues, and general approaches to navigate around what EPA may believe are cumbersome and time consuming FIFRA processes, will take the most time, energy, and attention of registrants, regulators, and other stakeholders.



Some registrant stakeholders fear EPA is pursuing a "new normal" to avoid the statutory procedures and opportunities for contesting EPA decisions.

ENDANGERED SPECIES

ESA implementation issues and litigation will continue to drive registration decisions for 2016. EPA and the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (the Services) continue to meet in efforts to coordinate review activities and especially to devise an assessment process that incorporates the recommendations made by the National Academy of Sciences (NAS) in 2013 in its report *Assessing Risk to Endangered and Threatened Species for Pesticides*. More information is available in our May 1, 2013, memorandum, "NAS Committee Releases Report Recommending Changes in Process Used by EPA and the Services to Assess Risks to Endangered and Threatened Species from Pesticides." The joint efforts have included a series of public workshops, the next one expected to be held in **early 2016**. These workshops have generally been sessions where various registrants and consultants, along with some from the non-governmental organization (NGO) community, contribute suggestions to EPA and the Services about ways to improve the current methods and how to incorporate recommendations made by NAS. There are varying views as to the progress made during the workshops, however. Meanwhile, EPA and the Services will continue to develop their review procedures and process through the first three assessment "pilots," which are due to be completed in **2017**.

As part of the pilot process, EPA only recently released the supporting documentation associated with the Biological Evaluations for the first three pilot chemicals (chlorpyrifos, diazinon, and malathion). These are not the draft assessments, but, as EPA states, these documents contain the analysis plan and underlying data that will be used to make effects determinations as part of the consultation process. They are effectively an EPA bolus of information about the fate and effects of the pesticides, the provisional models EPA used in its assessment, and the analysis plan that will go into the effects determination. This current information is estimated to be approximately 30,000 pages of material, with more to follow once the effects determination is complete. The magnitude of information and effort going into these assessments is controversial and of concern to many registrants, since such a system cannot be implemented for the many hundreds of ESA assessments that EPA and the Services will need to conduct if current procedures are maintained.

The problem of "how much is enough" or how to conduct an assessment has been a concern, but as the issue of endangered species protection has expanded to include legal challenges to new active ingredient registrations, the situation could swiftly become more heated. In early 2014, NGO groups filed challenges in both federal district court and federal appellate court to EPA's registration of new pesticide products with the new active ingredient cyantraniliprole. This set of challenges is of concern for many reasons and perhaps mostly because they were filed against a new pesticide. New active ingredients traditionally have been seen as generally "softer" on the environment and potentially affected species than the products they tend to replace in the existing markets. As a result, this challenge to a new product is considered by some to be a new front in the legal challenges to EPA's approval of pesticides and compliance with the ESA. And, if the outcome is that the court finds in favor of the NGO groups, the litigation that follows with regard to other pesticide products could be the train wreck some have predicted for years that may finally force a Congressional resolution of the question of how ESA and FIFRA should interact.

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EPA's "Proposal to Mitigate Exposure to Bees from Acutely Toxic Pesticide Products" included a list of 76 pesticides to which new labeling requirements would apply.

POLLINATORS

OPP actions regarding the pollinator issue continue to be driven by the 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. 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 call for a strategy is directed to all federal agencies and is designed to "expand Federal efforts and take new steps to reverse pollinator losses and help restore populations to healthy levels." Specifically, the Memorandum mentions that one of the strategies is to include "identification of existing and new methods and best practices to reduce pollinator exposure to pesticides, and new cost-effective ways to control bee pests and diseases." Finally, it directs the new federal task force to report back to the President in six months.

In May 2015, the White House released its "National Strategy to Promote the Health of Honey Bees and Other Pollinators" that led EPA later in May 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 now in the process of reviewing comments. Some critics of pesticides and some beekeepers commented that it was a step in the right direction, but that more needs to be done to address the issue. Some commenters stated that all neonicotinoid pesticides should simply be removed from the market. It is unclear at this time what the schedule is for EPA to complete its review or when to expect the next iteration of its May proposal.

Another important pollinator development came in October 2014. EPA published a report concluding that neonicotinoid seed treatments provide little or no overall benefits to soybean production in most situations covered by the published studies that were evaluated. The report concluded, based on selected studies and U.S. Department of Agriculture (USDA) Cooperative Extension Service research and other sources, that seed treatments for soybeans are only bioactive in soybean foliage within the first three to four weeks of planting, and that this period of bioactivity typically does not overlap with key periods of activity for major pests of concern. EPA's report concludes that most uses of neonicotinoid-treated soybean seeds are prophylactic. The report goes on to state that such treatments provide little or no economic benefit to soybean producers, and that more precisely timed applications of foliar sprays of neonicotinoids and other insecticides based on pest scouting would more effectively target the same pest spectrum as neonicotinoid seed treatments.

Registrants of these products intensely criticized the report as incomplete and have provided information to EPA to rebut the conclusions. EPA has previously announced its intention to issue a registration review assessment for imadacloprid before the end of

2015 -- which will, presumably, include any further conclusions about the 2014 benefits analysis. It is less clear when EPA will complete its response to the comments received on the May 2015 "Proposal to Mitigate Exposure to Bees from Acutely Toxic Pesticide Products."

WORKER PROTECTION STANDARD

In March 2014, EPA issued a proposed rule to update the WPS that generated a large volume of public comment 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 Bergeson & Campbell, P.C.'s (B&C®) 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. Some believe that EPA broadly and incorrectly overstated the current risks to workers that the rule is intended to address, resulting in overly conservative assumptions and unnecessary regulatory burdens. 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. In addition, over the intervening years, for a variety of reasons, many (not all) of the most hazardous pesticides have been removed from the market or otherwise are used less. 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 represents its attempt to balance these views. 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 may cause EPA to consider ways to further refine the requirement.

Currently, EPA has also issued a proposed rule to update its Certification and Training requirements. This proposed rule has also generated significant controversy and concern from grower groups, registrants, and states who would implement the new requirements. Although EPA has discussed the potential for 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. The proposed rule was issued in August 2015 and the comment period has been extended twice; it now closes on **January 22, 2016**. EPA has stated publicly on numerous occasions its intent to promulgate and implement the final rule expeditiously; this issue will consume significant attention over the next year from the states and grower groups most affected.

FORECAST FOR THE OFFICE OF POLLUTION PREVENTION AND TOXICS (OPPT)

Our Predictions memoranda for 2014 and 2015 emphasized the need for OPPT to conclude actions rather than make new commitments to act. With one year to go in the Obama Administration, OPPT has continued to make progress on its agenda, although a number of significant and difficult challenges are teed up for 2016. The biggest wild card is the enactment of TSCA reform legislation and its impact on OCSPP leadership and OPPT staff in potentially needing to undertake the hard work of implementing TSCA reform legislation.

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Congress could build on the momentum created in December by the Senate in passing S. 697 and pass TSCA reform legislation early in 2016 giving Assistant Administrator for OCSPP Jim Jones almost a full year to tackle implementation challenges. Jones is widely credited with the successful implementation of FQPA following its enactment in 1996, and his leadership and experience would be invaluable in implementing TSCA reform legislation.

Aside from possible TSCA reform implementation, OPPT will have its hands full. During 2015, OPPT:

- Proposed Significant New Use Rules (SNUR) on long-chain perfluoroalkyl carboxylate (PFAC) and perfluoroalkyl sulfonate (PFAS) chemicals and toluene diisocyanates (TDI);
- Proposed Section 8(a) reporting and recordkeeping requirements for existing chemical nanoscale materials;
- Promulgated a SNUR on hexabromocyclododecane (HBCD) used in textiles; and
- Amended the requirements for electronic submission of Section 5 notices, which take effect in **January 2016** (*see* our memorandum "TSCA: New Requirements for Submitting Section 5 Notices Take Effect in January 2016" for more information).

The unfinished business before OPPT in 2016, particularly regarding SNURs, includes promulgating final SNURs on the long-chain PFAC and PFAS chemicals and the TDIs. In addition, there are yet-to-be-final SNURs on certain nonylphenols/nonylphenol ethoxylates and polybrominated diphenylethers (PBDE), including decaBDE (this action, which was proposed in April 2012, also includes a TSCA Section 4 test rule). Many of these rules present complex issues and OPPT is likely to struggle as it reconciles the many comments it received and determines its approach in the final rules. Several of these SNURs also include that pesky issue of including imported articles within the rule's scope and we look to further evolution of OPPT's approach to this issue in 2016 (relevant expected actions include the SNURs on long-chain PFAC/PFAS and PBDE chemicals). Another open item is an expected proposed rule for Sections 8(a)/8(d) reporting on oil and gas production (*i.e.*, fracking) chemicals (this was the subject of a citizens' petition filed in 2011 under TSCA Section 21).

In the New Year, we will also see the second iteration of reporting (**June 1 through September 30, 2016**) under the updated TSCA Section 8(a) Chemical Data Reporting (CDR) rule. The rule includes some important changes from the requirements in 2012, including a reduction in the reporting threshold (from 25,000 lbs/year at a site to 2,500 lbs/year at a site) for chemicals subject to any of several TSCA actions (*e.g.*, test rules, pending or final SNURs, and Section 5(e) consent orders, among others) and a requirement that if a chemical triggers reporting in any one or more years between 2012 and 2015, the reporting must include that for each of the four years (additional information can be found in EPA's fact sheet "How to Report Under Chemical Data Reporting").

Aside from TSCA reform implementation, OPPT will have its hands full in 2016, particularly in the New Chemicals Program.

WORK PLAN CHEMICALS

Important progress was made in the Work Plan effort in 2015. As readers may recall, the Work Plan was updated in 2014 to contain approximately 90 existing chemical entries; to date OPPT has initiated assessments on 14 chemicals/clusters. Progress includes completed risk assessments on five chemicals (with three proceeding to risk management and two being dropped from further review (antimony trioxide and the fragrance ingredient 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta-[y]-2-benzopyran (HHCB)), four with ongoing risk assessments, one with a data needs assessment, and four cases that are in the initial assessment stage.

The chemicals proceeding to risk management include the paint removers N-methyl pyrollidone (NMP) and methylene chloride, and the chlorinated solvent trichloroethylene (TCE) when used as a degreaser, stain remover in dry cleaning, and spray fixative. EPA is considering both voluntary and regulatory actions, including using TSCA Section 6(a), to manage the identified risks. We expect that EPA will propose Section 6 regulations on one or more of these chemicals during 2016, given that the Administration will change in **2017**. This is the first time in many years that EPA has attempted to use this TSCA section since the celebrated *Corrosion Proof Fittings v. EPA* case (947 F.2d 1201 (5th Cir. 1991)) to regulate asbestos and the often overlooked use of TSCA Section 6 in regulating acrylamide's use in sewer grout in the early 1990s. The proposed rule on acrylamide was withdrawn in 2002 based on development of personal protective equipment used to mitigate worker exposures during the application of the grout. EPA's limited success in discharging its TSCA Section 6 authority and the fundamental difficulty in making and supporting a Section 6 rule means that EPA will have its hands full as it proceeds.

Concerning the other Work Plan chemicals in play, EPA in 2015 issued initial risk assessments and problem formulation documents on 1,4-dioxane and three flame retardant clusters containing ten chemicals (chlorinated phosphates (3), cyclic aliphatic bromides (3), tetrabromobisphenol A chemicals (4)). This was the first time that EPA released problem formulation documents on Work Plan chemicals. It received numerous critical comments from both environmental groups and industry about issues ranging from the adequacy of OPPT's general approach to developing problem formulations and the scope of chemicals, uses, exposures, and effects to be considered. Other comments focused on the broader implications of possible restrictions when, in the case of the flame retardants, they have been identified as alternatives to other chemicals that have been voluntarily phased-out. We look forward to understanding how EPA will respond to these comments as it moves forward in 2016. We expect that EPA will release risk assessment documents in the coming year for one or more of these chemicals/clusters as part of an effort to demonstrate that it can conduct and complete such assessments (and deal with problem formulation comments) in a timely way.

GREEN CHEMISTRY AND SAFER CHEMICALS AND PRODUCTS

Since 2014, Jim Jones, OCSPP's Assistant Administrator, has emphasized the need for greater progress in green chemistry and Design for the Environment (DfE). This can be seen in the efforts Jones has taken to recognize Presidential Green Chemistry Challenge winners (including making site visits) and in efforts

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Over the past year, we have seen an uptick in enforcement actions that use chemical identity issues as the starting point for actions that lead to submission of PMNs.

to upgrade the DfE program. Tangible progress was realized when, in February 2015, the new Safer Choice label was unveiled to generally but not universally positive reviews. OPPT also announced the inaugural Safer Choice Partner of the Year Awards in 2015; nominations for 2016 Partner of the Year Awards are due in **late January** with winners expected to be announced in the spring. The DfE Safer Choice program also has the goal to add hundreds of chemicals to the Safer Chemical Ingredient List (SCIL). Efforts to increase the visibility and market adoption of Award-winning green chemistry technologies remains a priority of OPPT management, although activity has been hampered by limited resources. We expect these efforts to continue to grow in 2016 and reiterate our encouragement to clients and friends to look carefully into these opportunities.

UPDATE ON OPPT'S RULEMAKINGS AND "SAFER AND GREENER" NEW CHEMICALS

Our 2015 Predictions memorandum discussed several 2014 existing chemical rulemakings that raised concerns about the due diligence exhibited in the rulemaking record. We are pleased to note that we did not find what we considered to be due diligence problems in the 2015 rules that EPA issued, so perhaps things are looking up. On the other hand, there have been instances of contradictory statements in proposed rules that required companies to seek clarification in comments in an abundance of caution and to clarify the record. Our 2015 Predictions memorandum also noted a number of issues we had experienced in working with clients to introduce safer and greener new chemicals into the marketplace. Here too the issues that we encountered in previous years seem to have subsided, or resolved in ways that do not commercially disadvantage the new, green technologies, so again, perhaps things are looking up. Being optimists, we predict that this upward trend will continue in 2016 and premanufacture notices (PMN) with well-developed Pollution Prevention statements will continue to receive due consideration to the risk reduction opportunities that the new chemicals offer.

IS OPPT RETURNING TO ITS APPROACH OF USING INVENTORY CHEMICAL IDENTITIES AS THE "THIN EDGE OF THE WEDGE?"

Readers may recall instances in the recent past when OPPT has used TSCA Inventory chemical identity issues as a way to challenge the presence of existing chemicals listed on the Inventory, and in some cases trigger the need for PMNs. Examples include the effort in the recent past to "clarify" the existing EPA guidance on statutory mixtures (we discussed this and related issues in a 2012 article entitled "Are TSCA Section 8(b)(2) statutory mixture categories subject to reporting under the Chemical Data Reporting rule?"), as well as recent efforts that used chemical identity issues as the basis for enforcement actions that resulted in companies agreeing to submit PMNs on what had been considered existing chemicals listed on the Inventory. We explored one such example in our 2013 memorandum "EPA's Enforcement Actions Target 'Fractions.'" Over the past year, we have seen an uptick in enforcement actions that use chemical identity issues as the starting point for actions that lead to submission of PMNs. Although enforcement is one of those murky areas of EPA endeavor where it can be

difficult to understand what is going on, we were surprised to see the following bullet points in a slide deck used by Jim Jones for a December 10, 2015, presentation at the Chemical Watch Regulatory Summit in Washington, D.C.:

- "Medium- and Long-Chain Chlorinated Paraffins (MCCPs and LCCPs)
  - MCCPs and LCCPs are not listed on the TSCA Inventory, despite their continued use in the marketplace.
  - In 2012, EPA and the manufacturers of these chemicals came to a resolution: they would submit PMNs to EPA under Section 5 of TSCA.
  - It is a longstanding Agency practice to require PMNs for chemicals not listed on the TSCA Inventory."

Regrettably, Jones was rushed at this point in his presentation and did not elaborate on these bullets. In late December, EPA took the somewhat unprecedented action of soliciting new information on certain chlorinated paraffins in different industries and for different uses to "inform the risk assessments of chlorinated paraffins submitted" as PMNs and disclosed the pending risk assessments for these PMNs in the public docket. This seems to indicate EPA's recognition that the MCCPs and LCCPs, while not, according to EPA, listed on the TSCA Inventory, are commercially available and that regulatory action taken on the PMNs would have far-reaching and adverse impacts on the current processors and users of the PMN substances. We are aware of other enforcement actions over the past year that seem to spring from OPPT's reinterpretation of the statutory mixture guidance. Relatedly, the SNUR on nonylphenols/nonylphenol ethoxylates, noted above, also included nomenclature issues concerning linear versus branched forms as one of the elements in the regulatory approach. We are not sure where this is headed in 2016, but we intend to watch the issue carefully and to report when we have something of note to say. We would appreciate hearing from our readers of other instances where EPA enforcement scrutiny is focusing on these or other Inventory/chemical identity issues. Some of these subtle issues related to chemical nomenclature and chemical identity may come to the forefront if the "Inventory reset" provisions of S. 697 are enacted and EPA engages with chemical manufacturers to clarify which substances are "active" in commerce and which are not.

NANOMATERIALS FORECAST

Since 2005, EPA has received more than 170 TSCA notifications for nanoscale materials. 2015 saw continued steady growth in the number of these notifications consistent with prior years. EPA proposed the much anticipated TSCA Section 8(a) rule on April 6, 2015, generally to vigorous criticism. EPA's fall 2015 Regulatory Agenda notes EPA's intention to issue a final rule in **October 2016**.

Other EPA program offices are now also focusing more on nanoscale materials. Specifically, on August 4, 2015, EPA announced the availability of its "Final 2014 Effluent Guidelines Program Plan," which includes findings from EPA's review of engineered nanomaterials in industrial wastewater. EPA intends to monitor ongoing research on engineered nanomaterials in future annual reviews and will collect any

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new information as it becomes available. The takeaway here is that EPA's Water Office will continue to look for and identify evidence of nanomaterials in industrial effluent with a view toward regulating it.

On March 19, 2015, EPA responded to the International Center for Technology Assessment's 2008 petition for rulemaking requesting that EPA regulate products containing nanosilver, a widely used nanoscale material, as pesticides under FIFRA, and to analyze nanosilver's potential human health and environmental risks. The petition also urged EPA to prohibit the sale of nanosilver products with unapproved claims of health benefits, and to assess human health and environmental risks of nanosilver under other laws, including FQPA and ESA. What impact, if any, the suit will have on EPA is unclear. EPA declined to provide the relief requested in the petition.

OPP's May 2015 announcement that it conditionally registered a second nanosilver pesticide product, Nanosilva, was immediately the subject of a federal lawsuit in the U.S. Court of Appeals for the Ninth Circuit. The Natural Resources Defense Council (NRDC), the Center for Food Safety, and the International Center for Technology Assessment once again teamed up to sue EPA for its decision to register the product. The court has consolidated the cases. Petitioners' opening briefs were filed in mid December. In brief, they claim EPA did not support with substantial evidence their contention that Nanosilva's product would reduce the amount of silver in the environment by replacing conventional silver, and that EPA did not support its view that Nanosilva lacked sufficient time to generate all required data even though EPA required the same studies for the nanosilver registration issued to HeiQ in 2011. EPA's answer is due **February 4, 2016**. How the court will rule in 2016 is, of course, unclear. What is clear is that judicial challenges to final OPP registration decisions seem inevitable.

BIOTECH FORECAST

The summer of 2015 was surprisingly busy in the industrial biotechnology policy and regulatory arenas, with three important announcements generating controversy. On July 2, 2015, the White House Office of Science and Technology Policy, the Office of Management and Budget, the U.S. Trade Representative, and the Council on Environmental Quality issued a memorandum directing EPA, the U.S. Food and Drug Administration (FDA), and USDA to update and modernize the Coordinated Framework for the Regulation of Biotechnology. More information is available in our memorandum "Biotechnology: White House Directs EPA, FDA, and USDA to Update the Coordinated Framework for the Regulation of Biotechnology." A few weeks later, OPPT announced a project intended to support public dialog concerning the development and use of biotechnology by developing a new algae "how to" document for TSCA purposes, and to help jump start much needed public discourse around the topic of biotechnology in general. More information is available in our memorandum "EPA Posts Information on Biotechnology Algae Project." Finally, OPPT also announced that it is updating its *Points to Consider in the Preparation of TSCA Biotechnology Submissions for Microorganisms*. Each of these developments is

important, and their further refinement in 2016 will be important for stakeholders. The professionals at B&C are also proud of our work in writing the report "The DNA of the U.S. Regulatory System: Are We Getting It Right for Synthetic Biology?" for the Woodrow Wilson International Center for Scholars Synthetic Biology Project (October 2015). The pathway to market for new products utilizing synthetic biology can be difficult to navigate, posing a challenge for companies in their efforts to commercialize new ideas, while the novelty posed by some of these products can make it difficult for regulatory agencies to determine proper regulatory oversight as well as evaluate risks. This report looks at the current regulatory oversight of synthetic biology in the U.S. through the lens of several different products. The case studies in the report look at synthetic organisms, synthetic chemicals, biopesticides, biomining products, and genetically modified plants, which are regulated by EPA, FDA, and USDA. Our report demonstrates the regulatory complexity and uncertainty that innovators face in seeking to commercialize their products. The report offers some common-sense and easily implemented solutions to help federal agencies do their jobs more efficiently, and offers suggestions for the regulated community to be more proactive in expanding the technological literacy of the agencies with jurisdictional oversight over their products. Federal agencies convened at FDA's offices in October 2015 for the first of three public meetings, consistent with the FDA's *Federal Register* notice, "Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology and Developing a Long-Term Strategy for the Regulation of the Products of Biotechnology," issued in response to the White House mandate for public input on its memorandum "Modernizing the Regulatory System for Biotechnology Products" (as detailed in White House blog item "Improving Transparency and Ensuring Continued Safety in Biotechnology"). The format allowed for only quick oral presentations, which was not conducive to true discussion and interaction with federal regulators. This is regrettable and we hope the remaining two meetings in 2016 will be of a different format to allow for greater interaction and discussion. Also, while FDA's comment deadline has closed, we expect that EPA and USDA will provide similar opportunities for input.

ENFORCEMENT

With EPA's Next Generation Compliance Initiative in full swing, and the very recent release of EPA's new centralized web-based "eDisclosure" portal to receive and automatically process self-disclosed civil violations of environmental law, 2016 should be an interesting year. EPA's Office of Enforcement and Compliance Assurance (OECA) announced its Next Generation Compliance Initiative in 2013, and in 2014 issued a "Next Generation Compliance: Strategic Plan 2014-2017." Next Generation compliance is intended to increase compliance and diminish pollution by using technology more efficiently, smartly, and transparently.

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On December 9, 2015, EPA announced a new portal available as a means for entities to "self-report" acts that may be construed by EPA as violations of law. Under the automated eDisclosure system, "large and small businesses will quickly be able to get some of their more routine types of disclosures resolved." The new eDisclosure portal manages only disclosures under EPA's Audit Policy and its Small Business Compliance Policy; the new owner self-disclosures and potential criminal violations disclosed to the Voluntary Disclosure Board will continue to be accepted and processed outside of the eDisclosure system. Potential violations through the new eDisclosure portal may qualify for one of two types of automated treatment. Category 1 disclosures include: Emergency Planning and Community Right-to-Know Act (EPCRA) violations that meet all Audit Policy conditions and EPCRA violations that meet all Small Business Compliance Policy conditions. Category 2 disclosures include: all non-EPCRA violations; EPCRA violations where the discloser can only certify compliance with Audit Policy Conditions 2-9 (*i.e.*, discovery was not systematic); and EPCRA/Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) violations excluded from Category 1.

Entities wishing to disclose potential violations through the eDisclosure system must follow a three-step process: (1) register with EPA's Central Data Exchange (CDX) system; (2) submit disclosure of any violation within 21 calendar days of the entity's discovery that such potential violations may have occurred to be considered prompt; and (3) submit a Compliance Certification, within 60 days for an Audit Policy disclosure and within 90 days for a Small Business Compliance Policy disclosure, identifying the specific violations, and certifying that the violations have been corrected and that policy conditions have been met. These modifications to the implementation of EPA's Audit Policy and Small Business Compliance Policy, and the launch of the eDisclosure portal, became effective on December 9, 2015. General information on EPA's eDisclosure portal is available online.

The eDisclosure portal is very much aligned with OECA's broader policy objectives of enhanced reliance on technology as a means to achieve compliance and diminished pollution. In that the new portal is just that -- new and untried -- it remains to be seen how user friendly it is, and how useful regulated entities will find it to be. As noted above, Category 2 violations will be addressed on a case-by-case basis, so whatever track record is developed and disclosed will be important to follow. It is also important to recognize EPA's statement that it "generally expects to make" Category 1 and 2 disclosures "publically available within a relatively short period of time after their receipt." Combined with EPA's Next Generation Compliance Initiative, which relies upon the public dissemination of data and information as a regulatory tool in itself, EPA use and public disclosure of self-disclosed violations will be an important aspect of the program to monitor in 2016.

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WE HOPE YOU FOUND THIS OVERVIEW USEFUL.
WE WISH YOU ALL THE BEST IN THE NEW YEAR.

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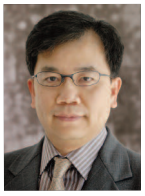

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